

Summary of 2020 Legislation

During the 2020 Session, the Legislature enacted a number of provisions that will have a significant impact on the Board and its licensees and registrants. The actual language that was enacted is included in Appendix A. Here is a summary of the provisions:

Minnesota Insulin Safety Net Program

In 2020, the Minnesota Legislature passed the Alec Smith Insulin Affordability Act, which Governor Tim Walz signed into law on April 15, 2020. (Codified primarily as Minn. Stats. §151.74). The Act creates an Insulin Safety Net Program that will aid individuals who can't afford insulin. One part of the program allows eligible individuals who are in urgent need of insulin to get a one-time, 30-day supply of insulin from their pharmacy, for a \$35 co-pay. An emergency supply can normally be obtained only once in a 12-month period. However, there is an option for some individuals to receive a second 30-day supply in certain circumstances. The insulin manufacturer will reimburse the pharmacy for the insulin or send the pharmacy a replacement supply.

The second part of the program requires manufacturers to provide insulin to eligible individuals for up to one year, with the option to renew annually. The manufacturers will have to provide up to a 90-day supply of insulin for a co-pay of no more than \$50. Individuals with insurance may also obtain insulin through a manufacturer's copay program, which waives all or part of the copay that the patient normally has to pay.

A Guidance issued by the Board at its May 20, 2020 meeting, plus other documents and resources that will help licensees comply with the law, are available on the Board's Web site at:

<https://mn.gov/boards/pharmacy/insulinsafetynetprogram/>

Independent prescribing by pharmacists of self-administered hormonal contraceptives, nicotine replacement medications and opiate antagonists.

Pharmacists will be able to independently prescribe self-administered contraceptives, nicotine replacement medications, and opiate antagonists, provided that:

- They follow a protocol developed by the Board of Pharmacy in consultation with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

- They complete appropriate training programs and continuing education.
- Provide appropriate counseling to patients.

The Board will provide additional information to pharmacists once the protocols have been developed. The Board has until January 1, 2021 to develop the protocols but will try to develop them by August 1, 2020 – the effective date of the legislation.

Medication Repository

A change was made to allow the Board to either issue a request for proposal or to work directly with the University of Minnesota to establish the repository.

COVID-19 vaccines

Pharmacists were authorized to administer and FDA-approved vaccine for COVID-19, down to the age of six.

The Board's recommendations concerning the scheduling of controlled substances were enacted.

Fentanyl analogs, synthetics cannabinoids, tianeptine, and benzodiazepines (that have not been approved by the FDA) were added to Schedule I. A dronabinol product (Syndros) was added to Schedule II. A veterinary product containing chorionic gonadotropin was exempted from the schedules.

Examinations for erectile dysfunction drugs

For purposes of prescribing these drugs, the requirement for a documented patient evaluation, including an examination, may be met through the use of telemedicine, as defined in section 147.033, subdivision 1.

Therapeutic interchange during a declared COVID-19 peacetime emergency

Pharmacists will be able to engage in therapeutic interchange during a declared COVID-19 peacetime emergency (and for 60 days after it ends) if:

- (1) the drug prescribed is in short supply and the pharmacist is unable to obtain it from the manufacturer, drug wholesalers, or other local pharmacies;
- (2) the pharmacist is unable to contact the prescriber within a reasonable period of time to get authorization to dispense a drug that is available;
- (3) the pharmacist determines a therapeutically equivalent drug to the one prescribed is available and is in the same American Hospital Formulary Service pharmacologic-therapeutic classification;

- (4) the pharmacist informs the patient as required in Minnesota Statutes, section 151.21, subdivision 7a, paragraph (b), and provides counseling to the patient, as required by the Board of Pharmacy rules, about the substituted drug;
- (5) the pharmacist informs the prescriber as soon as possible that the therapeutic interchange has been made

Issuance of prescriptions for substance use disorders during a declared COVID-19 peacetime emergency

During a declared COVID-19 peacetime emergency (and for 60 days after it ends), for purposes of Minnesota Statutes, section 151.37, subdivision 2, paragraph (d), the requirement for an examination shall be met if the prescribing practitioner has performed a telemedicine examination of the patient before issuing a prescription drug order for the treatment of a substance use disorder.

Language clarifying that physician assistants can prescribe controlled substances

Was added to Minn. Stats. §152.12.

Opiate manufacturer licensing fee and opiate fund clarifications

Language clarifying that opiate manufacturers must pay a licensing fee of \$55,260 (rather than \$55,000) was adopted. Clarifications concerning the opiate fund into which certain revenues that the Board collects were also adopted.

Clarifying Language related to medical gas dispensers

Language was adopted that changed references to “medical gas distributors” to “medical gas dispensers.” The entities that the Board has been registering as “medical gas distributors” are actually only allowed to dispense medical gases to patients, pursuant to a prescription. Facilities that sell medical gases at wholesale are licensed as medical gas wholesalers.

Clarification that a tribal identification can be used to show Minnesota residency for the Minnesota Insulin Safety Net Program

Language was adopted that clarifies that tribal identification cards as defined in section 171.072, paragraph can be used to establish the Minnesota residency of individuals applying for the Minnesota Insulin Safety Net Program.

Change in language required to be on generic substitution signs in pharmacies

Minnesota Statutes 2018, section 151.21, subdivision 4a, was amended to read

Subd. 4a. **Sign.** A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive,

generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor or advanced practice registered nurse, unless you object to this substitution."

This means that pharmacies will have to replace or modify their existing generic substitution signs by August 1, 2020.

APPENDIX A

(All language is from S.F. 13, unless otherwise noted)

Language related to pharmacist prescribing of contraceptives, nicotine-replacement medications, and opiate antagonists; to vaccinations; and to examination requirements of erectile dysfunction drugs.

Sec. 2. [62Q.529] COVERAGE FOR DRUGS PRESCRIBED AND DISPENSED BY PHARMACIES.

(a) A health plan that provides prescription coverage must provide coverage for self-administered hormonal contraceptives, nicotine replacement medications, and opiate antagonists for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 14, 15, or 16, under the same terms of coverage that would apply had the prescription drug been prescribed by a licensed physician, physician assistant, or advanced practice nurse practitioner.

(b) A health plan is not required to cover the drug if dispensed by an out-of-network pharmacy, unless the health plan covers prescription drugs dispensed by out-of-network pharmacies.

Sec. 19. Minnesota Statutes 2019 Supplement, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, ~~or~~ licensed advanced practice registered nurse. ~~For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (c), and (f); and 151.461, "practitioner" also means a, or licensed physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A. For purposes of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists under section 151.37, subdivision 14, 15, or 16.~~

Sec. 20. Minnesota Statutes 2019 Supplement, section 151.01, subdivision 27, is amended to read:

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

- (1) interpretation and evaluation of prescription drug orders;
- (2) compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);
- (3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs, including the performance of laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq., provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement;
- (4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; intramuscular and subcutaneous administration used for the treatment of alcohol or opioid dependence; drug regimen reviews; and drug or drug-related research;
- (5) drug administration, through intramuscular and subcutaneous administration used to treat mental illnesses as permitted under the following conditions:
 - (i) upon the order of a prescriber and the prescriber is notified after administration is complete; or
 - (ii) pursuant to a protocol or collaborative practice agreement as defined by section [151.01, subdivisions 27b](#) and [27c](#), and participation in the initiation, management, modification, administration, and discontinuation of drug therapy is according to the protocol or collaborative practice agreement between the pharmacist and a dentist, optometrist, physician, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section [148.235](#). Any changes in drug therapy or medication administration made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;
- (6) participation in administration of influenza vaccines and vaccines approved by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2 to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older by written protocol with a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section [148.235](#), provided that:
 - (i) the protocol includes, at a minimum:
 - (A) the name, dose, and route of each vaccine that may be given;
 - (B) the patient population for whom the vaccine may be given;
 - (C) contraindications and precautions to the vaccine;
 - (D) the procedure for handling an adverse reaction;

(E) the name, signature, and address of the physician, physician assistant, or advanced practice registered nurse;

(F) a telephone number at which the physician, physician assistant, or advanced practice registered nurse can be contacted; and

(G) the date and time period for which the protocol is valid;

(ii) the pharmacist has successfully completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the board;

(iii) the pharmacist utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza vaccines to individuals age nine and older;

(iv) the pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection; and

(v) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices, except that a pharmacist does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section [148.235](#), provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine;

(7) participation in the initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between:

(i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice registered nurses authorized to prescribe, dispense, and administer under section [148.235](#). Any changes in drug therapy made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

(8) participation in the storage of drugs and the maintenance of records;

(9) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices;

(10) offering or performing those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy; ~~and~~

(11) participation in the initiation, management, modification, and discontinuation of therapy with opiate antagonists, as defined in section [604A.04, subdivision 1](#), pursuant to:

(i) a written protocol as allowed under clause (6); or

(ii) a written protocol with a community health board medical consultant or a practitioner designated by the commissioner of health, as allowed under section [151.37](#), subdivision 13; and

(12) prescribing self-administered hormonal contraceptives; nicotine replacement medications; and opiate antagonists for the treatment of an acute opiate overdose pursuant to section 151.37, subdivision 14, 15, or 16.

