State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. 2545

02/27/2014 Authored by Liebling
The bill was read for the first time and referred to the Committee on Health and Human Services Policy
03/06/2014 Adoption of Report: Re-referred to the Committee on Civil Law
03/12/2014 Adoption of Report: Amended and re-referred to the Committee on Judiciary Finance and Policy

A bill for an act

relating to health; adding and modifying definitions; changing the requirements for pharmacist participation in immunizations; changing the powers and duties of the Board of Pharmacy; changing licensing requirements for businesses regulated by the Board of Pharmacy; clarifying requirements for compounding; allowing certain educational institutions to purchase legend drugs in limited circumstances; allowing certain entities to handle drugs in preparation for emergency use; clarifying the requirement that drug manufacturers report certain payments to the Board of Pharmacy; adding certain substances to the schedules for controlled substances; amending Minnesota Statutes 2012, sections 151.01; 151.06; 151.211; 151.26; 151.34; 151.35; 151.361, subdivision 2; 151.37, as amended; 151.44; 151.58, subdivisions 2, 3, 5; 152.02, subdivision 8b; Minnesota Statutes 2013 Supplement, sections 151.252, by adding a subdivision; 152.02, subdivision 2; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. Minnesota Statutes 2012, section 151.01, is amended to read:

151.01 DEFINITIONS.

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

Subd. 2. **Pharmacy.** "Pharmacy" means ~~an established~~ a place of business in which ~~prescriptions,~~ prescription drugs~~, medicines, chemicals, and poisons~~ are prepared, compounded, or dispensed~~, vended, or sold to or for the use of patients~~ 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.** The term "pharmacist" means an individual with a currently valid license issued by the Board of Pharmacy to practice pharmacy.

Subd. 5. **Drug.** The term "drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, vaccines and biologicals, and 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 that, 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.** The term "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.** The term "poisons" means any substance ~~which~~ that, when introduced into the system, directly or by absorption, produces violent, morbid, or fatal changes, or ~~which~~ that destroys living tissue with which it comes in contact.

Subd. 8. **Chemical.** The term "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 ~~State~~ Board of Pharmacy.** The term "board" or "~~State~~ Board of Pharmacy" means the Minnesota ~~State~~ Board of Pharmacy.

Subd. 10. **Director.** The term "director" means the executive director of the Minnesota ~~State~~ Board of Pharmacy.

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

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

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

Subd. 14. **Manufacturing.** The term "manufacturing" ~~except in the case of bulk compounding, prepackaging or extemporaneous compounding within a pharmacy,~~ means

~~and includes~~ the production, ~~quality control and standardization by mechanical, physical, chemical, or pharmaceutical means, packing, repacking, tableting, encapsulating, labeling, relabeling, filling or by any other process, of all drugs, medicines, chemicals, or poisons, without exception, for medicinal purposes.~~ 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.** The term "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.** The term "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 ~~State~~ 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.** The term "pharmacy technician" means a person not licensed as a pharmacist or a pharmacist intern, who assists the pharmacist in the preparation and dispensing of medications by performing computer entry of prescription data and other manipulative tasks. A pharmacy technician shall not perform tasks specifically reserved to a licensed pharmacist or requiring professional judgment.

Subd. 16. **Prescription drug order.** The term "prescription drug order" means a ~~signed~~ lawful written ~~order, or an~~, oral, or electronic order ~~reduced to writing, given by~~ of a practitioner ~~licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber.~~ 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.** The term "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.** The term "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 ~~which~~ that is required by federal law to ~~bear the following statement, "Caution: Federal law prohibits dispensing without prescription."~~ 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~~; and a requirement made by or under authority of Laws 1969, chapter 933 that~~. Any word, statement, or other information ~~appearing~~ required by or under the authority of this chapter to appear on the label shall ~~not be considered to be complied with unless such word, statement, or other information~~ also ~~appears~~ appear on the outside container or wrapper, if any there be, of the retail package of such drug or medicine, or ~~is~~ 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 ~~State~~ 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 osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, or licensed veterinarian. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A, or an advanced practice nurse authorized to prescribe, dispense, and administer under section 148.235. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

