State of Minnesota

HOUSE OF REPRESENTATIVES

NINETIETH SESSION

H. F. No. 4055

03/19/2018 Authored by Peterson
The bill was read for the first time and referred to the Committee on Health and Human Services Reform

A bill for an act

relating to health; adding and modifying definitions; changing licensing requirements for businesses regulated by the Board of Pharmacy; clarifying requirements for compounding; changing provisions related to the manufacture and wholesale distribution of drugs; clarifying grounds for disciplinary action; prohibiting certain interactions between practitioners and pharmacists and pharmacies; repealing obsolete language; amending Minnesota Statutes 2016, sections 144.999, subdivision 3; 151.065, subdivisions 1, 3, 6; 151.071, subdivision 2; 151.14; 151.15; 151.18; 151.19, subdivisions 1, 3; 151.252, subdivisions 1, 1a; 151.253, by adding a subdivision; 151.43; 151.44; 151.46; 151.47; 151.49; 151.50; 152.02, subdivision 6; 152.13; 295.50, subdivision 14, by adding a subdivision; 295.51, subdivision 1a; Minnesota Statutes 2017 Supplement, section 151.32; proposing coding for new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2016, sections 151.061; 151.13, subdivision 2; 151.19, subdivision 4; 151.27; 151.42; 151.51; 151.55; Minnesota Rules, part 6800.1600.

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

Section 1. Minnesota Statutes 2016, section 144.999, subdivision 3, is amended to read:

Subd. 3. **Obtaining and storing epinephrine auto-injectors.** (a) Notwithstanding section 151.37, an authorized entity may obtain and possess epinephrine auto-injectors to be provided or administered to an individual if, in good faith, an owner, manager, employee, or agent of an authorized entity believes that the individual is experiencing anaphylaxis regardless of whether the individual has a prescription for an epinephrine auto-injector. The administration of an epinephrine auto-injector in accordance with this section is not the practice of medicine.

(b) An authorized entity may obtain epinephrine auto-injectors from pharmacies licensed ~~as wholesale drug distributors~~ pursuant to section ~~151.47~~ 151.19. Prior to obtaining an epinephrine auto-injector, an owner, manager, or authorized agent of the entity must present to the pharmacy a valid certificate of training obtained pursuant to subdivision 5.

(c) An authorized entity shall store epinephrine auto-injectors in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements that may be established by the commissioner. An authorized entity shall designate employees or agents who have completed the training program required under subdivision 5 to be responsible for the storage, maintenance, and control of epinephrine auto-injectors obtained and possessed by the authorized entity.

Sec. 2. Minnesota Statutes 2016, section 151.065, subdivision 1, is amended to read:

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

(1) pharmacist licensed by examination, $145;

(2) pharmacist licensed by reciprocity, $240;

(3) pharmacy intern, $37.50;

(4) pharmacy technician, $37.50;

(5) pharmacy, $225;

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

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

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

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

(10) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, $150~~ third-party logistics provider, $235;

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

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

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

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

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

~~(16)~~ (15) medical gas distributor, $110;

~~(17)~~ (16) controlled substance researcher, $75; and

~~(18)~~ (17) pharmacy professional corporation, $125.

Sec. 3. Minnesota Statutes 2016, section 151.065, subdivision 3, is amended to read:

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

(1) pharmacist, $145;

(2) pharmacy technician, $37.50;

(3) pharmacy, $225;

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

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

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

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

(8) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, $150~~ third-party logistics provider, $235;

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

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

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

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

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

~~(14)~~ (13) medical gas distributor, $110;

~~(15)~~ (14) controlled substance researcher, $75; and

~~(16)~~ (15) pharmacy professional corporation, $75.

Sec. 4. Minnesota Statutes 2016, section 151.065, subdivision 6, is amended to read:

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

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

(c) An owner of a pharmacy, a drug wholesaler, ~~a~~ drug manufacturer, third-party logistics provider, or ~~a~~ medical gas distributor who has allowed the license of the establishment to

lapse may reinstate the license with board approval and upon payment of any fees and late fees in arrears.

