

**SENATE  
STATE OF MINNESOTA  
NINETY-FIRST SESSION**

**S.F. No. 2169**

(SENATE AUTHORS: ABELER)

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OFFICIAL STATUS  
Introduction and first reading  
Referred to Health and Human Services Finance and Policy

1.1 A bill for an act

1.2 relating to health; adding and modifying definitions; changing licensing

1.3 requirements for businesses regulated by Board of Pharmacy; clarifying

1.4 requirements for compounding; allowing compounding for veterinary office use

1.5 in certain situations; clarifying grounds for disciplinary action; prohibiting certain

1.6 interactions between practitioners and pharmacists and pharmacies; requiring

1.7 disclosure of certain interactions between veterinarians and pharmacists and

1.8 pharmacies; changing provisions related to the manufacture and wholesale

1.9 distribution of drugs; repealing obsolete language; amending Minnesota Statutes

1.10 2018, sections 151.01, subdivisions 31, 35, by adding subdivisions; 151.06,

1.11 subdivision 1; 151.065, subdivisions 1, 3, 6; 151.071, subdivision 2; 151.072,

1.12 subdivision 3; 151.15, subdivisions 1, 2, 3, by adding subdivisions; 151.18; 151.19,

1.13 subdivisions 1, 3; 151.211, subdivision 2; 151.22; 151.252, subdivisions 1, 1a, 3;

1.14 151.253, subdivision 2, by adding subdivisions; 151.26, subdivision 1, by adding

1.15 a subdivision; 151.32; 151.37, subdivision 2; 151.40, subdivisions 1, 2; 151.43;

1.16 151.46; 151.47, subdivision 1, by adding a subdivision; 152.01, by adding a

1.17 subdivision; 152.11, subdivisions 1, 1a, 2; 152.13; 295.50, subdivision 14, by

1.18 adding subdivisions; proposing coding for new law in Minnesota Statutes, chapters

1.19 62Q; 151; repealing Minnesota Statutes 2018, sections 151.13, subdivision 2;

1.20 151.19, subdivision 4; 151.27; 151.42; 151.44; 151.49; 151.50; 151.51; 151.55;

1.21 Minnesota Rules, part 6800.1600.

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

1.23 Section 1. **[62Q.528] DRUG COVERAGE IN EMERGENCY SITUATIONS.**

1.24 A health plan that provides prescription drug coverage must provide coverage for a

1.25 prescription drug dispensed by a pharmacist under section 151.221, under the terms of

1.26 coverage that would apply had the prescription drug been dispensed according to a

1.27 prescription.

2.1 Sec. 2. Minnesota Statutes 2018, section 151.01, subdivision 31, is amended to read:

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

2.7 Sec. 3. Minnesota Statutes 2018, section 151.01, subdivision 35, is amended to read:

2.8 Subd. 35. **Compounding.** "Compounding" means preparing, mixing, assembling,  
2.9 packaging, and labeling a drug for an identified individual patient as a result of a practitioner's  
2.10 prescription drug order. Compounding also includes anticipatory compounding, as defined  
2.11 in this section, and the preparation of drugs in which all bulk drug substances and components  
2.12 are nonprescription substances. Compounding does not include mixing or reconstituting a  
2.13 drug according to the product's labeling or to the manufacturer's directions, provided that  
2.14 such labeling has been approved by the United States Food and Drug Administration (FDA)  
2.15 or the manufacturer is licensed under section 151.252. Compounding does not include the  
2.16 preparation of a drug for the purpose of, or incident to, research, teaching, or chemical  
2.17 analysis, provided that the drug is not prepared for dispensing or administration to patients.  
2.18 All compounding, regardless of the type of product, must be done pursuant to a prescription  
2.19 drug order unless otherwise permitted in this chapter or by the rules of the board.  
2.20 Compounding does not include a minor deviation from such directions with regard to  
2.21 radioactivity, volume, or stability, which is made by or under the supervision of a licensed  
2.22 nuclear pharmacist or a physician, and which is necessary in order to accommodate  
2.23 circumstances not contemplated in the manufacturer's instructions, such as the rate of  
2.24 radioactive decay or geographical distance from the patient.

2.25 Sec. 4. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to  
2.26 read:

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

3.1 Sec. 5. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to  
3.2 read:

3.3 Subd. 43. **Commercially available drug product.** "Commercially available drug  
3.4 product" means a drug product currently offered for sale that has been approved for use by  
3.5 the United States Food and Drug Administration pursuant to the provisions of the federal  
3.6 Food, Drug, and Cosmetic Act, but does not include:

3.7 (1) a drug product for which manufacturing has been discontinued and which is no longer  
3.8 marketed; or

3.9 (2) a drug product that appears on the FDA drug shortage list in effect under United  
3.10 States Code, title 21, section 356e, provided that the drug product is in "currently in shortage"  
3.11 status.

3.12 Sec. 6. Minnesota Statutes 2018, section 151.06, subdivision 1, is amended to read:

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

3.15 (1) ~~to~~ regulate the practice of pharmacy;

3.16 (2) ~~to~~ regulate the manufacture, compounding, wholesale distribution, dispensing, and  
3.17 ~~retail~~ sale of drugs within this state;

3.18 (3) ~~to~~ regulate the identity, labeling, purity, and quality of all drugs and medicines  
3.19 dispensed in this state, using the United States Pharmacopeia and the National Formulary,  
3.20 or any revisions thereof, or standards adopted under the federal ~~act~~ Food, Drug, and Cosmetic  
3.21 and Controlled Substance Acts as the standard;

3.22 (4) ~~to~~ enter ~~and inspect~~ by its authorized representative any business which it licenses  
3.23 or registers and all other places where drugs, medicines, medical gases, or veterinary drugs  
3.24 or devices are sold, vended, given away, compounded, dispensed, manufactured, wholesaled,  
3.25 or held; it may conduct an inspection or a complaint investigation; it may secure samples  
3.26 or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after  
3.27 paying or offering to pay for such sample; it shall be entitled to inspect and make copies of  
3.28 any and all records ~~of~~ related to the dispensing, compounding, shipment, purchase,  
3.29 manufacture, quality control, and sale of these items provided, however, that such inspection  
3.30 shall not extend to financial ~~data, sales data,~~ or pricing data, unless such data is necessary  
3.31 to investigate a bona fide complaint alleging fraudulent sales or billing;