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

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

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

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

(1) interpretation and evaluation of prescription drug orders;

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

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

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

(5) participation in administration of influenza vaccines to all eligible individuals ten years of age and older and all other vaccines to patients 18 years of age and older ~~under standing orders from a physician licensed under chapter 147 or~~ by written protocol with a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs under section 148.235, provided that:

(i) the protocol includes, at a minimum:

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

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

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

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

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

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

~~(i)~~ (ii) the pharmacist ~~is trained in~~ has successfully completed a program approved by the ~~American~~ Accreditation Council ~~of Pharmaceutical~~ for Pharmacy Education specifically for the administration of immunizations or ~~graduated from a college of pharmacy in 2001 or thereafter~~ a program approved by the board; ~~and~~

~~(ii)~~ (iii) the pharmacist reports the administration of the immunization to the patient's primary physician or clinic or to the Minnesota Immunization Information Connection; and

(iv) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices, except that a pharmacist does not need to comply with those portions of the guidelines that establish

immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs under section 148.235, provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine;

(6) participation in the ~~practice of managing drug therapy and modifying~~ initiation, management, modification, and discontinuation of drug therapy~~, according to section 151.21, subdivision 1,~~ according to a written protocol or collaborative practice agreement between ~~the specific pharmacist~~: (i) one or more pharmacists and ~~the individual dentist, optometrist, physician, podiatrist, or veterinarian who is responsible for the patient's care and authorized to independently prescribe drugs~~ one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice nurses authorized to prescribe, dispense, and administer under section 148.235. Any ~~significant~~ changes in drug therapy made pursuant to a protocol or collaborative practice agreement must be ~~reported~~ documented by the pharmacist ~~to~~ in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

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

(8) ~~responsibility for participation in~~ patient counseling on therapeutic values, content, hazards, and uses of drugs and devices; and

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

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

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

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

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

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

Subd. 28. **Veterinary legend drug.** "Veterinary legend drug" means a drug that is required by federal law to ~~bear the following statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."~~ be dispensed only pursuant to the prescription of a licensed veterinarian.

Subd. 29. **Legend medical gas.** "Legend medical gas" means a liquid or gaseous substance used for medical purposes and that is required by federal law to ~~bear the following statement: "Caution: Federal law prohibits dispensing without a prescription."~~ be dispensed only pursuant to the prescription of a licensed practitioner.

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

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

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

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

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

Subd. 35. **Compounding.** "Compounding" means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order. Compounding also includes anticipatory compounding, as defined in this section, and the preparation of drugs in which all bulk drug substances and components are nonprescription substances. Compounding does

not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions. Compounding does not include the preparation of a drug for the purpose of, or incident to, research, teaching, or chemical analysis, provided that the drug is not prepared for dispensing or administration to patients. All compounding, regardless of the type of product, must be done pursuant to a prescription drug order unless otherwise permitted in this chapter or by the rules of the board.

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.

Sec. 2. Minnesota Statutes 2012, section 151.06, is amended to read:

151.06 POWERS AND DUTIES.

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

(1) to regulate the practice of pharmacy;

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

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

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

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

(6) to license wholesale drug distributors;

(7) to ~~deny, suspend, revoke, or refuse to renew~~ take disciplinary action against any registration or license required under this chapter~~, to any applicant or registrant or licensee~~ upon any of the ~~following~~ grounds~~:~~ listed in section 151.071, and in accordance with the provisions of section 151.071;

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

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

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

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

~~(v) unprofessional conduct or conduct endangering public health;~~

~~(vi) gross immorality;~~

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

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

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

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

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

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

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

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

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

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

~~(D) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall investigate any complaint of a violation of section 609.215, subdivision 1 or 2;~~

