

1.1 moves to amend H.F. No. 1718 as follows:

1.2 Delete everything after the enacting clause and insert:

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

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

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

1.10 Subd. 35. **Compounding.** "Compounding" means preparing, mixing, assembling,
1.11 packaging, and labeling a drug for an identified individual patient as a result of a practitioner's
1.12 prescription drug order. Compounding also includes anticipatory compounding, as defined
1.13 in this section, and the preparation of drugs in which all bulk drug substances and components
1.14 are nonprescription substances. Compounding does not include mixing or reconstituting a
1.15 drug according to the product's labeling or to the manufacturer's directions, provided that
1.16 such labeling has been approved by the United States Food and Drug Administration (FDA)
1.17 or the manufacturer is licensed under section 151.252. Compounding does not include the
1.18 preparation of a drug for the purpose of, or incident to, research, teaching, or chemical
1.19 analysis, provided that the drug is not prepared for dispensing or administration to patients.
1.20 All compounding, regardless of the type of product, must be done pursuant to a prescription
1.21 drug order unless otherwise permitted in this chapter or by the rules of the board.
1.22 Compounding does not include a minor deviation from such directions with regard to
1.23 radioactivity, volume, or stability, which is made by or under the supervision of a licensed
1.24 nuclear pharmacist or a physician, and which is necessary in order to accommodate

2.1 circumstances not contemplated in the manufacturer's instructions, such as the rate of
2.2 radioactive decay or geographical distance from the patient.

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

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

2.12 Sec. 4. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:

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

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

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

2.17 (3) pharmacy intern, \$37.50;

2.18 (4) pharmacy technician, \$37.50;

2.19 (5) pharmacy, \$225;

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

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

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

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

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

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

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

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

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

- 3.1 (15) ~~drug manufacturer, also licensed as a pharmacy in Minnesota, \$150;~~
3.2 ~~(16)~~ medical gas distributor, \$110;
3.3 ~~(17)~~ (16) controlled substance researcher, \$75; and
3.4 ~~(18)~~ (17) pharmacy professional corporation, \$125.

3.5 Sec. 5. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:

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

- 3.8 (1) pharmacist, \$145;
3.9 (2) pharmacy technician, \$37.50;
3.10 (3) pharmacy, \$225;
3.11 (4) drug wholesaler, legend drugs only, \$235;
3.12 (5) drug wholesaler, legend and nonlegend drugs, \$235;
3.13 (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210;
3.14 (7) drug wholesaler, medical gases, \$185;
3.15 (8) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, \$150~~ third-party logistics
3.16 provider, \$260;
3.17 (9) drug manufacturer, legend drugs only, \$235;
3.18 (10) drug manufacturer, legend and nonlegend drugs, \$235;
3.19 (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$210;
3.20 (12) drug manufacturer, medical gases, \$185;
3.21 (13) ~~drug manufacturer, also licensed as a pharmacy in Minnesota, \$150;~~
3.22 ~~(14)~~ medical gas distributor, \$110;
3.23 ~~(15)~~ (14) controlled substance researcher, \$75; and
3.24 ~~(16)~~ (15) pharmacy professional corporation, \$75.

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

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

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

4.8 (c) An owner of a pharmacy, a drug wholesaler, a drug manufacturer, third-party logistics
4.9 provider, or a medical gas distributor who has allowed the license of the establishment to
4.10 lapse may reinstate the license with board approval and upon payment of any fees and late
4.11 fees in arrears.

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

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

4.18 Sec. 7. Minnesota Statutes 2018, section 151.071, subdivision 2, is amended to read:

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

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

4.24 (2) obtaining a license by fraud or by misleading the board in any way during the
4.25 application process or obtaining a license by cheating, or attempting to subvert the licensing
4.26 examination process. Conduct that subverts or attempts to subvert the licensing examination
4.27 process includes, but is not limited to: (i) conduct that violates the security of the examination
4.28 materials, such as removing examination materials from the examination room or having
4.29 unauthorized possession of any portion of a future, current, or previously administered
4.30 licensing examination; (ii) conduct that violates the standard of test administration, such as
4.31 communicating with another examinee during administration of the examination, copying
4.32 another examinee's answers, permitting another examinee to copy one's answers, or