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

4.3 (6) ~~to~~ license or register pharmacies, drug manufacturers, outsourcing facilities, wholesale  
4.4 drug distributors, third-party logistics providers involved in drug distribution, and  
4.5 manufacturers, wholesalers, or distributors of medical gases;

4.6 (7) ~~to~~ take disciplinary action against any registration or license required under this  
4.7 chapter upon any of the grounds listed in section 151.071, and in accordance with the  
4.8 provisions of section 151.071;

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

4.10 (9) ~~to~~ register as pharmacy technicians and pharmacist interns all applicants who the  
4.11 board determines are qualified to carry out the duties of a pharmacy technician or pharmacist  
4.12 intern;

4.13 (10) enforce the provisions of the Pharmacy Practice and Wholesale Distribution Act  
4.14 and the rules promulgated thereunder; and

4.15 ~~(10) to~~ (11) perform such other duties and exercise such other powers as the provisions  
4.16 of the Pharmacy Practice and Wholesale Distribution Act may require; ~~and.~~

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

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

4.25 (c) If the United States Food and Drug Administration (FDA) determines that the  
4.26 substitution of drugs used for the treatment of epilepsy or seizures poses a health risk to  
4.27 patients, the board shall adopt rules in accordance with accompanying FDA interchangeability  
4.28 standards regarding the use of substitution for these drugs. If the board adopts a rule regarding  
4.29 the substitution of drugs used for the treatment of epilepsy or seizures that conflicts with  
4.30 the substitution requirements of section 151.21, subdivision 3, the rule shall supersede the  
4.31 conflicting statute. If the rule proposed by the board would increase state costs for state  
4.32 public health care programs, the board shall report to the chairs and ranking minority  
4.33 members of the senate Health and Human Services Budget Division and the house of

5.1 representatives Health Care and Human Services Finance Division the proposed rule and  
 5.2 the increased cost associated with the proposed rule before the board may adopt the rule.

5.3 Sec. 7. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:

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

5.6 (1) pharmacist licensed by examination, \$145;

5.7 (2) pharmacist licensed by reciprocity, \$240;

5.8 (3) pharmacy intern, \$37.50;

5.9 (4) pharmacy technician, \$37.50;

5.10 (5) pharmacy, \$225;

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

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

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

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

5.15 (10) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, \$150~~ third-party logistics  
 5.16 provider, \$260;

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

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

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

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

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

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

5.23 ~~(17)~~ (16) controlled substance researcher, \$75; and

5.24 ~~(18)~~ (17) pharmacy professional corporation, \$125.

5.25 Sec. 8. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:

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

- 6.1 (1) pharmacist, \$145;
- 6.2 (2) pharmacy technician, \$37.50;
- 6.3 (3) pharmacy, \$225;
- 6.4 (4) drug wholesaler, legend drugs only, \$235;
- 6.5 (5) drug wholesaler, legend and nonlegend drugs, \$235;
- 6.6 (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210;
- 6.7 (7) drug wholesaler, medical gases, \$185;
- 6.8 (8) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, \$150~~ third-party logistics
- 6.9 provider, \$260;
- 6.10 (9) drug manufacturer, legend drugs only, \$235;
- 6.11 (10) drug manufacturer, legend and nonlegend drugs, \$235;
- 6.12 (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$210;
- 6.13 (12) drug manufacturer, medical gases, \$185;
- 6.14 (13) ~~drug manufacturer, also licensed as a pharmacy in Minnesota, \$150~~;
- 6.15 ~~(14)~~ medical gas distributor, \$110;
- 6.16 ~~(15)~~ (14) controlled substance researcher, \$75; and
- 6.17 ~~(16)~~ (15) pharmacy professional corporation, \$75.

6.18 Sec. 9. Minnesota Statutes 2018, section 151.065, subdivision 6, is amended to read:

6.19 Subd. 6. **Reinstatement fees.** (a) A pharmacist who has allowed the pharmacist's license

6.20 to lapse may reinstate the license with board approval and upon payment of any fees and

6.21 late fees in arrears, up to a maximum of \$1,000.

6.22 (b) A pharmacy technician who has allowed the technician's registration to lapse may

6.23 reinstate the registration with board approval and upon payment of any fees and late fees

6.24 in arrears, up to a maximum of \$90.

6.25 (c) An owner of a pharmacy, ~~a drug wholesaler, a drug manufacturer,~~ third-party logistics

6.26 provider, or a medical gas distributor who has allowed the license of the establishment to

6.27 lapse may reinstate the license with board approval and upon payment of any fees and late

6.28 fees in arrears.

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

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

7.7 Sec. 10. Minnesota Statutes 2018, section 151.071, subdivision 2, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

8.33 (9) engaging in any unethical conduct; conduct likely to deceive, defraud, or harm the  
8.34 public, or demonstrating a willful or careless disregard for the health, welfare, or safety of



9.1 a patient; or pharmacy practice that is professionally incompetent, in that it may create  
9.2 unnecessary danger to any patient's life, health, or safety, in any of which cases, proof of  
9.3 actual injury need not be established;

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

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

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

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

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

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

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

10.4 (17) fee splitting, including without limitation:

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

10.8 (ii) referring a patient to any health care provider as defined in sections 144.291 to  
10.9 144.298 in which the licensee or registrant has a financial or economic interest as defined  
10.10 in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the  
10.11 licensee's or registrant's financial or economic interest in accordance with section 144.6521;  
10.12 and

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

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

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

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

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

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

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

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

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

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

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

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

11.18 Sec. 11. Minnesota Statutes 2018, section 151.072, subdivision 3, is amended to read:

11.19 Subd. 3. **Licensees and registrants of the board.** A licensee or registrant of the board  
11.20 shall report to the board personal knowledge of any conduct that the person reasonably  
11.21 believes constitutes grounds for disciplinary action under this chapter or the rules of the  
11.22 board by any ~~pharmacist, pharmacist intern, pharmacy technician, or controlled substance~~  
11.23 ~~researcher~~ other licensee or registrant of the board, including any conduct indicating that  
11.24 ~~the person~~ an individual may be professionally incompetent, or may have engaged in  
11.25 unprofessional conduct or may be medically or physically unable to engage safely in the  
11.26 practice of pharmacy or to carry out the duties permitted to the ~~person~~ individual by this  
11.27 chapter or the rules of the board. Failure to report violations as required by this subdivision  
11.28 is a basis for discipline pursuant to section 151.071, subdivision 2, clause (20).