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

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

Sec. 5. Minnesota Statutes 2016, section 151.071, subdivision 2, is amended to read:

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

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

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

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

registration if the applicant has been charged with a felony until the matter has been adjudicated;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) fee splitting, including without limitation:

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

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

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified about the arrangement and is given, upon request, information concerning the amount of reimbursement both the pharmacy and the veterinarian receive for specific prescriptions;

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

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

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

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

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

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

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

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

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

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

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

Sec. 6. Minnesota Statutes 2016, section 151.14, is amended to read:

151.14 REINSTATEMENTS.

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

Sec. 7. Minnesota Statutes 2016, section 151.15, is amended to read:

151.15 COMPOUNDING AND DISPENSING DRUGS UNLAWFUL UNDER CERTAIN CONDITIONS.

Subdivision 1. **Location.** It shall be unlawful for any ~~person~~ pharmacist to compound~~,~~ or dispense~~, vend, or sell~~ drugs~~, medicines, chemicals, or poisons~~ in any place other than a

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

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

Subd. 3. **Unlicensed persons; veterinary legend drugs.** It shall be unlawful for any person other than a licensed veterinarian or pharmacist to compound or dispense veterinary legend drugs except as provided in this chapter, chapter 156, and Minnesota Rules, chapters 6800 and 9100.

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

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

(1) the prescription drug order is for an emergency situation where waiting for the licensed pharmacy from which the prescription will be dispensed to open would likely cause the patient to experience significant physical harm or discomfort;

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

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

(4) in the case of an electronic prescription drug order, the order must be received through secure and encrypted electronic means;

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

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

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

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

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

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

(4) the prescription drug order is processed pursuant to this chapter and rules adopted under this chapter; and

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

Sec. 8. Minnesota Statutes 2016, section 151.18, is amended to read:

151.18 UNLAWFUL TO USE MISLEADING NAME.

It is unlawful for any person to carry on, conduct, or transact a retail business not licensed as a pharmacy under section 151.19 under a name ~~which contains as a part thereof~~ containing the words "drugs," "drug store," "pharmacy," "medicine," "apothecary," or "chemist shop," or any abbreviation, translation, extension, or variation ~~thereof~~ of those words; or in any manner by advertisement, circular, or poster, sign or otherwise, describe or refer to the place of business conducted by such person by such term, abbreviation, translation, extension, or variation ~~unless the place so conducted is a pharmacy.~~, with an intent to mislead the public into believing that the business is a licensed pharmacy.

Sec. 9. Minnesota Statutes 2016, section 151.19, subdivision 1, is amended to read:

Subdivision 1. **Pharmacy licensure requirements.** (a) No person shall operate a pharmacy without first obtaining a license from the board and paying any applicable fee

specified in section 151.065. The license shall be displayed in a conspicuous place in the pharmacy for which it is issued and expires on June 30 following the date of issue. It is unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

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

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

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

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

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

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

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

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

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

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

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

(h) This subdivision does not apply to a manufacturer licensed under section 151.252, subdivision 1, a wholesale drug distributor licensed under section 151.47, or a third-party logistics provider licensed under section 151.471, to the extent the manufacturer, wholesale drug distributor, or third-party logistics provider is engaged in the distribution of dialysate or devices necessary to perform home peritoneal dialysis on patients with end-stage renal disease, if:

(1) the manufacturer of the dialysate is licensed under section 151.252, and the manufacturer or its agent leases or owns the licensed manufacturing or wholesaling facility from which the dialysate or devices will be delivered;

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

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

(4) the dialysate or devices are delivered only upon (i) receipt of a physician's order by a Minnesota licensed pharmacy, and (ii) the review and processing of the prescription by a pharmacist licensed by the state in which the pharmacy is located, who is employed by or under contract to the pharmacy;

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

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

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

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

Sec. 10. Minnesota Statutes 2016, section 151.19, subdivision 3, is amended to read:

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

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

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

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

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

(f) ~~The board shall not issue~~ Before the board issues an initial or renewed registration for a medical gas distributor ~~unless~~, the board may require the medical gas distributor ~~passes~~ to pass 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. 11. Minnesota Statutes 2016, section 151.252, subdivision 1, is amended to read:

