ARTICLE 11

HEALTH-RELATED LICENSING BOARDS

Section 1. [144A.291] FEES.

Subdivision 1. **Nonrefundable fees.** All fees are nonrefundable.

Subd. 2. **Amounts.** (a) Fees may not exceed the following amounts but may be adjusted lower by board direction and are for the exclusive use of the board as required to sustain board operations. The maximum amounts of fees are:

(1) application for licensure, $200;

(2) for a prospective applicant for a review of education and experience advisory to the license application, $100, to be applied to the fee for application for licensure if the latter is submitted within one year of the request for review of education and experience;

(3) state examination, $125;

(4) initial license, $250 if issued between July 1 and December 31, $100 if issued between January 1 and June 30;

(5) acting administrator permit, $400;

(6) renewal license, $250;

(7) duplicate license, $50;

(8) reinstatement fee, $250;

(9) health services executive initial license, $200;

(10) health services executive renewal license, $200;

(11) reciprocity verification fee, $50;

(12) second shared administrator assignment, $250;

(13) continuing education fees:

(i) greater than 6 hours, $50; and

(ii) 7 hours or more, $75;

(14) education review, $100;

(15) fee to a sponsor for review of individual continuing education seminars, institutes, workshops, or home study courses:

(i) for less than seven clock hours, $30; and

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(ii) for seven or more clock hours, $50;

(16) fee to a licensee for review of continuing education seminars, institutes, workshops, or home study courses not previously approved for a sponsor and submitted with an application for license renewal:

(i) for less than seven clock hours total, $30; and

(ii) for seven or more clock hours total, $50;

(17) late renewal fee, $75;

(18) fee to a licensee for verification of licensure status and examination scores, $30;

(19) registration as a registered continuing education sponsor, $1,000; and

(20) mail labels, $75.

(b) The revenue generated from the fees must be deposited in an account in the state government special revenue fund.

Section 1. Minnesota Statutes 2018, section 147.037, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** The board shall issue a license to practice medicine to any person who satisfies the requirements in paragraphs (a) to (g).

(a) The applicant shall satisfy all the requirements established in section 147.02, subdivision 1, paragraphs (a), (e), (f), (g), and (h).

(b) The applicant shall present evidence satisfactory to the board that the applicant is a graduate of a medical or osteopathic school approved by the board as equivalent to accredited United States or Canadian schools based upon its faculty, curriculum, facilities, accreditation, or other relevant data. If the applicant is a graduate of a medical or osteopathic program that is not accredited by the Liaison Committee for Medical Education or the American Osteopathic Association, the applicant may use the Federation of State Medical Boards' Federation Credentials Verification Service (FCVS) or its successor. If the applicant uses this service as allowed under this paragraph, the physician application fee may be less than $200 but must not exceed the cost of administering this paragraph.

(c) The applicant shall present evidence satisfactory to the board that the applicant has been awarded a certificate by the Educational Council for Foreign Medical Graduates, and the applicant has a working ability in the English language sufficient to communicate with patients and physicians and to engage in the practice of medicine.

(d) The applicant shall present evidence satisfactory to the board of the completion of ~~two years~~ one year of graduate, clinical medical training in a program ~~located in the United States, its territories, or Canada and accredited by a national accrediting organization approved by the board~~ accredited by a national accrediting organization approved by the

board or other graduate training approved in advance by the board as meeting standards similar to those of a national accrediting organization. This requirement does not apply:

(1) to an applicant who is admitted as a permanent immigrant to the United States on or before October 1, 1991, as a person of exceptional ability in the sciences according to Code of Federal Regulations, title 20, section 656.22(d); or

(2) to an applicant holding a valid license to practice medicine in another country and issued a permanent immigrant visa after October 1, 1991, as a person of extraordinary ability in the field of science or as an outstanding professor or researcher according to Code of Federal Regulations, title 8, section 204.5(h) and (i), or a temporary nonimmigrant visa as a person of extraordinary ability in the field of science according to Code of Federal Regulations, title 8, section 214.2(o),

provided that a person under clause (1) or (2) is admitted pursuant to rules of the United States Department of Labor~~; or~~

~~(3) to an applicant who is licensed in another state, has practiced five years without disciplinary action in the United States, its territories, or Canada, has completed one year of the graduate, clinical medical training required by this paragraph, and has passed the Special Purpose Examination of the Federation of State Medical Boards within three attempts in the 24 months before licensing~~.

(e) The applicant must:

(1) have passed an examination prepared and graded by the Federation of State Medical Boards, the United States Medical Licensing Examination program in accordance with section 147.02, subdivision 1, paragraph (c), clause (2), or the Medical Council of Canada; and

(2) ~~have a current license from the equivalent licensing agency in another state or country and,~~ if the examination in clause (1) was passed more than ten years ago, either:

(i) pass the Special Purpose Examination of the Federation of State Medical Boards with a score of 75 or better within three attempts; or

(ii) have a current certification by a specialty board of the American Board of Medical Specialties, of the American Osteopathic Association, of the Royal College of Physicians and Surgeons of Canada, or of the College of Family Physicians of Canada; or

(3) if the applicant fails to meet the requirement established in section 147.02, subdivision 1, paragraph (c), clause (2), because the applicant failed to pass each of steps one, two, and three of the USMLE within the required three attempts, the applicant may be granted a license provided the applicant:

(i) has passed each of steps one, two, and three with passing scores as recommended by the USMLE program within no more than four attempts for any of the three steps;

(ii) is currently licensed in another state; and

(iii) has current certification by a specialty board of the American Board of Medical Specialties, the American Osteopathic Association, the Royal College of Physicians and Surgeons of Canada, or the College of Family Physicians of Canada.

(f) The applicant must not be under license suspension or revocation by the licensing board of the state or jurisdiction in which the conduct that caused the suspension or revocation occurred.

(g) The applicant must not have engaged in conduct warranting disciplinary action against a licensee, or have been subject to disciplinary action other than as specified in paragraph (f). If an applicant does not satisfy the requirements stated in this paragraph, the board may issue a license only on the applicant's showing that the public will be protected through issuance of a license with conditions or limitations the board considers appropriate.

