CHAPTER 151

PHARMACY PRACTICE AND WHOLESALE DISTRIBUTION ACT

PHARMACY PRACTICE ACT

151.01 DEFINITIONS.

Subdivision 1. **Scope.** 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 [Repealed, 1988 c 550 s 20]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, licensed advanced practice registered nurse, or licensed physician assistant. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 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. For purposes of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists under section 151.37, subdivision 14, 15, or 16, or authorized to prescribe drugs to prevent the acquisition of human immunodeficiency virus (HIV) under section 151.37, subdivision 17.

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 ordering and performing laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq. A pharmacist may collect specimens, interpret results, notify the patient of results, and refer the patient to other health care providers for follow-up care and may initiate, modify, or discontinue drug therapy only pursuant to a protocol or collaborative practice agreement. A pharmacist may delegate the authority to administer tests under this clause to a pharmacy technician or pharmacy intern. A pharmacy technician or pharmacy intern may perform tests authorized under this clause if the technician or intern is working under the direct supervision of a pharmacist;

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; intramuscular and subcutaneous drug administration under a prescription drug order; drug regimen reviews; and drug or drug-related research;

(5) drug administration, through intramuscular and subcutaneous administration used to treat mental illnesses as permitted under the following conditions:

(i) upon the order of a prescriber and the prescriber is notified after administration is complete; or

(ii) pursuant to a protocol or collaborative practice agreement as defined by section 151.01, subdivisions 27b and 27c, and participation in the initiation, management, modification, administration, and discontinuation of drug therapy is according to the protocol or collaborative practice agreement between the pharmacist and a dentist, optometrist, physician, physician assistant, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy or medication administration 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;

(6) initiating, ordering, and administering influenza and COVID-19 or SARS-CoV-2 vaccines authorized or approved by the United States Food and Drug Administration to all eligible individuals three years of age and older and all other United States Food and Drug Administration-approved vaccines to patients six years of age and older according to the federal Advisory Committee on Immunization Practices recommendations. A pharmacist may delegate the authority to administer vaccines under this clause to a pharmacy technician or pharmacy intern who has completed training in vaccine administration if:

(i) the pharmacist and the pharmacy technician or pharmacy intern have successfully completed a program approved by the Accreditation Council for Pharmacy Education (ACPE) specifically for the administration of immunizations or a program approved by the board;

(ii) 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;

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

(iv) if the patient is 18 years of age or younger, the pharmacist, pharmacy technician, or pharmacy intern informs the patient and any adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider; and

(v) in the case of a pharmacy technician administering vaccinations while being supervised by a licensed pharmacist:

(A) the supervision is in-person and must not be done through telehealth as defined under section 62A.673, subdivision 2;

(B) the pharmacist is readily and immediately available to the immunizing pharmacy technician;

(C) the pharmacy technician has a current certificate in basic cardiopulmonary resuscitation;

(D) the pharmacy technician has completed a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education as part of the pharmacy technician's two-year continuing education schedule; and

(E) the pharmacy technician has completed one of two training programs listed under Minnesota Rules, part 6800.3850, subpart 1h, item B;

(7) 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, physician assistants, 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 registered 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;

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

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

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

(11) 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 (7); 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;

(12) prescribing self-administered hormonal contraceptives; nicotine replacement medications; and opiate antagonists for the treatment of an acute opiate overdose pursuant to section 151.37, subdivision 14, 15, or 16;

(13) participation in the placement of drug monitoring devices according to a prescription, protocol, or collaborative practice agreement;

(14) prescribing, dispensing, and administering drugs for preventing the acquisition of human immunodeficiency virus (HIV) if the pharmacist meets the requirements in section 151.37, subdivision 17; and

(15) ordering, conducting, and interpreting laboratory tests necessary for therapies that use drugs for preventing the acquisition of HIV, if the pharmacist meets the requirements in section 151.37, subdivision 17.

[See Note.]

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 (7); or

(2) a specific written plan that authorizes a pharmacist to administer vaccines and that complies with subdivision 27, clause (6).

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. **Medical gas.** "Medical gas" means any gas or liquid manufactured or stored in a liquefied, nonliquefied, or cryogenic state that:

(1) has a chemical or physical action in or on the human body or animals or is used in conjunction with medical gas equipment; and

(2) is intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of disease.

Subd. 29a. **Medical gas manufacturer.** "Medical gas manufacturer" means any person:

(1) originally manufacturing a medical gas by chemical reaction, physical separation, compression of atmospheric air, purification, or other means;

(2) filling a medical gas into a dispensing container via gas to gas, liquid to gas, or liquid to liquid processes;

(3) combining two or more medical gases into a container to form a medically appropriate mixture; or

(4) filling a medical gas via liquid to liquid into a final use container at the point of use.

Subd. 29b. **Medical gas wholesaler.** "Medical gas wholesaler" means any person who sells a medical gas to another business or entity for the purpose of reselling or providing that medical gas to the ultimate consumer or patient.

Subd. 29c. **Medical gas dispenser.** "Medical gas dispenser" means any person, other than a licensed practitioner or pharmacy, who sells or provides a medical gas directly to the ultimate consumer or patient via a valid prescription.

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 performs those activities involved in the dispensing of a drug for another pharmacy, pursuant to the requirements of this chapter and the rules of the board.

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, provided that such labeling has been approved by the United States Food and Drug Administration (FDA) or the manufacturer is licensed under section 151.252. 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 United States 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 United States Food and Drug Administration publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

Subd. 42. **Self-administered hormonal contraceptive.** "Self-administered hormonal contraceptive" means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and is administered by the user.

Subd. 43. **Syringe services provider.** "Syringe services provider" means a community-based public health program that offers cost-free comprehensive harm reduction services, which may include: providing sterile needles, syringes, and other injection equipment; making safe disposal containers for needles and syringes available; educating participants and others about overdose prevention, safer injection practices, and infectious disease prevention; providing blood-borne pathogen testing or referrals to blood-borne pathogen testing; offering referrals to substance use disorder treatment, including substance use disorder treatment with medications for opioid use disorder; and providing referrals to medical treatment and services, mental health programs and services, and other social services.

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; 2019 c 63 art 2 s 3; 1Sp2019 c 9 art 9 s 3; art 10 s 24,25; 2020 c 83 art 1 s 40,41; 2020 c 115 art 2 s 19-21; 2021 c 30 art 4 s 1-4; 2022 c 58 s 87; 2022 c 98 art 3 s 20; 2023 c 52 art 15 s 2; 2024 c 127 art 60 s 2,3*

NOTE: Subdivision 27, clauses (14) and (15), as added by Laws 2024, chapter 127, article 60, section 3, are effective January 1, 2026. Laws 2024, chapter 127, article 60, section 3, the effective date.

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]

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) patient assistance programs offered by drug manufacturers, including information on how to access the programs;

(2) the insulin safety net program established in section 151.74, including information on how to access the program;

(3) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(4) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(5) availability of providers that are authorized to participate under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b;

(6) having a discussion with the pharmacist or the consumer's health care provider about alternatives to a prescribed drug, including a lower cost or generic drug if the drug prescribed is too costly for the consumer; and

(7) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board must prepare educational materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The materials must be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by health care practitioners who are licensed to prescribe. The board is not required to provide printed copies of these materials.

(c) The board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established under paragraph (a).

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; 1Sp2019 c 9 art 9 s 4; 2020 c 73 s 3*

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, $225;

(2) pharmacist licensed by reciprocity, $300;

(3) pharmacy intern, $75;

(4) pharmacy technician, $60;

(5) pharmacy, $450;

(6) drug wholesaler, legend drugs only, $5,500;

(7) drug wholesaler, legend and nonlegend drugs, $5,500;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,500;

(9) drug wholesaler, medical gases, $5,500 for the first facility and $500 for each additional facility;

(10) third-party logistics provider, $300;

(11) drug manufacturer, nonopiate legend drugs only, $5,500;

(12) drug manufacturer, nonopiate legend and nonlegend drugs, $5,500;

(13) drug manufacturer, nonlegend or veterinary legend drugs, $5,500;

(14) drug manufacturer, medical gases, $5,500 for the first facility and $500 for each additional facility;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,500;

(16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,500;

(17) medical gas dispenser, $400;

(18) controlled substance researcher, $150; and

(19) pharmacy professional corporation, $150.

Subd. 2. **Original license fee.** The pharmacist original licensure fee, $225.

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

(1) pharmacist, $225;

(2) pharmacy technician, $60;

(3) pharmacy, $450;

(4) drug wholesaler, legend drugs only, $5,500;

(5) drug wholesaler, legend and nonlegend drugs, $5,500;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,500;

(7) drug wholesaler, medical gases, $5,500 for the first facility and $500 for each additional facility;

(8) third-party logistics provider, $300;

(9) drug manufacturer, nonopiate legend drugs only, $5,500;

(10) drug manufacturer, nonopiate legend and nonlegend drugs, $5,500;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, $5,500;

(12) drug manufacturer, medical gases, $5,500 for the first facility and $500 for each additional facility;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,500;

(14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,500;

(15) medical gas dispenser, $400;

(16) controlled substance researcher, $150; and

(17) pharmacy professional corporation, $150.

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

(1) intern affidavit, $30;

(2) duplicate small license, $30; and

(3) duplicate large certificate, $30.

Subd. 4a. **Application and fee; relocation.** A person who is registered with or licensed by the board must submit a new application to the board before relocating the physical location of the person's business. An application must be submitted for each affected license. The application must set forth the proposed change of location on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the relocation application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (11) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the full application fee provided in subdivision 1. Upon approval of an application for a relocation, the board shall issue a new license or registration.

Subd. 4b. **Application and fee; change of ownership.** A person who is registered with or licensed by the board must submit a new application to the board before changing the ownership of the licensee or

registrant. An application must be submitted for each affected license. The application must set forth the proposed change of ownership on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (11) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the full application fee provided in subdivision 1. Upon approval of an application for a change of ownership, the board shall issue a new license or registration.

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 $250.

(c) An owner of a pharmacy, a drug wholesaler, a drug manufacturer, third-party logistics provider, or a medical gas dispenser 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.

Subd. 7. **Deposit of fees.** (a) The license fees collected under this section, with the exception of the fees identified in paragraph (b), shall be deposited in the state government special revenue fund.

(b) $5,000 of each fee collected under subdivision 1, clauses (6) to (9), and (11) to (15), and subdivision 3, clauses (4) to (7), and (9) to (13), and $55,000 of each fee collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response fund established in section 256.043.

Subd. 8. **Transfer of licenses.** Licenses and registrations granted by the board are not transferable.

History: *1Sp2011 c 9 art 5 s 17; 2015 c 71 art 10 s 29-32; 2019 c 63 art 1 s 2-4,10; 1Sp2019 c 9 art 10 s 26-29,52; 2020 c 71 art 2 s 5-7; 2020 c 115 art 3 s 4-7; 2023 c 70 art 6 s 22-26; 2024 c 125 art 3 s 1; 2024 c 127 art 48 s 1; art 60 s 4-6*

151.066 OPIATE PRODUCT REGISTRATION FEE.

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

(b) "Manufacturer" means a manufacturer licensed under section 151.252, excluding those exclusively licensed to manufacture medical gas.

(c) "Opiate" means any opiate-containing controlled substance listed in section 152.02, subdivisions 3 to 5, that is distributed, delivered, sold, or dispensed into or within this state.

(d) "Third-party logistics provider" means a third-party logistics provider licensed under section 151.471.

(e) "Wholesaler" means a wholesale drug distributor licensed under section 151.47, excluding those exclusively licensed to distribute medical gas.

Subd. 2. **Reporting requirements.** (a) By March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution within or into this state of any opiate that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted by section 151.37 to possess controlled substances for administration or dispensing to patients that occurred during the previous calendar year. Reporting must be in the automation of reports and consolidated orders system format unless otherwise specified by the board. If no reportable distributions occurred for a given year, notification must be provided to the board in a manner specified by the board. If a manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $500 per day. This penalty shall not be considered a form of disciplinary action.

(b) By March 1 of each year, beginning March 1, 2020, each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution into this state, of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the opiate, and the amount and date that the purchase occurred.

(c) By March 1 of each year, beginning March 1, 2025, each third-party logistics provider must report to the board any delivery or distribution into this state of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler or manufacturer. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year.

Subd. 3. **Determination of an opiate product registration fee.** (a) The board shall annually assess an opiate product registration fee on any manufacturer of an opiate that annually sells, delivers, or distributes an opiate within or into the state in a quantity of 2,000,000 or more units as reported to the board under subdivision 2.

(b) For purposes of assessing the annual registration fee under this section and determining the number of opiate units a manufacturer sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for substance use disorder treatment with medications for opioid use disorder.

(c) The annual registration fee for each manufacturer meeting the requirement under paragraph (a) is $250,000.

(d) In conjunction with the data reported under this section, and notwithstanding section 152.126, subdivision 6, the board may use the data reported under section 152.126, subdivision 4, to determine which manufacturers meet the requirement under paragraph (a) and are required to pay the registration fees under this subdivision.