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

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

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

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

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

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

(g) ~~The board shall not issue~~ Before the board issues an initial or renewed license for a drug manufacturing facility ~~unless~~, the board may require the facility ~~passes an~~ to pass a current good manufacturing practices inspection conducted by an authorized representative of the board. In the case of a drug manufacturing facility located outside of the state, the

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

Sec. 12. Minnesota Statutes 2016, section 151.252, subdivision 1a, is amended 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~~ a current good manufacturing practices inspection conducted by an authorized representative of the board. In the case of an outsourcing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board

with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of ~~an~~ a current good manufacturing practices inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 13. Minnesota Statutes 2016, section 151.253, is amended by adding a subdivision to read:

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

(1) the compounded drug product is needed to treat an animal in an urgent or emergency situation. For the purpose of this clause, "urgent or emergency situation" means a situation where the health of an animal is threatened, or where suffering or death of an animal is likely to result from failure to immediately treat;

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

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

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

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

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

Sec. 14. Minnesota Statutes 2017 Supplement, section 151.32, is amended to read:

151.32 CITATION.

The title of sections 151.01 to ~~151.40~~ 151.58 shall be the "Pharmacy Practice and Wholesale Distribution Act."

Sec. 15. Minnesota Statutes 2016, section 151.43, is amended to read:

151.43 SCOPE.

Sections ~~151.42~~ 151.43 to ~~151.51~~ 151.50 apply to any person~~, partnership, corporation, or business firm~~ engaging in the wholesale distribution of ~~prescription~~ drugs within the state and to persons operating as third-party logistics providers.

Sec. 16. Minnesota Statutes 2016, section 151.44, is amended to read:

151.44 DEFINITIONS.

Subdivision 1. **Scope.** As used in sections 151.43 to ~~151.51~~ 151.50, the following terms have the meanings given in ~~paragraphs (a) to (h):~~ this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subd. 9. **Product.** "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, but does not include

blood or blood components intended for transfusion; radioactive drugs or radioactive biological products as defined in Code of Federal Regulations, title 21, section 600.3(ee), that are regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with such commission under United States Code, title 42, section 2021; imaging drugs; an intravenous product described in subdivision 11, paragraph (b), clauses (14) to (16); any medical gas defined in United States Code, title 21, section 360ddd; homeopathic drugs marketed in accordance with applicable federal law; or a drug compounded in compliance with United States Code, title 21, section 353a or 353b.

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

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

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

(b) Transaction does not include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use, or the distribution of epinephrine under section 121A.2205, 121A.2207, or 144.999;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

Sec. 17. Minnesota Statutes 2016, section 151.46, is amended to read:

151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.

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

Sec. 18. Minnesota Statutes 2016, section 151.47, is amended to read:

151.47 WHOLESALE DRUG ~~DISTRIBUTOR LICENSING~~ DISTRIBUTION REQUIREMENTS.

Subdivision 1. **~~Requirements~~ Generally.** (a) ~~All wholesale drug distributors are subject to the requirements of this subdivision.~~ Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements in United States Code, title 21, section 360eee-1, with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving a product.

(b) If an entity meets the definition of more than one of the entities listed in the paragraph (a), the entity shall comply with all applicable requirements in United States Code, title 21, section 360eee-1, but is not required to duplicate requirements.

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

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

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

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

(e) No license may be issued or renewed for a ~~drug~~ wholesale distributor facility that is ~~required to be licensed or registered by the~~ located in another 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.~~ by the state in which a wholesale distributor is physically located or by the United States Food and Drug Administration.