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

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

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

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

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

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

~~(d)~~ (c) Substitution; rules. 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. ~~**Disciplinary action**~~ **Cease and desist orders.** ~~It shall be grounds for disciplinary action by the Board of Pharmacy against the registration of the pharmacy if the Board of Pharmacy determines that any person with supervisory responsibilities at the pharmacy sets policies that prevent a licensed pharmacist from providing drug utilization review and patient counseling as required by rules adopted under subdivision 1. The Board of Pharmacy shall follow the requirements of chapter 14 in any disciplinary actions taken under this section.~~ (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. 3. **Application of Administrative Procedure Act.** The board shall comply with the provisions of chapter 14, before it fails to issue, renew, suspends, or revokes any license or registration issued under this chapter.~~

~~Subd. 4. **Reinstatement.** Any license or registration which has been suspended or revoked may be reinstated by the board provided the holder thereof shall pay all costs~~

~~of the proceedings resulting in the suspension or revocation, and, in addition thereto, pay a fee set by the board.~~

~~Subd. 5. **Costs; penalties.** The board may impose a civil penalty not exceeding $10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including, but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members.~~

Sec. 3. **[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 designated settings; the imposition of retraining or rehabilitation requirements; the requirement of practice under supervision; the requirement of participation in a diversion program such as that established pursuant to section 214.31 or the conditioning of continued practice on demonstration of knowledge or skills by appropriate examination or other review of skill and competence;

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

(7) reprimand the licensee or registrant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

adjudication shall automatically suspend a license for the duration thereof unless the board orders otherwise;

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

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

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

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

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

(17) 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 or the dispensing of drugs or devices;

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

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

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

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

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

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

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

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

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(23) for a pharmacist, practice of pharmacy under a lapsed or nonrenewed license. For a pharmacist intern, pharmacy technician, or controlled substance researcher, performing duties permitted to such individuals by this chapter or the rules of the board under a lapsed or nonrenewed registration. For a facility required to be licensed under this chapter, operation of the facility under a lapsed or nonrenewed license or registration; and

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

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

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

regulated individual if, after a hearing before the board, the board finds that the felonious conduct would cause a serious risk of harm to the public.

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

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

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

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

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

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

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

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

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

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

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

Subd. 8. **Temporary suspension of license for pharmacies, drug wholesalers, drug manufacturers, medical gas manufacturers, and medical gas distributors.** In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend the license or registration of a pharmacy, drug wholesaler, drug manufacturer, medical gas manufacturer, or medical gas distributor if the board finds that the licensee or registrant has violated a statute or rule that the board is empowered to enforce and continued operation of the licensed facility would create a serious risk of harm to the public. The suspension shall take effect upon written notice to the licensee or registrant, specifying the statute or rule violated. The suspension shall remain in effect until the board issues a final order in the matter after a hearing. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The licensee or registrant shall be provided with at

least 20 days' notice of any hearing held pursuant to this subdivision. The hearing shall be scheduled to begin no later than 30 days after the issuance of the suspension order.

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

Subd. 10. **Mental examination; access to medical data.** (a) If the board 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) In addition to ordering a physical or mental examination, the board may, notwithstanding section 13.384, 144.651, or any other law limiting access to medical or other health data, 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, if the board has probable cause to believe that the individual falls under subdivision 2, clause (14). The medical data may be requested from a provider, as defined in section 144.291, subdivision 2, paragraph (h), an insurance company, or a government agency, including the Department of Human Services. A provider, insurance

company, or government agency shall comply with any written request of the board under this subdivision and is not liable in any action for damages for releasing the data requested by the board if the data are released pursuant to a written request under this subdivision, unless the information is false and the provider giving the information knew, or had reason to believe, the information was false. Information obtained under this subdivision is classified as private under sections 13.01 to 13.87.