Sec. 2. Minnesota Statutes 2018, section 147.0375, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** The board shall issue a license to practice medicine to any person who satisfies the requirements in paragraphs (a) to (d).

(a) The applicant must satisfy all the requirements established in section 147.02, subdivision 1, paragraphs (a), (e), (f), (g), and (h).

(b) The applicant must present evidence satisfactory to the board that the applicant is a graduate of a medical or osteopathic school approved by the board as equivalent to accredited United States or Canadian schools based upon its faculty, curriculum, facilities, accreditation, or other relevant data. If the applicant is a graduate of a medical or osteopathic program that is not accredited by the Liaison Committee for Medical Education or the American Osteopathic Association, the applicant may use the Federation of State Medical Boards' Federation Credentials Verification Service (FCVS) or its successor. If the applicant uses this service as allowed under this paragraph, the physician application fee may be less than $200 but must not exceed the cost of administering this paragraph.

(c) The applicant must present evidence satisfactory to the board of the completion of ~~two years~~ one year of graduate, clinical medical training in a program ~~located in the United States, its territories, or Canada and accredited by a national accrediting organization approved by the board~~ accredited by a national accrediting organization approved by the board or other graduate training approved in advance by the board as meeting standards similar to those of a national accrediting organization. This requirement does not apply:

(1) to an applicant who is admitted as a permanent immigrant to the United States on or before October 1, 1991, as a person of exceptional ability in the sciences according to Code of Federal Regulations, title 20, section 656.22 (d); or

(2) to an applicant holding a valid license to practice medicine in another state or country and issued a permanent immigrant visa after October 1, 1991, as a person of extraordinary ability in the field of science or as an outstanding professor or researcher according to Code

of Federal Regulations, title 8, section 204.5(h) and (i), or a temporary nonimmigrant visa or status as a person of extraordinary ability in the field of science according to Code of Federal Regulations, title 8, section 214.2(o)~~; or~~

~~(3) to an applicant who is licensed in another state, has practiced five years without disciplinary action in the United States, its territories, or Canada, has completed one year of the graduate, clinical medical training required by this paragraph, and has passed the Special Purpose Examination of the Federation of State Medical Boards within three attempts in the 24 months before licensing~~.

(d) The applicant must present evidence satisfactory to the board that the applicant has been appointed to serve as a faculty member of a medical school accredited by the Liaison Committee of Medical Education or an osteopathic medical school accredited by the American Osteopathic Association.

Sec. 2. Minnesota Statutes 2018, section 147D.27, is amended by adding a subdivision to read:

Subd. 5. **Additional fees.** (a) The following fees also apply:

(1) traditional midwifery annual registration fee, $100;

(2) traditional midwifery application fee, $100;

(3) traditional midwifery late fee, $75;

(4) traditional midwifery inactive status, $50;

(5) traditional midwifery temporary permit, $75;

(6) traditional midwifery certification fee, $25;

(7) duplicate license or registration fee, $20;

(8) certification letter, $25;

(9) education or training program approval fee, $100; and

(10) report creation and generation, $60 per hour billed in quarter-hour increments with a quarter-hour minimum.

(b) The revenue generated from the fees must be deposited in an account in the state government special revenue fund.

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

Sec. 3. Minnesota Statutes 2018, section 147E.40, subdivision 1, is amended to read:

Subdivision 1. **Fees.** (a) Fees are as follows:

(1) registration application fee, $200;

(2) renewal fee, $150;

(3) late fee, $75;

(4) inactive status fee, $50; ~~and~~

(5) temporary permit fee, $25~~.~~;

(6) naturopathic doctor certification fee, $25;

(7) naturopathic doctor duplicate license fee, $20;

(8) naturopathic doctor emeritus registration fee, $50;

(9) naturopathic doctor certification fee, $25;

(10) duplicate license or registration fee, $20;

(11) education or training program approval fee, $100; and

(12) report creation and generation, $60 per hour billed in quarter-hour increments with a quarter-hour minimum.

(b) The revenue generated from the fees must be deposited in an account in the state government special revenue fund.

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

Sec. 4. Minnesota Statutes 2018, section 147F.17, subdivision 1, is amended to read:

Subdivision 1. **Fees.** (a) Fees are as follows:

(1) license application fee, $200;

(2) initial licensure and annual renewal, $150; ~~and~~

(3) late fee, $75~~.~~;

(4) genetic counselor certification fee, $25;

(5) duplicate license fee, $20;

(6) education or training program approval fee, $100; and

(7) report creation and generation, $60 per hour billed in quarter-hour increments with a quarter-hour minimum.

(b) The revenue generated from the fees must be deposited in an account in the state government special revenue fund.

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

Sec. 5. Minnesota Statutes 2018, section 148.59, is amended to read:
148.59 LICENSE RENEWAL; LICENSE AND REGISTRATION FEES.

Sec. 3. Minnesota Statutes 2018, section 148.59, is amended to read:
148.59 LICENSE RENEWAL; LICENSE AND REGISTRATION FEES.

A licensed optometrist shall pay to the state Board of Optometry a fee as set by the board in order to renew a license as provided by board rule. No fees shall be refunded. Fees may not exceed the following amounts but may be adjusted lower by board direction and are for the exclusive use of the board:

(1) optometry licensure application, $160;

(2) optometry annual licensure renewal, ~~$135~~ $200;

(3) optometry late penalty fee, $75;

(4) annual license renewal card, $10;

(5) continuing education provider application, $45;

(6) emeritus registration, $10;

(7) endorsement/reciprocity application, $160;

(8) replacement of initial license, $12; ~~and~~

(9) license verification, $50~~.~~;

(10) state juris prudence examination, $75; and

(11) miscellaneous labels and data retrieval, $50.