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

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

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

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

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

(3) has a ~~viable~~ functioning security system that includes an ~~after hours~~ after-hours central alarm, or comparable entry detection capability~~;~~, and security policies and procedures that include provisions for restricted access to the premises~~;~~, comprehensive ~~employment~~ employee 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;~~ will maintain appropriate records of the distribution of drugs, which shall be kept for a minimum of two years and be made available to the board upon request;

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

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

~~(6) complete,~~ (7) will provide the board with updated information~~, to be provided to the board as a condition for obtaining and retaining a license,~~ about each wholesale ~~drug~~ distributor facility to be licensed, ~~including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary~~ as requested by the board;

~~(7)~~ (8) will develop and, as necessary, update written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or ~~product~~ drug shipping and receiving, outdated ~~product or other unauthorized product control~~ drugs, appropriate ~~disposition~~ handling of returned goods, and ~~product~~ drug recalls;

~~(8)~~ (9) will have sufficient ~~inspection~~ policies and procedures in place for the inspection of all incoming and outgoing ~~product~~ drug shipments; ~~and~~

~~(9) operations~~ (10) will operate in compliance with all state and federal requirements applicable to wholesale drug distribution~~.~~; and

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

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

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

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

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

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

(l) An applicant for the issuance or renewal of a wholesale distributor license shall execute and file a surety bond with the board that satisfies the following requirements:

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

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

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

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

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

Sec. 19. **[151.471] THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.**

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

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

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

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

(d) No license shall be issued or renewed for a third-party logistics provider unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

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

(f) The board shall require a separate license for each third-party logistics provider facility located within the state and for each third-party logistics provider facility located outside of the state from which drugs are shipped into the state or to which drugs are reverse distributed.

(g) The board shall not issue an initial or renewed license for a third-party logistics provider facility unless the facility passes an inspection conducted by an authorized representative of the board or is inspected and accredited by an accreditation program approved by the board. In the case of a third-party logistics provider facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant (1) furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board, or (2) furnishes the board with proof of current accreditation. The board may deny licensure if the deficiencies are noted in an inspection report unless the applicant submits documentation satisfactory to the board that any deficiencies have been corrected.

(h) In order to receive and retain a third-party logistics provider facility license issued under this section, an applicant must:

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

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

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

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

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

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

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

(8) develop and, as necessary, update written policies and procedures that assure reasonable preparation for, protection against, and handling of any facility security or operation problems, including but not limited to those caused by natural disaster or government emergency, inventory inaccuracies or drug shipping and receiving, outdated drugs, appropriate handling of returned goods, and drug recalls;

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

(10) comply with all state and federal requirements applicable to third-party logistics providers; and

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

(i) An agent or employee of any licensed third-party logistics provider need not seek licensure under this section.

(j) The board is authorized to and shall require fingerprint-based criminal background checks of facility managers or designated representatives. The criminal background checks shall be conducted as provided in section 214.075. The board shall use the criminal background check data to evaluate the qualifications of persons for ownership of or

employment by a licensed third-party logistics provider and shall not disseminate this data except as allowed by law.

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

Sec. 20. Minnesota Statutes 2016, 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~~ section 151.47 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. 21. Minnesota Statutes 2016, section 151.50, is amended to read:

151.50 RULES.

The board ~~shall~~ may adopt rules to carry out the purposes and enforce the provisions of sections ~~151.42~~ 151.43 to ~~151.51~~ 151.50. All rules adopted under this section shall conform to ~~wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration~~ United States Code, title 21, sections 360eee to 360eee-4, or the rules adopted thereunder; and in case of conflict between a rule adopted by the board and ~~a Food and Drug Administration wholesale drug distributor guideline, the latter shall control.~~ United States Code, title 21, sections 360eee to 360eee-4, or the rules adopted thereunder, the federal provisions shall prevail.

Sec. 22. Minnesota Statutes 2016, section 152.02, subdivision 6, is amended to read:

Subd. 6. **Schedule V; restrictions on methamphetamine precursor drugs.** (a) As used in this subdivision, the following terms have the meanings given:

(1) "methamphetamine precursor drug" means any compound, mixture, or preparation intended for human consumption containing ephedrine or pseudoephedrine as its sole active ingredient or as one of its active ingredients; and

(2) "over-the-counter sale" means a retail sale of a drug or product but does not include the sale of a drug or product pursuant to the terms of a valid prescription.

(b) The following items are listed in Schedule V:

(1) any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(i) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(ii) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(iii) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(iv) not more than 100 milligrams of opium per 100 milliliters or per 100 grams; or

(v) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: pyrovalerone.

