State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. 1208

03/04/2013 Authored by Mullery
The bill was read for the first time and referred to the Committee on Health and Human Services Policy

A bill for an act

relating to health; changing licensing requirements for businesses regulated by the Board of Pharmacy; clarifying requirements for compounding; making changes to the prescription monitoring program; amending Minnesota Statutes 2012, sections 151.01, subdivisions 14, 16, 17, 27, 28, 29, 30, by adding subdivisions; 151.19, subdivisions 1, 3; 151.211; 151.361, subdivision 2; 151.37, subdivision 2, by adding subdivisions; 151.44; 151.47, subdivision 1, by adding a subdivision; 151.49; 152.126; proposing coding for new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.37, subdivision 11; 151.45; 151.47, subdivision 2; 151.48.

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

Section 1. Minnesota Statutes 2012, section 151.01, subdivision 14, is amended to read:

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 bulk compounding of a drug within a licensed pharmacy, nor the labeling of a container within a pharmacy for the purpose of dispensing a drug to a patient with a valid prescription.

Sec. 2. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 13a. **Manufacturer.** "Manufacturer" means anyone engaged in manufacturing.

Sec. 3. Minnesota Statutes 2012, section 151.01, subdivision 16, is amended to read:

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.

Sec. 4. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

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 quality of the drug prescribed, directions for use, name and address of the practitioner, and 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 transmitted via facsimile must contain the practitioner's manual signature. An electronic prescription must contain the practitioner's electronic signature.

Sec. 5. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

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 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 a birth date or medical record number, the drug ordered, and any directions 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.

Sec. 6. Minnesota Statutes 2012, section 151.01, subdivision 17, is amended to read:

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.

Sec. 7. Minnesota Statutes 2012, section 151.01, subdivision 27, is amended to read:

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;

(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 provided that:

(i) the standing orders or protocol include, at a minimum, the name, dosage, and route of each vaccine that may be given, the patient population for whom the vaccine may be given, contraindications and precautions to the vaccine, the procedure for handling an adverse reaction, the name and signature of the physician, the address of the physician, a phone number at which the physician can be contacted, and the date and time period for which the standing orders or protocol are 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; and~~ a program approved according to rules adopted by the board;

(iii) the pharmacist completes continuing education concerning the administration of immunizations, as required by Minnesota Rules;

(iv) the pharmacist has a current cardiopulmonary resuscitation certificate;

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

(vi) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices (ACIP), except that a pharmacist does not need to comply with those guidelines if administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147 when the order is consistent with United States Food and Drug Administration approved labeling of the vaccine; and

(vii) the pharmacist complies with Centers for Disease Control and Prevention guidelines relating to immunization schedules, vaccine storage and handling, and vaccine administration and documentation;

(6) participation in the practice of managing drug therapy and modifying drug therapy~~, according to section 151.21, subdivision 1,~~ according to a written protocol between the specific pharmacist and the individual dentist, optometrist, physician, podiatrist, or veterinarian who is responsible for the patient's care and authorized to independently prescribe drugs. Any significant changes in drug therapy must be reported by the pharmacist to the patient's medical record;

(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.

Sec. 8. Minnesota Statutes 2012, section 151.01, subdivision 28, is amended to read:

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.

Sec. 9. Minnesota Statutes 2012, section 151.01, subdivision 29, is amended to read:

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.

Sec. 10. Minnesota Statutes 2012, section 151.01, subdivision 30, is amended to read:

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, including the preparation and delivery 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.

Sec. 11. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 35. **Compounding.** The term "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, or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, shall be done pursuant to a prescription drug order unless otherwise permitted in this chapter. Compounding also includes 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 the manufacturer's directions.

Sec. 12. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 36. **Anticipatory compounding.** The term "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 filling prescription drug orders. In the case of practitioners only, bulk 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. Bulk compounding is not the preparation of a compounded drug product for wholesale distribution.

Sec. 13. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 37. **Extemporaneous compounding.** The term "extemporaneous compounding" means compounding a drug product upon receipt of a prescription drug order for a specific patient.

Sec. 14. Minnesota Statutes 2012, section 151.01, is amended by adding a subdivision to read:

Subd. 38. **Compounded positron emission tomography drug.** (a) The term "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; and

(2) has been compounded by or on the order of a practitioner according to Minnesota Rules, chapters 4731 and 6800, for a patient or for research, teaching, or quality control.

(b) Compounded positron emission tomography drug includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program used in the preparation of a drug.