(e) By April 1 of each year, beginning April 1, 2020, the board shall notify a manufacturer that the manufacturer meets the requirement in paragraph (a) and is required to pay the annual registration fee in accordance with section 151.252, subdivision 1, paragraph (b).

(f) A manufacturer may dispute the board's determination that the manufacturer must pay the registration fee no later than 30 days after the date of notification. However, the manufacturer must still remit the fee as required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the assessment of the registration fee was incorrect. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the fee was incorrectly assessed, the board must refund the amount paid in error.

(g) For purposes of this subdivision, a unit means the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or gram.

(h) For the purposes of this subdivision, an opiate's units will be assigned to the manufacturer holding the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), as listed by the United States Food and Drug Administration.

Subd. 4. **Report.** (a) The Board of Pharmacy shall evaluate the registration fee on drug manufacturers established under this section, and whether the registration fee and the increased licensure fees have impacted the prescribing practices of opiates by reducing the number of opiate prescriptions issued during calendar years 2021, 2022, and 2023, or creating any unintended consequences in the availability of opiates for the treatment of chronic or intractable pain to the extent the board has the ability to effectively identify a correlation. Notwithstanding section 152.126, subdivision 6, the board may access the data reported under section 152.126, subdivision 4, to conduct this evaluation.

(b) The board shall submit the results of its evaluation to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by March 1, 2024.

Subd. 5. **Legislative review.** The legislature shall review the reports from the Opiate Epidemic Response Advisory Council under section 256.042, subdivision 5, paragraph (a), the reports from the commissioner of management and budget on the Results First evaluation activities under section 256.042, subdivision 5, paragraph (b), the report from the Board of Pharmacy under subdivision 4, and any other relevant report or information related to the opioid crisis in Minnesota, to make a determination about whether the opiate product registration fee assessed under this section should continue beyond July 1, 2024.

History: *2019 c 63 art 1 s 5; 1Sp2021 c 7 art 5 s 2; 2022 c 53 s 3; 2022 c 98 art 6 s 25; 2024 c 127 art 60 s 7-9*

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, except that a civil penalty not exceeding $25,000 may be imposed for each separate violation of section 62J.842, 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, use of alcohol, 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, use of alcohol, 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 dispenser, 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;

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

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, in writing and with each prescription

dispensed, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required;

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

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

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

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

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

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

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

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

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board must 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;

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

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

Subd. 2b. **Reproductive health care services.** (a) For purposes of this subdivision, "reproductive health care services" has the meaning given in section 147.091, subdivision 1c.

(b) Notwithstanding subdivision 1 and subdivision 2, clause (3), (6), or (7), the board shall not refuse to grant a license to an applicant for licensure or impose disciplinary action against a pharmacist, pharmacy technician, or pharmacist intern solely on one or more of the following grounds:

(1) the applicant or a pharmacist, pharmacy technician, or pharmacist intern provided or assisted in the provision of reproductive health care services in a manner that is lawful in this state and that is within the applicable scope of practice;

(2) the applicant or a pharmacist, pharmacy technician, or pharmacist intern was convicted in another jurisdiction of a felony resulting from conduct specified in clause (1); or

(3) the applicant or a pharmacist, pharmacy technician, or pharmacist intern was subject to disciplinary action in another jurisdiction or was refused a license to practice pharmacy in another jurisdiction resulting from conduct specified in clause (1).

Subd. 3. **Automatic suspension; suspension for failure to maintain name and address; name and address currency.** (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 dispensers.** 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 dispenser 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 must take effect upon written notice to the licensee or registrant, specifying the statute or rule violated. The suspension must 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 must schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The licensee or registrant must be provided with at least 20 days' notice of any hearing held pursuant to this subdivision. The hearing must 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 (i), 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; 1Sp2019 c 9 art 10 s 30; 2020 c 83 art 2 s 14; 2020 c 115 art 3 s 8,9; 2023 c 31 s 5; 2023 c 57 art 2 s 59,60*

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 or dispense drugs in any place other than a pharmacy, except as provided in this chapter; except that a licensed pharmacist or pharmacist intern working within a licensed hospital may receive a prescription drug order and access the hospital's pharmacy prescription processing system through secure and encrypted electronic means in order to process the prescription drug order.

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.

Subd. 5. **Receipt of emergency prescription orders.** A pharmacist, when that pharmacist is not present within a licensed pharmacy, may accept a written, verbal, or electronic prescription drug order from a practitioner only if:

(1) the prescription drug order is for an emergency situation where waiting for the pharmacist to travel to a licensed pharmacy to accept the prescription drug order would likely cause the patient to experience significant physical harm or discomfort;

(2) the pharmacy from which the prescription drug order will be dispensed is closed for business;

(3) the pharmacist has been designated to be on call for the licensed pharmacy that will fill the prescription drug order;

(4) electronic prescription drug orders are received through secure and encrypted electronic means;

(5) the pharmacist takes reasonable precautions to ensure that the prescription drug order will be handled in a manner consistent with federal and state statutes regarding the handling of protected health information; and

(6) the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.

Subd. 6. **Processing emergency prescription orders.** A pharmacist, when that pharmacist is not present within a licensed pharmacy, may access a pharmacy prescription processing system through secure and encrypted electronic means in order to process an emergency prescription accepted pursuant to subdivision 5 only if:

(1) the pharmacy from which the prescription drug order will be dispensed is closed for business;

(2) the pharmacist has been designated to be on call for the licensed pharmacy that will fill the prescription drug order;

(3) the prescription drug order is for a patient of a long-term care facility or a county correctional facility;

(4) the prescription drug order is not being processed pursuant to section 151.58;

(5) the prescription drug order is processed pursuant to this chapter and the rules promulgated thereunder; and

(6) the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.

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; 1Sp2019 c 9 art 10 s 31-33*

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) Prior to the issuance of an initial or renewed license for a pharmacy, the board may require the pharmacy to pass 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.

(h) This subdivision does not apply to a manufacturer licensed under section 151.252, subdivision 1, a wholesale drug distributor licensed under section 151.47, or a third-party logistics provider, to the extent the manufacturer, wholesale drug distributor, or third-party logistics provider is engaged in the distribution of dialysate or devices necessary to perform home peritoneal dialysis on patients with end-stage renal disease, if:

(1) the manufacturer or its agent leases or owns the licensed manufacturing or wholesaling facility from which the dialysate or devices will be delivered;

(2) the dialysate is comprised of dextrose or icodextrin and has been approved by the United States Food and Drug Administration;

(3) the dialysate is stored and delivered in its original, sealed, and unopened manufacturer's packaging;

(4) the dialysate or devices are delivered only upon:

(i) receipt of a physician's order by a Minnesota licensed pharmacy; and

(ii) the review and processing of the prescription by a pharmacist licensed by the state in which the pharmacy is located, who is employed by or under contract to the pharmacy;

(5) prescriptions, policies, procedures, and records of delivery are maintained by the manufacturer for a minimum of three years and are made available to the board upon request; and

(6) the manufacturer or the manufacturer's agent delivers the dialysate or devices directly to:

(i) a patient with end-stage renal disease for whom the prescription was written or the patient's designee, for the patient's self-administration of the dialysis therapy; or

(ii) a health care provider or institution, for administration or delivery of the dialysis therapy to a patient with end-stage renal disease for whom the prescription was written.

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

Subd. 3. MS 2020 [Repealed, 2021 c 30 art 4 s 6]

Subd. 4. **Licensing of physicians, advanced practice registered nurses, and physician assistants to dispense drugs; renewals.** (a) The board may grant a license to any physician licensed under chapter 147, advanced practice registered nurse licensed under chapter 148, or physician assistant licensed under chapter 147A who provides services in a health care facility located in a designated health professional shortage area authorizing the physician, advanced practice registered nurse, or physician assistant to dispense drugs to individuals for whom pharmaceutical care is not reasonably available. The license may be renewed annually. Any physician, advanced practice registered nurse, or physician assistant 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, advanced practice registered nurse, or physician assistant 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, advanced practice registered nurse, or physician assistant 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, advanced practice registered nurse, or physician assistant 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, advanced practice registered nurse, or physician assistant may supervise the pharmacy technician as long as the physician, advanced practice registered nurse, or physician assistant assumes responsibility for all functions performed by the technician. For purposes of this subdivision, supervision does not require the physician, advanced practice registered nurse, or physician assistant to be physically present if the physician, advanced practice registered nurse, physician assistant, or a licensed pharmacist is available, either electronically or by telephone.

(e) Nothing in this subdivision shall be construed to prohibit a physician, advanced practice registered nurse, or physician assistant 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; 2019 c 44 s 1; 1Sp2019 c 9 art 10 s 34,35; 2020 c 115 art 3 s 10; art 4 s 74; 2022 c 58 s 88*

151.191 LICENSING MEDICAL GAS FACILITIES; FEES; PROHIBITIONS.

Subdivision 1. **Medical gas manufacturers; requirements.** (a) No person shall act as a medical gas manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

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

(c) A license must not be issued or renewed for a medical gas manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) A license must not be issued or renewed for a medical gas 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 standards for the licensure of a medical gas manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(e) The board must require a separate license for each facility located within the state at which medical gas manufacturing occurs and for each facility located outside of the state at which medical gases that are shipped into the state are manufactured.

(f) Prior to the issuance of an initial or renewed license for a medical gas manufacturing facility, the board may require the facility to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas 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, 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) A duly licensed medical gas manufacturing facility may also wholesale or dispense any medical gas that is manufactured by the licensed facility, or manufactured or wholesaled by another properly licensed medical gas facility, without also obtaining a medical gas wholesaler license or medical gas dispenser registration.

(h) The filling of a medical gas into a final use container, at the point of use and by liquid to liquid transfer, is permitted as long as the facility used as the base of operations is duly licensed as a medical gas manufacturer.

Subd. 2. **Medical gas wholesalers; requirements.** (a) No person shall act as a medical gas wholesaler without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for a medical gas wholesaler license under this section must be made in a manner specified by the board.

(c) A license must not be issued or renewed for a medical gas wholesaler unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) A license must not be issued or renewed for a medical gas wholesaler 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 standards for the licensure of a medical gas wholesaler that is not required to be licensed or registered by the state in which it is physically located.

(e) The board must require a separate license for each facility located within the state at which medical gas wholesaling occurs and for each facility located outside of the state from which medical gases that are shipped into the state are wholesaled.

(f) Prior to the issuance of an initial or renewed license for a medical gas wholesaling facility, the board may require the facility to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas wholesaling 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. 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) A duly licensed medical gas wholesaling facility may also dispense any medical gas that is manufactured or wholesaled by another properly licensed medical gas facility.

Subd. 3. **Medical gas dispensers; requirements.** (a) A person or establishment not licensed as a pharmacy, practitioner, medical gas manufacturer, or medical gas dispenser must not engage in the dispensing of medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration must be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board.

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

(c) A registration must not be issued or renewed for a medical gas dispenser 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. A license must not be issued for a medical gas dispenser located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when dispensing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) A registration must not be issued or renewed for a medical gas dispenser 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 establish standards for the registration of a medical gas dispenser that is not required to be licensed or registered by the state in which it is physically located.

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

(f) Prior to the issuance of an initial or renewed registration for a medical gas dispenser, the board may require the medical gas dispenser to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas dispenser 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) A facility holding a medical gas dispenser registration must not engage in the manufacturing or wholesaling of medical gases, except that a medical gas dispenser may transfer medical gases from one of

its duly registered facilities to other duly registered medical gas manufacturing, wholesaling, or dispensing facilities owned or operated by that same company, without requiring a medical gas wholesaler license.

History: *2021 c 30 art 4 s 5*

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 United States 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, advanced practice registered nurse, or physician assistant, 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.** Subdivision 3 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. 7a. **Coverage by substitution.** (a) When a pharmacist receives a prescription order by paper or hard copy, by electronic transmission, or by oral instruction from the prescriber, in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated and the drug prescribed is not covered under the purchaser's health plan or prescription drug plan, the pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product that is covered under the purchaser's plan, if the pharmacist has a written protocol with the prescriber that outlines the class of drugs of the same generation and designed for the same indication that can be substituted and the required communication between the pharmacist and the prescriber.

(b) The pharmacist must inform the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product prescribed and the reason for the substitution.

(c) The pharmacist must communicate to the prescriber the name and manufacturer of the substituted drug that was dispensed and the reason for the substitution, in accordance with the written protocol.

Subd. 8. **List of excluded products.** The Drug Formulary Committee established under section 256B.0625, subdivision 13c, 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 United States 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; 2019 c 39 s 18,19; 2019 c 50 art 1 s 54; 2020 c 115 art 4 s 75; 2022 c 58 s 89*

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.** Except as provided in subdivision 3, 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.

