State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 1718

02/25/2019 Authored by Baker and Olson
The bill was read for the first time and referred to the Committee on Commerce
03/11/2019 By motion, recalled and re-referred to the Committee on Health and Human Services Policy
03/18/2019 Adoption of Report: Amended and re-referred to the Committee on Ways and Means

A bill for an act

relating to health; making clarifying changes to the Pharmacy Practice Act; modifying requirements for veterinary compounding; modifying licensure for wholesale distributors; establishing licensure for third-party logistics providers; modifying fees; amending Minnesota Statutes 2018, sections 151.01, subdivisions 31, 35, by adding a subdivision; 151.065, subdivisions 1, 3, 6; 151.071, subdivision 2; 151.15, subdivision 1, by adding subdivisions; 151.19, subdivisions 1, 3; 151.252, subdivisions 1, 1a, 3; 151.253, by adding a subdivision; 151.32; 151.40, subdivisions 1, 2; 151.43; 151.46; 151.47, subdivision 1, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2018, sections 151.42; 151.44; 151.49; 151.50; 151.51; 151.55.

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

Section 1. Minnesota Statutes 2018, section 151.01, subdivision 31, is amended to read:

Subd. 31. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that ~~may provide~~ performs those activities involved in the dispensing ~~functions,~~ of a drug ~~utilization review, packaging, labeling, or delivery of a prescription product to~~ for another pharmacy ~~for the purpose of filling a prescription~~, pursuant to the requirements of this chapter and the rules of the board.

Sec. 2. Minnesota Statutes 2018, section 151.01, subdivision 35, is amended to read:

Subd. 35. **Compounding.** "Compounding" means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order. Compounding also includes anticipatory compounding, as defined in this section, and the preparation of drugs in which all bulk drug substances and components are nonprescription substances. Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions, provided that

such labeling has been approved by the United States Food and Drug Administration (FDA) or the manufacturer is licensed under section 151.252. Compounding does not include the preparation of a drug for the purpose of, or incident to, research, teaching, or chemical analysis, provided that the drug is not prepared for dispensing or administration to patients. All compounding, regardless of the type of product, must be done pursuant to a prescription drug order unless otherwise permitted in this chapter or by the rules of the board. Compounding does not include a minor deviation from such directions with regard to radioactivity, volume, or stability, which is made by or under the supervision of a licensed nuclear pharmacist or a physician, and which is necessary in order to accommodate circumstances not contemplated in the manufacturer's instructions, such as the rate of radioactive decay or geographical distance from the patient.

Sec. 3. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

Subd. 42. **Syringe services provider.** "Syringe services provider" means a public health program, registered with the commissioner of health, that provides cost-free comprehensive harm reduction services, including: sterile needles, syringes, and other injection equipment; safe disposal containers for needles and syringes; education about overdose prevention, safer injection practices, and infectious disease prevention; referral to or provision of blood borne pathogen testing; referral to substance use disorder treatment, including medication-assisted treatment; and referral to medical, mental health, and social services.

Sec. 4. Minnesota Statutes 2018, 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, $260;

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

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

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

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

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

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

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

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

Sec. 5. Minnesota Statutes 2018, 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, $260;

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

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

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

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

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

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

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

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

Sec. 6. Minnesota Statutes 2018, 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. 7. Minnesota Statutes 2018, 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 alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills. In the case of registered pharmacy technicians, pharmacist interns, or controlled substance researchers, the inability to carry out duties allowed under this chapter or the rules of the board with reasonable skill and safety to patients by reason of illness, ~~drunkenness,~~ use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills;

(15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas 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,

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

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

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

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

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

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

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

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

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

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board 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. 8. Minnesota Statutes 2018, section 151.15, subdivision 1, is amended to read:

Subdivision 1. **Location.** It shall be unlawful for any person 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.

Sec. 9. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Sec. 10. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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 not being processed pursuant to section 151.58;

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

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

Sec. 11. Minnesota Statutes 2018, 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~~ Prior to the issuance of an initial or renewed license for a pharmacy ~~unless~~, the board may require the pharmacy ~~passes~~ to pass an inspection conducted by an authorized representative of the board. In the case of a pharmacy located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

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

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

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

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

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

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

(h) This subdivision does not apply to a manufacturer licensed under section 151.252, subdivision 1, a wholesale drug distributor licensed under section 151.47, or a third-party

logistics provider, to the extent the manufacturer, wholesale drug distributor, or third-party logistics provider is engaged in the distribution of dialysate or devices necessary to perform home peritoneal dialysis on patients with end-stage renal disease, if:

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

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

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

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

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

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

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

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

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

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

Sec. 12. Minnesota Statutes 2018, 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~~ Prior to the issuance of 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. 13. Minnesota Statutes 2018, 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~~ Prior to the issuance of 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. 14. Minnesota Statutes 2018, 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. 15. Minnesota Statutes 2018, section 151.252, subdivision 3, is amended to read:

Subd. 3. **Payment to practitioner; reporting.** Unless prohibited by United States Code, title 42, section 1320a-7h, a drug manufacturer or outsourcing facility shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement, or other compensation authorized under section

151.461, clauses (4) and (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this subdivision are public data.

Sec. 16. Minnesota Statutes 2018, section 151.253, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Sec. 17. Minnesota Statutes 2018, 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. 18. Minnesota Statutes 2018, section 151.40, subdivision 1, is amended to read:

Subdivision 1. **Generally.** ~~Except as otherwise provided in subdivision 2,~~ It is unlawful for any person to possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except ~~by~~ for:

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

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

(ii) licensed pharmacies and their employees or agents~~,~~;

(iii) licensed pharmacists~~, licensed doctors of veterinary medicine or their assistants,~~;

(iv) registered nurses~~,~~ and licensed practical nurses;

(v) registered medical technologists~~,~~;

(vi) medical interns~~,~~ and residents;

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

(viii) licensed hospitals~~,~~;

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

(x) licensed nursing homes~~, bona fide hospitals where animals are treated,~~;

(xi) licensed morticians~~,~~;

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

(xiii) persons engaged in animal husbandry~~,~~;

(xiv) clinical laboratories and their employees~~,~~;

(xv) persons engaged in bona fide research or education or industrial use of hypodermic syringes and needles provided such persons cannot use hypodermic syringes and needles for the administration of drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so~~,~~;

(xvi) persons who administer drugs pursuant to an order or direction of a licensed ~~doctor of medicine or of a licensed doctor of osteopathic medicine duly licensed to practice medicine.~~ practitioner; and

(xvii) syringe service providers and their employees or agents and individuals who obtain and dispose of hypodermic syringes and needles through such providers;

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

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

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

Sec. 19. Minnesota Statutes 2018, section 151.40, subdivision 2, is amended to read:

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

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

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

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

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

Sec. 20. Minnesota Statutes 2018, section 151.43, is amended to read:

151.43 SCOPE.

Sections ~~151.42~~ 151.43 to 151.51 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. 21. **[151.441] DEFINITIONS.**

Subdivision 1. **Scope.** As used in sections 151.43 to 151.51, the following terms have the meanings given in this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

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

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

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

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

(iii) a situation involving an action taken by the commissioner of health pursuant to 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 minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

Sec. 22. Minnesota Statutes 2018, 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. 23. Minnesota Statutes 2018, section 151.47, subdivision 1, is amended to read:

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

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

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

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

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

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

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

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

~~(1) adequate storage conditions and facilities;~~

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

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

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

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

~~(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all~~

~~pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;~~

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

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

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

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

Sec. 24. Minnesota Statutes 2018, section 151.47, is amended by adding a subdivision to read:

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

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

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

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

(e) No license may be issued or renewed for a wholesale distributor facility that is located in another state unless the applicant supplies the board with proof of licensure or registration

by the state in which the wholesale distributor is physically located or by the United States Food and Drug Administration.

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

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

(h) As a condition for receiving and retaining a wholesale drug distributor license issued under this section, an applicant shall satisfy the board that it:

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

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

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

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

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

who will be responsible for ensuring that the facility operates in a manner consistent with state and federal law;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 25. **[151.471] THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.**

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

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

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

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

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

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

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

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

(h) As a condition for receiving and retaining a third-party logistics provider facility license issued under this section, an applicant shall satisfy the board that it:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 26. **REPEALER.**

Minnesota Statutes 2018, sections 151.42; 151.44; 151.49; 151.50; 151.51; and 151.55, are repealed.

151.42 CITATION.

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

151.44 DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

Application blanks or notices for renewal of a license required by sections 151.42 to 151.51 shall be mailed or otherwise provided to each licensee on or before the first day of the month prior to the month in which the license expires and, if application for renewal of the license with the

required fee and supporting documents is not made before the expiration date, the existing license or renewal shall lapse and become null and void upon the date of expiration.

151.50 RULES.

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

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 website.

(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 this chapter 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 website.

(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.