Sec. 15. Minnesota Statutes 2012, section 151.19, subdivision 1, is amended to read:

Subdivision 1. **Pharmacy ~~registration~~ licensure requirements.** ~~The board shall require and provide for the annual registration of every pharmacy now or hereafter doing business within this state. Upon the payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to such persons as may be qualified by law to conduct a pharmacy. Such certificate shall be displayed in a conspicuous place in the pharmacy for which it is issued and expire on the 30th day of June following the date of issue. It shall be unlawful for any person to conduct a pharmacy unless such certificate has been issued to the person by the board.~~ (a) No person shall operate a pharmacy without first obtaining a license from the board and paying any applicable fee specified in section 151.065. The license shall be displayed in a conspicuous place in the pharmacy for which it is issued and expires on June 30 following the date of issue. It is unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

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

(c) No license shall be issued or renewed for a pharmacy located within the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal and state law and according to rules adopted by the board. No license shall be issued for a

pharmacy located outside of the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal law and, when dispensing medications for residents of this state, the laws of this state and Minnesota Rules.

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

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

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

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

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

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

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

(4) that, during its regular hours of operation, but no less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and

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

Sec. 16. Minnesota Statutes 2012, section 151.19, subdivision 3, is amended to read:

Subd. 3. **Sale of federally restricted medical gases.** ~~The board shall require and provide for the annual registration of every person or establishment not licensed as a pharmacy or a practitioner engaged in the retail sale or distribution of federally restricted medical gases. Upon the payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to those persons or places that may be qualified to sell or distribute federally restricted medical gases. The certificate shall be displayed in a conspicuous place in the business for which it is issued and expire on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.~~ (a) A person or establishment not licensed as a pharmacy or a practitioner shall not engage in the retail sale or distribution of federally restricted medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration shall be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.

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

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

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

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

(f) The board shall not issue an initial or renewed registration for a medical gas distributor unless the medical gas distributor passes an inspection conducted by an authorized representative of the board. In the case of a medical gas distributor located

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

Sec. 17. 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 unless they are converted to an electronic format that produces an exact and legible copy of the original document. Electronic systems used to process and store prescription drug orders must be compliant with the requirements of this chapter and Minnesota Rules.

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, section 152.11, and the rules of the board. The date of ~~such~~ the 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. 18. **[151.251] PHARMACY COMPOUNDING.**

Subdivision 1. **Exemption from manufacturing licensure requirement.** Section 151.25 shall not apply to a pharmacy or a practitioner that compounds a drug product if the drug product is compounded for an identified individual patient based on receipt of a valid prescription drug order, as defined in section 151.01, subdivision 16a, on which the prescribing practitioner has indicated that compounding of the drug product is medically necessary for the patient, if the drug product meets the requirements of this section and is not sold at wholesale and if the compounding:

(1) is by a licensed pharmacist or a licensed practitioner, on the prescription order for the individual patient made by a licensed practitioner authorized to prescribe drugs; or

(2) is by a licensed pharmacist or licensed practitioner in limited quantities before the receipt of a valid prescription order for the individual patient and:

(i) is not dispensed or otherwise distributed in any manner prior to receipt of a valid prescription order; and

(ii) is based on a history of the licensed pharmacist or licensed practitioner receiving valid prescription orders for the compounding of the drug product, and those orders have been generated solely within an established relationship between the licensed pharmacist or licensed practitioner and the individual patient for whom the prescription order will be provided or the licensed practitioner who will write the prescription order.

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

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

(i) complies 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 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 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, appears on a list developed by the United States Food and Drug Administration through regulations issued by the Secretary of the United States Department of Health and Human Services pursuant to the Food, Drugs, and Cosmetic Act, section 503a, subsection (d) and:

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

(B) are accompanied by valid certificates of analysis for each bulk drug substance; and

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

(b) A licensed pharmacist or licensed practitioner, when compounding a drug product, is prohibited from using any product that appears on a list published by the secretary of the United States Department of Health and Human Services in the Federal Register of drug products that have been withdrawn or removed from the market because the drug products or components of the drug products have been found to be unsafe or not effective.

(c) A licensed pharmacist or licensed practitioner shall not compound any drug product that is essentially a copy of a commercially available drug product. For purposes of this paragraph, "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 sufficient difference between the compounded drug and the comparable commercially available drug product, as determined by the prescribing practitioner.

Subd. 3. **Exceptions.** (a) This section does not apply to:

(1) drugs compounded 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;

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

(3) radiopharmaceuticals.