Subd. 3. **Emergency prescription refills.** (a) A pharmacist may, using sound professional judgment and in accordance with accepted standards of practice, dispense a legend drug without a current prescription drug order from a licensed practitioner if all of the following conditions are met:

(1) the patient has been compliant with taking the medication and has consistently had the drug filled or refilled as demonstrated by records maintained by the pharmacy;

(2) the pharmacy from which the legend drug is dispensed has a record of a prescription drug order for the drug in the name of the patient who is requesting it, but the prescription drug order does not provide for a refill or the time during which the refills were valid has elapsed;

(3) the pharmacist has tried but is unable to contact the practitioner who issued the prescription drug order, or another practitioner responsible for the patient's care, to obtain authorization to refill the prescription;

(4) the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition;

(5) failure to dispense the drug to the patient would result in harm to the health of the patient; and

(6) the drug is not a controlled substance listed in section 152.02, subdivisions 3 to 6, except for a controlled substance that has been specifically prescribed to treat a seizure disorder, in which case the pharmacist may dispense up to a 72-hour supply.

(b) If the conditions in paragraph (a) are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed a 30-day supply, or the quantity originally prescribed, whichever is less, except as provided for controlled substances in paragraph (a), clause (6). If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing.

(c) A pharmacist shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.

(d) A pharmacist must notify the practitioner who issued the prescription drug order not later than 72 hours after the drug is sold or dispensed. The pharmacist must request and receive authorization before any additional refills may be dispensed. If the practitioner declines to provide authorization for additional refills, the pharmacist must inform the patient of that fact.

(e) The record of a drug sold or dispensed under this section shall be maintained in the same manner required for prescription drug orders under this section.

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; 1Sp2019 c 9 art 9 s 5,6*

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.

Subd. 4. **Accessible prescription drug container labels.** (a) A pharmacy must:

(1) make reasonable efforts to inform the public that an accessible prescription drug container label is available at no additional cost, upon request of the patient or the patient's representative, to any patient who has difficulty seeing or reading standard printed labels on prescription drug containers; and

(2) if the pharmacy knows that the patient has difficulty seeing or reading standard printed labels on prescription drug containers, inform a patient that an accessible prescription drug container label is available at no additional cost upon request of the patient or the patient's representative.

(b) Subject to paragraph (e), if a patient requests an accessible container label, the pharmacy must provide the patient with a prescription drug container label in large print, Braille, or may provide any other method included in the best practices for access to prescription drug labeling information by the United States Access Board, or its successor organization, depending on the need and preference of the patient. The pharmacy must make reasonable efforts to ensure patient safety and access during the time it takes to provide the requested method of accessibility.

(c) The accessible container label must:

(1) be affixed on the container in compliance with section 151.212, subdivision 1;

(2) last for at least the duration of the prescription;

(3) contain the information required under subdivisions 1 and 2;

(4) be available in a timely manner relative to the industry standard time required to produce the accessible container label; and

(5) conform with the best practices established by the United States Access Board, or its successor organization, for large print and Braille accessible container labels.

(d) By January 1, 2025, the commissioner of health must publish a list of pharmacies that have informed the commissioner that the pharmacy has the technological capacity to provide an accessible container label to a patient in the timely manner required by paragraph (c), clause (4). The commissioner must update this list on a quarterly basis until January 1, 2026.

(e) Until January 1, 2026, if the pharmacy does not have the technological capacity to provide an accessible container label to a patient in the timely manner required by paragraph (c), clause (4), the pharmacy is not required to provide an accessible container label to a patient requesting such a label, but the pharmacy must inform the patient of the list of pharmacies with such capacity required pursuant to paragraph (d), if such list is published.

(f) On and after January 1, 2026, all pharmacies must be able to provide an accessible container label in the timely manner required by paragraph (c), clause (4).

(g) This subdivision does not apply to prescription drugs dispensed and administered by a correctional institution.

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; 2024 c 127 art 60 s 10*

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. MS 2018 [Repealed, 2019 c 39 s 23]

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) In addition to the license required under paragraph (a), each manufacturer required to pay the registration fee under section 151.066 must pay the fee by June 1 of each year, beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new owner must pay the registration fee specified under section 151.066, subdivision 3, that the original owner would have been assessed had the original owner retained ownership. The registration fee collected under this paragraph shall be deposited in the opiate epidemic response fund established under section 256.043.

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

(d) 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.

(e) 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.

(f) 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.

(g) 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, except a manufacturer of opiate-containing controlled substances shall not be required to pay the fee under section 151.065, subdivision 1, clause (16), or subdivision 3, clause (14), for more than one facility.

(h) Prior to the issuance of an initial or renewed license for a drug manufacturing facility, the board may require the facility to pass a current good manufacturing practices 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 a current good manufacturing practices 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 a current good manufacturing practices 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 or outsourcing facility 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; 2019 c 63 art 1 s 6; 1Sp2019 c 9 art 10 s 36-38; 2020 c 115 art 3 s 11*

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.

Subd. 4. **Emergency veterinary compounding.** A pharmacist working within a pharmacy licensed by the board in the veterinary pharmacy license category may compound and provide a drug product to a veterinarian without first receiving a patient-specific prescription only when:

(1) the compounded drug product is needed to treat animals in urgent or emergency situations, meaning where the health of an animal is threatened, or where suffering or death of an animal is likely to result from failure to immediately treat;

(2) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

(3) there is no commercially manufactured drug, approved by the United States Food and Drug Administration, that is suitable for treating the animal, or there is a documented shortage of such drug;

(4) the compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian, or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of ten days;

(5) the pharmacy has selected the sterile or nonsterile compounding license category, in addition to the veterinary pharmacy licensing category; and

(6) the pharmacy is appropriately registered by the United States Drug Enforcement Administration when providing compounded products that contain controlled substances.

History: *2014 c 291 art 5 s 9; 1Sp2019 c 9 art 10 s 39*

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]

151.32 CITATION.

The title of sections 151.01 to 151.58 shall be the "Pharmacy Practice and Wholesale Distribution Act."

History: *(5808-35) 1937 c 354 s 35; 1988 c 550 s 17; 2017 c 40 art 1 s 40; 1Sp2019 c 9 art 10 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*

151.335 DELIVERY THROUGH COMMON CARRIER; COMPLIANCE WITH TEMPERATURE REQUIREMENTS.

In addition to complying with the requirements of Minnesota Rules, part 6800.3000, a mail order or specialty pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must ensure that the drug is delivered in compliance with temperature requirements established by the manufacturer of the drug. The pharmacy must develop written policies and procedures that are consistent with United States Pharmacopeia, chapters 1079 and 1118, and with nationally recognized standards issued by standard-setting or accreditation organizations recognized by the board through guidance. The policies and procedures must be provided to the board upon request.

History: *1Sp2021 c 7 art 5 s 3*

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) 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 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; 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.

(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:

(1) an in-person examination has been completed in any of the following circumstances:

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

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

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

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

(v) 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 telehealth; or

(2) the prescription order is for a drug listed in paragraph (d), clause (6), or for substance use disorder treatment with medications for opioid use disorder, and the prescribing practitioner has completed an examination of the patient via telehealth as defined in section 62A.673, subdivision 2, paragraph (h).

(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. MS 2020 [Repealed, 2022 c 58 s 171]

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. 11a. **Exclusion for traditional midwives.** A traditional midwife licensed under chapter 147D is authorized, consistent with the midwife's scope of professional practice and as necessary for the practice of midwifery, to directly obtain supplies and devices; obtain, possess, and administer drugs and diagnostic tests as permitted under section 147D.09, paragraph (b); order tests; and receive reports.

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 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);

(3) correctional employees of a state or local political subdivision;

(4) staff of community-based health disease prevention or social service programs;

(5) a volunteer firefighter;

(6) a nurse or any other personnel employed by, or under contract with, a charter, public, or private school; and

(7) transit rider investment program personnel authorized under section 473.4075.

(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.

(d) Notwithstanding section 148.235, subdivisions 8 and 9, a licensed practical nurse is authorized to possess and administer according to this subdivision an opiate antagonist in a school setting.

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.

Subd. 14. **Self-administered hormonal contraceptives.** (a) A pharmacist is authorized to prescribe self-administered hormonal contraceptives if the intended use is contraception in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing self-administrated hormonal contraceptives. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; the Minnesota section of the American Congress of Obstetricians and Gynecologists; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses. The protocol must, at a minimum, include:

(1) requiring the patient to complete a self-screening tool to identify patient risk factors for the use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria for Contraceptive Use developed by the federal Centers for Disease Control and Prevention;

(2) requiring the pharmacist to review the screening tool with the patient;

(3) other assessments the pharmacist should make before prescribing self-administered hormonal contraceptives;

(4) situations when the prescribing of self-administered hormonal contraceptives by a pharmacist is contraindicated;

(5) situations when the pharmacist must refer a patient to the patient's primary care provider or, if the patient does not have a primary care provider, to a nearby clinic or hospital; and

(6) any additional information concerning the requirements and prohibitions in this subdivision that the board considers necessary.

(b) Before a pharmacist is authorized to prescribe a self-administered hormonal contraceptive to a patient under this subdivision, the pharmacist shall successfully complete a training program on prescribing self-administered hormonal contraceptives that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing a self-administered hormonal contraceptive, the pharmacist shall follow the standardized protocol developed under paragraph (a), and if appropriate, may prescribe a self-administered hormonal contraceptive to a patient, if the patient is:

(1) 18 years of age or older; or

(2) under the age of 18 if the patient has previously been prescribed a self-administered hormonal contraceptive by a licensed physician, physician assistant, or advanced practice registered nurse.

(d) The pharmacist shall provide counseling to the patient on the use of self-administered hormonal contraceptives and provide the patient with a fact sheet that includes but is not limited to the contraindications for use of the drug, the appropriate method for using the drug, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the self-administered hormonal contraceptive prescribed by the pharmacist.

(e) If a pharmacist prescribes and dispenses a self-administered hormonal contraceptive under this subdivision, the pharmacist shall not prescribe a refill to the patient unless the patient has evidence of a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the preceding three years.

(f) A pharmacist who is authorized to prescribe a self-administered hormonal contraceptive is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for a self-administered hormonal contraceptive, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(g) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol or collaborative agreement as authorized in this section and in section 151.01, subdivision 27.

Subd. 15. **Nicotine replacement medications.** (a) A pharmacist is authorized to prescribe nicotine replacement medications approved by the United States Food and Drug Administration in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing nicotine replacement medications. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe nicotine replacement medications under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing nicotine replacement medications that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing a nicotine replacement medication, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient a nicotine replacement medication.

(d) The pharmacist shall provide counseling to the patient on the use of the nicotine replacement medication and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of a nicotine replacement medication, the appropriate method for using the medication or product, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the medication prescribed by the pharmacist.

(e) A pharmacist who is authorized to prescribe a nicotine replacement medication under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for the medication, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(f) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol or collaborative agreement as authorized in this section and in section 151.01, subdivision 27.

Subd. 16. **Opiate antagonists for the treatment of an acute opiate overdose.** (a) A pharmacist is authorized to prescribe opiate antagonists for the treatment of an acute opiate overdose. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing an opiate antagonist. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe an opiate antagonist under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing opiate antagonists for the treatment of an acute opiate overdose that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing an opiate antagonist under this subdivision, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient an opiate antagonist.

(d) The pharmacist shall provide counseling to the patient on the use of the opiate antagonist and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of the opiate antagonist, the appropriate method for using the opiate antagonist, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the opiate antagonist prescribed by the pharmacist.

(e) A pharmacist who prescribes an opiate antagonist under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare the prescription for the opiate antagonist, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(f) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol as authorized in this section and in section 151.01, subdivision 27.

Subd. 17. **Drugs for preventing the acquisition of HIV.** (a) A pharmacist is authorized to prescribe and administer drugs to prevent the acquisition of human immunodeficiency virus (HIV) in accordance with this subdivision.

(b) By January 1, 2025, the Board of Pharmacy shall develop a standardized protocol for a pharmacist to follow in prescribing the drugs described in paragraph (a). In developing the protocol, the board may consult with community health advocacy groups, the Board of Medical Practice, the Board of Nursing, the commissioner of health, professional pharmacy associations, and professional associations for physicians, physician assistants, and advanced practice registered nurses.

(c) Before a pharmacist is authorized to prescribe a drug described in paragraph (a), the pharmacist must successfully complete a training program specifically developed for prescribing drugs for preventing the acquisition of HIV that is offered by a college of pharmacy, a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(d) Before prescribing a drug described in paragraph (a), the pharmacist shall follow the appropriate standardized protocol developed under paragraph (b) and, if appropriate, may dispense to a patient a drug described in paragraph (a).

(e) Before dispensing a drug described in paragraph (a) that is prescribed by the pharmacist, the pharmacist must provide counseling to the patient on the use of the drugs and must provide the patient with a fact sheet that includes the indications and contraindications for the use of these drugs, the appropriate method for using these drugs, the need for medical follow up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be provided to a patient during the counseling process.