Sec. 21. Minnesota Statutes 2018, section 151.01, is amended by adding a subdivision to read:

Subd. 42. Self-administered hormonal contraceptive.

"Self-administered hormonal contraceptive" means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and is administered by the user.

Sec. 22. Minnesota Statutes 2018, section 151.37, subdivision 2, is amended to read:

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

(b) The commissioner of health, if a licensed practitioner, or a person designated by the commissioner who is a licensed practitioner, may prescribe a legend drug to an individual or by protocol for mass dispensing purposes where the commissioner finds that the conditions triggering section [144.4197](#) or [144.4198, subdivision 2](#), paragraph (b), exist. The commissioner, if a licensed practitioner, or a designated licensed practitioner, may prescribe, dispense, or administer a legend drug or other substance listed in subdivision 10 to control tuberculosis and other communicable diseases. The commissioner may modify state drug labeling requirements, and medical screening criteria and documentation, where time is critical and limited labeling and screening are most likely to ensure legend drugs reach the maximum number of persons in a timely fashion so as to reduce morbidity and mortality.

(c) A licensed practitioner that dispenses for profit a legend drug that is to be administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must file with the practitioner's licensing board a statement indicating that the practitioner dispenses legend

drugs for profit, the general circumstances under which the practitioner dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to dispense legend drugs for profit after July 31, 1990, unless the statement has been filed with the appropriate licensing board. For purposes of this paragraph, "profit" means (1) any amount received by the practitioner in excess of the acquisition cost of a legend drug for legend drugs that are purchased in prepackaged form, or (2) any amount received by the practitioner in excess of the acquisition cost of a legend drug plus the cost of making the drug available if the legend drug requires compounding, packaging, or other treatment. The statement filed under this paragraph is public data under section [13.03](#). This paragraph does not apply to a licensed doctor of veterinary medicine or a registered pharmacist. Any person other than a licensed practitioner with the authority to prescribe, dispense, and administer a legend drug under paragraph (a) shall not dispense for profit. To dispense for profit does not include dispensing by a community health clinic when the profit from dispensing is used to meet operating expenses.

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

- (1) controlled substance drugs listed in section [152.02, subdivisions 3](#) to 5;
- (2) drugs defined by the Board of Pharmacy as controlled substances under section [152.02, subdivisions 7, 8, and 12](#);
- (3) muscle relaxants;
- (4) centrally acting analgesics with opioid activity;
- (5) drugs containing butalbital; or
- (6) phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.

For purposes of prescribing drugs listed in clause (6), the requirement for a documented patient evaluation, including an examination, may be met through the use of telemedicine, as defined in section 147.033, subdivision 1.

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

- (1) the prescribing practitioner examines the patient at the time the prescription or drug order is issued;
- (2) the prescribing practitioner has performed a prior examination of the patient;
- (3) another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;
- (4) a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or
- (5) the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

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

(g) Nothing in this chapter prohibits a licensed practitioner from issuing a prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy in the

Management of Sexually Transmitted Diseases guidance document issued by the United States Centers for Disease Control.

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

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

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

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

Sec. 23. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 14. Self-administered hormonal contraceptives. (a) A pharmacist is authorized to prescribe self-administered hormonal contraceptives if the intended use is contraception in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing self-administrated hormonal contraceptives. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; the Minnesota section of the American Congress of Obstetricians and Gynecologists; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses. The protocol must, at a minimum, include:

(1) requiring the patient to complete a self-screening tool to identify patient risk factors for the use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria for Contraceptive Use developed by the federal Centers for Disease Control and Prevention;

(2) requiring the pharmacist to review the screening tool with the patient;

(3) other assessments the pharmacist should make before prescribing self-administered hormonal contraceptives;

(4) situations when the prescribing of self-administered hormonal contraceptives by a pharmacist is contraindicated;

(5) situations when the pharmacist must refer a patient to the patient's primary care provider or, if the patient does not have a primary care provider, to a nearby clinic or hospital; and

(6) any additional information concerning the requirements and prohibitions in this subdivision that the board considers necessary.

(b) Before a pharmacist is authorized to prescribe a self-administered hormonal contraceptive to a patient under this subdivision, the pharmacist shall successfully complete a training program on prescribing self-administered hormonal contraceptives that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing a self-administered hormonal contraceptive, the pharmacist shall follow the standardized protocol developed under paragraph (a), and if appropriate, may prescribe a self-administered hormonal contraceptive to a patient, if the patient is:

(1) 18 years of age or older; or

(2) under the age of 18 if the patient has previously been prescribed a self-administered hormonal contraceptive by a licensed physician, physician assistant, or advanced practice registered nurse.

(d) The pharmacist shall provide counseling to the patient on the use of self-administered hormonal contraceptives and provide the patient with a fact sheet that includes but is not limited to the contraindications for use of the drug, the appropriate method for using the drug, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the self-administered hormonal contraceptive prescribed by the pharmacist.

(e) If a pharmacist prescribes and dispenses a self-administered hormonal contraceptive under this subdivision, the pharmacist shall not prescribe a refill to the patient unless the patient has evidence of a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the preceding three years.

(f) A pharmacist who is authorized to prescribe a self-administered hormonal contraceptive is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for a self-administered hormonal contraceptive, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(g) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol or collaborative agreement as authorized in this section and in section 151.01, subdivision 27.

Sec. 24. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 15. Nicotine replacement medications. (a) A pharmacist is authorized to prescribe nicotine replacement medications approved by the United States Food and Drug Administration in accordance with this subdivision. By January 1, 2021, the board shall develop a standardized protocol for the pharmacist to follow in prescribing nicotine replacement medications. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe nicotine replacement medications under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing nicotine replacement medications that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing a nicotine replacement medication, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient a nicotine replacement medication.

(d) The pharmacist shall provide counseling to the patient on the use of the nicotine replacement medication and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of a nicotine replacement medication, the appropriate method for using the medication or product, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the medication prescribed by the pharmacist.

(e) A pharmacist who is authorized to prescribe a nicotine replacement medication under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare a prescription for the medication, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(f) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol or collaborative agreement as authorized in this section and in section 151.01, subdivision 27.

Sec. 25. Minnesota Statutes 2018, section 151.37, is amended by adding a subdivision to read:

Subd. 16. Opiate antagonists for the treatment of an acute opiate overdose.

(a) A pharmacist is authorized to prescribe opiate antagonists for the treatment of an acute opiate overdose. By January 1, 2021, the board shall develop a standardized protocol for

the pharmacist to follow in prescribing an opiate antagonist. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.

(b) Before a pharmacist is authorized to prescribe an opiate antagonist under this subdivision, the pharmacist shall successfully complete a training program specifically developed for prescribing opiate antagonists for the treatment of an acute opiate overdose that is offered by a college of pharmacy or by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

(c) Before prescribing an opiate antagonist under this subdivision, the pharmacist shall follow the appropriate standardized protocol developed under paragraph (a), and if appropriate, may dispense to a patient an opiate antagonist.

(d) The pharmacist shall provide counseling to the patient on the use of the opiate antagonist and provide the patient with a fact sheet that includes but is not limited to the indications and contraindications for use of the opiate antagonist, the appropriate method for using the opiate antagonist, the need for medical follow-up, and any additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be given to a patient during the counseling process. The pharmacist shall also provide the patient with a written record of the opiate antagonist prescribed by the pharmacist.

(e) A pharmacist who prescribes an opiate antagonist under this subdivision is prohibited from delegating the prescribing of the medication to any other person. A pharmacist intern registered pursuant to section 151.101 may prepare the prescription for the opiate antagonist, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

(f) Nothing in this subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol as authorized in this section and in section 151.01, subdivision 27.

Sec. 28. Minnesota Statutes 2019 Supplement, section 256B.0625, subdivision 13, is amended to read:

Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs when specifically used to enhance fertility, if prescribed by a licensed practitioner and dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance program as a dispensing physician, or by a physician, physician assistant, or a nurse practitioner employed by or under contract with a community health board as defined in section [145A.02, subdivision 5](#), for the purposes of communicable disease control.

(b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, unless authorized by the commissioner.