Sec. 6. Minnesota Statutes 2018, section 148.6445, subdivision 1, is amended to read:

Subdivision 1. **Initial licensure fee.** The initial licensure fee for occupational therapists is ~~$145~~ $185. The initial licensure fee for occupational therapy assistants is ~~$80~~ $105. ~~The board shall prorate fees based on the number of quarters remaining in the biennial licensure period.~~

Sec. 7. Minnesota Statutes 2018, section 148.6445, subdivision 2, is amended to read:

Subd. 2. **Licensure renewal fee.** The biennial licensure renewal fee for occupational therapists is ~~$145~~ $185. The biennial licensure renewal fee for occupational therapy assistants is ~~$80~~ $105.

Sec. 8. Minnesota Statutes 2018, section 148.6445, subdivision 2a, is amended to read:

Subd. 2a. **Duplicate license fee.** The fee for a duplicate license is ~~$25~~ $30.

Sec. 9. Minnesota Statutes 2018, section 148.6445, subdivision 3, is amended to read:

Subd. 3. **Late fee.** The fee for late submission of a renewal application is ~~$25~~ $50.

Sec. 10. Minnesota Statutes 2018, section 148.6445, subdivision 4, is amended to read:

Subd. 4. **Temporary licensure fee.** The fee for temporary licensure is ~~$50~~ $75.

A licensed optometrist shall pay to the state Board of Optometry a fee as set by the board in order to renew a license as provided by board rule. No fees shall be refunded. Fees may not exceed the following amounts but may be adjusted lower by board direction and are for the exclusive use of the board:

(1) optometry licensure application, $160;

(2) optometry annual licensure renewal, ~~$135~~ $170;

(3) optometry late penalty fee, $75;

(4) annual license renewal card, $10;

(5) continuing education provider application, $45;

(6) emeritus registration, $10;

(7) endorsement/reciprocity application, $160;

(8) replacement of initial license, $12; ~~and~~

(9) license verification, $50~~.~~;

(10) jurisprudence state examination, $75;

(11) Optometric Education Continuing Education data bank registration, $20; and

(12) data requests and labels, $50.

Sec. 11. Minnesota Statutes 2018, section 148.6445, subdivision 5, is amended to read:

Subd. 5. **Limited licensure fee.** The fee for limited licensure is ~~$96~~ $100.

Sec. 12. Minnesota Statutes 2018, section 148.6445, subdivision 6, is amended to read:

Subd. 6. **Fee for course approval after lapse of licensure.** The fee for course approval after lapse of licensure is ~~$96~~ $100.

Sec. 13. Minnesota Statutes 2018, section 148.6445, subdivision 10, is amended to read:

Subd. 10. **Use of fees.** (a) All fees are nonrefundable. The board shall only use fees collected under this section for the purposes of administering this chapter. The legislature must not transfer money generated by these fees from the state government special revenue fund to the general fund.

(b) Licensure fees are for the exclusive use of the board and shall be established by the board not to exceed the nonrefundable amounts in this section.

Sec. 14. Minnesota Statutes 2018, section 148.7815, subdivision 1, is amended to read:

Subdivision 1. **Fees.** (a) The board shall establish fees as follows:

(1) application fee, $50; ~~and~~

(2) annual license fee, $100~~.~~;

(3) athletic trainer certification fee, $25;

(4) athletic trainer duplicate license fee, $20;

(5) duplicate license or registration fee, $20;

(6) education or training program approval fee, $100;

(7) report creation and generation, $60 per hour billed in quarter-hour increments with a quarter-hour minimum; and

(8) examination administrative fee:

(i) half day, $50; and

(ii) full day, $80.

(b) The revenue generated from the fees must be deposited in an account in the state government special revenue fund.

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

Sec. 15. [148.981] FEES.

Subdivision 1. **Licensing fees.** The nonrefundable fees for licensure shall be established by the board, not to exceed the following amounts:

(1) application for admission to national standardized examination, $150;

(2) application for professional responsibility examination, $150;

(3) application for licensure as a licensed psychologist, $500;

(4) renewal of license for a licensed psychologist, $500;

(5) late renewal of license for a licensed psychologist, $250;

(6) application for converting from master's to doctoral level licensure, $150;

(7) application for guest licensure, $150;

(8) certificate replacement fee, $25;

(9) mailing and duplication fee, $5;

(10) statute and rule book fee, $10;

(11) verification fee, $20; and

(12) fee for optional preapproval of postdoctoral supervision, $50.

Subd. 2. **Continuing education sponsor fee.** A sponsor applying for approval of a continuing education activity pursuant to Minnesota Rules, part 7200.3830, subpart 2, shall submit with the application a fee to be established by the board, not to exceed $80 for each activity.

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

Sec. 16. Minnesota Statutes 2018, section 148E.180, is amended to read:
148E.180 FEE AMOUNTS.

Subdivision 1. **Application fees.** Nonrefundable application fees for licensure ~~are as follows~~ may not exceed the following amounts but may be adjusted lower by board action:

(1) for a licensed social worker, ~~$45~~ $75;

(2) for a licensed graduate social worker, ~~$45~~ $75;

(3) for a licensed independent social worker, ~~$45~~ $75;

(4) for a licensed independent clinical social worker, ~~$45~~ $75;

(5) for a temporary license, $50; and

(6) for a ~~licensure~~ license by endorsement, ~~$85~~ $115.

Sec. 4. Minnesota Statutes 2018, section 148E.180, is amended to read:
148E.180 FEE AMOUNTS.

Subdivision 1. **Application fees.** Nonrefundable application fees for licensure ~~are as follows~~ may not exceed the following amounts:

(1) for a licensed social worker, ~~$45~~ $54;

(2) for a licensed graduate social worker, ~~$45~~ $54;

(3) for a licensed independent social worker, ~~$45~~ $54;

(4) for a licensed independent clinical social worker, ~~$45~~ $54;

(5) for a temporary license, $50; and

(6) for a licensure by endorsement, ~~$85~~ $92.

The fee for criminal background checks is the fee charged by the Bureau of Criminal Apprehension. The criminal background check fee must be included with the application fee as required according to section 148E.055.