(f) A pharmacist is prohibited from delegating the prescribing authority provided under this subdivision to any other person. A pharmacist intern registered under section 151.101 may prepare the prescription, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(g) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol as authorized in this section and in section 151.01, subdivision 27.

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; 2019 c 63 art 2 s 4; 2020 c 115 art 2 s 22-25; 1Sp2021 c 7 art 6 s 3,28; 2022 c 55 art 1 s 44; 2022 c 58 s 90,91; 2022 c 98 art 6 s 25; 2023 c 68 art 4 s 13; 2023 c 70 art 3 s 47; 2024 c 77 s 2; 2024 c 127 art 60 s 11*

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.** It is unlawful for any person to manufacture or sell hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except for:

(1) the following persons when acting in the course of their practice or employment:

(i) licensed practitioners and their employees, agents, or delegates;

(ii) licensed pharmacies and their employees or agents;

(iii) licensed pharmacists;

(iv) registered nurses and licensed practical nurses;

(v) registered medical technologists;

(vi) medical interns and residents;

(vii) licensed drug wholesalers and their employees or agents;

(viii) licensed hospitals;

(ix) bona fide hospitals in which animals are treated;

(x) licensed nursing homes;

(xi) licensed morticians;

(xii) syringe and needle manufacturers and their dealers and agents;

(xiii) persons engaged in animal husbandry;

(xiv) clinical laboratories and their employees;

(xv) 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;

(xvi) persons who administer drugs pursuant to an order or direction of a licensed practitioner; and

(xvii) syringe services providers and their employees and agents;

(2) a person who self-administers drugs pursuant to either the prescription or the direction of a practitioner, or a family member, caregiver, or other individual who is designated by such person to assist the person in obtaining and using needles and syringes for the administration of such drugs;

(3) a person who is disposing of hypodermic syringes and needles through an activity or program developed under section 325F.785;

(4) a person who sells or handles hypodermic syringes and needles pursuant to subdivision 2; or

(5) a participant receiving services from a syringe services provider, who accesses or receives new syringes or needles from a syringe services provider or returns used syringes or needles to a syringe services provider.

Subd. 2. **Sales of clean needles and syringes.** (a) A registered pharmacy or a licensed pharmacist may sell, without the prescription or direction of a practitioner, unused hypodermic needles and syringes 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) 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.

(d) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes under this subdivision 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; 1Sp2019 c 9 art 10 s 41,42; 2023 c 52 art 15 s 3,4*

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

151.42 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

151.43 SCOPE.

Sections 151.43 to 151.471 apply to any person engaging in the wholesale distribution of drugs within the state and to persons operating as third-party logistics providers.

History: *1990 c 526 s 6; 1990 c 568 art 2 s 21; 1Sp2019 c 9 art 10 s 43; 2020 c 83 art 1 s 42*

151.44 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

151.441 DEFINITIONS.

Subdivision 1. **Scope.** As used in sections 151.43 to 151.471, the following terms have the meanings given in this section.

Subd. 2. **Dispenser.** "Dispenser" means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor, but does not include a person who dispenses only products to be used in animals in accordance with United States Code, title 21, section 360b(a)(5).

Subd. 3. **Disposition.** "Disposition," with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

Subd. 4. **Distribute or distribution.** "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with United States Code, title 21, section 353(b)(1), or the dispensing of a product approved under United States Code, title 21, section 360b(b).

Subd. 5. **Manufacturer.** "Manufacturer" means, with respect to a product:

(1) a person who holds an application approved under United States Code, title 21, section 355, or a license issued under United States Code, title 42, section 262, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(2) a co-licensed partner of the person described in clause (1) that obtains the product directly from a person described in this subdivision; or

(3) an affiliate of a person described in clause (1) or (2) that receives the product directly from a person described in this subdivision.

Subd. 6. **Medical convenience kit.** "Medical convenience kit" means a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user.

Subd. 7. **Package.** "Package" means the smallest individual salable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this subdivision, an "individual salable unit" is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

Subd. 8. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 9. **Product.** "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, but does not include blood or blood components intended for transfusion; radioactive drugs or radioactive biological products as defined in Code of Federal Regulations, title 21, section 600.3(ee), that are regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with such commission under United States Code, title 42, section 2021; imaging drugs; an intravenous product described in subdivision 12, paragraph (b), clauses (14) to (16); any medical gas defined in United States Code, title 21, section 360ddd; homeopathic drugs marketed in accordance with applicable federal law; or a drug compounded in compliance with United States Code, title 21, section 353a or 353b.

Subd. 10. **Repackager.** "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or for distribution without a further transaction.

Subd. 11. **Third-party logistics provider.** "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or disposition of the product.

Subd. 12. **Transaction.** (a) "Transaction" means the transfer of a product between persons in which a change of ownership occurs.

(b) The term "transaction" does not include:

(1) intracompany distribution of any product between members of an affiliate or within a manufacturer;

(2) the distribution of a product among hospitals or other health care entities that are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including:

(i) a public health emergency declaration pursuant to United States Code, title 42, section 247d;

(ii) a national security or peacetime emergency declared by the governor pursuant to section 12.31; or

(iii) a situation involving an action taken by the commissioner of health pursuant to section 144.4197, 144.4198, or 151.37, subdivisions 2, paragraph (b), and 10, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a valid prescription issued by a licensed practitioner;

(5) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with United States Code, title 21, section 353(d);

(6) the distribution of blood or blood components intended for transfusion;

(7) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(8) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in United States Code, title 26, section 501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(9) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(10) the dispensing of a product approved under United States Code, title 21, section 360b(c);

(11) transfer of products to or from any facility that is licensed by the Nuclear Regulatory Commission or by a state pursuant to an agreement with such commission under United States Code, title 42, section 2021;

(12) transfer of a combination product that is not subject to approval under United States Code, title 21, section 355, or licensure under United States Code, title 42, section 262, and that is:

(i) a product comprised of a device and one or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(ii) two or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(iii) two or more finished medical devices plus one or more drug or biological products that are packaged together in a medical convenience kit;

(13) the distribution of a medical convenience kit if:

(i) the medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer in accordance with United States Code, title 21, section 360(b)(2);

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970, United States Code, title 21, section 801, et seq.;

(iii) in the case of a medical convenience kit that includes a product, the person who manufactures the kit:

(A) purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is:

(A) an intravenous solution intended for the replenishment of fluids and electrolytes;

(B) a product intended to maintain the equilibrium of water and minerals in the body;

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

(14) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium; or calories, such as dextrose and amino acids;

(15) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of a medical gas as defined in United States Code, title 21, section 360ddd; or

(18) the distribution or sale of any licensed product under United States Code, title 42, section 262, that meets the definition of a device under United States Code, title 21, section 321(h).

Subd. 13. **Wholesale distribution.** "Wholesale distribution" means the distribution of a drug to a person other than a consumer or patient, or receipt of a drug by a person other than the consumer or patient, but does not include:

(1) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) the distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including:

(i) a public health emergency declaration pursuant to United States Code, title 42, section 247d;

(ii) a national security or peacetime emergency declared by the governor pursuant to section 12.31; or

(iii) a situation involving an action taken by the commissioner of health pursuant to section 144.4197, 144.4198, or 151.37, subdivisions 2, paragraph (b), and 10, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a valid prescription issued by a licensed practitioner;

(5) the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) the distribution of a drug by the manufacturer of such drug;

(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(10) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with United States Code, title 21, section 360eee-1(e);

(12) salable drug returns when conducted by a dispenser;

(13) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, referred to in this section as a medical convenience kit, if:

(i) the medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer in accordance with United States Code, title 21, section 360(b)(2);

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970, United States Code, title 21, section 801, et seq.;

(iii) in the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(A) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(B) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is:

(A) an intravenous solution intended for the replenishment of fluids and electrolytes;

(B) a product intended to maintain the equilibrium of water and minerals in the body;

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

(14) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium; or calories, such as dextrose and amino acids;

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas, as defined in United States Code, title 21, section 360ddd;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in United States Code, title 21, section 360eee(16)(B), and registered under United States Code, title 21, section 360, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Subd. 14. **Wholesale distributor.** "Wholesale distributor" means a person engaged in wholesale distribution but does not include a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager.

History: *1Sp2019 c 9 art 10 s 44; 2020 c 83 art 1 s 43*

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 and licensed third-party logistics providers shall not dispense or distribute 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; 1Sp2019 c 9 art 10 s 45*

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. **Generally.** Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in United States Code, title 21, section 360eee-1, with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving a product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in United States Code, title 21, section 360eee-1, but shall not be required to duplicate requirements.

Subd. 1a. **Licensing.** (a) The board shall license wholesale distributors in a manner that is consistent with United States Code, title 21, section 360eee-2, and the regulations promulgated thereunder. In the event that the provisions of this section, or of the rules of the board, conflict with the provisions of United States Code, title 21, section 360eee-2, or the rules promulgated thereunder, the federal provisions shall prevail. The board shall not license a person as a wholesale distributor unless the person is engaged in wholesale distribution.

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

(c) Application for a wholesale 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 distributor 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 wholesale distributor facility that is located in another state unless the applicant supplies the board with proof of licensure or registration by the state in which the wholesale distributor is physically located or by the United States Food and Drug Administration.

(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 inspected and 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 this section, an applicant shall satisfy the board that it:

(1) has adequate storage conditions and facilities to allow for the safe receipt, storage, handling, and sale of drugs;

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

(3) has a functioning security system that includes an after-hours central alarm or comparable entry detection capability, and security policies and procedures that include provisions for restricted access to the premises, comprehensive employee applicant screening, and safeguards against all forms of employee theft;

(4) will maintain appropriate records of the distribution of drugs, which shall be kept for a minimum of two years and be made available to the board upon request;

(5) employs principals and other persons, including officers, directors, primary shareholders, and key management executives, who will at all times demonstrate and maintain their capability of conducting business in conformity with state and federal law, at least one of whom will serve as the primary designated representative for each licensed facility and who will be responsible for ensuring that the facility operates in a manner consistent with state and federal law;

(6) will ensure that all personnel have sufficient education, training, and experience, in any combination, so that they may perform assigned duties in a manner that maintains the quality, safety, and security of drugs;

(7) will provide the board with updated information about each wholesale distributor facility to be licensed, as requested by the board;

(8) will develop and, as necessary, update 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 drug shipping and receiving, outdated drugs, appropriate handling of returned goods, and drug recalls;

(9) will have sufficient policies and procedures in place for the inspection of all incoming and outgoing drug shipments;

(10) will operate in compliance with all state and federal requirements applicable to wholesale drug distribution; and

(11) will meet the requirements for inspections found in this subdivision.

(i) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section. Paragraphs (i) to (p) apply to wholesaler personnel.

(j) The board is authorized to and shall require fingerprint-based criminal background checks of facility managers or designated representatives, as required under United States Code, title 21, section 360eee-2. The criminal background checks shall be conducted as provided in section 214.075. The board shall use the criminal background check data received to evaluate the qualifications of persons for ownership of or employment by a licensed wholesaler and shall not disseminate this data except as allowed by law.

(k) A licensed wholesaler shall not be owned by, or employ, a person who has:

(1) been convicted of any felony for conduct relating to wholesale distribution, any felony violation of United States Code, title 21, section 331, subsection (i) or (k), or any felony violation of United States Code, title 18, section 1365, relating to product tampering; or

(2) engaged in a pattern of violating the requirements of United States Code, title 21, section 360eee-2, or the regulations promulgated thereunder, or state requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

(l) An applicant for the issuance or renewal of a wholesale distributor license shall execute and file with the board a surety bond.

(m) Prior to issuing or renewing a wholesale distributor license, the board shall require an applicant that is not a government owned and operated wholesale distributor to submit a surety bond of $100,000, except that if the annual gross receipts of the applicant for the previous tax year is $10,000,000 or less, a surety bond of $25,000 shall be required.

(n) If a wholesale distributor can provide evidence satisfactory to the board that it possesses the required bond in another state, the requirement for a bond shall be waived.

(o) The purpose of the surety bond required under this subdivision is to secure payment of any civil penalty imposed by the board pursuant to section 151.071, subdivision 1. The board may make a claim against the bond if the licensee fails to pay a civil penalty within 30 days after the order imposing the fine or costs become final.

(p) A single surety bond shall satisfy the requirement for the submission of a bond for all licensed wholesale distributor facilities under common ownership.

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; 1Sp2019 c 9 art 10 s 46,47*

151.471 THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.

Subdivision 1. **Generally.** Each third-party logistics provider shall comply with the requirements set forth in United States Code, title 21, sections 360eee to 360eee-4, that are applicable to third-party logistics providers.

Subd. 2. **Licensing.** (a) The board shall license third-party logistics providers in a manner that is consistent with United States Code, title 21, section 360eee-3, and the regulations promulgated thereunder. In the event that the provisions of this section or of the rules of the board conflict with the provisions of United States Code, title 21, section 360eee-3, or the rules promulgated thereunder, the federal provisions shall prevail. The board shall not license a person as a third-party logistics provider unless the person is operating as such.