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

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

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

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

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

(d) A licensee or applicant must provide the licensee's or applicant's Social Security number and Minnesota business identification number on all license applications. Upon request of the commissioner of revenue, the board must provide to the commissioner of revenue a list of all licensees and applicants that includes the licensee's or applicant's name, address, Social Security number, and business identification number. The

commissioner of revenue may request a list of the licensees and applicants no more than once each calendar year.

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

Sec. 4. **[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. **Courts.** The court administrator of a district court or any other court of competent jurisdiction shall report to the board any judgment or other determination of

the court that: adjudges or includes a finding that a licensee or registrant of the board is mentally ill, mentally incompetent, guilty of a felony, or guilty of a violation of federal or state narcotics laws or controlled substances act, guilty of an abuse or fraud under Medicare or Medicaid; appoints a guardian of the licensee or registrant pursuant to sections 524.5-101 to 524.5-502; or commits a licensee or registrant pursuant to chapter 253B.

Subd. 5. **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 or 4.

Subd. 6. **Deadlines; forms.** Reports required by subdivisions 2 to 5 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. 7. **Subpoenas.** The board may issue subpoenas for the production of any reports required by subdivisions 2 to 5 or any related documents.

Sec. 5. **[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 of the rules of the board, or persons participating in the investigation or testifying regarding charges of violations, are immune from civil liability and criminal prosecution 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 and criminal prosecution for any actions, transactions, or publications in the execution of, or relating to, their duties under section 151.301.

Sec. 6. **[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.

Sec. 7. Minnesota Statutes 2012, section 151.211, is amended to read:

151.211 RECORDS OF PRESCRIPTIONS.

Subdivision 1. **Retention of prescription drug orders.** All ~~prescriptions dispensed~~ prescription drug orders shall be kept on file at the location ~~in~~ from which ~~such~~ dispensing ~~occurred~~ 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.** ~~No~~ A prescription ~~shall~~ drug order may be refilled ~~except~~ 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.

Sec. 8. **[151.251] 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:

(a) 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):

(1) that:

(i) 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;

(ii) 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

(iii) 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);

(2) 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

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

(b) 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;

(c) 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;

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

(e) 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.

Sec. 9. Minnesota Statutes 2013 Supplement, section 151.252, is amended by adding a subdivision to read:

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

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

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

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

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

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

(g) The board shall not issue an initial or renewed license for an outsourcing facility unless the facility passes an inspection conducted by an authorized representative of the

board. In the case of an outsourcing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 10. Minnesota Statutes 2012, section 151.26, is amended to read:

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, other than a controlled substance, that was packaged by a manufacturer and provided to the dispenser for distribution as a professional sample.

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 that, 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 ~~which~~ 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 that, 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.

Sec. 11. Minnesota Statutes 2012, section 151.34, is amended to read:

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 ~~which~~ 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 ~~which~~ 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; ~~or~~

(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 that, 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.

Sec. 12. Minnesota Statutes 2012, section 151.35, is amended to read:

151.35 DRUGS, ADULTERATION.

A drug shall be deemed to be adulterated:

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

or deleterious substance which may render the contents injurious to health; or it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act, or it is a color additive, the intended use of which in or on drugs is for the purposes of coloring only, and is unsafe within the meaning of the federal act;

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

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

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

Sec. 13. Minnesota Statutes 2012, section 151.361, subdivision 2, is amended to read:

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 ~~which~~ that render the product impractical for the imprinting required by this section.