11.29 Sec. 12. Minnesota Statutes 2018, section 151.15, subdivision 1, is amended to read:

11.30 Subdivision 1. **Location.** It shall be unlawful for any person to compound; or dispense;  
11.31 ~~vend, or sell~~ drugs, medicines, chemicals, or poisons in any place other than a pharmacy,  
11.32 except as provided in this chapter; except that a licensed pharmacist or pharmacist intern

12.1 working within a licensed hospital may receive a prescription drug order and access the  
12.2 hospital's pharmacy prescription processing system through secure and encrypted electronic  
12.3 means in order to process the prescription drug order.

12.4 Sec. 13. Minnesota Statutes 2018, section 151.15, subdivision 2, is amended to read:

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

12.10 Sec. 14. Minnesota Statutes 2018, section 151.15, subdivision 3, is amended to read:

12.11 Subd. 3. **Unlicensed persons; veterinary legend drugs.** It shall be unlawful for any  
12.12 person other than a licensed veterinarian or pharmacist to compound or dispense veterinary  
12.13 legend drugs except as provided in this chapter, chapter 156, and Minnesota Rules, chapters  
12.14 6800 and 9100.

12.15 Sec. 15. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to  
12.16 read:

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

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

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

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

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

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

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

13.4 Sec. 16. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to  
 13.5 read:

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

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

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

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

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

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

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

13.22 Sec. 17. Minnesota Statutes 2018, section 151.18, is amended to read:

13.23 **151.18 UNLAWFUL TO USE MISLEADING NAME.**

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

14.1 Sec. 18. Minnesota Statutes 2018, section 151.19, subdivision 1, is amended to read:

14.2 Subdivision 1. **Pharmacy licensure requirements.** (a) No person shall operate a  
14.3 pharmacy without first obtaining a license from the board and paying any applicable fee  
14.4 specified in section 151.065. The license shall be displayed in a conspicuous place in the  
14.5 pharmacy for which it is issued and expires on June 30 following the date of issue. It is  
14.6 unlawful for any person to operate a pharmacy unless the license has been issued to the  
14.7 person by the board.

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

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

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

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

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

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

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

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

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

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

15.12 (5) that, upon request of a resident of a long-term care facility located in this state, the  
15.13 resident's authorized representative, or a contract pharmacy or licensed health care facility  
15.14 acting on behalf of the resident, the pharmacy will dispense medications prescribed for the  
15.15 resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision  
15.16 5.

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

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

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

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

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

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

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

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

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

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

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

16.10 Sec. 19. Minnesota Statutes 2018, section 151.19, subdivision 3, is amended to read:

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

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

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

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

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



17.1 (f) ~~The board shall not issue~~ Prior to the issuance of an initial or renewed registration  
 17.2 ~~for a medical gas distributor unless,~~ the board may require the medical gas distributor ~~passes~~  
 17.3 to pass an inspection conducted by an authorized representative of the board. In the case of  
 17.4 a medical gas distributor located outside of the state, the board may require the applicant  
 17.5 to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the  
 17.6 applicant furnishes the board with a report, issued by the appropriate regulatory agency of  
 17.7 the state in which the facility is located, of an inspection that has occurred within the 24  
 17.8 months immediately preceding receipt of the license application by the board. The board  
 17.9 may deny licensure unless the applicant submits documentation satisfactory to the board  
 17.10 that any deficiencies noted in an inspection report have been corrected.

17.11 Sec. 20. Minnesota Statutes 2018, section 151.211, subdivision 2, is amended to read:

17.12 Subd. 2. **Refill requirements.** Except as provided in section 151.221, a prescription  
 17.13 drug order may be refilled only with the written, electronic, or verbal consent of the prescriber  
 17.14 and in accordance with the requirements of this chapter, the rules of the board, and where  
 17.15 applicable, section 152.11. The date of such refill must be recorded and initialed upon the  
 17.16 original prescription drug order, or within the electronically maintained record of the original  
 17.17 prescription drug order, by the pharmacist, pharmacist intern, or practitioner who refills the  
 17.18 prescription.

17.19 Sec. 21. Minnesota Statutes 2018, section 151.22, is amended to read:

17.20 **151.22 LIABILITY FOR PHARMACY OPERATION AND QUALITY OF DRUGS.**

17.21 Subdivision 1. Liability for quality of drugs. ~~Every~~ Both the pharmacist in charge ~~or~~  
 17.22 ~~proprietor~~ and the owner of a pharmacy shall be responsible for the quality of all drugs,  
 17.23 medicines, chemicals, and poisons procured for use and sold therein, except proprietary  
 17.24 medicines or other articles sold in the original package of the manufacturer.

17.25 Subd. 2. Liability for operation of pharmacy. Both the pharmacist in charge and the  
 17.26 owner of a pharmacy shall be responsible for ensuring that the pharmacy operates in  
 17.27 accordance with all federal, state, and local statutes, rules, and ordinances relating to the  
 17.28 practice of pharmacy.

17.29 Sec. 22. **[151.221] REFILLS WITHOUT CURRENT PRESCRIPTION.**

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

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

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

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

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

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

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

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

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

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

18.29 (e) The record of a drug sold or dispensed under this section shall be maintained in the  
18.30 same manner required for prescription drug orders under section 151.211.

19.1 Sec. 23. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

19.2 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without  
19.3 first obtaining a license from the board and paying any applicable fee specified in section  
19.4 151.065.

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

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

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

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

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

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

20.1 Sec. 24. Minnesota Statutes 2018, section 151.252, subdivision 1a, is amended to read:

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

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

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

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

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

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

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

21.1 Sec. 25. Minnesota Statutes 2018, section 151.252, subdivision 3, is amended to read:

21.2 Subd. 3. **Payment to practitioner; reporting.** Unless prohibited by United States Code,  
21.3 title 42, section 1320a-7h, a drug manufacturer or outsourcing facility shall file with the  
21.4 board an annual report, in a form and on the date prescribed by the board, identifying all  
21.5 payments, honoraria, reimbursement, or other compensation authorized under section  
21.6 151.461, clauses (4) and (5), paid to practitioners in Minnesota during the preceding calendar  
21.7 year. The report shall identify the nature and value of any payments totaling \$100 or more  
21.8 to a particular practitioner during the year, and shall identify the practitioner. Reports filed  
21.9 under this subdivision are public data.