(b) No person shall act as a third-party logistics provider without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(c) Application for a third-party logistics provider license under this section shall be made in a manner specified by the board.

(d) No license shall be issued or renewed for a third-party logistics provider 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 third-party logistics provider facility that is located in another state unless the applicant supplies the board with proof of licensure or registration by the state in which the third-party logistics provider facility is physically located or by the United States Food and Drug Administration.

(f) The board shall require a separate license for each third-party logistics provider facility located within the state and for each third-party logistics provider 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 third-party logistics provider facility unless the facility passes an inspection conducted by an authorized representative of the board or is inspected and accredited by an accreditation program approved by the board. In the case of a third-party logistics provider 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 third-party logistics provider facility license issued under this section, an applicant shall satisfy the board that it:

(1) has adequate storage conditions and facilities to allow for the safe receipt, storage, handling, and transfer of drugs;

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

(3) has a functioning security system that includes an after-hours central alarm or comparable entry detection capability, and security policies and procedures that include provisions for restricted access to the premises, comprehensive employee applicant screening, and safeguards against all forms of employee theft;

(4) will maintain appropriate records of the handling of drugs, which shall be kept for a minimum of two years and be made available to the board upon request;

(5) employs principals and other persons, including officers, directors, primary shareholders, and key management executives, who will at all times demonstrate and maintain their capability of conducting business in conformity with state and federal law, at least one of whom will serve as the primary designated representative for each licensed facility and who will be responsible for ensuring that the facility operates in a manner consistent with state and federal law;

(6) will ensure that all personnel have sufficient education, training, and experience, in any combination, so that they may perform assigned duties in a manner that maintains the quality, safety, and security of drugs;

(7) will provide the board with updated information about each third-party logistics provider facility to be licensed by the board;

(8) will develop and, as necessary, update written policies and procedures that ensure reasonable 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 drug shipping and receiving, outdated drugs, appropriate handling of returned goods, and drug recalls;

(9) will have sufficient policies and procedures in place for the inspection of all incoming and outgoing drug shipments;

(10) will operate in compliance with all state and federal requirements applicable to third-party logistics providers; and

(11) will meet the requirements for inspections found in this subdivision.

(i) An agent or employee of any licensed third-party logistics provider need not seek licensure under this section. Paragraphs (j) and (k) apply to third-party logistics provider personnel.

(j) The board is authorized to and shall require fingerprint-based criminal background checks of facility managers or designated representatives. The criminal background checks shall be conducted as provided in section 214.075. The board shall use the criminal background check data received to evaluate the qualifications of persons for ownership of or employment by a licensed third-party logistics provider and shall not disseminate this data except as allowed by law.

(k) A licensed third-party logistics provider shall not have as a facility manager or designated representative any person who has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of United States Code, title 21, section 331, subsection (i) or (k), or any felony violation of United States Code, title 18, section 1365, relating to product tampering.

History: *1Sp2019 c 9 art 10 s 48*

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

151.49 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

151.50 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

151.51 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

CANCER DRUG REPOSITORY PROGRAM

151.55 MS 2018 [Repealed, 1Sp2019 c 9 art 10 s 53]

151.555 MEDICATION REPOSITORY PROGRAM.

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

(b) "Central repository" means a wholesale distributor that meets the requirements under subdivision 3 and enters into a contract with the Board of Pharmacy in accordance with this section.

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

(d) "Donor" means:

(1) an individual at least 18 years of age, provided that the drug or medical supply that is donated was obtained legally and meets the requirements of this section for donation; or

(2) any entity legally authorized to possess medicine with a license or permit in good standing in the state in which it is located, without further restrictions, including but not limited to a health care facility, skilled nursing facility, assisted living facility, pharmacy, wholesaler, and drug manufacturer.

(e) "Drug" means any prescription drug that has been approved for medical use in the United States, is listed in the United States Pharmacopoeia or National Formulary, and meets the criteria established under this section for donation; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

(f) "Health care facility" means:

(1) a physician's office or health care clinic where licensed practitioners provide health care to patients;

(2) a hospital licensed under section 144.50;

(3) a pharmacy licensed under section 151.19 and located in Minnesota; or

(4) a nonprofit community clinic, including a federally qualified health center; a rural health clinic; public health clinic; or other community clinic that provides health care utilizing a sliding fee scale to patients who are low-income, uninsured, or underinsured.

(g) "Local repository" means a health care facility that elects to accept donated drugs and medical supplies and meets the requirements of subdivision 4.

(h) "Medical supplies" or "supplies" means any prescription or nonprescription medical supplies needed to administer a drug.

(i) "Original, sealed, unopened, tamper-evident packaging" means packaging that is sealed, unopened, and tamper-evident, including a manufacturer's original unit dose or unit-of-use container, a repackager's original unit dose or unit-of-use container, or unit-dose packaging prepared by a licensed pharmacy according to the standards of Minnesota Rules, part 6800.3750.

(j) "Practitioner" has the meaning given in section 151.01, subdivision 23, except that it does not include a veterinarian.

Subd. 2. **Establishment; contract and oversight.** (a) The Board of Pharmacy shall establish a medication repository program, through which donors may donate a drug or medical supply for use by an individual who meets the eligibility criteria specified under subdivision 5.

(b) The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the medication repository program. The contract must:

(1) require payment by the board to the central repository any amount appropriated by the legislature for the operation and administration of the medication repository program;

(2) require the central repository to report the following performance measures to the board:

(i) the number of individuals served and the types of medications these individuals received;

(ii) the number of clinics, pharmacies, and long-term care facilities with which the central repository partnered;

(iii) the number and cost of medications accepted for inventory, disposed of, and dispensed to individuals in need; and

(iv) locations within the state to which medications were shipped or delivered; and

(3) require the board to annually audit the expenditure by the central repository of any money appropriated by the legislature and paid under a contract by the board to ensure that the amount appropriated is used only for purposes specified in the contract.

Subd. 3. **Central repository requirements.** (a) The board may publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the medication repository program. If the board publishes a request for proposal, it shall follow all applicable state procurement procedures in the selection process. The board may also work directly with the University of Minnesota to establish a central repository.

(b) To be eligible to act as the central repository, the participant must be a wholesale drug distributor located in Minnesota, licensed pursuant to section 151.47, and in compliance with all applicable federal and state statutes, rules, and regulations.

(c) The central repository shall be subject to inspection by the board pursuant to section 151.06, subdivision 1.

(d) The central repository shall comply with all applicable federal and state laws, rules, and regulations pertaining to the medication repository program, drug storage, and dispensing. The facility must maintain in good standing any state license or registration that applies to the facility.

Subd. 4. **Local repository requirements.** (a) To be eligible for participation in the medication repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the medication repository program, drug storage, and dispensing. The facility must also agree to maintain in good standing any required state license or registration that may apply to the facility.

(b) A local repository may elect to participate in the program by submitting the following information to the central repository on a form developed by the board and made available on the board's website:

(1) the name, street address, and telephone number of the health care facility and any state-issued license or registration number issued to the facility, including the issuing state agency;

(2) the name and telephone number of a responsible pharmacist or practitioner who is employed by or under contract with the health care facility; and

(3) a statement signed and dated by the responsible pharmacist or practitioner indicating that the health care facility meets the eligibility requirements under this section and agrees to comply with this section.

(c) Participation in the medication repository program is voluntary. A local repository may withdraw from participation in the medication repository program at any time by providing written notice to the central repository on a form developed by the board and made available on the board's website.

Subd. 5. **Individual eligibility and application requirements.** (a) At the time of or before receiving donated drugs or supplies as a new eligible patient, an individual must submit to a local repository an electronic or physical intake application form that is signed by the individual and attests that the individual:

(1) is a resident of Minnesota;

(2) is uninsured, has no prescription drug coverage, or is underinsured;

(3) acknowledges that the drugs or medical supplies to be received through the program may have been donated; and

(4) consents to a waiver of the child-resistant packaging requirements of the federal Poison Prevention Packaging Act.

(b) The local repository shall send a copy of the intake application form to the central repository by regular mail, facsimile, or secured email within ten days from the date the application is approved by the local repository.

(c) The board shall develop and make available on the board's website an application form.

Subd. 6. **Standards and procedures for accepting donations of drugs and supplies.** (a) Notwithstanding any other law or rule, a donor may donate drugs or medical supplies to the central repository or a local repository if the drug or supply meets the requirements of this section as determined by a pharmacist or practitioner who is employed by or under contract with the central repository or a local repository.

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

(1) the drug's expiration date is at least six months after the date the drug was donated. If a donated drug bears an expiration date that is less than six months from the donation date, the drug may be accepted and distributed if the drug is in high demand and can be dispensed for use by a patient before the drug's expiration date;

(2) the drug is in its original, sealed, unopened, tamper-evident packaging that includes the expiration date. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened;

(3) the drug or the packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

(4) the drug does not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, unless the drug is being donated directly by its manufacturer, a wholesale drug distributor, or a pharmacy located in Minnesota; and

(5) the drug is not a controlled substance.

(c) A medical supply is eligible for donation under the medication repository program if the following requirements are met:

(1) the supply has no physical signs of tampering, misbranding, or alteration and there is no reason to believe it has been adulterated, tampered with, or misbranded;

(2) the supply is in its original, unopened, sealed packaging; and

(3) if the supply bears an expiration date, the date is at least six months later than the date the supply was donated. If the donated supply bears an expiration date that is less than six months from the date the supply was donated, the supply may be accepted and distributed if the supply is in high demand and can be dispensed for use by a patient before the supply's expiration date.

(d) The board shall develop the medication repository donor form and make it available on the board's website. Prior to the first donation from a new donor, a central repository or local repository shall verify and record the following information on the donor form:

(1) the donor's name, address, phone number, and license number, if applicable;

(2) that the donor will only make donations in accordance with the program;

(3) to the best of the donor's knowledge, only drugs or supplies that have been properly stored under appropriate temperature and humidity conditions will be donated; and

(4) to the best of the donor's knowledge, only drugs or supplies that have never been opened, used, tampered with, adulterated, or misbranded will be donated.

(e) Notwithstanding any other law or rule, a central repository or a local repository may receive donated drugs from donors. Donated drugs and supplies may be shipped or delivered to the premises of the central repository or a local repository, and shall be inspected by a pharmacist or an authorized practitioner who is employed by or under contract with the repository and who has been designated by the repository prior to dispensing. A drop box must not be used to deliver or accept donations.

(f) The central repository and local repository shall maintain a written or electronic inventory of all drugs and supplies donated to the repository upon acceptance of each drug or supply. For each drug, the inventory must include the drug's name, strength, quantity, manufacturer, expiration date, and the date the drug was donated. For each medical supply, the inventory must include a description of the supply, its manufacturer, the date the supply was donated, and, if applicable, the supply's brand name and expiration date. The board may waive the requirement under this paragraph if an entity is under common ownership or control with a central repository or local repository and either the entity or the repository maintains an inventory containing all the information required under this paragraph.

Subd. 7. **Standards and procedures for inspecting and storing donated drugs and supplies.** (a) A pharmacist or authorized practitioner who is employed by or under contract with the central repository or a local repository shall inspect all donated drugs and supplies before the drug or supply is dispensed to determine, to the extent reasonably possible in the professional judgment of the pharmacist or practitioner, that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe and suitable for dispensing, has not been subject to a recall, and meets the requirements for donation. If a local repository receives drugs and supplies from the central repository, the local repository does not need to reinspect the drugs and supplies.

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory.

(c) The central repository and local repositories shall dispose of all drugs and medical supplies that are not suitable for donation in compliance with applicable federal and state statutes, regulations, and rules concerning hazardous waste.

(d) In the event that controlled substances or drugs that can only be dispensed to a patient registered with the drug's manufacturer are shipped or delivered to a central or local repository for donation, the shipment delivery must be documented by the repository and returned immediately to the donor or the donor's representative that provided the drugs.

(e) Each repository must develop drug and medical supply recall policies and procedures. If a repository receives a recall notification, the repository shall destroy all of the drug or medical supply in its inventory that is the subject of the recall and complete a record of destruction form in accordance with paragraph (f). If a drug or medical supply that is the subject of a Class I or Class II recall has been dispensed, the repository shall immediately notify the recipient of the recalled drug or medical supply. A drug that potentially is subject to a recall need not be destroyed if its packaging bears a lot number and that lot of the drug is not subject to the recall. If no lot number is on the drug's packaging, it must be destroyed.

(f) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 8, are subject to a recall under paragraph (e), or are not suitable for donation shall be maintained by the repository for at least two 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 drug destroyed; and

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

No other record of destruction is required.