5.1 possessing unauthorized materials; or (iii) impersonating an examinee or permitting an
5.2 impersonator to take the examination on one's own behalf;

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

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

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

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

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

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

6.1 of this state's health licensing agencies until the action has been dismissed or otherwise
6.2 resolved;

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

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

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

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

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

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

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

6.32 (14) for a pharmacist, the inability to practice pharmacy with reasonable skill and safety
6.33 to patients by reason of illness, ~~drunkenness~~, use of alcohol, drugs, narcotics, chemicals, or

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

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

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

7.14 (17) fee splitting, including without limitation:

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

7.18 (ii) referring a patient to any health care provider as defined in sections 144.291 to
7.19 144.298 in which the licensee or registrant has a financial or economic interest as defined
7.20 in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the
7.21 licensee's or registrant's financial or economic interest in accordance with section 144.6521;
7.22 and

7.23 (iii) any arrangement through which a pharmacy, in which the prescribing practitioner
7.24 does not have a significant ownership interest, fills a prescription drug order and the
7.25 prescribing practitioner is involved in any manner, directly or indirectly, in setting the price
7.26 for the filled prescription that is charged to the patient, the patient's insurer or pharmacy
7.27 benefit manager, or other person paying for the prescription or, in the case of veterinary
7.28 patients, the price for the filled prescription that is charged to the client or other person
7.29 paying for the prescription, except that a veterinarian and a pharmacy may enter into such
7.30 an arrangement provided that the client or other person paying for the prescription is notified,
7.31 in writing and with each prescription dispensed, about the arrangement, unless such
7.32 arrangement involves pharmacy services provided for livestock, poultry, and agricultural
7.33 production systems, in which case client notification would not be required;

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

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

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

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

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

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

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

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

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

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

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

8.30 Sec. 8. Minnesota Statutes 2018, section 151.15, subdivision 1, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.13 Sec. 11. Minnesota Statutes 2018, section 151.19, subdivision 1, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

11.27 (5) that, upon request of a resident of a long-term care facility located in this state, the
11.28 resident's authorized representative, or a contract pharmacy or licensed health care facility
11.29 acting on behalf of the resident, the pharmacy will dispense medications prescribed for the
11.30 resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision
11.31 5.

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

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

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

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

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

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

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

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

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

12.16 and

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

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

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

12.23 Sec. 12. Minnesota Statutes 2018, section 151.19, subdivision 3, is amended to read:

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

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

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

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

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

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

13.27 Sec. 13. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

13.28 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without
13.29 first obtaining a license from the board and paying any applicable fee specified in section
13.30 151.065.

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

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

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

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

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

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

14.28 Sec. 14. Minnesota Statutes 2018, section 151.252, subdivision 1a, is amended to read:

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

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

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

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

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

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

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

15.29 Sec. 15. Minnesota Statutes 2018, section 151.252, subdivision 3, is amended to read:

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

16.1 151.461, clauses (4) and (5), paid to practitioners in Minnesota during the preceding calendar
16.2 year. The report shall identify the nature and value of any payments totaling \$100 or more
16.3 to a particular practitioner during the year, and shall identify the practitioner. Reports filed
16.4 under this subdivision are public data.

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

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

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

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

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

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

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

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

16.26 Sec. 17. Minnesota Statutes 2018, section 151.32, is amended to read:

16.27 **151.32 CITATION.**

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

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

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

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

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

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

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

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

17.11 (v) registered medical technologists;

17.12 (vi) medical interns, and residents;

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

17.14 (viii) licensed hospitals;

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

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

17.17 (xi) licensed morticians;

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

17.19 (xiii) persons engaged in animal husbandry;

17.20 (xiv) clinical laboratories and their employees;

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

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

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

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

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

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

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

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

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

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

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

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

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

19.2 **151.43 SCOPE.**

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

19.6 Sec. 21. **[151.441] DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21.10 (i) a public health emergency declaration pursuant to United States Code, title 42, section
21.11 247d;

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

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

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

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

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

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

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

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

22.1 (10) the dispensing of a product approved under United States Code, title 21, section
22.2 360b(c);