(c) For the purpose of this subdivision and subdivision 13d, an "active pharmaceutical ingredient" is defined as a substance that is represented for use in a drug and when used in the manufacturing, processing, or packaging of a drug becomes an active ingredient of the drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle for a drug. The commissioner shall establish a list of active pharmaceutical ingredients and excipients which are included in the medical assistance formulary. Medical assistance covers selected active pharmaceutical ingredients and excipients used in compounded prescriptions when the compounded combination is specifically approved by the commissioner or when a commercially available product:

- (1) is not a therapeutic option for the patient;
- (2) does not exist in the same combination of active ingredients in the same strengths as the compounded prescription; and
- (3) cannot be used in place of the active pharmaceutical ingredient in the compounded prescription.

(d) Medical assistance covers the following over-the-counter drugs when prescribed by a licensed practitioner or by a licensed pharmacist who meets standards established by the commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, family planning products, aspirin, insulin, products for the treatment of lice, vitamins for adults with documented vitamin deficiencies, vitamins for children under the age of seven and pregnant or nursing women, and any other over-the-counter drug identified by the commissioner, in consultation with the Formulary Committee, as necessary, appropriate, and cost-effective for the treatment of certain specified chronic diseases, conditions, or disorders, and this determination shall not be subject to the requirements of chapter 14. A pharmacist may prescribe over-the-counter medications as provided under this paragraph for purposes of receiving reimbursement under Medicaid. When prescribing over-the-counter drugs under this paragraph, licensed pharmacists must consult with the recipient to determine necessity, provide drug counseling, review drug therapy for potential adverse interactions, and make referrals as needed to other health care professionals.

(e) Effective January 1, 2006, medical assistance shall not cover drugs that are coverable under Medicare Part D as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-2(e), for individuals eligible for drug coverage as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-1(a)(3)(A). For these individuals, medical assistance may cover drugs from the drug classes listed in United States Code, title 42, section 1396r-8(d)(2), subject to this subdivision and subdivisions 13a to 13g, except that drugs listed in United States Code, title 42, section 1396r-8(d)(2)(E), shall not be covered.

(f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B covered entities and ambulatory pharmacies under common ownership of the 340B covered entity. Medical assistance does not cover drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies.

(g) Notwithstanding paragraph (a), medical assistance covers self-administered hormonal contraceptives prescribed and dispensed by a licensed pharmacist in accordance with

section 151.37, subdivision 14; nicotine replacement medications prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 15; and opiate antagonists used for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 16.

Sec. 29. Minnesota Statutes 2018, section 256B.0625, subdivision 13h, is amended to read:

Subd. 13h. **Medication therapy management services.** (a) Medical assistance covers medication therapy management services for a recipient taking prescriptions to treat or prevent one or more chronic medical conditions. For purposes of this subdivision, "medication therapy management" means the provision of the following pharmaceutical care services by a licensed pharmacist to optimize the therapeutic outcomes of the patient's medications:

- (1) performing or obtaining necessary assessments of the patient's health status;
- (2) formulating a medication treatment plan, which may include prescribing medications or products in accordance with section 151.37, subdivision 14, 15, or 16;
- (3) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- (4) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (5) documenting the care delivered and communicating essential information to the patient's other primary care providers;
- (6) providing verbal education and training designed to enhance patient understanding and appropriate use of the patient's medications;
- (7) providing information, support services, and resources designed to enhance patient adherence with the patient's therapeutic regimens; and
- (8) coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.

Nothing in this subdivision shall be construed to expand or modify the scope of practice of the pharmacist as defined in section [151.01, subdivision 27](#).

(b) To be eligible for reimbursement for services under this subdivision, a pharmacist must meet the following requirements:

- (1) have a valid license issued by the Board of Pharmacy of the state in which the medication therapy management service is being performed;
- (2) have graduated from an accredited college of pharmacy on or after May 1996, or completed a structured and comprehensive education program approved by the Board of Pharmacy and the American Council of Pharmaceutical Education for the provision and documentation of pharmaceutical care management services that has both clinical and didactic elements;
- (3) be practicing in an ambulatory care setting as part of a multidisciplinary team or have developed a structured patient care process that is offered in a private or semiprivate patient care area that is separate from the commercial business that also occurs in the setting, or in home settings, including long-term care settings, group homes, and facilities providing assisted living services, but excluding skilled nursing facilities; and

(4) make use of an electronic patient record system that meets state standards.

(c) For purposes of reimbursement for medication therapy management services, the commissioner may enroll individual pharmacists as medical assistance providers. The commissioner may also establish contact requirements between the pharmacist and recipient, including limiting the number of reimbursable consultations per recipient.

(d) If there are no pharmacists who meet the requirements of paragraph (b) practicing within a reasonable geographic distance of the patient, a pharmacist who meets the requirements may provide the services via two-way interactive video. Reimbursement shall be at the same rates and under the same conditions that would otherwise apply to the services provided. To qualify for reimbursement under this paragraph, the pharmacist providing the services must meet the requirements of paragraph (b), and must be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3). The patient must also be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3). Services provided under this paragraph may not be transmitted into the patient's residence.

(e) Medication therapy management services may be delivered into a patient's residence via secure interactive video if the medication therapy management services are performed electronically during a covered home care visit by an enrolled provider. Reimbursement shall be at the same rates and under the same conditions that would otherwise apply to the services provided. To qualify for reimbursement under this paragraph, the pharmacist providing the services must meet the requirements of paragraph (b) and must be located within an ambulatory care setting that meets the requirements of paragraph (b), clause (3).

Language related to the medication repository program

Sec. 26. Minnesota Statutes 2019 Supplement, section 151.555, subdivision 3, is amended to read:

Subd. 3. **Central repository requirements.** (a) The board ~~shall~~ may publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the drug repository program. ~~The board~~ If the board publishes a request for proposal, it shall follow all applicable state procurement procedures in the selection process. The board may also work directly with the University of Minnesota to establish a central repository.

(b) To be eligible to act as the central repository, the participant must be a wholesale drug distributor located in Minnesota, licensed pursuant to section [151.47](#), and in compliance with all applicable federal and state statutes, rules, and regulations.

(c) The central repository shall be subject to inspection by the board pursuant to section [151.06, subdivision 1](#).

(d) The central repository shall comply with all applicable federal and state laws, rules, and regulations pertaining to the drug repository program, drug storage, and dispensing. The

facility must maintain in good standing any state license or registration that applies to the facility.

Language clarifying that physician assistants can prescribe controlled substances

Sec. 27. Minnesota Statutes 2018, section 152.12, subdivision 1, is amended to read:

Subdivision 1. **Prescribing, dispensing, administering controlled substances in Schedules II through V.** A licensed doctor of medicine, a doctor of osteopathic medicine, duly licensed to practice medicine, a doctor of dental surgery, a doctor of dental medicine, a licensed doctor of podiatry, a licensed advanced practice registered nurse, a licensed physician assistant, or a licensed doctor of optometry limited to Schedules IV and V, and in the course of professional practice only, may prescribe, administer, and dispense a controlled substance included in Schedules II through V of section 152.02, may cause the same to be administered by a nurse, an intern or an assistant under the direction and supervision of the doctor, and may cause a person who is an appropriately certified and licensed health care professional to prescribe and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes.

Language related to therapeutic interchange during a declared COVID-19 peacetime emergency.

Sec. 33. **THERAPEUTIC INTERCHANGE.**

Subdivision 1. Applicability during a peacetime emergency.

This section applies during a peacetime emergency declared by the governor under Minnesota Statutes, section 12.31, subdivision 2, for an outbreak of COVID-19.

Subd. 2. Therapeutic interchange. Notwithstanding Minnesota Statutes, section 151.21, subdivision 7a, paragraph (a), a pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product, without having a protocol in place, provided:

(1) the drug prescribed is in short supply and the pharmacist is unable to obtain it from the manufacturer, drug wholesalers, or other local pharmacies;

(2) the pharmacist is unable to contact the prescriber within a reasonable period of time to get authorization to dispense a drug that is available;

(3) the pharmacist determines a therapeutically equivalent drug to the one prescribed is available and is in the same American Hospital Formulary Service pharmacologic-therapeutic classification;

(4) the pharmacist informs the patient as required in Minnesota Statutes, section 151.21, subdivision 7a, paragraph (b), and provides counseling to the patient, as required by the Board of Pharmacy rules, about the substituted drug;

(5) the pharmacist informs the prescriber as soon as possible that the therapeutic interchange has been made; and

(6) the therapeutic interchange pursuant to this section is allowed only until the expiration date under subdivision 3.

Subd. 3. **Expiration.** This section expires 60 days after the peacetime emergency specified in subdivision 1 is terminated or rescinded by proper authority.

Language related to issuance of prescriptions to treat substance abuse disorders during a declared COVID-19 peacetime emergency.

Sec. 30. ISSUANCE OF PRESCRIPTIONS TO TREAT SUBSTANCE USE DISORDERS.

Subdivision 1. **Applicability during a peacetime emergency.** This section applies during a peacetime emergency declared by the governor under Minnesota Statutes, section 12.31, subdivision 2, for an outbreak of COVID-19.