Subd. 2. **License fees.** Nonrefundable license fees ~~are as follows~~ may not exceed the following amounts but may be adjusted lower by board action:

(1) for a licensed social worker, ~~$81~~ $115;

(2) for a licensed graduate social worker, ~~$144~~ $210;

(3) for a licensed independent social worker, ~~$216~~ $305;

(4) for a licensed independent clinical social worker, ~~$238.50~~ $335;

(5) for an emeritus inactive license, ~~$43.20~~ $65;

(6) for an emeritus active license, one-half of the renewal fee specified in subdivision 3; and

(7) for a temporary leave fee, the same as the renewal fee specified in subdivision 3.

If the licensee's initial license term is less or more than 24 months, the required license fees must be prorated proportionately.

Subd. 3. **Renewal fees.** Nonrefundable renewal fees for licensure ~~are as follows~~ may not exceed the following amounts but may be adjusted lower by board action:

(1) for a licensed social worker, ~~$81~~ $115;

(2) for a licensed graduate social worker, ~~$144~~ $210;

(3) for a licensed independent social worker, ~~$216~~ $305; and

(4) for a licensed independent clinical social worker, ~~$238.50~~ $335.

Subd. 4. **Continuing education provider fees.** Continuing education provider fees are ~~as follows~~ the following nonrefundable amounts:

(1) for a provider who offers programs totaling one to eight clock hours in a one-year period according to section 148E.145, $50;

(2) for a provider who offers programs totaling nine to 16 clock hours in a one-year period according to section 148E.145, $100;

(3) for a provider who offers programs totaling 17 to 32 clock hours in a one-year period according to section 148E.145, $200;

(4) for a provider who offers programs totaling 33 to 48 clock hours in a one-year period according to section 148E.145, $400; and

The fee for criminal background checks is the fee charged by the Bureau of Criminal Apprehension. The criminal background check fee must be included with the application fee as required according to section 148E.055.

Subd. 2. **License fees.** Nonrefundable license fees ~~are as follows~~ may not exceed the following amounts but may be adjusted lower by board action:

(1) for a licensed social worker, ~~$81~~ $97;

(2) for a licensed graduate social worker, ~~$144~~ $172;

(3) for a licensed independent social worker, ~~$216~~ $258;

(4) for a licensed independent clinical social worker, ~~$238.50~~ $284;

(5) for an emeritus inactive license, ~~$43.20~~ $51;

(6) for an emeritus active license, one-half of the renewal fee specified in subdivision 3; and

(7) for a temporary leave fee, the same as the renewal fee specified in subdivision 3.

If the licensee's initial license term is less or more than 24 months, the required license fees must be prorated proportionately.

Subd. 3. **Renewal fees.** Nonrefundable renewal fees for ~~licensure are as follows~~ the two-year renewal term may not exceed the following amounts but may be adjusted lower by board action:

(1) for a licensed social worker, ~~$81~~ $97;

(2) for a licensed graduate social worker, ~~$144~~ $172;

(3) for a licensed independent social worker, ~~$216~~ $258; and

(4) for a licensed independent clinical social worker, ~~$238.50~~ $284.

Subd. 4. **Continuing education provider fees.** Continuing education provider fees are ~~as follows~~ the following nonrefundable amounts:

(1) for a provider who offers programs totaling one to eight clock hours in a one-year period according to section 148E.145, ~~$50~~ $60;

(2) for a provider who offers programs totaling nine to 16 clock hours in a one-year period according to section 148E.145, ~~$100~~ $120;

(3) for a provider who offers programs totaling 17 to 32 clock hours in a one-year period according to section 148E.145, ~~$200~~ $240;

(4) for a provider who offers programs totaling 33 to 48 clock hours in a one-year period according to section 148E.145, ~~$400~~ $480; and

(5) for a provider who offers programs totaling 49 or more clock hours in a one-year period according to section 148E.145, $600.

Subd. 5. **Late fees.** Late fees are ~~as follows~~ the following nonrefundable amounts:

(1) renewal late fee, one-fourth of the renewal fee specified in subdivision 3;

(2) supervision plan late fee, $40; and

(3) license late fee, $100 plus the prorated share of the license fee specified in subdivision 2 for the number of months during which the individual practiced social work without a license.

Subd. 6. **License cards and wall certificates.** (a) The nonrefundable fee for a license card as specified in section 148E.095 is $10.

(b) The nonrefundable fee for a license wall certificate as specified in section 148E.095 is $30.

Subd. 7. **Reactivation fees.** Reactivation fees are ~~as follows~~ the following nonrefundable amounts:

(1) reactivation from a temporary leave or emeritus status, the prorated share of the renewal fee specified in subdivision 3; and

(2) reactivation of an expired license, 1-1/2 times the renewal fees specified in subdivision 3.

(5) for a provider who offers programs totaling 49 or more clock hours in a one-year period according to section 148E.145, ~~$600~~ $720.

Subd. 5. **Late fees.** Late fees are ~~as follows~~ the following nonrefundable amounts:

(1) renewal late fee, one-fourth of the renewal fee specified in subdivision 3;

(2) supervision plan late fee, $40; and

(3) license late fee, $100 plus the prorated share of the license fee specified in subdivision 2 for the number of months during which the individual practiced social work without a license.

Subd. 6. **License cards and wall certificates.** (a) The fee for a license card as specified in section 148E.095 is $10.

(b) The fee for a license wall certificate as specified in section 148E.095 is $30.

Subd. 7. **Reactivation fees.** Reactivation fees are ~~as follows~~ the following nonrefundable amounts:

(1) reactivation from a temporary leave or emeritus status, the prorated share of the renewal fee specified in subdivision 3; and

(2) reactivation of an expired license, 1-1/2 times the renewal fees specified in subdivision 3.

Sec. 5. Minnesota Statutes 2018, section 150A.06, subdivision 3, is amended to read:

Subd. 3. **Waiver of examination.** (a) All or any part of the examination for dentists, dental therapists, dental hygienists, or dental assistants, except that pertaining to the law of Minnesota relating to dentistry and the rules of the board, may, at the discretion of the board, be waived for an applicant who presents a certificate of having passed all components of the National Board Dental Examinations or evidence of having maintained an adequate scholastic standing as determined by the board.