21.10 Sec. 26. Minnesota Statutes 2018, section 151.253, subdivision 2, is amended to read:

21.11 Subd. 2. **Compounded drug.** A drug product may be compounded under this section  
21.12 if a pharmacist or practitioner:

21.13 (1) compounds the drug product using bulk drug substances, as defined in the federal  
21.14 regulations published in Code of Federal Regulations, title 21, section 207.3(a)(4):

21.15 (i) that:

21.16 (A) comply with the standards of an applicable United States Pharmacopoeia or National  
21.17 Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter  
21.18 on pharmacy compounding;

21.19 (B) if such a monograph does not exist, are drug substances that are components of drugs  
21.20 approved for use in this country by the United States Food and Drug Administration; or

21.21 (C) if such a monograph does not exist and the drug substance is not a component of a  
21.22 drug approved for use in this country by the United States Food and Drug Administration,  
21.23 that appear on a list developed by the United States Food and Drug Administration through  
21.24 regulations issued by the secretary of the federal Department of Health and Human Services  
21.25 pursuant to section 503A of the Food, Drug and Cosmetic Act under paragraph (d);

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

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

21.30 (2) compounds the drug product using ingredients, other than bulk drug substances, that  
21.31 comply with the standards of an applicable United States Pharmacopoeia or National

22.1 Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapters  
22.2 on pharmacy compounding;

22.3 (3) does not compound a drug product that appears on a list published by the secretary  
22.4 of the federal Department of Health and Human Services in the Federal Register of drug  
22.5 products that have been withdrawn or removed from the market because such drug products  
22.6 or components of such drug products have been found to be unsafe or not effective;

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

22.9 (5) does not compound extended, controlled, or sustained release products, lyophilized  
22.10 products, products meant to be implanted subcutaneously or subdermally, transdermal  
22.11 patches, metered-dose inhalers, or any drug product that has been identified pursuant to  
22.12 United States Code, title 21, section 353a, as a drug product that presents demonstrable  
22.13 difficulties for compounding that reasonably demonstrate an adverse effect on the safety or  
22.14 effectiveness of that drug product.

22.15 A drug product is "essentially a copy of a commercially available drug product" if the  
22.16 compounded drug product has the same active pharmaceutical ingredient or ingredients as  
22.17 any commercially available drug product, and a commercially available drug product can  
22.18 be administered by the same route of administration, whether or not that route of  
22.19 administration is listed in the Food and Drug Administration approved labeling of the  
22.20 commercially available drug product. The term "essentially a copy of a commercially  
22.21 available drug product" does not include a drug product in which there is a change, made  
22.22 for an identified individual patient, that produces for that patient a significant clinical  
22.23 difference, as determined by the prescribing practitioner, between the compounded drug  
22.24 and the comparable commercially available drug product. The specific reason for such  
22.25 change must be documented by the practitioner on each prescription drug order or, if the  
22.26 compounding is to be done by a pharmacy, may be provided to a pharmacist employed by  
22.27 the pharmacy through other means of communication. The provision of such specific reason  
22.28 by the prescribing practitioner does not relieve a pharmacist of the duty to use sound  
22.29 professional judgment to assess the clinical necessity for dispensing a product that is  
22.30 essentially a copy of a commercially available drug product.

23.1 Sec. 27. Minnesota Statutes 2018, section 151.253, is amended by adding a subdivision  
23.2 to read:

23.3 Subd. 2a. **Compounding standards.** (a) All persons engaged in nonsterile drug  
23.4 compounding, including pharmacies licensed by the board and licensed practitioners, must  
23.5 follow the standards put forth in chapter 795 of the United States Pharmacopeia.

23.6 (b) All persons engaged in sterile drug compounding, including pharmacies licensed by  
23.7 the board and licensed practitioners, must follow the standards put forth in chapter 797 of  
23.8 the United States Pharmacopeia.

23.9 (c) All persons who handle hazardous drug preparations, including pharmacies licensed  
23.10 by the board and licensed practitioners, must follow the standards put forth in chapter 800  
23.11 of the United States Pharmacopeia.

23.12 **EFFECTIVE DATE.** Paragraph (c) is effective December 1, 2019.

23.13 Sec. 28. Minnesota Statutes 2018, section 151.253, is amended by adding a subdivision  
23.14 to read:

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

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

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

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

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

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

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

24.3 Sec. 29. Minnesota Statutes 2018, section 151.26, subdivision 1, is amended to read:

24.4 Subdivision 1. **Generally Practitioners.** (a) Nothing in this chapter shall subject a person  
24.5 duly licensed in this state to ~~practice medicine, dentistry, or veterinary medicine~~ as a  
24.6 practitioner, to inspection by the State Board of Pharmacy, nor prevent the person from  
24.7 administering drugs, medicines, chemicals, or poisons in the person's practice, nor prevent  
24.8 a duly licensed practitioner from furnishing to a patient properly packaged and labeled  
24.9 drugs, medicines, chemicals, or poisons as may be considered appropriate in the treatment  
24.10 of such patient; unless the person is engaged in the compounding, dispensing, sale, or  
24.11 distribution of drugs and the board provides reasonable notice of an inspection.

24.12 (b) Except for the provisions of section 151.37, nothing in this chapter applies to or  
24.13 interferes with the dispensing, in its original package and at no charge to the patient, of a  
24.14 legend drug that was packaged by a manufacturer and provided to the dispenser for dispensing  
24.15 as a professional sample. Samples of a controlled substance shall only be dispensed when  
24.16 one of the approved indications for the controlled substance is a seizure disorder and when  
24.17 the sample is prepared and distributed pursuant to Code of Federal Regulations, title 21,  
24.18 part 203, subpart D.

24.19 (c) Nothing in this chapter shall prevent the sale of drugs, medicines, chemicals, or  
24.20 poisons at wholesale, by persons licensed under section 151.46, to licensed ~~physicians,~~  
24.21 ~~dentists and veterinarians~~ practitioners for use in their practice, nor to hospitals for use  
24.22 therein.