~~(c) The provisions of clauses (a) and (b) shall not apply to any of the following:~~

~~(1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.~~

~~(2) Drugs which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed.~~

Sec. 14. Minnesota Statutes 2012, section 151.37, as amended by Laws 2013, chapter 43, section 30, Laws 2013, chapter 55, section 2, and Laws 2013, chapter 108, article 10, section 5, is amended to read:

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

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

Subd. 2. **Prescribing and filing.** (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a licensed dietitian or licensed nutritionist, pursuant to section 148.634; a nurse, pursuant to section 148.235, subdivisions 8 and 9; physician assistant; medical student or resident; or pharmacist according to section 151.01, subdivision 27, to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

(b) The commissioner of health, if a licensed practitioner, or a person designated by the commissioner who is a licensed practitioner, may prescribe a legend drug to an individual or by protocol for mass dispensing purposes where the commissioner finds that the conditions triggering section 144.4197 or 144.4198, subdivision 2, paragraph (b), exist. The commissioner, if a licensed practitioner, or a designated licensed practitioner, may prescribe, dispense, or administer a legend drug or other substance listed in subdivision 10 to control tuberculosis and other communicable diseases. The commissioner may modify state drug labeling requirements, and medical screening criteria and documentation, where

time is critical and limited labeling and screening are most likely to ensure legend drugs reach the maximum number of persons in a timely fashion so as to reduce morbidity and mortality.

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

(d) A prescription ~~or~~ drug order for the following drugs is not valid, unless it can be established that the prescription ~~or~~ 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) phoshodiesterase type 5 inhibitors when used to treat erectile dysfunction.

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

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

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

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

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

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

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

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

(h) Nothing in paragraph (d) or (e) limits prescription, administration, or dispensing of legend drugs through a public health clinic or other distribution mechanism approved by the commissioner of health or a board of health 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 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 licensed under section 151.19, subdivision 2, may dispense a legend drug to a resident of this state based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (d).

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

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

and medical devices, subject to the requirements in chapter 147A and other requirements established by the Board of Medical Practice in rules.

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

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

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

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

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

(3) dispensing and distribution of research drugs by pharmacies shall not be considered ~~compounding,~~ 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 the following entities from possessing a legend drug for the purpose of disposing of the legend drug as pharmaceutical waste:

(1) a law enforcement officer;

(2) a hazardous waste transporter licensed by the Department of Transportation;

(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 a very small quantity generator collection program or a minimal generator;

(5) a county that collects, stores, transports, or disposes of a legend drug pursuant to a program in compliance with applicable federal law or a person authorized by the county to conduct one or more of these activities; or

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

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 prescription drug has been dispensed in accordance with a valid prescription issued by a practitioner from transferring the legend drug to a county that collects, stores, transports, or disposes of a legend drug pursuant to a program in compliance with applicable federal law or to a person authorized by the county to conduct one or more of these activities.

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 360.bbb-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. ~~**Complaint reporting**~~ **Exclusion for health care educational programs.** ~~The Board of Pharmacy shall report on a quarterly basis to the Board of Optometry any complaints received regarding the prescription or administration of legend drugs under section 148.576.~~ 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:

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

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

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

(d) 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).

Sec. 15. Minnesota Statutes 2012, section 151.44, is amended to read:

151.44 DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

(b) "Wholesale drug distributor" means anyone engaged in wholesale drug distribution including, but not limited to, manufacturers; ~~repackers~~ repackagers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale drug distributor does not include a common carrier or individual hired primarily to transport prescription or nonprescription drugs.

(c) "Manufacturer" ~~means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug~~ has the meaning provided in section 151.01, subdivision 14b.

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

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

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

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

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

Sec. 16. Minnesota Statutes 2012, section 151.58, subdivision 2, is amended to read:

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

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

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

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

Sec. 17. Minnesota Statutes 2012, section 151.58, subdivision 3, is amended to read:

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.

Sec. 18. Minnesota Statutes 2012, section 151.58, subdivision 5, is amended to read:

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; 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.