Subd. 2. **Use of telemedicine allowed.** For purposes of Minnesota Statutes, section 151.37, subdivision 2, paragraph (d), the requirement for an examination shall be met if the prescribing practitioner has performed a telemedicine examination of the patient before issuing a prescription drug order for the treatment of a substance use disorder.

Subd. 3. **Expiration.** This section expires 60 days after the peacetime emergency specified in subdivision 1 is terminated or rescinded by proper authority.

Language clarifying the licensing fee paid by opiate manufacturers

Sec. 4. Minnesota Statutes 2019 Supplement, section 151.065, subdivision 1, as amended by Laws 2020, chapter 71, article 2, section 5, is amended to read:

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

- (1) pharmacist licensed by examination, \$175;
- (2) pharmacist licensed by reciprocity, \$275;
- (3) pharmacy intern, \$50;
- (4) pharmacy technician, \$50;
- (5) pharmacy, \$260;
- (6) drug wholesaler, legend drugs only, \$5,260;
- (7) drug wholesaler, legend and nonlegend drugs, \$5,260;
- (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260;
- (9) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (10) third-party logistics provider, \$260;
- (11) drug manufacturer, nonopiate legend drugs only, \$5,260;
- (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;

- (13) drug manufacturer, nonlegend or veterinary legend drugs, \$5,260;
- (14) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (15) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;
- (16) drug manufacturer of opiate-containing controlled substances listed in section [152.02, subdivisions 3](#) to 5, ~~\$55,000~~ \$55,260;
- (17) medical gas ~~distributor~~ dispenser, \$260;
- (18) controlled substance researcher, \$75; and
- (19) pharmacy professional corporation, \$150.

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

Sec. 7 Minnesota Statutes 2019 Supplement, section 151.065, subdivision 7, as amended by Laws 2020, chapter 71, article 2, section 7, is amended to read:

Subd. 7. **Deposit of fees.** (a) The license fees collected under this section, with the exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state government special revenue fund.

(b) \$5,000 of each fee collected under subdivision 1, clauses (6) to (9), and (11) to (15), and subdivision 3, clauses (4) to (7), and (9) to (13), and ~~the fees \$55,000 of each fee~~ collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response ~~account~~ fund established in section [256.043](#).

(c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14), are reduced under section 256.043, \$5,000 of the reduced fee shall be deposited in the opiate epidemic response ~~account~~ fund in section [256.043](#).

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

Sec. 5. Minnesota Statutes 2019 Supplement, section 151.065, subdivision 3, as amended by Laws 2020, chapter 71, article 2, section 6, is amended to read:

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

- (1) pharmacist, \$175;
- (2) pharmacy technician, \$50;
- (3) pharmacy, \$260;
- (4) drug wholesaler, legend drugs only, \$5,260;
- (5) drug wholesaler, legend and nonlegend drugs, \$5,260;
- (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260;
- (7) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (8) third-party logistics provider, \$260;

- (9) drug manufacturer, nonopiate legend drugs only, \$5,260;
- (10) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;
- (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$5,260;
- (12) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (13) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;
- (14) drug manufacturer of opiate-containing controlled substances listed in section [152.02, subdivisions 3](#) to 5, ~~\$55,000~~ \$55,260;
- (15) medical gas ~~distributor~~ dispenser, \$260;
- (16) controlled substance researcher, \$75; and
- (17) pharmacy professional corporation, \$100.

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

Sec. 11. Minnesota Statutes 2019 Supplement, 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) In addition to the license required under paragraph (a), each manufacturer required to pay the registration fee under section [151.066](#) must pay the fee by June 1 of each year, beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new owner must pay the registration fee specified under section 151.066, subdivision 3, that the original owner would have been assessed had the original owner retained ownership. The registration fee collected under this paragraph shall be deposited in the opiate epidemic response ~~account~~ fund established under section [256.043](#).

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

(d) 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.

(e) 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.

(f) 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.

(g) 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, except a manufacturer of opiate-containing controlled substances shall not be required to pay the fee under section [151.065, subdivision 1](#), clause (16), or subdivision 3, clause (14), for more than one facility.

(h) Prior to the issuance of an initial or renewed license for a drug manufacturing facility, the board may require the facility 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.

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

Clarifying Language related to medical gas dispensers

Sec. 8. Minnesota Statutes 2019 Supplement, 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, 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, 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~~ dispenser, 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;

(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~~ must 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.

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

Sec. 9. Minnesota Statutes 2018, section 151.071, subdivision 8, is amended to read:

Subd. 8. Temporary suspension of license for pharmacies, drug wholesalers, drug manufacturers, medical gas manufacturers, and medical gas ~~distributors~~ dispensers.

In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend the license or registration of a pharmacy, drug wholesaler, drug manufacturer, medical gas manufacturer, or medical gas ~~distributor~~ dispenser if the board finds that the licensee or registrant has violated a statute or rule that the board is empowered to enforce and continued operation of the licensed facility would create a serious risk of harm to the public. The suspension ~~shall~~ must take effect upon written notice to the licensee or registrant, specifying the statute or rule violated. The suspension ~~shall~~ must remain in effect until the board issues a final order in the matter after a hearing. At the time it issues the suspension notice, the board ~~shall~~ must schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The licensee or registrant ~~shall~~ must be provided with at least 20 days' notice of any hearing held pursuant to this subdivision. The hearing ~~shall~~ must be scheduled to begin no later than 30 days after the issuance of the suspension order.

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

Sec. 10. Minnesota Statutes 2019 Supplement, 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~~ must not engage in the retail sale or ~~distribution~~ dispensing 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~~ must 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~~ dispense federally restricted medical gases unless a certificate has been issued to that person by the board.

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

(c) ~~No~~ A registration ~~shall~~ must not be issued or renewed for a medical gas ~~distributor~~ dispenser 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~~ A license ~~shall~~ must not be issued for a medical gas ~~distributor~~ dispenser located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when ~~distributing~~ dispensing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) ~~No~~ A registration ~~shall~~ must not be issued or renewed for a medical gas ~~distributor~~ dispenser 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~~ dispenser that is not required to be licensed or registered by the state in which it is physically located.

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

(f) Prior to the issuance of an initial or renewed registration for a medical gas ~~distributor~~ dispenser, the board may require the medical gas ~~distributor~~ dispenser to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas ~~distributor~~ dispenser 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.

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

Clarification that a tribal identification can be used to show Minnesota residency for the Minnesota Insulin Safety Net Program

Sec. 37. Laws 2020, chapter 73, section 4, subdivision 3, is amended to read:

Subd. 3. **Access to urgent-need insulin.** (a) MNSure shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subdivision 2. The form shall be accessible through MNSure's website. MNSure shall also make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(b) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification indicating Minnesota residency in the form of a valid Minnesota identification card, driver's license, or permit, or tribal identification card as defined in section 171.072, paragraph (b). If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(remainder of subdivision omitted for brevity)

Sec. 38. Laws 2020, chapter 73, section 4, subdivision 4, is amended to read:

Subd. 4. **Continuing safety net program; general.** (a) Each manufacturer shall make a patient assistance program available to any individual who meets the requirements of this

subdivision. Each manufacturer's patient assistance programs must meet the requirements of this section. Each manufacturer shall provide the Board of Pharmacy with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing their patient assistance program.

(b) To be eligible to participate in a manufacturer's patient assistance program, the individual must:

(1) be a Minnesota resident with a valid Minnesota identification card that indicates Minnesota residency in the form of a Minnesota identification card ~~or~~, driver's license or permit, or tribal identification card as defined in section 171.072, paragraph (b). If the individual is under the age of 18, the individual's parent or legal guardian must provide proof of residency; *(remainder of subdivision omitted for brevity)*

Change in language required to be on generic substitution signs in pharmacies

Sec. 75. Minnesota Statutes 2018, section 151.21, subdivision 4a, is amended to read:

Subd. 4a. **Sign.** A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor or advanced practice registered nurse, unless you object to this substitution."