(b) The board shall waive the clinical examination required for licensure for any dentist applicant who is a graduate of a dental school accredited by the Commission on Dental Accreditation, who has passed all components of the National Board Dental Examinations, and who has satisfactorily completed a ~~Minnesota-based~~ postdoctoral general dentistry residency program (GPR) or an advanced education in general dentistry (AEGD) program after January 1, 2004. The postdoctoral program must be accredited by the Commission on Dental Accreditation, be of at least one year's duration, and include an outcome assessment evaluation assessing the resident's competence to practice dentistry. The board may require the applicant to submit any information deemed necessary by the board to determine whether the waiver is applicable.

Sec. 17. Minnesota Statutes 2018, section 150A.06, is amended by adding a subdivision to read:

Subd. 10. **Emeritus inactive license.** A person licensed to practice dentistry, dental therapy, dental hygiene, or dental assisting pursuant to section 150A.05 or Minnesota Rules, part 3100.8500, who retires from active practice in the state may apply to the board for emeritus inactive licensure. An application for emeritus inactive licensure may be made on the biennial licensing form or by petitioning the board, and the applicant must pay a onetime application fee pursuant to section 150A.091, subdivision 19. In order to receive emeritus inactive licensure, the applicant must be in compliance with board requirements and cannot be the subject of current disciplinary action resulting in suspension, revocation, disqualification, condition, or restriction of the licensee to practice dentistry, dental therapy, dental hygiene, or dental assisting. An emeritus inactive license is not a license to practice, but is a formal recognition of completion of a person's dental career in good standing.

EFFECTIVE DATE. This section is effective July 1, 2019.

Sec. 18. Minnesota Statutes 2018, section 150A.06, is amended by adding a subdivision to read:

Subd. 11. **Emeritus active licensure.** (a) A person licensed to practice dentistry, dental therapy, dental hygiene, or dental assisting may apply for an emeritus active license if the person is retired from active practice, is in compliance with board requirements, and is not the subject of current disciplinary action resulting in suspension, revocation, disqualification, condition, or restriction of the license to practice dentistry, dental therapy, dental hygiene, or dental assisting.

(b) An emeritus active licensee may engage only in the following types of practice:

(1) pro bono or volunteer dental practice;

(2) paid practice not to exceed 500 hours per calendar year for the exclusive purpose of providing licensing supervision to meet the board's requirements; or

(3) paid consulting services not to exceed 500 hours per calendar year.

(c) An emeritus active licensee shall not hold out as a full licensee and may only hold out as authorized to practice as described in this subdivision. The board may take disciplinary or corrective action against an emeritus active licensee based on violations of applicable law or board requirements.

(d) A person may apply for an emeritus active license by completing an application form specified by the board and must pay the application fee pursuant to section 150A.091, subdivision 20.

Sec. 6. Minnesota Statutes 2018, section 150A.06, is amended by adding a subdivision to read:

Subd. 10. **Emeritus inactive license.** A person licensed to practice dentistry, dental therapy, dental hygiene, or dental assisting pursuant to section 150A.05 or Minnesota Rules, part 3100.8500, who retires from active practice in the state may apply to the board for emeritus inactive licensure. An application for emeritus inactive licensure may be made on the biennial licensing form or by petitioning the board, and the applicant must pay a onetime application fee pursuant to section 150A.091, subdivision 19. In order to receive emeritus inactive licensure, the applicant must be in compliance with board requirements and cannot be the subject of current disciplinary action resulting in suspension, revocation, disqualification, condition, or restriction of the licensee to practice dentistry, dental therapy, dental hygiene, or dental assisting. An emeritus inactive license is not a license to practice, but is a formal recognition of completion of a person's dental career in good standing.

Sec. 7. Minnesota Statutes 2018, section 150A.06, is amended by adding a subdivision to read:

Subd. 11. **Emeritus active licensure.** (a) A person licensed to practice dentistry, dental therapy, dental hygiene, or dental assisting may apply for an emeritus active license if the person is retired from active practice, is in compliance with board requirements, and is not the subject of current disciplinary action resulting in suspension, revocation, disqualification, condition, or restriction of the license to practice dentistry, dental therapy, dental hygiene, or dental assisting.

(b) An emeritus active licensee may engage only in the following types of practice:

(1) pro bono or volunteer dental practice;

(2) paid practice not to exceed 500 hours per calendar year for the exclusive purpose of providing licensing supervision to meet the board's requirements; or

(3) paid consulting services not to exceed 500 hours per calendar year.

(c) An emeritus active licensee shall not hold out as a full licensee and may only hold out as authorized to practice as described in this subdivision. The board may take disciplinary or corrective action against an emeritus active licensee based on violations of applicable law or board requirements.

(d) A person may apply for an emeritus active license by completing an application form specified by the board and must pay the application fee pursuant to section 150A.091, subdivision 20.

(e) If an emeritus active license is not renewed every two years, the license expires. The renewal date is the same as the licensee's renewal date when the licensee was in active practice. In order to renew an emeritus active license, the licensee must:

(1) complete an application form as specified by the board;

(2) pay the required renewal fee pursuant to section 150A.091, subdivision 20; and

(3) report at least 25 continuing education hours completed since the last renewal, which must include:

(i) at least one hour in two different required CORE areas;

(ii) at least one hour of mandatory infection control;

(iii) for dentists and dental therapists, at least 15 hours of fundamental credits for dentists and dental therapists, and for dental hygienists and dental assistants, at least seven hours of fundamental credits; and

(iv) for dentists and dental therapists, no more than ten elective credits, and for dental hygienists and dental assistants, no more than six elective credits.

EFFECTIVE DATE. This section is effective July 1, 2019.

Sec. 19. Minnesota Statutes 2018, section 150A.091, is amended by adding a subdivision to read:

Subd. 19. **Emeritus inactive license.** An individual applying for emeritus inactive licensure under section 150A.06, subdivision 10, must pay a onetime fee of $50. There is no renewal fee for an emeritus inactive license.