Sec. 19. Minnesota Statutes 2013 Supplement, section 152.02, subdivision 2, is amended to read:

Subd. 2. **Schedule I.** (a) Schedule I consists of the substances listed in this subdivision.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following substances, including their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the analogs, isomers, esters, ethers, and salts is possible:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate);

(4) alphameprodine;

(5) alphamethadol;

(6) alpha-methylfentanyl benzethidine;

(7) betacetylmethadol;

(8) betameprodine;

(9) betamethadol;

(10) betaprodine;

(11) clonitazene;

(12) dextromoramide;

(13) diampromide;

(14) diethyliambutene;

(15) difenoxin;

(16) dimenoxadol;

(17) dimepheptanol;

(18) dimethyliambutene;

(19) dioxaphetyl butyrate;

(20) dipipanone;

(21) ethylmethylthiambutene;

(22) etonitazene;

(23) etoxeridine;

(24) furethidine;

(25) hydroxypethidine;

(26) ketobemidone;

(27) levomoramide;

(28) levophenacylmorphan;

(29) 3-methylfentanyl;

(30) acetyl-alpha-methylfentanyl;

(31) alpha-methylthiofentanyl;

(32) benzylfentanyl beta-hydroxyfentanyl;

(33) beta-hydroxy-3-methylfentanyl;

(34) 3-methylthiofentanyl;

(35) thenylfentanyl;

(36) thiofentanyl;

(37) para-fluorofentanyl;

(38) morpheridine;

(39) 1-methyl-4-phenyl-4-propionoxypiperidine;

(40) noracymethadol;

(41) norlevorphanol;

(42) normethadone;

(43) norpipanone;

(44) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);

(45) phenadoxone;

(46) phenampromide;

(47) phenomorphan;

(48) phenoperidine;

(49) piritramide;

(50) proheptazine;

(51) properidine;

(52) propiram;

(53) racemoramide;

(54) tilidine;

(55) trimeperidine.;

(56) N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl).

(c) Opium derivatives. Any of the following substances, their analogs, salts, isomers, and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) acetorphine;

(2) acetyldihydrocodeine;

(3) benzylmorphine;

(4) codeine methylbromide;

(5) codeine-n-oxide;

(6) cyprenorphine;

(7) desomorphine;

(8) dihydromorphine;

(9) drotebanol;

(10) etorphine;

(11) heroin;

(12) hydromorphinol;

(13) methyldesorphine;

(14) methyldihydromorphine;

(15) morphine methylbromide;

(16) morphine methylsulfonate;

(17) morphine-n-oxide;

(18) myrophine;

(19) nicocodeine;

(20) nicomorphine;

(21) normorphine;

(22) pholcodine;

(23) thebacon.

(d) Hallucinogens. Any material, compound, mixture or preparation which contains any quantity of the following substances, their analogs, salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) methylenedioxy amphetamine;

(2) methylenedioxymethamphetamine;

(3) methylenedioxy-N-ethylamphetamine (MDEA);

(4) n-hydroxy-methylenedioxyamphetamine;

(5) 4-bromo-2,5-dimethoxyamphetamine (DOB);

(6) 2,5-dimethoxyamphetamine (2,5-DMA);

(7) 4-methoxyamphetamine;

(8) 5-methoxy-3, 4-methylenedioxy amphetamine;

(9) alpha-ethyltryptamine;

(10) bufotenine;

(11) diethyltryptamine;

(12) dimethyltryptamine;

(13) 3,4,5-trimethoxy amphetamine;

(14) 4-methyl-2, 5-dimethoxyamphetamine (DOM);

(15) ibogaine;

(16) lysergic acid diethylamide (LSD);

(17) mescaline;

(18) parahexyl;

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) psilocybin;

(22) psilocyn;

(23) tenocyclidine (TPCP or TCP);

(24) N-ethyl-1-phenyl-cyclohexylamine (PCE);

(25) 1-(1-phenylcyclohexyl) pyrrolidine (PCPy);

(26) 1-[1-(2-thienyl)cyclohexyl]-pyrrolidine (TCPy);

(27) 4-chloro-2,5-dimethoxyamphetamine (DOC);

(28) 4-ethyl-2,5-dimethoxyamphetamine (DOET);

(29) 4-iodo-2,5-dimethoxyamphetamine (DOI);