Controlled Substances Scheduling Changes

Section 1. Minnesota Statutes 2018, section 152.02, subdivision 2, is amended to read:

Subd. 2. **Schedule I.** (a) Schedule I consists of the substances listed in this subdivision.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following substances, including their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the analogs, isomers, esters, ethers, and salts is possible:

- (1) acetylmethadol;
- (2) allylprodine;
- (3) alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate);
- (4) alphameprodine;
- (5) alphasubstituted methadol;
- (6) alpha-methylfentanyl benzethidine;
- (7) betacetylmethadol;

- (8) betameprodine;
- (9) betamethadol;
- (10) betaprodine;
- (11) clonitazene;
- (12) dextromoramide;
- (13) diampromide;
- (14) diethylambutene;
- (15) difenoxin;
- (16) dimenoxadol;
- (17) dimepheptanol;
- (18) dimethylambutene;
- (19) dioxaphetyl butyrate;
- (20) dipipanone;
- (21) ethylmethylthiambutene;
- (22) etonitazene;
- (23) etoxeridine;
- (24) furethidine;
- (25) hydroxypethidine;
- (26) ketobemidone;
- (27) levomoramide;
- (28) levophenacilmorphan;
- (29) 3-methylfentanyl;
- (30) acetyl-alpha-methylfentanyl;
- (31) alpha-methylthiofentanyl;
- (32) benzylfentanyl beta-hydroxyfentanyl;
- (33) beta-hydroxy-3-methylfentanyl;
- (34) 3-methylthiofentanyl;
- (35) thenylfentanyl;
- (36) thiofentanyl;
- (37) para-fluorofentanyl;
- (38) morpheridine;
- (39) 1-methyl-4-phenyl-4-propionoxypiperidine;
- (40) noracymethadol;
- (41) norlevorphanol;
- (42) normethadone;
- (43) norpipanone;
- (44) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);
- (45) phenadoxone;
- (46) phenampromide;
- (47) phenomorphan;
- (48) phenoperidine;
- (49) piritramide;
- (50) proheptazine;

(51) properidine;
(52) propiram;
(53) racemoramide;
(54) tilidine;
(55) trimeperidine;
(56) N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl);
(57) 3,4-dichloro-N-[(1R,2R)-2-(dimethylamino)cyclohexyl]-N-methylbenzamide(U47700);
(58) N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide(furanylfentanyl); ~~and~~
(59) 4-(4-bromophenyl)-4-dimethylamino-1-phenethylcyclohexanol (bromadol);
(60) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropyl fentanyl);
(61) N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide (butyryl fentanyl);
(62) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45);
(63) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl);
(64) N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl);
(65) N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide (valeryl fentanyl);
(66) N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-chloroisobutyryl fentanyl);
(67) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-fluorobutyryl fentanyl);
(68) N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-methoxybutyryl fentanyl);
(69) N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil);
(70) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (4-fluoroisobutyryl fentanyl or para-fluoroisobutyryl fentanyl);
(71) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryl fentanyl or acryloylfentanyl);
(72) 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl);
(73) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl);
(74) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl); and
(75) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, meaning any substance not otherwise listed under another federal Administration Controlled Substance Code Number or not otherwise listed in this section, and for which no exemption or approval is in effect under section 505 of the Federal Food,

Drug, and Cosmetic Act, United States Code , title 21, section 355, that is structurally related to fentanyl by one or more of the following modifications:

(i) replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(ii) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iii) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iv) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; or

(v) replacement of the N-propionyl group by another acyl group.

(c) Opium derivatives. Any of the following substances, their analogs, salts, isomers, and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

- (1) acetorphine;
- (2) acetyldihydrocodeine;
- (3) benzylmorphine;
- (4) codeine methylbromide;
- (5) codeine-n-oxide;
- (6) cyprenorphine;
- (7) desomorphine;
- (8) dihydromorphine;
- (9) drotebanol;
- (10) etorphine;
- (11) heroin;
- (12) hydromorphenol;
- (13) methyl-desorphine;
- (14) methyldihydromorphine;
- (15) morphine methylbromide;
- (16) morphine methylsulfonate;
- (17) morphine-n-oxide;
- (18) myrophine;
- (19) nicocodeine;
- (20) nicomorphine;
- (21) normorphine;
- (22) pholcodine; and
- (23) thebacon.

(d) Hallucinogens. Any material, compound, mixture or preparation which contains any quantity of the following substances, their analogs, salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

- (1) methylenedioxy amphetamine;

- (2) methylenedioxyamphetamine;
- (3) methylenedioxy-N-ethylamphetamine (MDEA);
- (4) n-hydroxy-methylenedioxyamphetamine;
- (5) 4-bromo-2,5-dimethoxyamphetamine (DOB);
- (6) 2,5-dimethoxyamphetamine (2,5-DMA);
- (7) 4-methoxyamphetamine;
- (8) 5-methoxy-3,4-methylenedioxyamphetamine;
- (9) alpha-ethyltryptamine;
- (10) bufotenine;
- (11) diethyltryptamine;
- (12) dimethyltryptamine;
- (13) 3,4,5-trimethoxyamphetamine;
- (14) 4-methyl-2,5-dimethoxyamphetamine (DOM);
- (15) ibogaine;
- (16) lysergic acid diethylamide (LSD);
- (17) mescaline;
- (18) parahexyl;
- (19) N-ethyl-3-piperidyl benzilate;
- (20) N-methyl-3-piperidyl benzilate;
- (21) psilocybin;
- (22) psilocyn;
- (23) tenocyclidine (TPCP or TCP);
- (24) N-ethyl-1-phenyl-cyclohexylamine (PCE);
- (25) 1-(1-phenylcyclohexyl) pyrrolidine (PCPy);
- (26) 1-[1-(2-thienyl)cyclohexyl]-pyrrolidine (TCPy);
- (27) 4-chloro-2,5-dimethoxyamphetamine (DOC);
- (28) 4-ethyl-2,5-dimethoxyamphetamine (DOET);
- (29) 4-iodo-2,5-dimethoxyamphetamine (DOI);
- (30) 4-bromo-2,5-dimethoxyphenethylamine (2C-B);
- (31) 4-chloro-2,5-dimethoxyphenethylamine (2C-C);
- (32) 4-methyl-2,5-dimethoxyphenethylamine (2C-D);
- (33) 4-ethyl-2,5-dimethoxyphenethylamine (2C-E);
- (34) 4-iodo-2,5-dimethoxyphenethylamine (2C-I);
- (35) 4-propyl-2,5-dimethoxyphenethylamine (2C-P);
- (36) 4-isopropylthio-2,5-dimethoxyphenethylamine (2C-T-4);
- (37) 4-propylthio-2,5-dimethoxyphenethylamine (2C-T-7);
- (38) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2-CB-FLY);
- (39) bromo-benzodifuranyl-isopropylamine (Bromo-DragonFLY);
- (40) alpha-methyltryptamine (AMT);
- (41) N,N-diisopropyltryptamine (DiPT);
- (42) 4-acetoxy-N,N-dimethyltryptamine (4-AcO-DMT);
- (43) 4-acetoxy-N,N-diethyltryptamine (4-AcO-DET);

- (44) 4-hydroxy-N-methyl-N-propyltryptamine (4-HO-MPT);
- (45) 4-hydroxy-N,N-dipropyltryptamine (4-HO-DPT);
- (46) 4-hydroxy-N,N-diallyltryptamine (4-HO-DALT);
- (47) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);
- (48) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DiPT);
- (49) 5-methoxy-?-methyltryptamine (5-MeO-AMT);
- (50) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);
- (51) 5-methylthio-N,N-dimethyltryptamine (5-MeS-DMT);
- (52) 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT);
- (53) 5-methoxy-?-ethyltryptamine (5-MeO-AET);
- (54) 5-methoxy-N,N-dipropyltryptamine (5-MeO-DPT);
- (55) 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);
- (56) 5-methoxy-N,N-diallyltryptamine (5-MeO-DALT);
- (57) methoxetamine (MXE);
- (58) 5-iodo-2-aminoindane (5-IAI);
- (59) 5,6-methylenedioxy-2-aminoindane (MDAI);
- (60) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe);
- (61) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe);
- (62) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe);
- (63) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);
- (64) 2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C-T-2);
- (65) N,N-Dipropyltryptamine (DPT);
- (66) 3-[1-(Piperidin-1-yl)cyclohexyl]phenol (3-HO-PCP);
- (67) N-ethyl-1-(3-methoxyphenyl)cyclohexanamine (3-MeO-PCE);
- (68) 4-[1-(3-methoxyphenyl)cyclohexyl]morpholine (3-MeO-PCMo);
- (69) 1-[1-(4-methoxyphenyl)cyclohexyl]-piperidine (methoxydine, 4-MeO-PCP);
- (70) 2-(2-Chlorophenyl)-2-(ethylamino)cyclohexan-1-one (N-Ethylorketamine, ethketamine, NENK);
- (71) methylenedioxy-N,N-dimethylamphetamine (MDDMA);
- (72) 3-(2-Ethyl(methyl)aminoethyl)-1H-indol-4-yl (4-AcO-MET); and
- (73) 2-Phenyl-2-(methylamino)cyclohexanone (deschloroketamine).

(e) Peyote. All parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church, and members of the American Indian Church are exempt from registration. Any person who manufactures peyote for or distributes peyote to the American Indian Church, however, is required to obtain federal registration annually and to comply with all other requirements of law.