24.23 ~~Nothing in this chapter shall prevent the sale of drugs, chemicals, or poisons either at~~  
24.24 ~~wholesale or retail for use for commercial purposes, or in the arts, nor interfere with the~~  
24.25 ~~sale of insecticides, as defined in Minnesota Statutes 1974, section 24.069, and nothing in~~  
24.26 ~~this chapter shall prevent the sale of common household preparations and other drugs,~~  
24.27 ~~chemicals, and poisons sold exclusively for use for nonmedicinal purposes; provided that~~  
24.28 ~~this exception does not apply to any compound, substance, or derivative that is not approved~~  
24.29 ~~for human consumption by the United States Food and Drug Administration or specifically~~  
24.30 ~~permitted for human consumption under Minnesota law, and, when introduced into the~~  
24.31 ~~body, induces an effect similar to that of a Schedule I or Schedule II controlled substance~~  
24.32 ~~listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and~~  
24.33 ~~6800.4220, regardless of whether the substance is marketed for the purpose of human~~  
24.34 ~~consumption.~~



25.1 ~~Nothing in this chapter shall apply to or interfere with the vending or retailing of any~~  
25.2 ~~nonprescription medicine or drug not otherwise prohibited by statute that is prepackaged,~~  
25.3 ~~fully prepared by the manufacturer or producer for use by the consumer, and labeled in~~  
25.4 ~~accordance with the requirements of the state or federal Food and Drug Act; nor to the~~  
25.5 ~~manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics,~~  
25.6 ~~perfumes, spices, and other commonly used household articles of a chemical nature, for use~~  
25.7 ~~for nonmedicinal purposes; provided that this exception does not apply to any compound,~~  
25.8 ~~substance, or derivative that is not approved for human consumption by the United States~~  
25.9 ~~Food and Drug Administration or specifically permitted for human consumption under~~  
25.10 ~~Minnesota law, and, when introduced into the body, induces an effect similar to that of a~~  
25.11 ~~Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and~~  
25.12 ~~3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance~~  
25.13 ~~is marketed for the purpose of human consumption. Nothing in this chapter shall prevent~~  
25.14 ~~the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years~~  
25.15 ~~of age.~~

25.16 Sec. 30. Minnesota Statutes 2018, section 151.26, is amended by adding a subdivision to  
25.17 read:

25.18 Subd. 3. **Miscellaneous exceptions.** (a) Nothing in this chapter shall prevent the sale of  
25.19 nonprescription drugs, chemicals, or poisons either at wholesale or retail for use for  
25.20 commercial purposes, or in the arts, nor interfere with the sale of pesticides, as defined in  
25.21 section 18B.01, and nothing in this chapter shall prevent the sale of common household  
25.22 preparations and other nonprescription drugs, chemicals, and poisons sold exclusively for  
25.23 use for nonmedicinal purposes; provided that this exception does not apply to any compound,  
25.24 substance, or derivative that is not approved for human consumption by the United States  
25.25 Food and Drug Administration or specifically permitted for human consumption under  
25.26 Minnesota law, and, when introduced into the body, induces an effect similar to that of a  
25.27 Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and  
25.28 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance  
25.29 is marketed for the purpose of human consumption.

25.30 (b) Nothing in this chapter shall apply to or interfere with the retail sale of any  
25.31 nonprescription drug that is manufactured, packaged, and labeled in accordance with the  
25.32 requirements of the federal Food, Drug, and Cosmetic Act; nor to the manufacture,  
25.33 wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes,  
25.34 spices, and other commonly used household articles of a chemical nature, for use for  
25.35 nonmedicinal purposes; provided that this exception does not apply to any compound,

26.1 substance, or derivative that is not approved for human consumption by the United States  
26.2 Food and Drug Administration or specifically permitted for human consumption under  
26.3 Minnesota law, and, when introduced into the body, induces an effect similar to that of a  
26.4 Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and  
26.5 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance  
26.6 is marketed for the purpose of human consumption. Nothing in this chapter shall prevent  
26.7 the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years  
26.8 of age.

26.9 Sec. 31. Minnesota Statutes 2018, section 151.32, is amended to read:

26.10 **151.32 CITATION.**

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

26.13 Sec. 32. Minnesota Statutes 2018, section 151.37, subdivision 2, is amended to read:

26.14 Subd. 2. **Prescribing and filing.** (a) A licensed practitioner in the course of professional  
26.15 practice only, may prescribe, administer, and dispense a legend drug, and may cause the  
26.16 same to be administered by a nurse, a physician assistant, or medical student or resident  
26.17 under the practitioner's direction and supervision, and may cause a person who is an  
26.18 appropriately certified, registered, or licensed health care professional to prescribe, dispense,  
26.19 and administer the same within the expressed legal scope of the person's practice as defined  
26.20 in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference  
26.21 to a specific patient, by directing a licensed dietitian or licensed nutritionist, pursuant to  
26.22 section 148.634; a nurse, pursuant to section 148.235, subdivisions 8 and 9; physician  
26.23 assistant; medical student or resident; or pharmacist according to section 151.01, subdivision  
26.24 27, to adhere to a particular practice guideline or protocol when treating patients whose  
26.25 condition falls within such guideline or protocol, and when such guideline or protocol  
26.26 specifies the circumstances under which the legend drug is to be prescribed and administered.  
26.27 An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic  
26.28 order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug.  
26.29 This paragraph applies to a physician assistant only if the physician assistant meets the  
26.30 requirements of section 147A.18.

26.31 (b) The commissioner of health, if a licensed practitioner, or a person designated by the  
26.32 commissioner who is a licensed practitioner, may prescribe a legend drug to an individual  
26.33 or by protocol for mass dispensing purposes where the commissioner finds that the conditions

27.1 triggering section 144.4197 or 144.4198, subdivision 2, paragraph (b), exist. The  
27.2 commissioner, if a licensed practitioner, or a designated licensed practitioner, may prescribe,  
27.3 dispense, or administer a legend drug or other substance listed in subdivision 10 to control  
27.4 tuberculosis and other communicable diseases. The commissioner may modify state drug  
27.5 labeling requirements, and medical screening criteria and documentation, where time is  
27.6 critical and limited labeling and screening are most likely to ensure legend drugs reach the  
27.7 maximum number of persons in a timely fashion so as to reduce morbidity and mortality.