(b) As used in this section, "compounding" does not include mixing, reconstituting, or other acts performed according to directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Sec. 19. **[151.252] LICENSING OF DRUG MANUFACTURERS; FEES; PROHIBITIONS.**

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

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

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

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

(e) No license shall be issued or renewed for a manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant

supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a manufacturer that is not required to be licensed or registered by the state in which it is physically located.

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

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

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

Sec. 20. 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~~ United States 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 render the product impractical for the imprinting required by this section.

(c) ~~The provisions of clauses~~ Paragraphs (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~~.~~; and

(2) drugs ~~which~~ that are ~~manufactured~~ compounded 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. 21. Minnesota Statutes 2012, section 151.37, subdivision 2, is amended to read:

Subd. 2. **Prescribing and filing.** (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, 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).

Sec. 22. Minnesota Statutes 2012, section 151.37, is amended by adding a subdivision to read:

Subd. 10a. **Emergency use authorizations.** Nothing in this chapter prohibits the purchase, possession, or use of a legend drug by an entity authorized by 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.

Sec. 23. Minnesota Statutes 2012, section 151.37, is amended by adding a subdivision to read:

Subd. 10b. **Exclusion for health care educational programs.** (a) Nothing in this chapter prohibits an accredited public or private postsecondary school from possessing a legend drug that is not a controlled substance listed in section 152.02, provided that:

(1) the school is approved by the United States Secretary of Education according to the Higher Education Act of 1965, as amended, published in United States Code, title 20, chapter 28;

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

(3) the school only possesses those drugs necessary for instruction of individuals; and

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

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

Sec. 24. 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 13a.

(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. 25. Minnesota Statutes 2012, section 151.47, subdivision 1, is amended to read:

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

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

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

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

~~(c) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within the state, or for a parent entity with divisions, subsidiaries, or affiliate companies within the state, when operations are conducted at more than one location and joint ownership and control exists among all the entities.~~

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

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

(g) The board shall not issue an initial or renewed license for a drug wholesale distributor facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug wholesale distributor facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. 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.

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

(1) adequate storage conditions and facilities;

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

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

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

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

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

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

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

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

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

~~(f) A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this provision are public data.~~

Sec. 26. Minnesota Statutes 2012, section 151.47, is amended by adding a subdivision to read:

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

Sec. 27. Minnesota Statutes 2012, section 151.49, is amended to read:

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

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

Sec. 28. Minnesota Statutes 2012, section 152.126, is amended to read:

152.126 ~~CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM~~ PRESCRIPTION MONITORING PROGRAM.

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

~~(a)~~ (b) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

~~(b)~~ (c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to ~~5~~ 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12. For the purpose of this section only, "controlled substances" includes tramadol and butalbital.

~~(c)~~ (d) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

~~(d)~~ (e) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

~~(e)~~ (f) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1.

~~(f)~~ (g) "Prescription" has the meaning given in section 151.01, subdivision 16.

Subd. 1a. **Treatment of intractable pain.** This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

Subd. 2. **Prescription electronic reporting system.** (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

Subd. 3. **Prescription ~~Electronic Reporting~~ Monitoring Program Advisory Committee.** (a) The board shall convene an advisory committee. The committee must include at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association;

(6) a professional nursing association;

(7) a professional dental association;

(8) a consumer privacy or security advocate; ~~and~~

(9) a consumer or patient rights organization; and

(10) an association of medical examiners and coroners.

(b) The advisory committee shall advise the board on the development and operation of the ~~electronic reporting system~~ prescription monitoring program, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data; and

(3) an evaluation process for the program.

Subd. 4. **Reporting requirements; notice.** (a) Each dispenser must submit the following data to the board or its designated vendor~~, subject to the notice required under paragraph (d)~~:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) prescription number;

(6) name of the patient for whom the prescription was written;

(7) address of the patient for whom the prescription was written;

(8) date of birth of the patient for whom the prescription was written;

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for~~:~~

~~(1) individuals residing in licensed skilled nursing or intermediate care facilities;~~

~~(2) individuals receiving assisted living services under chapter 144G or through a medical assistance home and community-based waiver;~~

~~(3) individuals receiving medication intravenously;~~

~~(4) individuals receiving hospice and other palliative or end-of-life care; and~~

~~(5) individuals receiving services from a home care provider regulated under chapter 144A.~~ individuals residing in a health care facility as defined in section 151.58, subdivision 2, paragraph (b), when a drug is distributed through the use of an automated drug distribution system according to section 151.58.