(30) 4-bromo-2,5-dimethoxyphenethylamine (2C-B);

(31) 4-chloro-2,5-dimethoxyphenethylamine (2C-C);

(32) 4-methyl-2,5-dimethoxyphenethylamine (2-CD);

(33) 4-ethyl-2,5-dimethoxyphenethylamine (2C-E);

(34) 4-iodo-2,5-dimethoxyphenethylamine (2C-I);

(35) 4-propyl-2,5-dimethoxyphenethylamine (2C-P);

(36) 4-isopropylthio-2,5-dimethoxyphenethylamine (2C-T-4);

(37) 4-propylthio-2,5-dimethoxyphenethylamine (2C-T-7);

(38) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2-CB-FLY);

(39) bromo-benzodifuranyl-isopropylamine (Bromo-DragonFLY);

(40) alpha-methyltryptamine (AMT);

(41) N,N-diisopropyltryptamine (DiPT);

(42) 4-acetoxy-N,N-dimethyltryptamine (4-AcO-DMT);

(43) 4-acetoxy-N,N-diethyltryptamine (4-AcO-DET);

(44) 4-hydroxy-N-methyl-N-propyltryptamine (4-HO-MPT);

(45) 4-hydroxy-N,N-dipropyltryptamine (4-HO-DPT);

(46) 4-hydroxy-N,N-diallyltryptamine (4-HO-DALT);

(47) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);

(48) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DiPT);

(49) 5-methoxy-α-methyltryptamine (5-MeO-AMT);

(50) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(51) 5-methylthio-N,N-dimethyltryptamine (5-MeS-DMT);

(52) 5-methoxy-N-methyl-N-propyltryptamine (5-MeO-MiPT);

(53) 5-methoxy-α-ethyltryptamine (5-MeO-AET);

(54) 5-methoxy-N,N-dipropyltryptamine (5-MeO-DPT);

(55) 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);

(56) 5-methoxy-N,N-diallytryptamine (5-MeO-DALT);

(57) methoxetamine (MXE);

(58) 5-iodo-2-aminoindane (5-IAI);

(59) 5,6-methylenedioxy-2-aminoindane (MDAI);

(60) 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (25I-NBOMe).

(e) Peyote. All parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation

of the plant, its seeds or extracts. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church, and members of the American Indian Church are exempt from registration. Any person who manufactures peyote for or distributes peyote to the American Indian Church, however, is required to obtain federal registration annually and to comply with all other requirements of law.

(f) Central nervous system depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) mecloqualone;

(2) methaqualone;

(3) gamma-hydroxybutyric acid (GHB), including its esters and ethers;

(4) flunitrazepam.

(g) Stimulants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) aminorex;

(2) cathinone;

(3) fenethylline;

(4) methcathinone;

(5) methylaminorex;

(6) N,N-dimethylamphetamine;

(7) N-benzylpiperazine (BZP);

(8) methylmethcathinone (mephedrone);

(9) 3,4-methylenedioxy-N-methylcathinone (methylone);

(10) methoxymethcathinone (methedrone);

(11) methylenedioxypyrovalerone (MDPV);

(12) fluoromethcathinone;

(13) methylethcathinone (MEC);

(14) 1-benzofuran-6-ylpropan-2-amine (6-APB);

(15) dimethylmethcathinone (DMMC);

(16) fluoroamphetamine;

(17) fluoromethamphetamine;

(18) α-methylaminobutyrophenone (MABP or buphedrone);

(19) β-keto-N-methylbenzodioxolylpropylamine (bk-MBDB or butylone);

(20) 2-(methylamino)-1-(4-methylphenyl)butan-1-one (4-MEMABP or BZ-6378);

(21) naphthylpyrovalerone (naphyrone); ~~and~~

(22) (RS)-1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (alpha-PVP or alpha-pyrrolidinovalerophenone;

(23) (RS)-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-hexanone (4-Me-PHP oe MPHP); and

~~(22)~~ (24) any other substance, except bupropion or compounds listed under a different schedule, that is structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

(i) by substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;

(ii) by substitution at the 3-position with an acyclic alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or

(iv) by inclusion of the 2-amino nitrogen atom in a cyclic structure.