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

27.27 (d) A prescription drug order for the following drugs is not valid, unless it can be  
27.28 established that the prescription drug order was based on a documented patient evaluation,  
27.29 including an examination, adequate to establish a diagnosis and identify underlying conditions  
27.30 and contraindications to treatment:

27.31 (1) controlled substance drugs listed in section 152.02, subdivisions 3 to 5;

27.32 (2) drugs defined by the Board of Pharmacy as controlled substances under section  
27.33 152.02, subdivisions 7, 8, and 12;

27.34 (3) muscle relaxants;

28.1 (4) centrally acting analgesics with opioid activity;

28.2 (5) drugs containing butalbital; or

28.3 (6) phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.

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

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

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

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

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

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

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

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

28.22 (h) Nothing in paragraph (d) or (e) limits prescription, administration, or dispensing of  
28.23 legend drugs through a public health clinic or other distribution mechanism approved by  
28.24 the commissioner of health or a community health board in order to prevent, mitigate, or  
28.25 treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of  
28.26 a biological, chemical, or radiological agent.

28.27 (i) No pharmacist employed by, under contract to, or working for a pharmacy located  
28.28 within the state and licensed under section 151.19, subdivision 1, may dispense a legend  
28.29 drug based on a prescription that the pharmacist knows, or would reasonably be expected  
28.30 to know, is not valid under paragraph (d).

28.31 (j) No pharmacist employed by, under contract to, or working for a pharmacy located  
28.32 outside the state and licensed under section 151.19, subdivision 1, may dispense a legend

29.1 drug to a resident of this state based on a prescription that the pharmacist knows, or would  
 29.2 reasonably be expected to know, is not valid under paragraph (d).

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

29.8 Sec. 33. Minnesota Statutes 2018, section 151.40, subdivision 1, is amended to read:

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

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

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

29.15 (ii) licensed pharmacies and their employees or agents;

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

29.17 (iv) registered nurses; and licensed practical nurses;

29.18 (v) registered medical technologists;

29.19 (vi) medical interns; and residents;

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

29.21 (viii) licensed hospitals;

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

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

29.24 (xi) licensed morticians;

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

29.26 (xiii) persons engaged in animal husbandry;

29.27 (xiv) clinical laboratories and their employees;

29.28 (xv) persons engaged in bona fide research or education or industrial use of hypodermic  
 29.29 syringes and needles provided such persons cannot use hypodermic syringes and needles

30.1 for the administration of drugs to human beings unless such drugs are prescribed, dispensed,  
30.2 and administered by a person lawfully authorized to do so;

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

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

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

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

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

30.16 Sec. 34. Minnesota Statutes 2018, section 151.40, subdivision 2, is amended to read:

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

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

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

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

30.31 ~~(e)~~ (d) A registered pharmacy or licensed pharmacist that sells hypodermic needles or  
30.32 syringes under this subdivision must certify to the commissioner of health participation in

31.1 an activity, including but not limited to those developed under section 325F.785, that supports  
 31.2 proper disposal of used hypodermic needles or syringes.

31.3 Sec. 35. Minnesota Statutes 2018, section 151.43, is amended to read:

31.4 **151.43 SCOPE.**

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

31.8 Sec. 36. **[151.441] DEFINITIONS.**

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

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

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

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

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

31.30 (1) a person who holds an application approved under United States Code, title 21,  
 31.31 section 355, or a license issued under United States Code, title 42, section 262, for such

32.1 product, or if such product is not the subject of an approved application or license, the person  
32.2 who manufactured the product;

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

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

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

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

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

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

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

32.31 Subd. 11. **Third-party logistics provider.** "Third-party logistics provider" means an  
32.32 entity that provides or coordinates warehousing or other logistics services of a product in  
32.33 interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a



33.1 product, but does not take ownership of the product nor have responsibility to direct the  
33.2 sale or disposition of the product.

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

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

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

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

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

33.12 (i) a public health emergency declaration pursuant to United States Code, title 42, section  
33.13 247d;

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

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

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

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

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

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

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

33.30 (9) the distribution of a product pursuant to the sale or merger of a pharmacy or  
33.31 pharmacies or a wholesale distributor or wholesale distributors, except that any records

34.1 required to be maintained for the product shall be transferred to the new owner of the  
34.2 pharmacy or pharmacies or wholesale distributor or wholesale distributors;

34.3 (10) the dispensing of a product approved under United States Code, title 21, section  
34.4 360b(c);

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

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

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

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

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

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

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

34.22 (ii) the medical convenience kit does not contain a controlled substance that appears in  
34.23 a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of  
34.24 1970, United States Code, title 21, section 801, et seq.;

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

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

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

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

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

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

35.3 (C) a product intended for irrigation or reconstitution;

35.4 (D) an anesthetic;

35.5 (E) an anticoagulant;

35.6 (F) a vasopressor; or

35.7 (G) a sympathomimetic;

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

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

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

35.15 (17) the distribution of a medical gas as defined in United States Code, title 21, section  
35.16 360ddd; or

35.17 (18) the distribution or sale of any licensed product under United States Code, title 42,  
35.18 section 262, that meets the definition of a device under United States Code, title 21, section  
35.19 321(h).

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

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

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

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

35.29 (i) a public health emergency declaration pursuant to United States Code, title 42, section  
35.30 247d;

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

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

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

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

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

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

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

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

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

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

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

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

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

36.30 (ii) the medical convenience kit does not contain a controlled substance that appears in  
36.31 a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of  
36.32 1970, United States Code, title 21, section 801, et seq.;

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

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

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

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

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

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

37.11 (C) a product intended for irrigation or reconstitution;

37.12 (D) an anesthetic;

37.13 (E) an anticoagulant;

37.14 (F) a vasopressor; or

37.15 (G) a sympathomimetic;

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

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

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

37.23 (17) the distribution of medical gas, as defined in United States Code, title 21, section  
37.24 360ddd;

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

37.27 (19) the transfer of a product by a hospital or other health care entity, or by a wholesale  
37.28 distributor or manufacturer operating at the direction of the hospital or other health care  
37.29 entity, to a repackager described in United States Code, title 21, section 360eee(16)(B), and  
37.30 registered under United States Code, title 21, section 360, for the purpose of repackaging  
37.31 the drug for use by that hospital, or other health care entity and other health care entities

38.1 that are under common control, if ownership of the drug remains with the hospital or other  
 38.2 health care entity at all times.