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

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

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

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

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

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

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

22.20 (ii) the medical convenience kit does not contain a controlled substance that appears in
22.21 a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of
22.22 1970, United States Code, title 21, section 801, et seq.;

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

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

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

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

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

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

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

23.3 (D) an anesthetic;

23.4 (E) an anticoagulant;

23.5 (F) a vasopressor; or

23.6 (G) a sympathomimetic;

23.7 (14) the distribution of an intravenous product that, by its formulation, is intended for

23.8 the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium; or

23.9 calories, such as dextrose and amino acids;

23.10 (15) the distribution of an intravenous product used to maintain the equilibrium of water

23.11 and minerals in the body, such as dialysis solutions;

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

23.13 intended for such purposes or for injection;

23.14 (17) the distribution of a medical gas as defined in United States Code, title 21, section

23.15 360ddd; or

23.16 (18) the distribution or sale of any licensed product under United States Code, title 42,

23.17 section 262, that meets the definition of a device under United States Code, title 21, section

23.18 321(h).

23.19 Subd. 13. **Wholesale distribution.** "Wholesale distribution" means the distribution of

23.20 a drug to a person other than a consumer or patient, or receipt of a drug by a person other

23.21 than the consumer or patient, but does not include:

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

23.23 manufacturer;

23.24 (2) the distribution of a drug or an offer to distribute a drug among hospitals or other

23.25 health care entities that are under common control;

23.26 (3) the distribution of a drug or an offer to distribute a drug for emergency medical

23.27 reasons, including:

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

23.29 247d;

23.30 (ii) a national security or peacetime emergency declared by the governor pursuant to

23.31 section 12.31; or

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

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

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

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

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

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

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

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

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

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

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

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

24.28 (ii) the medical convenience kit does not contain a controlled substance that appears in
24.29 a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of
24.30 1970, United States Code, title 21, section 801, et seq.;

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

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

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

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

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

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

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

25.10 (D) an anesthetic;

25.11 (E) an anticoagulant;

25.12 (F) a vasopressor; or

25.13 (G) a sympathomimetic;

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

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

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

25.21 (17) the distribution of medical gas, as defined in United States Code, title 21, section
25.22 360ddd;

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

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

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

26.4 Sec. 22. Minnesota Statutes 2018, section 151.46, is amended to read:

26.5 **151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.**

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

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

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

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

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

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

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

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

27.4 ~~(g) The board shall not issue an initial or renewed license for a drug wholesale distributor~~
27.5 ~~facility unless the facility passes an inspection conducted by an authorized representative~~
27.6 ~~of the board, or is accredited by an accreditation program approved by the board. In the~~
27.7 ~~case of a drug wholesale distributor facility located outside of the state, the board may~~
27.8 ~~require the applicant to pay the cost of the inspection, in addition to the license fee in section~~
27.9 ~~151.065, unless the applicant furnishes the board with a report, issued by the appropriate~~
27.10 ~~regulatory agency of the state in which the facility is located, of an inspection that has~~
27.11 ~~occurred within the 24 months immediately preceding receipt of the license application by~~
27.12 ~~the board, or furnishes the board with proof of current accreditation. The board may deny~~
27.13 ~~licensure unless the applicant submits documentation satisfactory to the board that any~~
27.14 ~~deficiencies noted in an inspection report have been corrected.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31.12 (o) The purpose of the surety bond required under this subdivision is to secure payment
31.13 of any civil penalty imposed by the board pursuant to section 151.071, subdivision 1. The
31.14 board may make a claim against the bond if the licensee fails to pay a civil penalty within
31.15 30 days after the order imposing the fine or costs become final.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

34.1 (k) A licensed third-party logistics provider shall not have as a facility manager or
34.2 designated representative any person who has been convicted of any felony for conduct
34.3 relating to wholesale distribution, any felony violation of United States Code, title 21, section
34.4 331, subsection (i) or (k), or any felony violation of United States Code, title 18, section
34.5 1365, relating to product tampering.

34.6 Sec. 26. **REPEALER.**

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

34.9 Amend the title accordingly