(f) Central nervous system depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity

of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

- (1) mecloqualone;
- (2) methaqualone;
- (3) gamma-hydroxybutyric acid (GHB), including its esters and ethers;
- (4) flunitrazepam; ~~and~~
- (5) 2-(2-Methoxyphenyl)-2-(methylamino)cyclohexanone (2-MeO-2-deschloroketamine, methoxyketamine)-;

(6) tianeptine;

(7) clonazolam;

(8) etizolam;

(9) flubromazolam; and

(10) flubromazepam.

(g) Stimulants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

- (1) aminorex;
- (2) cathinone;
- (3) fenethylamine;
- (4) methcathinone;
- (5) methylaminorex;
- (6) N,N-dimethylamphetamine;
- (7) N-benzylpiperazine (BZP);
- (8) methylmethcathinone (mephedrone);
- (9) 3,4-methylenedioxy-N-methylcathinone (methylone);
- (10) methoxymethcathinone (methedrone);
- (11) methylenedioxypropylamphetamine (MDPV);
- (12) 3-fluoro-N-methylcathinone (3-FMC);
- (13) methylethcathinone (MEC);
- (14) 1-benzofuran-6-ylpropan-2-amine (6-APB);
- (15) dimethylmethcathinone (DMMC);
- (16) fluoroamphetamine;
- (17) fluoromethamphetamine;
- (18) ?-methylaminobutyrophenone (MABP or buphedrone);
- (19) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone);
- (20) 2-(methylamino)-1-(4-methylphenyl)butan-1-one (4-MEMABP or BZ-6378);
- (21) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl) pentan-1-one (naphthylpyrovalerone or naphyrone);
- (22) (alpha-pyrrolidinopentiophenone (alpha-PVP);
- (23) (RS)-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-hexanone (4-Me-PHP or MPHP);
- (24) 2-(1-pyrrolidinyl)-hexanophenone (Alpha-PHP);
- (25) 4-methyl-N-ethylcathinone (4-MEC);

- (26) 4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP);
- (27) 2-(methylamino)-1-phenylpentan-1-one (pentedrone);
- (28) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentyllone);
- (29) 4-fluoro-N-methylcathinone (4-FMC);
- (30) 3,4-methylenedioxy-N-ethylcathinone (ethylone);
- (31) alpha-pyrrolidinobutiophenone (?-PBP);
- (32) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (5-APDB);
- (33) 1-phenyl-2-(1-pyrrolidinyl)-1-heptanone (PV8);
- (34) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (6-APDB);
- (35) 4-methyl-alpha-ethylaminopentiophenone (4-MEAPP);
- (36) 4'-chloro-alpha-pyrrolidinopropiophenone (4'-chloro-PPP);
- (37) 1-(1,3-Benzodioxol-5-yl)-2-(dimethylamino)butan-1-one (dibutylone, bk-DMBDB);
- (38) 1-(3-chlorophenyl) piperazine (meta-chlorophenylpiperazine or mCPP); ~~and~~

(39) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (N-ethylpentyllone, ephylone); and

(40) any other substance, except bupropion or compounds listed under a different schedule, that is structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

(i) by substitution in the ring system to any extent with alkyl, alkylendioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;

(ii) by substitution at the 3-position with an acyclic alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or

(iv) by inclusion of the 2-amino nitrogen atom in a cyclic structure.

(h) Marijuana, tetrahydrocannabinols, and synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(1) marijuana;

(2) tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant, or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including but not limited to, 1 cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol;

(3) synthetic cannabinoids, including the following substances:

(i) Naphthoylindoles, which are any compounds containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl,

cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylindoles include, but are not limited to:

- (A) 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM-678);
- (B) 1-Butyl-3-(1-naphthoyl)indole (JWH-073);
- (C) 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081);
- (D) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
- (E) 1-Propyl-2-methyl-3-(1-naphthoyl)indole (JWH-015);
- (F) 1-Hexyl-3-(1-naphthoyl)indole (JWH-019);
- (G) 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
- (H) 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210);
- (I) 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
- (J) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201).

(ii) Naphthylmethylindoles, which are any compounds containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindoles include, but are not limited to:

- (A) 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane (JWH-175);
- (B) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl)methane (JWH-184).

(iii) Naphthoylpyrroles, which are any compounds containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylpyrroles include, but are not limited to, (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone (JWH-307).

(iv) Naphthylmethylindenes, which are any compounds containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindenes include, but are not limited to, E-1-[1-(1-naphthalenylmethylene)-1H-inden-3-yl]pentane (JWH-176).

(v) Phenylacetylindoles, which are any compounds containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of phenylacetylindoles include, but are not limited to:

- (A) 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (RCS-8);
- (B) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(C) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251);

(D) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

(vi) Cyclohexylphenols, which are compounds containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of cyclohexylphenols include, but are not limited to:

(A) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47,497);

(B) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol

(Cannabicyclohexanol or CP 47,497 C8 homologue);

(C) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl]-phenol (CP 55,940).

(vii) Benzoylindoles, which are any compounds containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of benzoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(4-methoxybenzoyl)indole (RCS-4);

(B) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694);

(C) (4-methoxyphenyl-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone

(WIN

48,098 or Pravadoline).

(viii) Others specifically named:

(A) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210);

(B) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (Dexanabinol or HU-211);

(C) 2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl-1-naphthalenylmethanone (WIN 55,212-2);

(D) (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

(E) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);

(F) 1-pentyl-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indazole-3-carboxamide (AKB-48(APINACA));

(G) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5-Fluoro-AKB-48);

(H) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);

(I) 8-quinolinyl ester-1-(5-fluoropentyl)-1H-indole-3-carboxylic acid (5-Fluoro PB-22);

(J) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA);

(K) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (AB-FUBINACA);

(L) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide(AB-CHMINACA);

(M) (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (5-fluoro-AMB);

(N) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl) methanone (THJ-2201);

(O) (1-(5-fluoropentyl)-1H-benzo[d]imidazol-2-yl)(naphthalen-1-yl)methanone (FUBIMINA);

(P) (7-methoxy-1-(2-morpholinoethyl)-N-((1S,2S,4R)-1,3,3-trimethylbicyclo[2.2.1]heptan-2-yl)-1H-indole-3-carboxamide (MN-25 or UR-12);

(Q) (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-fluoro-ABICA);

(R) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide;

(S) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide;

(T) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate;

(U) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)-1H-indazole-3-carboxamide (MAB-CHMINACA);

(V) N-(1-Amino-3,3-dimethyl-1-oxo-2-butanyl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA);

(W) methyl (1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate (FUB-AMB);

(X) N-[(1S)-2-amino-2-oxo-1-(phenylmethyl)ethyl]-1-(cyclohexylmethyl)-1H-Indazole-3-carboxamide. (APP-CHMINACA);

(Y) quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (FUB-PB-22); and

(Z) methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA).

(ix) Additional substances specifically named:

(A) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-B]pyridine-3-carboxamide (5F-CUMYL-P7AICA);

(B) 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (4-CN-Cumyl-Butinaca);

(C) naphthalen-1-yl-1-(5-fluoropentyl)-1H-indole-3-carboxylate (NM2201; CBL2201);

(D) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5F-ABPINACA);

(E) methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (MDMB CHMICA);

(F) methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (5F-ADB; 5F-MDMB-PINACA); and

(G) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)1H-indazole-3-carboxamide (ADB-FUBINACA).

(i) A controlled substance analog, to the extent that it is implicitly or explicitly intended for human consumption.

Sec. 2. Minnesota Statutes 2018, section 152.02, subdivision 3, is amended to read:

Subd. 3. **Schedule II.** (a) Schedule II consists of the substances listed in this subdivision.

(b) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(i) Excluding:

(A) apomorphine;

(B) thebaine-derived butorphanol;

(C) dextrophan;

(D) nalbuphine;

(E) nalmefene;

(F) naloxegol;

(G) naloxone;

(H) naltrexone; and

(I) their respective salts;

(ii) but including the following:

(A) opium, in all forms and extracts;

(B) codeine;

(C) dihydroetorphine;

(D) ethylmorphine;

(E) etorphine hydrochloride;

(F) hydrocodone;

(G) hydromorphone;

(H) metopon;

(I) morphine;

(J) oxycodone;

(K) oxymorphone;

(L) thebaine;

(M) oripavine;

(2) any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, cocaine compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, or unless listed in another schedule, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