EFFECTIVE DATE. This section is effective July 1, 2019.

Sec. 20. Minnesota Statutes 2018, section 150A.091, is amended by adding a subdivision to read:

Subd. 20. **Emeritus active license.** An individual applying for emeritus active licensure under section 150A.06, subdivision 11, must pay a fee upon application and upon renewal every two years. The fees for emeritus active license application and renewal are as follows: dentist, $212; dental therapist, $100; dental hygienist, $75; and dental assistant, $55.

EFFECTIVE DATE. This section is effective July 1, 2019.

Sec. 21. Minnesota Statutes 2018, section 151.01, subdivision 31, is amended to read:

Subd. 31. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that ~~may provide~~ performs those activities involved in the dispensing ~~functions,~~ of a drug

(e) If an emeritus active license is not renewed every two years, the license expires. The renewal date is the same as the licensee's renewal date when the licensee was in active practice. In order to renew an emeritus active license, the licensee must:

(1) complete an application form as specified by the board;

(2) pay the required renewal fee pursuant to section 150A.091, subdivision 20; and

(3) report at least 25 continuing education hours completed since the last renewal, which must include:

(i) at least one hour in two different required CORE areas;

(ii) at least one hour of mandatory infection control;

(iii) for dentists and dental therapists, at least 15 hours of fundamental credits for dentists and dental therapists, and for dental hygienists and dental assistants, at least seven hours of fundamental credits; and

(iv) for dentists and dental therapists, no more than ten elective credits, and for dental hygienists and dental assistants, no more than six elective credits.

Sec. 8. Minnesota Statutes 2018, section 150A.091, is amended by adding a subdivision to read:

Subd. 19. **Emeritus inactive license.** An individual applying for emeritus inactive licensure under section 150A.06, subdivision 10, must pay a onetime fee of $50. There is no renewal fee for an emeritus inactive license.

Sec. 9. Minnesota Statutes 2018, section 150A.091, is amended by adding a subdivision to read:

Subd. 20. **Emeritus active license.** An individual applying for emeritus active licensure under section 150A.06, subdivision 11, must pay a fee upon application and upon renewal every two years. The fees for emeritus active license application and renewal are as follows: dentist, $212; dental therapist, $100; dental hygienist, $75; and dental assistant, $55.

FOR SECTIONS 10 TO 14, SEE ARTICLE 10 SIDE BY SIDE

~~utilization review, packaging, labeling, or delivery of a prescription product to~~ for another pharmacy ~~for the purpose of filling a prescription~~, pursuant to the requirements of this chapter and the rules of the board.

Sec. 22. Minnesota Statutes 2018, section 151.01, subdivision 35, is amended to read:

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

Sec. 23. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

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

Sec. 24. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:

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

(1) pharmacist licensed by examination, ~~$145~~ $175;

(2) pharmacist licensed by reciprocity, ~~$240~~ $275;

(3) pharmacy intern, ~~$37.50~~ $50;

(4) pharmacy technician, ~~$37.50~~ $50;

(5) pharmacy, ~~$225~~ $260;

(6) drug wholesaler, legend drugs only, ~~$235~~ $260;

(7) drug wholesaler, legend and nonlegend drugs, ~~$235~~ $260;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~$210~~ $260;

(9) drug wholesaler, medical gases, ~~$175~~ $260;

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

(11) drug manufacturer, legend drugs only, ~~$235~~ $260;

(12) drug manufacturer, legend and nonlegend drugs, ~~$235~~ $260;

(13) drug manufacturer, nonlegend or veterinary legend drugs, ~~$210~~ $260;

(14) drug manufacturer, medical gases, ~~$185~~ $260;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~$150~~ $260;

(16) medical gas distributor, ~~$110~~ $260; and

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

~~(18)~~ (17) pharmacy professional corporation, ~~$125~~ $150.

Sec. 25. Minnesota Statutes 2018, section 151.065, subdivision 2, is amended to read:

Subd. 2. **Original license fee.** The pharmacist original licensure fee, ~~$145~~ $175.

Sec. 26. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:

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

(1) pharmacist, ~~$145~~ $175;

(2) pharmacy technician, ~~$37.50~~ $50;

(3) pharmacy, ~~$225~~ $260;

(4) drug wholesaler, legend drugs only, ~~$235~~ $260;

(5) drug wholesaler, legend and nonlegend drugs, ~~$235~~ $260;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~$210~~ $260;

(7) drug wholesaler, medical gases, ~~$185~~ $260;

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

(9) drug manufacturer, legend drugs only, ~~$235~~ $260;

(10) drug manufacturer, legend and nonlegend drugs, ~~$235~~ $260;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, ~~$210~~ $260;

(12) drug manufacturer, medical gases, ~~$185~~ $260;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~$150~~ $260;

(14) medical gas distributor, ~~$110~~ $260; and

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

~~(16)~~ (15) pharmacy professional corporation, ~~$75~~ $100.

Sec. 27. Minnesota Statutes 2018, section 151.065, subdivision 6, is amended to read:

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

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

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

(d) A controlled substance ~~researcher~~ registrant who has allowed ~~the researcher's~~ a registration issued pursuant to subdivision 4 to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears.

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

Sec. 28. Minnesota Statutes 2018, section 151.071, subdivision 2, is amended to read:

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

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

(2) obtaining a license by fraud or by misleading the board in any way during the application process or obtaining a license by cheating, or attempting to subvert the licensing examination process. Conduct that subverts or attempts to subvert the licensing examination

process includes, but is not limited to: (i) conduct that violates the security of the examination materials, such as removing examination materials from the examination room or having unauthorized possession of any portion of a future, current, or previously administered licensing examination; (ii) conduct that violates the standard of test administration, such as communicating with another examinee during administration of the examination, copying another examinee's answers, permitting another examinee to copy one's answers, or possessing unauthorized materials; or (iii) impersonating an examinee or permitting an impersonator to take the examination on one's own behalf;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills;

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

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

(17) fee splitting, including without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 29. Minnesota Statutes 2018, section 151.15, subdivision 1, is amended to read:

Subdivision 1. **Location.** It shall be unlawful for any person to compound~~,~~ or dispense~~, vend, or sell~~ drugs~~, medicines, chemicals, or poisons~~ in any place other than a pharmacy, except as provided in this chapter; except that a licensed pharmacist or pharmacist intern working within a licensed hospital may receive a prescription drug order and access the hospital's pharmacy prescription processing system through secure and encrypted electronic means in order to process the prescription drug order.