(d) A dispenser must ~~not submit data under this subdivision unless~~ provide a conspicuous notice of the reporting requirements of this section is given to the patient for whom the prescription was written.

Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database of the data reported under subdivision 4. The board shall maintain data that could identify an individual prescriber or dispenser in encrypted form. The database may be used by permissible users identified under subdivision 6 for the identification of:

(1) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances, including standards accepted by national and international pain management associations; and

(2) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

(b) No permissible user identified under subdivision 6 may access the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order.

(c) No personnel of a state or federal occupational licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber when the disciplinary action relates to allegations involving unusual or excessive prescribing of the drugs for which data is collected under subdivision 4.

(d) Data reported under subdivision 4 shall be retained by the board in ~~the~~ an active database for a 12-month period, and shall be removed from the active database no later than 12 months from the last day of the month during which the data was received. The board may transfer data into an inactive database provided that the data thus transferred may only be used by the authorized staff of the board for the purposes of administering, operating, and maintaining the prescription monitoring program and conducting trend analyses and other studies as necessary to evaluate the effectiveness of the program. Data in the inactive database shall not be accessible to any other persons for any reason.

Subd. 6. **Access to reporting system data.** (a) Except as indicated in this subdivision, the data submitted to the board under subdivision 4 is private data on individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

(b) Except as specified in subdivision 5, the following persons shall be considered permissible users and may access the data submitted under subdivision 4 in the same or similar manner, and for the same or similar purposes, as those persons who are authorized to access similar private data on individuals under federal and state law:

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is prescribing or considering prescribing any controlled substance or to whom the prescriber is providing other medical treatment for which access to the data may be necessary and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance or to whom the dispenser is providing other pharmaceutical care for which access to the data may be necessary and with the provision that the dispenser remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or guardian of a minor, or health care agent of the individual acting under a health care directive under chapter 145C;

(4) personnel of ~~the~~ a health-related licensing board ~~specifically~~ listed in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board assigned to conduct a bona fide investigation of a complaint received by that board alleging that a specific licensee is chemically dependent, has diverted controlled substances, or has engaged in the behavior specified in subdivision 5, paragraph (a);

(5) personnel of the board engaged in the collection of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

(6) authorized personnel of a vendor under contract with the board who are engaged in the design, implementation, operation, and maintenance of the ~~electronic reporting system~~ prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities;

(7) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant; ~~and~~

(8) personnel of the ~~medical assistance program~~ Minnesota health care programs assigned to use the data collected under this section to identify and manage recipients whose usage of controlled substances may warrant restriction to a single primary care ~~physician~~ provider, a single outpatient pharmacy, ~~or~~ and a single hospital;

(9) a coroner or medical examiner, or an agent or employee of the coroner or medical examiner to whom the coroner or medical examiner has delegated the task of accessing the data, conducting an investigation pursuant to section 390.11, and with the provision that the coroner or medical examiner remains responsible for the use or misuse of data accessed by a delegated agent or employee; and

(10) personnel of the health professionals services program established pursuant to section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program and provided that the information cannot be given to a health-related licensing board except as provided by section 214.33, subdivision 3.

For purposes of clause (3), access by an individual includes persons in the definition of an individual under section 13.02.

(c) Any permissible user identified in paragraph (b), who directly accesses the data electronically, shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(d) The board shall not release data submitted under this section unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

(e) ~~The board shall not release the name of a prescriber without the written consent of the prescriber or a valid search warrant or court order. The board shall provide a mechanism for a prescriber to submit to the board a signed consent authorizing the release of the prescriber's name when data containing the prescriber's name is requested.~~

~~(f)~~ The board shall maintain a log of all persons who access the data for a period of at least five years and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

~~(g)~~ (f) Section 13.05, subdivision 6, shall apply to any contract the board enters into pursuant to subdivision 2. A vendor shall not use data collected under this section for any purpose not specified in this section.

(g) The board may participate in an interstate prescription monitoring program data exchange system provided that permissible users in other states may have access to the data only as allowed under this section and that section 13.05, subdivision 6, shall apply to any contract or memorandum of understanding that the board enters into under this paragraph.

Subd. 7. **Disciplinary action.** (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.