Subd. 8. **Dispensing requirements.** (a) Donated prescription drugs and supplies may be dispensed if the drugs or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist or practitioner. A repository shall dispense drugs and supplies to eligible individuals in the following priority order: (1) individuals who are uninsured; (2) individuals with no prescription drug coverage; and (3) individuals who are underinsured. A repository shall dispense donated drugs in compliance with applicable federal and state laws and regulations for dispensing drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(b) Before dispensing or administering a drug or supply, the pharmacist or practitioner shall visually inspect the drug or supply for adulteration, misbranding, tampering, 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 must not be dispensed or administered.

(c) Before the first drug or supply is dispensed or administered to an individual, the individual must sign an electronic or physical drug repository recipient form acknowledging that the individual understands:

(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 or supply 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 central repository or local repository, the Board of Pharmacy, and any other participant of the medication repository program cannot guarantee the safety of the drug or medical 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 medical supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

Subd. 9. **Handling fees.** (a) The central or local 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 drug or medical supply dispensed or administered by that repository.

(b) A repository that dispenses or administers a drug or medical supply through the medication repository program shall not receive reimbursement under the medical assistance program or the MinnesotaCare program for that dispensed or administered drug or supply.

(c) A supply or handling fee must not be charged to an individual enrolled in the medical assistance or MinnesotaCare program.

Subd. 10. **Distribution of donated drugs and supplies.** (a) The central repository and local repositories may distribute drugs and supplies donated under the medication repository program to other participating repositories for use pursuant to this program.

(b) A local repository that elects not to dispense donated drugs or supplies must transfer all donated drugs and supplies to the central repository. A copy of the donor form that was completed by the original donor under subdivision 6 must be provided to the central repository at the time of transfer.

Subd. 11. **Forms and record-keeping requirements.** (a) The following forms developed for the administration of this program shall be available on the board's website:

(1) intake application form described under subdivision 5;

(2) local repository participation form described under subdivision 4;

(3) local repository withdrawal form described under subdivision 4;

(4) medication repository donor form described under subdivision 6;

(5) record of destruction form described under subdivision 7; and

(6) medication repository recipient form described under subdivision 8.

Participants may use substantively similar electronic or physical forms.

(b) All records, including drug inventory and disposal of donated drugs and medical supplies, must be maintained by a repository for a minimum of two years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

(c) Data collected by the medication repository program from all local repositories shall be submitted quarterly or upon request to the central repository. Data collected may consist of the information, records, and forms required to be collected under this section.

(d) The central repository shall submit reports to the board as required by the contract or upon request of the board.

Subd. 12. **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 health care facility 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, a donor of a drug or medical supply, or a person or entity that facilitates any of the above is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the drug or supply is dispensed and no disciplinary action by a health-related licensing board shall be taken against a person or entity 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 drug or medical supply.

Subd. 13. **Drug returned for credit.** Nothing in this section allows a long-term care facility to donate a drug to a central or local repository when federal or state law requires the drug to be returned to the pharmacy that initially dispensed it, so that the pharmacy can credit the payer for the amount of the drug returned.

Subd. 14. **Cooperation.** The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

Subd. 15. **Funding.** The central repository may seek grants and other money from nonprofit charitable organizations, the federal government, and other sources to fund the ongoing operations of the medication repository program.

History: *1Sp2019 c 9 art 9 s 7; 2020 c 115 art 2 s 26; 7Sp2020 c 1 art 6 s 25; 2021 c 30 art 5 s 2-5; 2023 c 70 art 6 s 27; 2024 c 127 art 60 s 12-20*

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; an assisted living facility licensed under chapter 144G; a home provider licensed under chapter 144A 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 Direct Care and Treatment.

(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; 7Sp2020 c 1 art 6 s 25; 2024 c 125 art 5 s 42; 2024 c 127 art 50 s 42*

151.60 MS 2018 [Repealed, 2019 c 39 s 23]

151.61 MS 2018 [Repealed, 2019 c 39 s 23]

151.62 MS 2018 [Repealed, 2019 c 39 s 23]

151.63 MS 2018 [Repealed, 2019 c 39 s 23]

151.64 MS 2018 [Repealed, 2019 c 39 s 23]

151.65 MS 2018 [Repealed, 2019 c 39 s 23]

151.66 MS 2018 [Repealed, 2019 c 39 s 23]

151.67 MS 2018 [Repealed, 2019 c 39 s 23]

151.68 MS 2018 [Repealed, 2019 c 39 s 23]

151.69 MS 2018 [Repealed, 2019 c 39 s 23]

151.70 MS 2018 [Repealed, 2019 c 39 s 23]

MAXIMUM ALLOWABLE COST PRICING

151.71 MS 2018 [Repealed, 2019 c 39 s 23]

151.72 SALE OF CERTAIN CANNABINOID PRODUCTS.

Subdivision 1. **Definitions.** For the purposes of this section, the following terms have the meanings given.

(a) "Artificially derived cannabinoid" means a cannabinoid extracted from a hemp plant or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. Artificially derived cannabinoid includes but is not limited to any tetrahydrocannabinol created from cannabidiol.

(b) "Batch" means a specific quantity of a specific product containing cannabinoids derived from hemp, including an edible cannabinoid product, that is manufactured at the same time and using the same methods, equipment, and ingredients that is uniform and intended to meet specifications for identity, strength, purity,

and composition, and that is manufactured, packaged, and labeled according to a single batch production record executed and documented.

(c) "Certified hemp" means hemp plants that have been tested and found to meet the requirements of chapter 18K and the rules adopted thereunder.

(d) "Distributor" means a person who sells, arranges a sale, or delivers a product containing cannabinoids derived from hemp, including an edible cannabinoid product, that the person did not manufacture to a retail establishment for sale to consumers. Distributor does not include a common carrier used only to complete delivery to a retailer.

(e) "Edible cannabinoid product" means any product that is intended to be eaten or consumed as a beverage by humans, contains a cannabinoid in combination with food ingredients, and is not a drug.

(f) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 3.

(g) "Label" has the meaning given in section 151.01, subdivision 18.

(h) "Labeling" means all labels and other written, printed, or graphic matter that are:

(1) affixed to the immediate container in which a product regulated under this section is sold;

(2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets; or

(3) provided on that portion of a manufacturer's website that is linked by a scannable barcode or matrix barcode.

(i) "Matrix barcode" means a code that stores data in a two-dimensional array of geometrically shaped dark and light cells capable of being read by the camera on a smartphone or other mobile device.

(j) "Nonintoxicating cannabinoid" means substances extracted from certified hemp plants that do not produce intoxicating effects when consumed by any route of administration.

(k) "Office" means the director of the Office of Cannabis Management.

(l) "Synthetic cannabinoid" means a substance with a similar chemical structure and pharmacological activity to a cannabinoid, but which is not extracted or derived from hemp plants, or hemp plant parts and is instead created or produced by chemical or biochemical synthesis.

Subd. 2. **Scope.** (a) This section applies to the sale of any product that contains cannabinoids extracted from hemp and that is an edible cannabinoid product or is intended for human or animal consumption by any route of administration.

(b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.

(c) The office must have no authority over food products, as defined in section 34A.01, subdivision 4, that do not contain cannabinoids extracted or derived from hemp.

Subd. 3. **Sale of cannabinoids derived from hemp.** (a) Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids, including an edible cannabinoid product, may be sold for human or animal consumption only if all of the requirements of this section are met. A product sold for human or animal consumption must not contain more than 0.3 percent of any tetrahydrocannabinol

and an edible cannabinoid product must not contain an amount of any tetrahydrocannabinol that exceeds the limits established in subdivision 5a, paragraph (f).

(b) A product containing nonintoxicating cannabinoids, other than an edible cannabinoid product, may be sold for human or animal consumption only if it is intended for application externally to a part of the body of a human or animal. Such a product must not be manufactured, marketed, distributed, or intended to be consumed:

(1) by combustion or vaporization of the product and inhalation of smoke, aerosol, or vapor from the product;

(2) through chewing, drinking, or swallowing; or

(3) through injection or application to a mucous membrane or nonintact skin.

(c) No other substance extracted or otherwise derived from hemp may be sold for human consumption if the substance is intended:

(1) for external or internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(2) to affect the structure or any function of the bodies of humans or other animals.

(d) No product containing any cannabinoid or tetrahydrocannabinol extracted or otherwise derived from hemp may be sold to any individual who is under the age of 21.

(e) Products that meet the requirements of this section are not controlled substances under section 152.02.

(f) Products may be sold for on-site consumption if all of the following conditions are met:

(1) the retailer must also hold an on-sale license issued under chapter 340A;

(2) products, other than products that are intended to be consumed as a beverage, must be served in original packaging, but may be removed from the products' packaging by customers and consumed on site;

(3) products must not be sold to a customer who the retailer knows or reasonably should know is intoxicated;

(4) products must not be permitted to be mixed with an alcoholic beverage; and

(5) products that have been removed from packaging must not be removed from the premises.

(g) Edible cannabinoid products that are intended to be consumed as a beverage may be served outside of the products' packaging if the information that is required to be contained on the label of an edible cannabinoid product is posted or otherwise displayed by the retailer.

Subd. 4. **Testing requirements.** (a) A manufacturer of a product regulated under this section must submit representative samples of each batch of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the office. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and, at a minimum, the testing must confirm that the product:

(1) contains the amount or percentage of cannabinoids that is stated on the label of the product;

(2) does not contain more than trace amounts of any mold, residual solvents or other catalysts, pesticides, fertilizers, or heavy metals; and

(3) does not contain more than 0.3 percent of any tetrahydrocannabinol.

(b) A manufacturer of a product regulated under this section must disclose all known information regarding pesticides, fertilizers, solvents, or other foreign materials applied to industrial hemp or added to industrial hemp during any production or processing stages of any batch from which a representative sample has been sent for testing, including any catalysts used to create artificially derived cannabinoids. The disclosure must be made to the laboratory performing testing or sampling and, upon request, to the office. The disclosure must include all information known to the manufacturer regardless of whether the application or addition was made intentionally or accidentally, or by the manufacturer or any other person.

(c) Upon the request of the office, the manufacturer of the product must provide the office with the results of the testing required in this section.

(d) The office may determine that any testing laboratory that does not operate formal management systems under the International Organization for Standardization is not an accredited laboratory and require that a representative sample of a batch of the product be retested by a testing laboratory that meets this requirement.

(e) Testing of the hemp from which the nonintoxicating cannabinoid was derived, or possession of a certificate of analysis for such hemp, does not meet the testing requirements of this section.

Subd. 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:

(1) the name, location, contact phone number, and website of the manufacturer of the product;

(2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product;

(3) the batch number; and

(4) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed.

(b) The information in paragraph (a) may be provided on an outer package if the immediate container that holds the product is too small to contain all of the information.

(c) The information required in paragraph (a) may be provided through the use of a scannable barcode or matrix barcode that links to a page on the manufacturer's website if that page contains all of the information required by this subdivision.

(d) The label must also include a statement stating that the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

(e) The information required by this subdivision must be prominently and conspicuously placed on the label or displayed on the website in terms that can be easily read and understood by the consumer.

(f) The labeling must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Subd. 5a. **Additional requirements for edible cannabinoid products.** (a) In addition to the testing and labeling requirements under subdivisions 4 and 5, an edible cannabinoid must meet the requirements of this subdivision.

(b) An edible cannabinoid product must not:

(1) bear the likeness or contain cartoon-like characteristics of a real or fictional person, animal, or fruit that appeals to children;

(2) be modeled after a brand of products primarily consumed by or marketed to children;

(3) be made by applying an extracted or concentrated hemp-derived cannabinoid to a commercially available candy or snack food item;

(4) be substantively similar to a meat food product; poultry food product as defined in section 31A.02, subdivision 10; or a dairy product as defined in section 32D.01, subdivision 7;

(5) contain an ingredient, other than a hemp-derived cannabinoid, that is not approved by the United States Food and Drug Administration for use in food;

(6) be packaged in a way that resembles the trademarked, characteristic, or product-specialized packaging of any commercially available food product; or

(7) be packaged in a container that includes a statement, artwork, or design that could reasonably mislead any person to believe that the package contains anything other than an edible cannabinoid product.

(c) An edible cannabinoid product must be prepackaged in packaging or a container that is child-resistant, tamper-evident, and opaque or placed in packaging or a container that is child-resistant, tamper-evident, and opaque at the final point of sale to a customer. The requirement that packaging be child-resistant does not apply to an edible cannabinoid product that is intended to be consumed as a beverage.

(d) If an edible cannabinoid product, other than a product that is intended to be consumed as a beverage, is intended for more than a single use or contains multiple servings, each serving must be indicated by scoring, wrapping, or other indicators designating the individual serving size that appear on the edible cannabinoid product. If it is not possible to indicate a single serving by scoring or use of another indicator that appears on the product, the edible cannabinoid product may not be packaged in a manner that includes more than a single serving in each container, except that a calibrated dropper, measuring spoon, or similar device for measuring a single serving, when sold with the product, may be used for any edible cannabinoid products that are intended to be combined with food or beverage products prior to consumption.