(3) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(i) ezogabine;

(ii) pregabalin;

(iii) lacosamide.

(4) Any compound, mixture, or preparation containing ephedrine or pseudoephedrine as its sole active ingredient or as one of its active ingredients.

(c) No person may sell in a single over-the-counter sale more than two packages of a methamphetamine precursor drug or a combination of methamphetamine precursor drugs or any combination of packages exceeding a total weight of six grams, calculated as the base.

(d) Over-the-counter sales of methamphetamine precursor drugs are limited to:

(1) packages containing not more than a total of three grams of one or more methamphetamine precursor drugs, calculated in terms of ephedrine base or pseudoephedrine base; or

(2) for nonliquid products, sales in blister packs, where each blister contains not more than two dosage units, or, if the use of blister packs is not technically feasible, sales in unit dose packets or pouches.

(e) A business establishment that offers for sale methamphetamine precursor drugs in an over-the-counter sale shall ensure that all packages of the drugs are displayed behind a checkout counter where the public is not permitted and are offered for sale only by a licensed pharmacist, a registered pharmacy technician, or a pharmacy clerk. The establishment shall ensure that the person making the sale requires the buyer:

(1) to provide photographic identification showing the buyer's date of birth; and

(2) to sign a written or electronic document detailing the date of the sale, the name of the buyer, and the amount of the drug sold.

A document described under clause (2) must be retained by the establishment for at least three years and must at all reasonable times be open to the inspection of any law enforcement agency.

Nothing in this paragraph requires the buyer to obtain a prescription for the drug's purchase.

(f) No person may acquire through over-the-counter sales more than six grams of methamphetamine precursor drugs, calculated as the base, within a 30-day period.

(g) No person may sell in an over-the-counter sale a methamphetamine precursor drug to a person under the age of 18 years. It is an affirmative defense to a charge under this paragraph if the defendant proves by a preponderance of the evidence that the defendant reasonably and in good faith relied on proof of age as described in section 340A.503, subdivision 6.

(h) A person who knowingly violates paragraph (c), (d), (e), (f), or (g) is guilty of a misdemeanor and may be sentenced to imprisonment for not more than 90 days, or to payment of a fine of not more than $1,000, or both.

(i) An owner, operator, supervisor, or manager of a business establishment that offers for sale methamphetamine precursor drugs whose employee or agent is convicted of or

charged with violating paragraph (c), (d), (e), (f), or (g) is not subject to the criminal penalties for violating any of those paragraphs if the person:

(1) did not have prior knowledge of, participate in, or direct the employee or agent to commit the violation; and

(2) documents that an employee training program was in place to provide the employee or agent with information on the state and federal laws and regulations regarding methamphetamine precursor drugs.

(j) Any person employed by a business establishment that offers for sale methamphetamine precursor drugs who sells such a drug to any person in a suspicious transaction shall report the transaction to the owner, supervisor, or manager of the establishment. The owner, supervisor, or manager may report the transaction to local law enforcement. A person who reports information under this subdivision in good faith is immune from civil liability relating to the report.

(k) Paragraphs (b) to (j) do not apply to:

(1) pediatric products labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instructions;

(2) methamphetamine precursor drugs that are certified by the Board of Pharmacy as being manufactured in a manner that prevents the drug from being used to manufacture methamphetamine;

(3) methamphetamine precursor drugs in gel capsule or liquid form; or

(4) compounds, mixtures, or preparations in powder form where pseudoephedrine constitutes less than one percent of its total weight and is not its sole active ingredient.

(l) The Board of Pharmacy, in consultation with the Department of Public Safety, shall certify methamphetamine precursor drugs that meet the requirements of paragraph (k), clause (2), and publish an annual listing of these drugs.

(m) Wholesale drug distributors licensed ~~and regulated~~ by the Board of Pharmacy pursuant to ~~sections 151.42 to 151.51 and~~ section 151.47 and third-party logistics providers licensed pursuant to section 151.471, which are also registered with and regulated by the United States Drug Enforcement Administration, are exempt from the methamphetamine precursor drug storage requirements of this section.