Sec. 30. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Sec. 31. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Sec. 32. Minnesota Statutes 2018, section 151.19, subdivision 1, is amended to read:

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

unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

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

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

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

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

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

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

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

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

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

(4) that, during its regular hours of operation, but no less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has

access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 33. Minnesota Statutes 2018, section 151.19, subdivision 3, is amended to read:

Subd. 3. **Sale of federally restricted medical gases.** (a) A person or establishment not licensed as a pharmacy or a practitioner shall not engage in the retail sale or distribution of federally restricted medical gases without first obtaining a registration from the board and

paying the applicable fee specified in section 151.065. The registration shall be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.

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

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

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

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

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

Sec. 34. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

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

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

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

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

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

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

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

Sec. 35. Minnesota Statutes 2018, section 151.252, subdivision 1a, is amended to read:

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

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

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

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

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

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

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

Sec. 36. Minnesota Statutes 2018, section 151.252, subdivision 3, is amended to read:

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

Sec. 37. Minnesota Statutes 2018, section 151.253, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Sec. 38. Minnesota Statutes 2018, section 151.32, is amended to read:

151.32 CITATION.

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

Sec. 39. Minnesota Statutes 2018, section 151.40, subdivision 1, is amended to read:

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

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

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

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

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

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

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

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

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

(viii) licensed hospitals~~,~~;

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

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

(xi) licensed morticians~~,~~;

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

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

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

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

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

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

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

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

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

Sec. 40. Minnesota Statutes 2018, section 151.40, subdivision 2, is amended to read:

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

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

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

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

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

Sec. 41. Minnesota Statutes 2018, section 151.43, is amended to read:

151.43 SCOPE.

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

Sec. 42. [151.441] DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

Sec. 43. Minnesota Statutes 2018, section 151.46, is amended to read:

151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.

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

Sec. 44. Minnesota Statutes 2018, section 151.47, subdivision 1, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 45. Minnesota Statutes 2018, section 151.47, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 46. [151.471] THIRD-PARTY LOGISTICS PROVIDER REQUIREMENTS.

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

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

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

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

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

(e) No license may be issued or renewed for a third-party logistics provider facility that is located in another state unless the applicant supplies the board with proof of licensure or

registration by the state in which the third-party logistics provider facility is physically located or by the United States Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 47. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read:

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

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

Sec. 15. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read:

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

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

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is:

(i) prescribing or considering prescribing any controlled substance;

(ii) providing emergency medical treatment for which access to the data may be necessary;

(iii) providing care, and the prescriber has reason to believe, based on clinically valid indications, that the patient is potentially abusing a controlled substance; or

(iv) providing other medical treatment for which access to the data may be necessary for a clinically valid purpose and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

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

(3) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary to the extent that the information relates specifically to a current patient for whom the pharmacist is providing pharmaceutical care: (i) if the patient has consented to access to the submitted data; or (ii) if the pharmacist is consulted by a prescriber who is requesting data in accordance with clause (1);

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

(5) personnel or designees of a health-related licensing board listed in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is impaired by use of a drug for which data is collected under subdivision 4, has engaged in activity that would constitute a crime as defined in section 152.025, or has engaged in the behavior specified in subdivision 5, paragraph (a);

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

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

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is:

(i) prescribing or considering prescribing any controlled substance;

(ii) providing emergency medical treatment for which access to the data may be necessary;

(iii) providing care, and the prescriber has reason to believe, based on clinically valid indications, that the patient is potentially abusing a controlled substance; or

(iv) providing other medical treatment for which access to the data may be necessary for a clinically valid purpose and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

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

(3) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary to the extent that the information relates specifically to a current patient for whom the pharmacist is providing pharmaceutical care: (i) if the patient has consented to access to the submitted data; or (ii) if the pharmacist is consulted by a prescriber who is requesting data in accordance with clause (1);

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

(5) personnel or designees of a health-related licensing board listed in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is impaired by use of a drug for which data is collected under subdivision 4, has engaged in activity that would constitute a crime as defined in section 152.025, or has engaged in the behavior specified in subdivision 5, paragraph (a);

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

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

duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

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

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

(10) personnel of the Department of Human Services assigned to access the data pursuant to paragraph (i);

(11) personnel of the health professionals services program established under section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program, and the individual consents to access to that information. The health professionals services program personnel shall not provide this data to a health-related licensing board or the Emergency Medical Services Regulatory Board, except as permitted under section 214.33, subdivision 3.

For purposes of clause (4), access by an individual includes persons in the definition of an individual under section 13.02; and

(12) personnel or designees of a health-related licensing board listed in section 214.01, subdivision 2, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is inappropriately prescribing controlled substances as defined in this section.

(c) By July 1, 2017, every prescriber licensed by a health-related licensing board listed in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe controlled substances for humans and who holds a current registration issued by the federal Drug Enforcement Administration, and every pharmacist licensed by the board and practicing within the state, shall register and maintain a user account with the prescription monitoring program. Data submitted by a prescriber, pharmacist, or their delegate during the registration application process, other than their name, license number, and license type, is classified as private pursuant to section 13.02, subdivision 12.

(d) Only permissible users identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), may directly access the data electronically. No other permissible users may directly access the data electronically. If the data is directly accessed electronically, the permissible user shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized

duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

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

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

(10) personnel of the Department of Human Services assigned to access the data pursuant to paragraph (i);

(11) personnel of the health professionals services program established under section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program, and the individual consents to access to that information. The health professionals services program personnel shall not provide this data to a health-related licensing board or the Emergency Medical Services Regulatory Board, except as permitted under section 214.33, subdivision 3.