(e) A label containing at least the following information must be affixed to the packaging or container of all edible cannabinoid products sold to consumers:

(1) the serving size;

(2) the cannabinoid profile per serving and in total;

(3) a list of ingredients, including identification of any major food allergens declared by name; and

(4) the following statement: "Keep this product out of reach of children."

(f) An edible cannabinoid product must not contain more than five milligrams of any tetrahydrocannabinol in a single serving. An edible cannabinoid product, other than a product that is intended to be consumed as a beverage, may not contain more than a total of 50 milligrams of any tetrahydrocannabinol per package. An edible cannabinoid product that is intended to be consumed as a beverage may not contain more than two servings per container.

(g) An edible cannabinoid product may contain delta-8 tetrahydrocannabinol or delta-9 tetrahydrocannabinol that is extracted from hemp plants or hemp plant parts or is an artificially derived cannabinoid. Edible cannabinoid products are prohibited from containing any other artificially derived cannabinoid, including but not limited to THC-P, THC-O, and HHC, unless the office authorizes use of the artificially derived cannabinoid in edible cannabinoid products. Edible cannabinoid products are prohibited from containing synthetic cannabinoids.

(h) Every person selling edible cannabinoid products to consumers, other than products that are intended to be consumed as a beverage, must ensure that all edible cannabinoid products are displayed behind a checkout counter where the public is not permitted or in a locked case.

Subd. 5b. **Registration; prohibitions.** (a) Every person selling an edible cannabinoid product to a consumer must be registered with the office. Existing registrations through the Department of Health must be transferred to the office by July 1, 2024. All other persons required to register must register in a form and manner established by the office. The sale of edible cannabinoid products by a person who is not registered with the office is prohibited and subject to the penalties in section 342.09, subdivision 6; any applicable criminal penalty; and any other applicable civil or administrative penalty.

(b) The registration form must contain an attestation of compliance and each registrant must affirm that it is operating and will continue to operate in compliance with the requirements of this section and all other applicable state and local laws and ordinances.

(c) The office must not charge a fee for registration under this subdivision.

Subd. 5c. **Age verification.** (a) Prior to initiating a sale or otherwise providing an edible cannabinoid product to an individual, an employee of a retailer must verify that the individual is at least 21 years of age.

(b) Proof of age may be established only by one of the following:

(1) a valid driver's license or identification card issued by Minnesota, another state, or a province of Canada and including the photograph and date of birth of the licensed person;

(2) a valid Tribal identification card as defined in section 171.072, paragraph (b);

(3) a valid passport issued by the United States;

(4) a valid instructional permit issued under section 171.05 to a person of legal age to purchase edible cannabinoid products, which includes a photograph and the date of birth of the person issued the permit; or

(5) in the case of a foreign national, by a valid passport.

(c) A registered retailer may seize a form of identification listed under paragraph (b) if the registered retailer has reasonable grounds to believe that the form of identification has been altered or falsified or is being used to violate any law. A registered retailer that seizes a form of identification as authorized under this paragraph must deliver it to a law enforcement agency within 24 hours of seizing it.

Subd. 6. **Noncompliant products; enforcement.** (a) A product regulated under this section, including an edible cannabinoid product, shall be considered a noncompliant product if the product is offered for sale in this state or if the product is manufactured, imported, distributed, or stored with the intent to be offered for sale in this state in violation of any provision of this section, including but not limited to if:

(1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;

(2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;

(3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(4) it contains any food additives, color additives, or excipients that have been found by the FDA to be unsafe for human or animal consumption;

(5) it contains an amount or percentage of nonintoxicating cannabinoids that is different than the amount or percentage stated on the label;

(6) it contains more than 0.3 percent of any tetrahydrocannabinol or, if the product is an edible cannabinoid product, an amount of tetrahydrocannabinol that exceeds the limits established in subdivision 5a, paragraph (f); or

(7) it contains more than trace amounts of mold, residual solvents, pesticides, fertilizers, or heavy metals.

(b) A product regulated under this section shall be considered a noncompliant product if the product's labeling is false or misleading in any manner or in violation of the requirements of this section.

(c) The office may assume that any product regulated under this section that is present in the state, other than a product lawfully possessed for personal use, has been manufactured, imported, distributed, or stored with the intent to be offered for sale in this state if a product of the same type and brand was sold in the state on or after July 1, 2023, or if the product is in the possession of a person who has sold any product in violation of this section.

(d) The office may enforce this section, including enforcement against a manufacturer or distributor of a product regulated under this section, under section 342.19.

(e) The office may enter into an interagency agreement with the commissioner of agriculture to perform inspections and take other enforcement actions on behalf of the office.

Subd. 7. **Violations; criminal penalties.** (a) A person who does any of the following regarding a product regulated under this section is guilty of a gross misdemeanor and may be sentenced to imprisonment for not more than 364 days or to payment of a fine of not more than $3,000, or both:

(1) knowingly alters or otherwise falsifies testing results;

(2) intentionally alters or falsifies any information required to be included on the label of an edible cannabinoid product; or

(3) intentionally makes a false material statement to the office.

(b) A person who does any of the following on the premises of a registered retailer or another business that sells retail goods to customers is guilty of a gross misdemeanor and may be sentenced to imprisonment for not more than 364 days or to payment of a fine of not more than $3,000, or both:

(1) sells an edible cannabinoid product knowing that the product does not comply with the limits on the amount or types of cannabinoids that a product may contain;

(2) sells an edible cannabinoid product knowing that the product does not comply with the applicable testing, packaging, or labeling requirements; or

(3) sells an edible cannabinoid product to a person under the age of 21, except that it is an affirmative defense to a charge under this clause if the defendant proves by a preponderance of the evidence that the defendant reasonably and in good faith relied on proof of age as described in subdivision 5c.

History: *1Sp2019 c 9 art 11 s 76; 2021 c 30 art 3 s 27; 2022 c 98 art 13 s 3-9; 2023 c 52 art 6 s 16; 2023 c 63 art 7 s 2,6; 2024 c 121 art 2 s 4-11,154*

151.74 INSULIN SAFETY NET PROGRAM.

Subdivision 1. **Establishment.** (a) By July 1, 2020, each manufacturer must establish procedures to make insulin available in accordance with this section to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply.

(b) For purposes of this section, the following definitions apply:

(1) "manufacturer" means a manufacturer engaged in the manufacturing of insulin that is self-administered on an outpatient basis;

(2) "MNsure" means the Board of Directors of MNsure established in chapter 62V;

(3) "navigator" has the meaning provided in section 62V.02; and

(4) "pharmacy" means a pharmacy located in Minnesota and licensed under section 151.19 that operates in the community or outpatient license category under Minnesota Rules, part 6800.0350.

(c) Any manufacturer with an annual gross revenue of $2,000,000 or less from insulin sales in Minnesota is exempt from this section. To request a waiver under this paragraph, the manufacturer must submit a request to the Board of Pharmacy that includes documentation indicating that the manufacturer is eligible for an exemption.

(d) An insulin product is exempt from this section if the wholesale acquisition cost of the insulin is $8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually based on the Consumer Price Index.

Subd. 2. **Eligibility for urgent-need safety net program.** (a) To be eligible to receive an urgent-need supply of insulin under this section, an individual must attest to:

(1) being a resident of Minnesota;

(2) not being enrolled in medical assistance or MinnesotaCare;

(3) not being enrolled in prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance, to $75 or less, regardless of the type or amount of insulin prescribed;

(4) not having received an urgent-need supply of insulin through this program within the previous 12 months, unless authorized under subdivision 9; and

(5) being in urgent need of insulin.

(b) For purposes of this subdivision, "urgent need of insulin" means having readily available for use less than a seven-day supply of insulin and in need of insulin in order to avoid the likelihood of suffering significant health consequences.

Subd. 3. **Access to urgent-need insulin.** (a) MNsure shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subdivision 2. The form shall be accessible through MNsure's website. MNsure shall also make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(b) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification indicating Minnesota residency in the form of a valid Minnesota identification card, driver's license or permit, individual taxpayer identification number, or Tribal identification card as defined in section 171.072, paragraph (b). If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(c) Upon receipt of a completed and signed application, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy must notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(d) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

(e) The pharmacy may collect an insulin co-payment from the individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $35 for the 30-day supply of insulin dispensed.

(f) The pharmacy shall also provide each eligible individual with the information sheet described in subdivision 7 and a list of trained navigators provided by the Board of Pharmacy for the individual to contact if the individual needs to access ongoing insulin coverage options, including assistance in:

(1) applying for medical assistance or MinnesotaCare;

(2) applying for a qualified health plan offered through MNsure, subject to open and special enrollment periods;

(3) accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

(4) accessing insulin manufacturers' patient assistance programs, co-payment assistance programs, and other foundation-based programs.

(g) The pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

(h) A manufacturer may submit to the commissioner of administration a request for reimbursement in an amount not to exceed $35 for each 30-day supply of insulin the manufacturer provides under paragraph (d). The commissioner of administration shall determine the manner and format for submitting and processing requests for reimbursement. After receiving a reimbursement request, the commissioner of administration shall reimburse the manufacturer in an amount not to exceed $35 for each 30-day supply of insulin the manufacturer provided under paragraph (d).

Subd. 4. **Continuing safety net program; general.** (a) Each manufacturer shall make a patient assistance program available to any individual who meets the requirements of this subdivision. Each manufacturer's patient assistance programs must meet the requirements of this section. Each manufacturer shall provide the Board of Pharmacy with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing their patient assistance program.

(b) To be eligible to participate in a manufacturer's patient assistance program, the individual must:

(1) be a Minnesota resident with a valid Minnesota identification card that indicates Minnesota residency in the form of a Minnesota identification card, driver's license or permit, individual taxpayer identification number, or Tribal identification card as defined in section 171.072, paragraph (b). If the individual is under the age of 18, the individual's parent or legal guardian must provide proof of residency;

(2) have a family income that is equal to or less than 400 percent of the federal poverty guidelines;

(3) not be enrolled in medical assistance or MinnesotaCare;

(4) not be eligible to receive health care through a federally funded program or receive prescription drug benefits through the Department of Veterans Affairs; and

(5) not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing that an enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance to $75 or less, regardless of the type or amount of insulin needed.

(c) Notwithstanding the requirement in paragraph (b), clause (4), an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if the individual has spent $1,000 on prescription drugs in the current calendar year and meets the eligibility requirements in paragraph (b), clauses (1) to (3).

(d) An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer; apply through the individual's health care practitioner, if the practitioner participates; or contact a trained navigator for assistance in finding a long-term insulin supply solution, including assistance in applying to a manufacturer's patient assistance program.

Subd. 5. **Continuing safety net program; manufacturer's responsibilities.** (a) Upon receipt of an application for the manufacturer's patient assistance program, the manufacturer shall process the application and determine eligibility. The manufacturer shall notify the applicant of the determination within ten business days of receipt of the application. If necessary, the manufacturer may request additional information from the applicant. If additional information is needed, the manufacturer must notify the applicant within five business days of receipt of the application as to what information is being requested. Within three business days of receipt of the requested information, the manufacturer must determine eligibility and notify the applicant of the determination. If the individual has been determined to be not eligible, the manufacturer

must include the reasons for denying eligibility in the notification. The individual may seek an appeal of the determination in accordance with subdivision 8.

(b) If the individual is determined to be eligible, the manufacturer shall provide the individual with an eligibility statement or other indication that the individual has been determined eligible for the manufacturer's patient assistance program. An individual's eligibility is valid for 12 months and is renewable upon a redetermination of eligibility.

(c) If the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer may determine that the individual's insulin needs are better addressed through the use of the manufacturer's co-payment assistance program, in which case, the manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy. In no instance shall an eligible individual be required to pay more than the co-payment amount specified under subdivision 6, paragraph (e).

Subd. 6. **Continuing safety net program; process.** (a) The individual shall submit to a pharmacy the statement of eligibility provided by the manufacturer under subdivision 5, paragraph (b). Upon receipt of an individual's eligibility status, the pharmacy shall submit an order containing the name of the insulin product and the daily dosage amount as contained in a valid prescription to the product's manufacturer.

(b) The pharmacy must include with the order to the manufacturer the following information:

(1) the pharmacy's name and shipping address;

(2) the pharmacy's office telephone number, fax number, email address, and contact name; and

(3) any specific days or times when deliveries are not accepted by the pharmacy.

(c) Upon receipt of an order from a pharmacy and the information described in paragraph (b), the manufacturer shall send to the pharmacy a 90-day supply of insulin as ordered, unless a lesser amount is requested in the order, at no charge to the individual or pharmacy.

(d) Except as authorized under paragraph (e), the pharmacy shall provide the insulin to the individual at no charge to the individual. The pharmacy shall not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order. The pharmacy shall not seek reimbursement for the insulin received from the manufacturer or from any third-party payer.

(e) The pharmacy may collect a co-payment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed $50 for each 90-day supply if the insulin is sent to the pharmacy.