(h) Marijuana, tetrahydrocannabinols, and synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(1) marijuana;

(2) tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant, or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including, but not limited to, 1 cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol;

(3) synthetic cannabinoids, including the following substances:

(i) Naphthoylindoles, which are any compounds containing a 3-(1-napthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any

extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM-678);

(B) ~~1-Butul-3-(1-naphthoyl)indole~~ 1-Butyl-3-(1-naphthoyl)indole (JWH-073);

(C) 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081);

(D) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(E) 1-Propyl-2-methyl-3-(1-naphthoyl)indole (JWH-015);

(F) 1-Hexyl-3-(1-naphthoyl)indole (JWH-019);

(G) 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(H) 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210);

(I) 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(J) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201).

(ii) Napthylmethylindoles, which are any compounds containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindoles include, but are not limited to:

(A) 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane (JWH-175);

(B) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl)methan (JWH-184).

(iii) Naphthoylpyrroles, which are any compounds containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylpyrroles include, but are not limited to, (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone (JWH-307).

(iv) Naphthylmethylindenes, which are any compounds containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an allkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthylemethylindenes include, but are not limited to, E-1-[1-(1-naphthalenylmethylene)-1H-inden-3-yl]pentane (JWH-176).

(v) Phenylacetylindoles, which are any compounds containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl,

alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of phenylacetylindoles include, but are not limited to:

(A) 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (RCS-8);

(B) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(C) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251);

(D) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

(vi) Cyclohexylphenols, which are compounds containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of cyclohexylphenols include, but are not limited to:

(A) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47,497);

(B) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (Cannabicyclohexanol or CP 47,497 C8 homologue);

(C) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl] -phenol (CP 55,940).

(vii) Benzoylindoles, which are any compounds containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of benzoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(4-methoxybenzoyl)indole (RCS-4);

(B) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694);

(C) (4-methoxyphenyl-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (WIN 48,098 or Pravadoline).

(viii) Others specifically named:

(A) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210);

(B) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (Dexanabinol or HU-211);

(C) 2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de] -1,4-benzoxazin-6-yl-1-naphthalenylmethanone (WIN 55,212-2);

(D) (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

(E) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);

(F) 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide (AKB-48(APINACA));

(G) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5-Fluoro-AKB-48);

(H) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);

(I) 8-quinolinyl ester-1-(5-fluoropentyl)-1H-indole-3-carboxylic acid (5-Fluoro PB-22).;

(J) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA);

(K) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (AB-FUBINACA).

(i) A controlled substance analog, to the extent that it is implicitly or explicitly intended for human consumption.

Sec. 20. Minnesota Statutes 2012, section 152.02, subdivision 8b, is amended to read:

Subd. 8b. **Board of Pharmacy; expedited scheduling of additional substances.** ~~(a)~~ The state Board of Pharmacy may, by rule, add a substance to Schedule I provided that it finds that the substance has a high potential for abuse, has no currently accepted medical use in the United States, has a lack of accepted safety for use under medical supervision, has known adverse health effects, and is currently available for use within the state. For the purposes of this subdivision only, the board may use the expedited rulemaking process under section 14.389. ~~The scheduling of a substance under this subdivision expires the day after the adjournment of the legislative session immediately following the substance's scheduling unless the legislature by law ratifies the action.~~

~~(b) If the board schedules a substance under this subdivision, the board shall notify in a timely manner the chairs and ranking minority members of the senate and house of representatives committees having jurisdiction over criminal justice and health policy and finance of the action and the reasons for it. The notice must include a copy of the administrative law judge's decision on the matter.~~

~~(c) This subdivision expires August 1, 2014.~~