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

38.6 Sec. 37. Minnesota Statutes 2018, section 151.46, is amended to read:

38.7 **151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.**

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

38.13 Sec. 38. Minnesota Statutes 2018, section 151.47, subdivision 1, is amended to read:

38.14 Subdivision 1. **Requirements Generally.** ~~(a) All wholesale drug distributors are subject~~  
 38.15 ~~to the requirements of this subdivision.~~ Each manufacturer, repackager, wholesale distributor,  
 38.16 and dispenser shall comply with the requirements set forth in United States Code, title 21,  
 38.17 section 360eee-1, with respect to the role of such manufacturer, repackager, wholesale  
 38.18 distributor, or dispenser in a transaction involving a product. If an entity meets the definition  
 38.19 of more than one of the entities listed in the preceding sentence, such entity shall comply  
 38.20 with all applicable requirements in United States Code, title 21, section 360eee-1, but shall  
 38.21 not be required to duplicate requirements.

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

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

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

38.29 ~~(e) No license may be issued or renewed for a drug wholesale distributor that is required~~  
 38.30 ~~to be licensed or registered by the state in which it is physically located unless the applicant~~  
 38.31 ~~supplies the board with proof of licensure or registration. The board may establish, by rule,~~

39.1 ~~standards for the licensure of a drug wholesale distributor that is not required to be licensed~~  
39.2 ~~or registered by the state in which it is physically located.~~

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

39.6 ~~(g) The board shall not issue an initial or renewed license for a drug wholesale distributor~~  
39.7 ~~facility unless the facility passes an inspection conducted by an authorized representative~~  
39.8 ~~of the board, or is accredited by an accreditation program approved by the board. In the~~  
39.9 ~~case of a drug wholesale distributor facility located outside of the state, the board may~~  
39.10 ~~require the applicant to pay the cost of the inspection, in addition to the license fee in section~~  
39.11 ~~151.065, unless the applicant furnishes the board with a report, issued by the appropriate~~  
39.12 ~~regulatory agency of the state in which the facility is located, of an inspection that has~~  
39.13 ~~occurred within the 24 months immediately preceding receipt of the license application by~~  
39.14 ~~the board, or furnishes the board with proof of current accreditation. The board may deny~~  
39.15 ~~licensure unless the applicant submits documentation satisfactory to the board that any~~  
39.16 ~~deficiencies noted in an inspection report have been corrected.~~

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

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

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

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

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

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

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

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

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

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

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

40.17 Sec. 39. Minnesota Statutes 2018, section 151.47, is amended by adding a subdivision to  
40.18 read:

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

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

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

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



41.1 (e) No license may be issued or renewed for a wholesale distributor facility that is located  
41.2 in another state unless the applicant supplies the board with proof of licensure or registration  
41.3 by the state in which the wholesale distributor is physically located or by the United States  
41.4 Food and Drug Administration.

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

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

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

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

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

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

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

41.31 (5) employs principals and other persons, including officers, directors, primary  
41.32 shareholders, and key management executives, who will at all times demonstrate and maintain  
41.33 their capability of conducting business in conformity with state and federal law, at least one

42.1 of whom will serve as the primary designated representative for each licensed facility and  
42.2 who will be responsible for ensuring that the facility operates in a manner consistent with  
42.3 state and federal law;

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

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

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

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

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

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

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

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

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

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

42.31 or

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

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

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

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

43.12 (o) The purpose of the surety bond required under this subdivision is to secure payment  
43.13 of any civil penalty imposed by the board pursuant to section 151.071, subdivision 1. The  
43.14 board may make a claim against the bond if the licensee fails to pay a civil penalty within  
43.15 30 days after the order imposing the fine or costs become final.

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

43.18 **Sec. 40. [151.471] THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

46.1 (k) A licensed third-party logistics provider shall not have as a facility manager or  
46.2 designated representative any person who has been convicted of any felony for conduct  
46.3 relating to wholesale distribution, any felony violation of United States Code, title 21, section  
46.4 331, subsection (i) or (k), or any felony violation of United States Code, title 18, section  
46.5 1365, relating to product tampering.

46.6 Sec. 41. Minnesota Statutes 2018, section 152.01, is amended by adding a subdivision to  
46.7 read:

46.8 Subd. 25. **Practitioner.** "Practitioner" has the meaning given in section 151.01,  
46.9 subdivision 23.

46.10 Sec. 42. Minnesota Statutes 2018, section 152.11, subdivision 1, is amended to read:

46.11 Subdivision 1. **General prescription requirements for controlled substances.** (a) A  
46.12 written prescription or an oral prescription reduced to writing, when issued for a controlled  
46.13 substance in Schedule II, III, IV, or V, is void unless (1) it is written in ink and contains the  
46.14 name and address of the person for whose use it is intended; (2) it states the amount of the  
46.15 controlled substance to be ~~compounded~~ or dispensed, with directions for its use; (3) if a  
46.16 written prescription, it contains the handwritten signature of the prescriber, the prescriber's  
46.17 address, and the federal registry number of the prescriber and a designation of the branch  
46.18 of the healing art pursued by the prescriber; and if an oral prescription, the name and address  
46.19 of the prescriber and a designation of the prescriber's branch of the healing art; and (4) it  
46.20 shows the date when signed by the prescriber, or the date of acceptance in the pharmacy if  
46.21 an oral prescription.

46.22 (b) An electronic prescription for a controlled substance in Schedule II, III, IV, or V is  
46.23 void unless it complies with the standards established pursuant to section 62J.497 and with  
46.24 those portions of Code of Federal Regulations, title 21, parts 1300, 1304, 1306, and 1311,  
46.25 that pertain to electronic prescriptions.

46.26 (c) A prescription for a controlled substance in Schedule II, III, IV, or V that is transmitted  
46.27 by facsimile, either computer to facsimile machine or facsimile machine to facsimile machine,  
46.28 is void unless it complies with the applicable requirements of Code of Federal Regulations,  
46.29 title 21, part 1306.

46.30 (d) Every licensed pharmacy that dispenses a controlled substance prescription shall  
46.31 retain the original prescription in a file for a period of not less than two years, open to  
46.32 inspection by any officer of the state, county, or municipal government whose duty it is to  
46.33 aid and assist with the enforcement of this chapter. An original electronic or facsimile

47.1 prescription may be stored in an electronic database, provided that the database provides a  
47.2 means by which original prescriptions can be retrieved, as transmitted to the pharmacy, for  
47.3 a period of not less than two years.