- (1) alfentanil;
- (2) alphaprodine;
- (3) anileridine;
- (4) bezitramide;
- (5) bulk dextropropoxyphene (nondosage forms);
- (6) carfentanil;
- (7) dihydrocodeine;
- (8) dihydromorphinone;
- (9) diphenoxylate;
- (10) fentanyl;
- (11) isomethadone;
- (12) levo-alpha-acetylmethadol (LAAM);
- (13) levomethorphan;
- (14) levorphanol;
- (15) metazocine;
- (16) methadone;
- (17) methadone - intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane;
- (18) moramide - intermediate, 2-methyl-3-morpholino-1,1-diphenyl-propane-carboxylic acid;
- (19) pethidine;
- (20) pethidine - intermediate - a, 4-cyano-1-methyl-4-phenylpiperidine;
- (21) pethidine - intermediate - b, ethyl-4-phenylpiperidine-4-carboxylate;
- (22) pethidine - intermediate - c, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
- (23) phenazocine;
- (24) piminodine;
- (25) racemethorphan;
- (26) racemorphan;
- (27) remifentanil;
- (28) sufentanil;
- (29) tapentadol;
- (30) ~~4-Anilino-N-phenethyl-4-piperidine (ANPP)~~ 4-Anilino-N-phenethylpiperidine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

- (1) amphetamine, its salts, optical isomers, and salts of its optical isomers;
- (2) methamphetamine, its salts, isomers, and salts of its isomers;
- (3) phenmetrazine and its salts;
- (4) methylphenidate;
- (5) lisdexamfetamine.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) amobarbital;
- (2) glutethimide;
- (3) secobarbital;
- (4) pentobarbital;
- (5) phencyclidine;
- (6) phencyclidine immediate precursors:
 - (i) 1-phenylcyclohexylamine;
 - (ii) 1-piperidinocyclohexanecarbonitrile;
- (7) phenylacetone.
- (f) ~~Hallucinogenic substances~~ Cannabinoids:

(1) nabilone;
(2) dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration.

Sec. 3. Minnesota Statutes 2018, section 152.02, subdivision 4, is amended to read:

Subd. 4. **Schedule III.** (a) Schedule III consists of the substances listed in this subdivision.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) benzphetamine;
- (2) chlorphentermine;
- (3) clortermine;
- (4) phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following

substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the food and drug administration for marketing only as a suppository;

(3) any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules;

(4) any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug, and Cosmetic Act;

(5) any of the following substances:

(i) chlorhexadol;

(ii) ketamine, its salts, isomers and salts of isomers;

(iii) lysergic acid;

(iv) lysergic acid amide;

(v) methyprylon;

(vi) sulfondiethylmethane;

(vii) sulfonethylmethane;

(viii) sulfonmethane;

(ix) tiletamine and zolazepam and any salt thereof;

(x) embutramide;

(xi) Perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl)-1,2-Dihydropyridin-3-yl] benzonitrile].

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(4) not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(f) Anabolic steroids, human growth hormone, and chorionic gonadotropin.

(1) Anabolic steroids, for purposes of this subdivision, means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone, and includes:

- (i) 3[beta],17[beta]-dihydroxy-5[alpha]-androstane;
- (ii) 3[alpha],17[beta]-dihydroxy-5[alpha]-androstane;
- (iii) androstenedione (5[alpha]-androst-3,17-dione);
- (iv) 1-androstenediol (3[beta],17[beta]-dihydroxy-5[alpha]-androst-1-ene);
- (v) 3[alpha],17[beta]-dihydroxy-5[alpha]-androst-1-ene);
- (vi) 4-androstenediol (3[beta],17[beta]-dihydroxy-androst-4-ene);
- (vii) 5-androstenediol (3[beta],17[beta]-dihydroxy-androst-5-ene);
- (viii) 1-androstenedione (5[alpha]-androst-1-en-3,17-dione);
- (ix) 4-androstenedione (androst-4-en-3,17-dione);
- (x) 5-androstenedione (androst-5-en-3,17-dione);
- (xi) bolasterone (7[alpha],17[alpha]-dimethyl-17[beta]-hydroxyandrost-4-en-3-one);
- (xii) boldenone (17[beta]-hydroxyandrost-1,4-diene-3-one);
- (xiii) boldione (androsta-1,4-diene-3,17-dione);
- (xiv) calusterone (7[beta],17[alpha]-dimethyl-17[beta]-hydroxyandrost-4-en-3-one);
- (xv) clostebol (4-chloro-17[beta]-hydroxyandrost-4-en-3-one);
- (xvi) dehydrochloromethyltestosterone (4-chloro-17[beta]-hydroxy-17[alpha]-methylandrost-1,4-dien-3-one);
- (xvii) desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol);
- (xviii) [delta]1-dihydrotestosterone- (17[beta]-hydroxy-5[alpha]-androst-1-en-3-one);
- (xix) 4-dihydrotestosterone (17[beta]-hydroxy-androstan-3-one);
- (xx) drostanolone (17[beta]hydroxy-2[alpha]-methyl-5[alpha]-androstan-3-one);
- (xxi) ethylestrenol (17[alpha]-ethyl-17[beta]-hydroxyestr-4-ene);
- (xxii) fluoxymesterone (9-fluoro-17[alpha]-methyl-11[beta],17[beta]-dihydroxyandrost-4-en-3-one);
- (xxiii) formebolone (2-formyl-17[alpha]-methyl-11[alpha],17[beta]-dihydroxyandrost-1,4-dien-3-one);
- (xxiv) furazabol (17[alpha]-methyl-17[beta]-hydroxyandrostano[2,3-c]-furazan)13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one;
- (xxv) 4-hydroxytestosterone (4,17[beta]-dihydroxyandrost-4-en-3-one);
- (xxvi) 4-hydroxy-19-nortestosterone (4,17[beta]-dihydroxyestr-4-en-3-one);
- (xxvii) mestanolone (17[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androstan-3-one);
- (xxviii) mesterolone (1[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androstan-3-one);
- (xxix) methandienone (17[alpha]-methyl-17[beta]-hydroxyandrost-1,4-dien-3-one);

(xxx) methandriol (17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-5-ene);
 (xxxi) methasterone (2 alpha-17 alpha-dimethyl-5 alpha-androstan-17beta-ol-3-one);
 (xxxii) methenolone (1-methyl-17[beta]-hydroxy-5[alpha]-androst-1-en-3-one);
 (xxxiii) 17[alpha]-methyl-3[beta],17[beta]-dihydroxy-5[alpha]-androstane;
 (xxxiv) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy-5[alpha]-androstane;
 (xxxv) 17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-4-ene;
 (xxxvi) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one);
 (xxxvii) methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3-one);
 (xxxviii) methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-one);
 (xxxix) methyltestosterone (17[alpha]-methyl-17[beta]-hydroxyandrost-4-en-3-one);
 (xl) mibolerone (7[alpha],17[alpha]-dimethyl-17[beta]-hydroxyestr-4-en-3-one);
 (xli) 17[alpha]-methyl-[delta]1-dihydrotestosterone (17[beta]-hydroxy-17[alpha]-methyl-5[alpha]-androst-1-en-3-one);
 (xlii) nandrolone (17[beta]-hydroxyestr-4-en-3-one);
 (xliii) 19-nor-4-androstenediol (3[beta],17[beta]-dihydroxyestr-4-ene);
 (xliv) 3[alpha],17[beta]-dihydroxyestr-4-ene; 19-nor-5-androstenediol (3[beta],17[beta]-dihydroxyestr-5-ene);
 (xlv) 3[alpha],17[beta]-dihydroxyestr-5-ene);
 (xlvi) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
 (xlvii) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
 (xlviii) norbolethone (13[beta],17[alpha]-diethyl-17[beta]-hydroxygon-4-en-3-one);
 (xlix) norclostebol (4-chloro-17[beta]-hydroxyestr-4-en-3-one);
 (l) norethandrolone (17[alpha]-ethyl-17[beta]-hydroxyestr-4-en-3-one);
 (li) normethandrolone (17[alpha]-methyl-17[beta]-hydroxyestr-4-en-3-one);
 (lii) oxandrolone (17[alpha]-methyl-17[beta]-hydroxy-2-oxa-5[alpha]-androstan-3-one);
 (liii) oxymesterone (17[alpha]-methyl-4,17[beta]-dihydroxyandrost-4-en-3-one);
 (liv) oxymetholone (17[alpha]-methyl-2-hydroxymethylene-17[beta]-hydroxy-5[alpha]-androstan-3-one);
 (lv) prostanazol (17 beta-hydroxy-5 alpha-androstano[3,2-C]pyrazole);
 (lvi) stanozolol (17[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androst-2-eno[3,2-c]-pyrazole);
 (lvii) stebolone (17[beta]-hydroxy-2-methyl-5[alpha]-androst-1-en-3-one);
 (lviii) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
 (lix) testosterone (17[beta]-hydroxyandrost-4-en-3-one);
 (lx) tetrahydrogestrinone (13[beta],17[alpha]-diethyl-17[beta]-hydroxygon-4,9,11-trien-3-one);
 (lxi) trenbolone (17[beta]-hydroxyestr-4,9,11-trien-3-one);
 (lxii) any salt, ester, or ether of a drug or substance described in this paragraph.

Anabolic steroids are not included if they are: (A) expressly intended for administration through implants to cattle or other nonhuman species; and (B) approved by the United States Food and Drug Administration for that use;

(2) Human growth hormones.