(f) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer must send to the pharmacy an additional 90-day supply of the product, unless a lesser amount is requested, at no charge to the individual or pharmacy if the individual's eligibility statement has not expired.

(g) Notwithstanding paragraph (c), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

(h) A manufacturer may submit to the commissioner of administration a request for reimbursement in an amount not to exceed $105 for each 90-day supply of insulin the manufacturer provides under paragraphs (c) and (f). The commissioner of administration shall determine the manner and format for submitting and processing requests for reimbursement. After receiving a reimbursement request, the commissioner of

administration shall reimburse the manufacturer in an amount not to exceed $105 for each 90-day supply of insulin the manufacturer provided under paragraphs (c) and (f). If the manufacturer provides less than a 90-day supply of insulin under paragraphs (c) and (f), the manufacturer may submit a request for reimbursement not to exceed $35 for each 30-day supply of insulin provided.

Subd. 7. **Board of Pharmacy and MNsure responsibilities.** (a) The Board of Pharmacy shall develop an information sheet to post on its website and provide a link to the information sheet on the board's website for pharmacies, health care practitioners, hospital emergency departments, urgent care clinics, and community health clinics. The information sheet must contain:

(1) a description of the urgent-need insulin safety net program, including how to access the program;

(2) a description of each insulin manufacturer's patient assistance program and cost-sharing assistance program, including contact information on accessing the assistance programs for each manufacturer;

(3) information on how to contact a trained navigator for assistance in applying for medical assistance, MinnesotaCare, a qualified health plan, or an insulin manufacturer's patient assistance programs;

(4) information on how to contact the Board of Pharmacy if a manufacturer determines that an individual is not eligible for the manufacturer's patient assistance program; and

(5) notification that an individual in need of assistance may contact their local county social service department for more information or assistance in accessing ongoing affordable insulin options.

(b) The board shall also inform each individual who accesses urgent-need insulin through the insulin safety net program or accesses a manufacturer's patient assistance program that the individual may participate in a survey conducted by the Department of Health regarding satisfaction with the program. The board shall provide contact information for the individual to learn more about the survey and how to participate. This information may be included on the information sheet described in paragraph (a).

(c) MNsure, in consultation with the Board of Pharmacy and the commissioner of human services, shall develop a training program for navigators to provide navigators with information and resources necessary to assist individuals in accessing appropriate long-term insulin options.

(d) MNsure, in consultation with the Board of Pharmacy, shall compile a list of navigators who have completed the training program and who are available to assist individuals in accessing affordable insulin coverage options. The list shall be made available through the board's website and to pharmacies and health care practitioners who dispense and prescribe insulin.

(e) If a navigator assists an individual in accessing an insulin manufacturer's patient assistance program, MNsure, within the available appropriation, shall pay the navigator a onetime application assistance bonus of no less than $25. If a navigator receives a payment per enrollee of an assistance bonus under section 62V.05, subdivision 4, or 256.962, subdivision 5, the navigator shall not receive compensation under this paragraph.

Subd. 8. **Dispute resolution.** (a) If an individual disagrees with a manufacturer's determination of eligibility under subdivision 5, the individual may contact the Board of Pharmacy to request the use of a three-person panel to review eligibility. The panel shall be composed of three members of the board. The individual requesting the review shall submit to the board, with the request, all documents submitted by the individual to the manufacturer. The board shall provide the panel with the documents submitted by the individual. The panel shall render a decision within ten business days of receipt of all the necessary documents from the individual. The decision of the panel is final.

(b) If the panel determines that the individual is eligible, the manufacturer shall provide the individual with an eligibility statement in accordance with subdivision 5.

Subd. 9. **Additional 30-day urgent-need insulin supply.** (a) If an individual has applied for medical assistance or MinnesotaCare but has not been determined eligible or has been determined eligible but coverage has not become effective or the individual has been determined ineligible for the manufacturer's patient assistance program by the manufacturer and the individual has requested a review pursuant to subdivision 8 but the panel has not rendered a decision, the individual may access urgent-need insulin under subdivision 3 if the individual is in urgent need of insulin as defined under subdivision 2, paragraph (b).

(b) To access an additional 30-day supply of insulin, the individual must attest to the pharmacy that the individual meets the requirements of paragraph (a) and must comply with subdivision 3, paragraph (b).

Subd. 10. **Penalty.** (a) If a manufacturer fails to comply with this section, the board may assess an administrative penalty of $200,000 per month of noncompliance, with the penalty increasing to $400,000 per month if the manufacturer continues to be in noncompliance after six months, and increasing to $600,000 per month if the manufacturer continues to be in noncompliance after one year. The penalty shall remain at $600,000 per month for as long as the manufacturer continues to be in noncompliance.

(b) In addition, a manufacturer is subject to the administrative penalties specified in paragraph (a) if the manufacturer fails to:

(1) provide a hotline for individuals to call or access between 8 a.m. and 10 p.m. on weekdays and between 10 a.m. and 6 p.m. on Saturdays; and

(2) list on the manufacturer's website the eligibility requirements for the manufacturer's patient assistance programs for Minnesota residents.

(c) Any penalty assessed under this subdivision shall be deposited in a separate insulin assistance account in the special revenue fund.

Subd. 11. **Data.** (a) Any data collected, created, received, maintained, or disseminated by the Board of Pharmacy, the legislative auditor, the commissioner of health, MNsure, or a trained navigator under this section related to an individual who is seeking to access urgent-need insulin or participate in a manufacturer's patient assistance program under this section is classified as private data on individuals as defined in section 13.02, subdivision 12, and may not be retained for longer than ten years.

(b) A manufacturer must maintain the privacy of all data received from any individual applying for the manufacturer's patient assistance program under this section and is prohibited from selling, sharing, or disseminating data received under this section unless required to under this section or the individual has provided the manufacturer with a signed authorization.

Subd. 12. **State and federal antikickback provisions.** (a) The conduct of any person or entity participating in or administering the insulin safety net program under this section is not subject to liability under section 62J.23, subdivisions 1 and 2.

(b) No person or entity, including but not limited to any drug manufacturer, pharmacy, pharmacist, or third-party administrator, as part of the person's or entity's participation in or administration of the insulin safety net program established under this section, shall request or seek, or cause another to request or seek, any reimbursement or other compensation for which payment may be made in whole or in part under a federal health care program, as defined in United States Code, title 42, section 1320a-7b(f).

Subd. 13. **Reports.** (a) By February 15 of each year, beginning February 15, 2021, each manufacturer shall report to the Board of Pharmacy the following:

(1) the number of Minnesota residents who accessed and received insulin on an urgent-need basis under this section in the preceding calendar year;

(2) the number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Minnesota residents who the manufacturer determined were ineligible for their patient assistance program; and

(3) the value of the insulin provided by the manufacturer under clauses (1) and (2).

For purposes of this paragraph, "value" means the wholesale acquisition cost of the insulin provided.

(b) By March 15 of each year, beginning March 15, 2021, the Board of Pharmacy shall submit the information reported in paragraph (a) to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The board shall also include in the report any administrative penalties assessed under subdivision 10, including the name of the manufacturer and amount of the penalty assessed.

Subd. 14. **Program review; legislative auditor.** (a) The legislative auditor is requested to conduct a program review to determine:

(1) whether the manufacturers are meeting the responsibilities required under this section, including but not limited to:

(i) reimbursing pharmacies for urgent-need insulin dispensed under subdivision 3;

(ii) determining eligibility in a timely manner and notifying the individuals as required under subdivision 5; and

(iii) providing pharmacies with insulin product under the manufacturers' patient assistance programs; and

(2) whether the training program developed for navigators is adequate and easily accessible for navigators interested in becoming trained, and that there is a sufficient number of trained navigators to provide assistance to individuals in need of assistance.

(b) The legislative auditor may access application forms retained by pharmacies under subdivision 3, paragraph (g), to determine whether urgent-need insulin is being dispensed in accordance with this section.

Subd. 15. **Program satisfaction; surveys.** (a) The commissioner of health, in consultation with the Board of Pharmacy and individuals who are insulin-dependent, shall develop and conduct a survey of individuals who have accessed urgent-need insulin through the program and who are accessing or have accessed a manufacturer's patient assistance program since the commencement of the insulin safety net program; and a survey of pharmacies that have dispensed insulin on an urgent-need basis under the program and have participated in the manufacturers' patient assistance programs under this section.

(b) The survey for individuals shall cover overall satisfaction with the program, including but not limited to:

(1) accessibility to urgent-need insulin;

(2) adequacy of the information sheet and list of navigators received from the pharmacy;

(3) whether the individual contacted a trained navigator and, if so, if the navigator was helpful and knowledgeable;

(4) whether the individual accessed the manufacturer's patient assistance program and, if so, how easy it was to access application forms, apply to the manufacturer's programs, and receive the insulin product from the pharmacy; and

(5) whether the individual is still in need of a long-term solution for affordable insulin.

(c) The survey for the pharmacies shall include, but is not limited to:

(1) timeliness of reimbursement from the manufacturers for urgent-need insulin dispensed by the pharmacy;

(2) ease in submitting insulin product orders to the manufacturers; and

(3) timeliness of receiving insulin orders from the manufacturers.

(d) The commissioner may contract with a nonprofit entity to develop and conduct the survey and to evaluate the survey results.

(e) By January 15, 2022, the commissioner shall submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance containing the results of the surveys.

Subd. 16. MS 2022 [Repealed, 2024 c 127 art 56 s 8]

History: *2020 c 73 s 4; 2020 c 115 art 3 s 37,38; 2022 c 55 art 1 s 45; 2023 c 70 art 6 s 28,29; 2024 c 127 art 56 s 4,5*

151.741 INSULIN MANUFACTURER REGISTRATION FEE.

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

(b) "Board" means the Minnesota Board of Pharmacy under section 151.02.

(c) "Manufacturer" means a manufacturer licensed under section 151.252 and engaged in the manufacturing of prescription insulin.

Subd. 2. **Assessment of registration fee.** (a) The board shall assess each manufacturer an annual registration fee of $100,000, except as provided in paragraph (b). The board shall notify each manufacturer of this requirement beginning November 1, 2024, and each November 1 thereafter.

(b) A manufacturer may request an exemption from the annual registration fee. The board shall exempt a manufacturer from the annual registration fee if the manufacturer can demonstrate to the board, in the form and manner specified by the board, that gross revenue from sales of prescription insulin produced by that manufacturer and sold or delivered within or into Minnesota was less than five percent of the total gross revenue from sales of prescription insulin produced by all manufacturers and sold or delivered within or into Minnesota in the previous calendar year.

Subd. 3. **Payment of the registration fee; deposit of fee.** (a) Each manufacturer must pay the registration fee by March 1, 2025, and by each March 1 thereafter. In the event of a change in ownership of the manufacturer, the new owner must pay the registration fee that the original owner would have been assessed

had the original owner retained ownership. The board may assess a late fee of ten percent per month or any portion of a month that the registration fee is paid after the due date.

(b) The registration fee, including any late fees, must be deposited in the insulin safety net program account.

Subd. 4. **Insulin safety net program account.** The insulin safety net program account is established in the special revenue fund in the state treasury. Money in the account is appropriated each fiscal year to:

(1) the MNsure board in an amount sufficient to carry out assigned duties under section 151.74, subdivision 7; and

(2) the Board of Pharmacy in an amount sufficient to cover costs incurred by the board in assessing and collecting the registration fee under this section and in administering the insulin safety net program under section 151.74.

Subd. 5. **Insulin repayment account; annual transfer from health care access fund.** (a) The insulin repayment account is established in the special revenue fund in the state treasury. Money in the account is appropriated each fiscal year to the commissioner of administration to reimburse manufacturers for insulin dispensed under the insulin safety net program in section 151.74, in accordance with section 151.74, subdivisions 3, paragraph (h), and 6, paragraph (h), and to cover costs incurred by the commissioner in providing these reimbursement payments.

(b) By June 30, 2025, and each June 30 thereafter, the commissioner of administration shall certify to the commissioner of management and budget the total amount expended in the prior fiscal year for:

(1) reimbursement to manufacturers for insulin dispensed under the insulin safety net program in section 151.74, in accordance with section 151.74, subdivisions 3, paragraph (h), and 6, paragraph (h); and

(2) costs incurred by the commissioner of administration in providing the reimbursement payments described in clause (1).

(c) The commissioner of management and budget shall transfer from the health care access fund to the special revenue fund, beginning July 1, 2025, and each July 1 thereafter, an amount equal to the amount to which the commissioner of administration certified pursuant to paragraph (b).

Subd. 6. **Contingent transfer by commissioner.** If subdivisions 2 and 3, or the application of subdivisions 2 and 3 to any person or circumstance, are held invalid for any reason in a court of competent jurisdiction, the invalidity of subdivisions 2 and 3 does not affect other provisions of this act, and the commissioner of management and budget shall annually transfer from the health care access fund to the insulin safety net program account an amount sufficient to implement subdivision 4.

History: *2024 c 127 art 56 s 6*