(n) This section preempts all local ordinances or regulations governing the sale by a business establishment of over-the-counter products containing ephedrine or pseudoephedrine. All ordinances enacted prior to the effective date of this act are void.

Sec. 23. Minnesota Statutes 2016, section 152.13, is amended to read:

152.13 DUTIES OF STATE BOARD OF PHARMACY.

It shall be the duty of the state board to enforce the provisions of this chapter, and the power and authority of the board, as now defined by the laws of this state, are hereby extended so as to be commensurate with the duties hereby imposed~~.~~; except that the board shall not have the duty or power to enforce those sections of this chapter relating to the Therapeutic Research Act and medical cannabis, or to criminal investigations and prosecutions.

Sec. 24. Minnesota Statutes 2016, section 295.50, subdivision 14, is amended to read:

Subd. 14. **Wholesale drug distributor.** "Wholesale drug distributor" means a ~~wholesale drug distributor required to be licensed under sections 151.42 to 151.51.~~ person who sells or delivers legend drugs or legend medical gases in Minnesota at wholesale in person, by common carrier, or by mail unless the legend drugs are delivered to another person who sells legend drugs exclusively at wholesale. For purposes of this subdivision, "wholesale" means sale or distribution of legend drugs to a person other than to an individual to whom the drug is dispensed or administered.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 25. Minnesota Statutes 2016, section 295.50, is amended by adding a subdivision to read:

Subd. 16. **Legend medical gas.** "Legend medical gas" means a liquid or gaseous substance used for medical purposes and that is required by federal law to be dispensed only pursuant to the prescription of a licensed practitioner.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 26. Minnesota Statutes 2016, section 295.51, subdivision 1a, is amended to read:

Subd. 1a. **Nexus in Minnesota.** A ~~wholesale drug distributor~~ person has nexus in Minnesota if its contacts with or presence in Minnesota is sufficient to satisfy the requirements of the United States Constitution.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 27. **REVISOR'S INSTRUCTION.**

The revisor of statutes shall change the term "pharmacist in charge" to "pharmacist-in-charge" wherever it appears in Minnesota Statutes and Minnesota Rules, and may make any necessary grammatical changes related to the change in terms.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 28. **REPEALER.**

(a) Minnesota Statutes 2016, sections 151.061; 151.13, subdivision 2; 151.19, subdivision 4; 151.27; 151.42; 151.51; and 151.55, are repealed.

(b) Minnesota Rules, part 6800.1600, is repealed.

151.061 UNFAIR PRICE DISCRIMINATION.

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

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

151.13 RENEWAL FEE; CONTINUING EDUCATION.

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

151.19 REGISTRATION; FEES.

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

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

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

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

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

151.27 EXPENSES.

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

151.42 CITATION.

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

151.51 BOARD ACCESS TO WHOLESALE DRUG DISTRIBUTOR RECORDS.

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

151.55 CANCER DRUG REPOSITORY PROGRAM.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) the drug is not adulterated or misbranded.

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

(1) the supplies are not adulterated or misbranded;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) individuals who are uninsured;

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

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

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

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

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

(c) If a cancer drug repository distributes drugs or supplies under paragraph (a) or (b), the repository shall complete a cancer drug repository donor form provided by the board. The completed

form and a copy of the donor form that was completed by the original donor under subdivision 5 shall be provided to the fully participating cancer drug repository at the time of distribution.

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

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

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

(1) the date of destruction;

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

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

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

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

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

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

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

6800.1600 CONTINUING EDUCATION ADVISORY TASK FORCE.

The Continuing Education Advisory Task Force shall consist of not more than ten members. Three members of the advisory task force shall be pharmacists designated by the Minnesota State Pharmaceutical Association, three members shall be pharmacists designated by the Minnesota Society of Hospital Pharmacists, two members shall be pharmacists designated by the College of Pharmacy of the University of Minnesota, and two members shall be designated by the board. The Continuing Education Advisory Task Force shall meet at least quarterly and shall annually elect a chair and vice chair from its membership. The executive director of the Board of Pharmacy shall act as secretary to the task force.