For purposes of clause (4), access by an individual includes persons in the definition of an individual under section 13.02; and

(12) personnel or designees of a health-related licensing board listed in section 214.01, subdivision 2, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is inappropriately prescribing controlled substances as defined in this section.

(c) By July 1, 2017, every prescriber licensed by a health-related licensing board listed in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe controlled substances for humans and who holds a current registration issued by the federal Drug Enforcement Administration, and every pharmacist licensed by the board and practicing within the state, shall register and maintain a user account with the prescription monitoring program. Data submitted by a prescriber, pharmacist, or their delegate during the registration application process, other than their name, license number, and license type, is classified as private pursuant to section 13.02, subdivision 12.

(d) Only permissible users identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), may directly access the data electronically. No other permissible users may directly access the data electronically. If the data is directly accessed electronically, the permissible user shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized

disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(e) The board shall not release data submitted under subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

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

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

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

(i) With available appropriations, the commissioner of human services shall establish and implement a system through which the Department of Human Services shall routinely access the data for the purpose of determining whether any client enrolled in an opioid treatment program licensed according to chapter 245A has been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid treatment program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

If determined necessary, the commissioner of human services shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 2.34, paragraph (c), prior to implementing this paragraph.

(j) The board shall review the data submitted under subdivision 4 on at least a quarterly basis and shall establish criteria, in consultation with the advisory task force, for referring information about a patient to prescribers and dispensers who prescribed or dispensed the prescriptions in question if the criteria are met.

(k) The board shall conduct periodic audits, on at least an annual basis, of electronic access by permissible users, as identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), and of nonelectronic access by permissible users, as identified in paragraph (b),

disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(e) The board shall not release data submitted under subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

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

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

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

(i) With available appropriations, the commissioner of human services shall establish and implement a system through which the Department of Human Services shall routinely access the data for the purpose of determining whether any client enrolled in an opioid treatment program licensed according to chapter 245A has been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid treatment program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

If determined necessary, the commissioner of human services shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 2.34, paragraph (c), prior to implementing this paragraph.

(j) The board shall review the data submitted under subdivision 4 on at least a quarterly basis and shall establish criteria, in consultation with the advisory task force, for referring information about a patient to prescribers and dispensers who prescribed or dispensed the prescriptions in question if the criteria are met.

(k) The board shall conduct random audits, on at least a quarterly basis, of electronic access by permissible users, as identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), to the data in subdivision 4, to ensure compliance with permissible use as defined

clauses (4), (5), (8), (11), and (12), to the data in subdivision 4, to ensure compliance with permissible use as defined in this section. A permissible user whose account has been selected for audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted. Failure to respond may result in deactivation of access to the data in subdivision 4, and referral to the relevant health licensing board, the commissioner of human services, or other appropriate entity. The board shall report the results of periodic audits to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and government data practices.

(l) A permissible user who has delegated the task of accessing the data in subdivision 4 to an agent or employee shall audit the use of the electronic system by delegated agents or employees on at least a quarterly basis to ensure compliance with permissible use as defined in this section. When a delegated agent or employee has been identified as inappropriately accessing data, the permissible user must immediately remove access for that individual and notify the board within seven days. The board shall notify all permissible users associated with the delegated agent or employee of the alleged violation.

(m) A permissible user who delegates access to the data submitted under subdivision 4 to an agent or employee shall terminate that individual's access to the data, within three business days of the agent or employee leaving employment with the permissible user. The board may conduct random audits to determine compliance with this requirement.

Sec. 48. Minnesota Statutes 2018, section 152.126, subdivision 7, is amended to read:

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

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

(c) A prescriber or dispenser authorized to access the data who fails to comply with subdivision 6, paragraph (l) or (m), shall be subject to disciplinary action by the appropriate health-related licensing board.

Sec. 49. Minnesota Statutes 2018, section 152.126, is amended by adding a subdivision to read:

Subd. 10a. **Patient information on record access.** A patient who has been prescribed a controlled substance may access the prescription monitoring program database in order to obtain information on access by permissible users to the patient's data record, including the name and organizational affiliation of the permissible user and the date of access. In order to obtain this information, the patient must complete, notarize, and submit a request

in this section. A permissible user whose account has been selected for a random audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted. Failure to respond may result in deactivation of access to the electronic system and referral to the appropriate health licensing board, or the commissioner of human services, for further action.

(l) A permissible user who has delegated the task of accessing the data in subdivision 4 to an agent or employee shall audit the use of the electronic system by delegated agents or employees on at least a quarterly basis to ensure compliance with permissible use as defined in this section. When a delegated agent or employee has been identified as inappropriately accessing data, the permissible user must immediately remove access for that individual and notify the board within seven days. The board shall notify all permissible users associated with the delegated agent or employee of the alleged violation.

form developed by the board. The board shall make this form available to the public on the board's website.

Sec. 50. **REPEALER.**

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

(b) Minnesota Rules, parts 6400.6970; 7200.6100; and 7200.6105, are repealed.

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

FOR SECTION 16, SEE ARTICLE 10 SIDE BY SIDE

Sec. 17. **GUIDELINES AUTHORIZING PATIENT-ASSISTED MEDICATION ADMINISTRATION IN EMERGENCIES.**

(a) Within the limits of the board's available appropriation, the Emergency Medical Services Regulatory Board shall propose guidelines authorizing EMTs, AEMTs, and paramedics certified under Minnesota Statutes, section 144E.28, to assist a patient in emergency situations with administering prescription medications that are:

(1) carried by a patient;

(2) intended to treat adrenal insufficiency or other rare conditions that require emergency treatment with a previously prescribed medication;

(3) intended to treat a specific life-threatening condition; and

(4) administered via routes of delivery that are within the scope of training of the EMT, AEMT, or paramedic.

(b) The Emergency Medical Services Regulatory Board shall submit the proposed guidelines and draft legislation as necessary to the chairs and ranking minority members of the legislative committees with jurisdiction over health care by January 1, 2020.

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