47.4 (e) Every licensed pharmacy shall distinctly label the container in which a controlled  
47.5 substance is dispensed with the directions contained in the prescription for the use of that  
47.6 controlled substance.

47.7 Sec. 43. Minnesota Statutes 2018, section 152.11, subdivision 1a, is amended to read:

47.8 Subd. 1a. **Prescription requirements for Schedule II controlled substances.** No person  
47.9 may dispense a controlled substance included in Schedule II of section 152.02 without a  
47.10 prescription issued by a ~~doctor of medicine, a doctor of osteopathic medicine licensed to~~  
47.11 ~~practice medicine, a doctor of dental surgery, a doctor of dental medicine, a doctor of~~  
47.12 ~~podiatry, or a doctor of veterinary medicine,~~ practitioner lawfully licensed to prescribe in  
47.13 this state or by a practitioner licensed to prescribe controlled substances by the state in which  
47.14 the prescription is issued, and having a current federal ~~Drug Enforcement Administration~~  
47.15 controlled substance registration number. The prescription must either be printed or written  
47.16 in ink and contain the handwritten signature of the prescriber or be transmitted electronically  
47.17 or by facsimile as permitted under subdivision 1. Provided that in emergency situations, as  
47.18 authorized by federal law, such drug may be dispensed upon oral prescription reduced  
47.19 promptly to writing and filed by the pharmacist. Such prescriptions shall be retained in  
47.20 conformity with section 152.101. No prescription for a Schedule II substance may be refilled.

47.21 Sec. 44. Minnesota Statutes 2018, section 152.11, subdivision 2, is amended to read:

47.22 Subd. 2. **Prescription requirements for Schedule III or IV controlled substances.** No  
47.23 person may dispense a controlled substance included in Schedule III or IV of section 152.02  
47.24 without a prescription issued, as permitted under subdivision 1, by a ~~doctor of medicine, a~~  
47.25 ~~doctor of osteopathic medicine licensed to practice medicine, a doctor of dental surgery, a~~  
47.26 ~~doctor of dental medicine, a doctor of podiatry, a doctor of optometry limited to Schedule~~  
47.27 ~~IV, or a doctor of veterinary medicine,~~ practitioner lawfully licensed to prescribe in this  
47.28 state or from a practitioner licensed to prescribe controlled substances by the state in which  
47.29 the prescription is issued, and having a current federal ~~drug enforcement administration~~  
47.30 controlled substance registration number. Such prescription may not be dispensed or refilled  
47.31 except with the documented consent of the prescriber, and in no event more than six months  
47.32 after the date on which such prescription was issued and no such prescription may be refilled  
47.33 more than five times.

48.1 Sec. 45. Minnesota Statutes 2018, section 152.13, is amended to read:

48.2 **152.13 DUTIES OF STATE BOARD OF PHARMACY.**

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

48.8 Sec. 46. Minnesota Statutes 2018, section 295.50, is amended by adding a subdivision to  
48.9 read:

48.10 Subd. 2b. **Emergency medical reasons.** "Emergency medical reasons" means a public  
48.11 health emergency declaration pursuant to United States Code, title 42, section 247d; a  
48.12 national security or peacetime emergency declared by the governor pursuant to section  
48.13 12.31; or a situation involving an action by the commissioner of health pursuant to section  
48.14 144.4197, 144.4198, or 151.37, subdivisions 2, paragraph (b), and 10; except that, for  
48.15 purposes of this subdivision, a drug shortage not caused by a public health emergency shall  
48.16 not constitute an emergency medical reason.

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

48.18 Sec. 47. Minnesota Statutes 2018, section 295.50, is amended by adding a subdivision to  
48.19 read:

48.20 Subd. 7a. **Manufacturer.** "Manufacturer" has the meaning given in section 151.01,  
48.21 subdivision 14a.

48.22 Sec. 48. Minnesota Statutes 2018, section 295.50, subdivision 14, is amended to read:

48.23 Subd. 14. **Wholesale drug distributor.** "Wholesale drug distributor" means ~~a wholesale~~  
48.24 drug distributor required to be licensed under sections 151.42 to 151.51 any person engaged  
48.25 in wholesale drug distribution including but not limited to manufacturers; repackagers;  
48.26 own-label distributors; jobbers; brokers; warehouses, including manufacturers' and  
48.27 distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;  
48.28 independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution.  
48.29 A wholesale drug distributor does not include a common carrier or individual hired primarily  
48.30 to transport legend drugs.

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



49.1 Sec. 49. Minnesota Statutes 2018, section 295.50, is amended by adding a subdivision to  
49.2 read:

49.3 Subd. 16. Wholesale drug distribution. "Wholesale drug distribution" means the sale  
49.4 or distribution of legend drugs to a person other than a consumer or patient, but does not  
49.5 include:

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

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

49.12 (3) the sale, purchase, or trade of a legend drug by a charitable organization described  
49.13 in section 501(c)(3) of the Internal Revenue Code of 1986, as amended through December  
49.14 31, 1988, to a nonprofit affiliate of the organization to the extent otherwise permitted by  
49.15 law;

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

49.18 (5) the sale, purchase, or trade of a legend drug for emergency medical reasons;

49.19 (6) the transfer of legend drugs by a retail pharmacy to another retail pharmacy to alleviate  
49.20 a temporary shortage; or

49.21 (7) the distribution of legend drug samples by manufacturer representatives.

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

49.23 Sec. 50. **REPEALER.**

49.24 (a) Minnesota Statutes 2018, sections 151.13, subdivision 2; 151.19, subdivision 4;  
49.25 151.27; 151.42; 151.44; 151.49; 151.50; 151.51; and 151.55, are repealed.

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

**151.13 RENEWAL FEE; CONTINUING EDUCATION.**

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

**151.19 REGISTRATION; FEES.**

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

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

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

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

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

**151.27 EXPENSES.**

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

**151.42 CITATION.**

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

**151.44 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;

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(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

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(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.

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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:

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(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.

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

**6800.1600 CONTINUING EDUCATION ADVISORY TASK FORCE.**

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