~~Subd. 8. **Evaluation and reporting.** (a) The board shall evaluate the prescription electronic reporting system to determine if the system is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.~~

~~(b) The board shall submit the evaluation of the system to the legislature by July 15, 2011.~~

Subd. 9. **Immunity from liability; no requirement to obtain information.** (a) A pharmacist, prescriber, or other dispenser making a report to the program in good faith under this section is immune from any civil, criminal, or administrative liability, which might otherwise be incurred or imposed as a result of the report, or on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program.

(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting, receiving, or using information from the program.

Subd. 10. **Funding.** (a) The board may seek grants and private funds from nonprofit charitable foundations, the federal government, and other sources to fund the enhancement and ongoing operations of the prescription ~~electronic reporting system~~ monitoring program established under this section. Any funds received shall be appropriated to the board for this purpose. The board may not expend funds to enhance the program in a way that conflicts with this section without seeking approval from the legislature.

(b) Notwithstanding any other section, the administrative services unit for the health-related licensing boards shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Podiatric Medicine, the Board of Optometry, the Board of Veterinary Medicine, and the Board of Pharmacy an amount to be paid through fees by each respective board. The amount apportioned to each board shall equal each board's share of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for operating the prescription ~~electronic reporting system~~ monitoring program under this section. Each board's apportioned share shall be based on the number of prescribers or dispensers that each board identified in this paragraph licenses as a percentage of the total number of prescribers and dispensers licensed collectively by these boards. Each respective board may adjust the fees that the boards are required to collect to compensate for the amount apportioned to each board by the administrative services unit.

Sec. 29. **REPEALER.**

Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.37, subdivision 11; 151.45; 151.47, subdivision 2; and 151.48, are repealed.

151.19 REGISTRATION; FEES.

Subd. 2. **Nonresident pharmacies.** The board shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this state that regularly dispense medications for Minnesota residents and mail, ship, or deliver prescription medications into this state. Nonresident special pharmacy registration shall be granted by the board upon payment of any applicable fee specified in section 151.065 and the disclosure and certification by a pharmacy:

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

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

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

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

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

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

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

151.25 REGISTRATION OF MANUFACTURERS; FEE; PROHIBITIONS.

The board shall require and provide for the annual registration of every person engaged in manufacturing drugs, medicines, chemicals, or poisons for medicinal purposes, now or hereafter doing business with accounts in this state. Upon a payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to such manufacturer. Such registration certificate shall be displayed in a conspicuous place in such manufacturer's or wholesaler's place of business for which it is issued and expire on the date set by the board. It shall be unlawful for any person to manufacture drugs, medicines, chemicals, or poisons for medicinal purposes unless such a certificate has been issued to the person by the board. It shall be unlawful for any person engaged in the manufacture of drugs, medicines, chemicals, or poisons for medicinal purposes, or the person's agent, to sell legend drugs to other than a pharmacy, except as provided in this chapter.

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

Subd. 11. **Complaint reporting.** 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.

151.45 WHOLESALE DRUG DISTRIBUTOR ADVISORY TASK FORCE.

The board shall appoint a Wholesale Drug Distributor Advisory Task Force composed of five members, to be selected and to perform duties and responsibilities as follows:

(a) One member shall be a pharmacist who is neither a member of the board nor a board employee.

(b) Two members shall be representatives of wholesale drug distributors as defined in section 151.44, paragraph (b).

(c) One member shall be a representative of drug manufacturers.

(d) One member shall be a public member as defined by section 214.02.

(e) The advisory task force shall review and make recommendations to the board on the merit of all rules dealing with wholesale drug distributors and drug manufacturers that are proposed by the board; and no rule affecting wholesale drug distributors proposed by the board shall be adopted without first being submitted to the task force for review and comment.

(f) In making advisory task force appointments, the board shall consider recommendations received from each of the wholesale drug distributor, pharmacist, and drug manufacturer classes cited in paragraphs (a) to (c), and shall adopt rules that provide for solicitation of the recommendations.

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.

Subd. 2. **Requirements must conform with federal law.** All requirements set forth in this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a wholesale drug distributor licensing requirement imposed by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter shall control.

151.48 OUT-OF-STATE WHOLESALE DRUG DISTRIBUTOR LICENSING.

(a) It is unlawful for an out-of-state wholesale drug distributor to conduct business in the state without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for an out-of-state wholesale drug distributor license under this section shall be made on a form furnished by the board.

(c) No person acting as principal or agent for any out-of-state wholesale drug distributor may sell or distribute drugs in the state unless the distributor has obtained a license.

(d) The board may adopt regulations that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor:

(1) possesses a valid license granted by another state under legal standards comparable to those that must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(2) can show that the other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.