(3) Chorionic gonadotropin, except that a product containing chorionic gonadotropin is not included if it is:

(i) expressly intended for administration to cattle or other nonhuman species; and

(ii) approved by the United States Food and Drug Administration for that use.

(g) Hallucinogenic substances. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product.

(h) Any material, compound, mixture, or preparation containing the following narcotic drug or its salt: buprenorphine.

CHAPTER 73--H. F. No. 3100 (Alec Smith Insulin Affordability Act)

An act relating to health care; requiring a dependent child notice; establishing the Alec Smith Insulin Affordability Act; requiring reports; requiring a public awareness campaign; appropriating money; amending Minnesota Statutes 2019 Supplement, sections 151.06, subdivision 6; 214.122; proposing coding for new law in Minnesota Statutes, chapters 62Q; 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:
Section 1.

CITATION. This act may be cited as the "Alec Smith Insulin Affordability Act."

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

Sec. 2. **[62Q.678] DEPENDENT CHILD NOTICE.** Group health plans and health plan companies that offer group or individual health plans with dependent coverage must provide written notice to an enrollee with dependent child coverage that the dependent child's coverage ends when the child reaches the age of 26. Notice must be sent to the enrollee at the enrollee's last known address at least 60 days before the dependent child reaches the age of 26. The notice must include the date on which coverage ends and information on accessing the MNsure website as applicable.

Sec. 3. Minnesota Statutes 2019 Supplement, section 151.06, subdivision 6, is amended to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) patient assistance programs offered by drug manufacturers, including information on how to access the programs;

(2) the insulin safety net program established in section 151.74, including information on how to access the program;

~~(3)~~ (3) the prescription drug assistance program established by the Minnesota Board of Aging under section [256.975, subdivision 9](#);

~~(3)~~ (4) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

~~(4)~~ (5) availability of providers that are authorized to participate under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b;

~~(5)~~ (6) having a discussion with the pharmacist or the consumer's health care provider about alternatives to a prescribed drug, including a lower cost or generic drug if the drug prescribed is too costly for the consumer; and

~~(6)~~ (7) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board must prepare educational materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The materials must be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by health care practitioners who are licensed to prescribe. The board is not required to provide printed copies of these materials.

(c) The board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established under paragraph (a).

Sec. 4. **[151.74] INSULIN SAFETY NET PROGRAM.**

Subdivision 1. Establishment. (a) By July 1, 2020, each manufacturer must establish procedures to make insulin available in accordance with this section to eligible individuals who are in urgent need of insulin or who are in need of access to an affordable insulin supply.

(b) For purposes of this section, the following definitions apply:

(1) "manufacturer" means a manufacturer engaged in the manufacturing of insulin that is self-administered on an outpatient basis;

(2) "MNsure" means the Board of Directors of MNsure established in chapter 62V;

(3) "navigator" has the meaning provided in section 62V.02; and

(4) "pharmacy" means a pharmacy located in Minnesota and licensed under section 151.19 that operates in the community or outpatient license category under Minnesota Rules, part 6800.0350.

(c) Any manufacturer with an annual gross revenue of \$2,000,000 or less from insulin sales in Minnesota is exempt from this section. To request a waiver under this paragraph, the manufacturer must submit a request to the Board of Pharmacy that includes documentation indicating that the manufacturer is eligible for an exemption.

(d) An insulin product is exempt from this section if the wholesale acquisition cost of the insulin is \$8 or less per milliliter or applicable National Council for Prescription Drug Plan

billing unit, for the entire assessment time period, adjusted annually based on the consumer price index.

Subd. 2. Eligibility for urgent-need safety net program. (a) To be eligible to receive an urgent-need supply of insulin under this section, an individual must attest to:

(1) being a resident of Minnesota;

(2) not being enrolled in medical assistance or MinnesotaCare;

(3) not being enrolled in prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance, to \$75 or less, regardless of the type or amount of insulin prescribed;

(4) not having received an urgent-need supply of insulin through this program within the previous 12 months, unless authorized under subdivision 9; and

(5) being in urgent need of insulin.

(b) For purposes of this subdivision, "urgent need of insulin" means having readily available for use less than a seven-day supply of insulin and in need of insulin in order to avoid the likelihood of suffering significant health consequences.

Subd. 3. Access to urgent-need insulin. (a) MNsure shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subdivision 2. The form shall be accessible through MNsure's website. MNsure shall also make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(b) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification indicating Minnesota residency in the form of a valid Minnesota identification card, driver's license, or permit. If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(c) Upon receipt of a completed and signed application, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy must notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(d) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

(e) The pharmacy may collect an insulin co-payment from the individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed \$35 for the 30-day supply of insulin dispensed.

(f) The pharmacy shall also provide each eligible individual with the information sheet described in subdivision 7 and a list of trained navigators provided by the Board of Pharmacy for the individual to contact if the individual is in need of accessing ongoing insulin coverage options, including assistance in:

(1) applying for medical assistance or MinnesotaCare;

(2) applying for a qualified health plan offered through MNsure, subject to open and special enrollment periods;

(3) accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

(4) accessing insulin manufacturers' patient assistance programs, co-payment assistance programs, and other foundation-based programs.

(g) The pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

Subd. 4. Continuing safety net program; general. (a) Each manufacturer shall make a patient assistance program available to any individual who meets the requirements of this subdivision. Each manufacturer's patient assistance programs must meet the requirements of this section. Each manufacturer shall provide the Board of Pharmacy with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing their patient assistance program.

(b) To be eligible to participate in a manufacturer's patient assistance program, the individual must:

(1) be a Minnesota resident with a valid Minnesota identification card that indicates Minnesota residency in the form of a Minnesota identification card or driver's license or permit. If the individual is under the age of 18, the individual's parent or legal guardian must provide proof of residency;

(2) have a family income that is equal to or less than 400 percent of the federal poverty guidelines;

(3) not be enrolled in medical assistance or MinnesotaCare;

(4) not be eligible to receive health care through a federally funded program or receive prescription drug benefits through the Department of Veterans Affairs; and

(5) not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing that an enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance to \$75 or less, regardless of the type or amount of insulin needed.

(c) Notwithstanding the requirement in paragraph (b), clause (4), an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if the individual has spent \$1,000 on prescription drugs in the current calendar year and meets the eligibility requirements in paragraph (b), clauses (1) to (3).

(d) An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer; apply through the individual's health care practitioner, if the practitioner participates; or contact a trained navigator for assistance in finding a long-term insulin supply solution, including assistance in applying to a manufacturer's patient assistance program.

Subd. 5. Continuing safety net program; manufacturer's responsibilities. (a) Upon receipt of an application for the manufacturer's patient assistance program, the manufacturer shall process the application and determine eligibility. The manufacturer shall notify the applicant of the determination within ten business days of receipt of the application. If necessary, the manufacturer may request additional information from the applicant. If additional information is needed, the manufacturer must notify the applicant within five business days of receipt of the application as to what information is being requested. Within three business days of receipt of the requested information, the manufacturer must determine eligibility and notify the applicant of the determination. If the individual has been determined to be not eligible, the manufacturer must include the reasons for denying eligibility in the notification. The individual may seek an appeal of the determination in accordance with subdivision 8.

(b) If the individual is determined to be eligible, the manufacturer shall provide the individual with an eligibility statement or other indication that the individual has been determined eligible for the manufacturer's patient assistance program. An individual's eligibility is valid for 12 months, and is renewable upon a redetermination of eligibility.

(c) If the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer may determine that the individual's insulin needs are better addressed through the use of the manufacturer's co-payment assistance program, in which case, the manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy. In no instance shall an eligible individual be required to pay more than the co-payment amount specified under subdivision 6, paragraph (e).

Subd. 6. Continuing safety net program; process. (a) The individual shall submit to a pharmacy the statement of eligibility provided by the manufacturer under subdivision 5, paragraph (b). Upon receipt of an individual's eligibility status, the pharmacy shall submit an order containing the name of the insulin product and the daily dosage amount as contained in a valid prescription to the product's manufacturer.

(b) The pharmacy must include with the order to the manufacturer the following information:

- (1) the pharmacy's name and shipping address;
- (2) office telephone number, fax number, e-mail address, and contact name; and
- (3) any specific days or times when deliveries are not accepted by the pharmacy.

(c) Upon receipt of an order from a pharmacy and the information described in paragraph (b), the manufacturer shall send to the pharmacy a 90-day supply of insulin as ordered, unless a lesser amount is requested in the order, at no charge to the individual or pharmacy.

(d) Except as authorized under paragraph (e), the pharmacy shall provide the insulin to the individual at no charge to the individual. The pharmacy shall not provide insulin received from the manufacturer to any individual other than the individual associated with the specific order. The pharmacy shall not seek reimbursement for the insulin received from the manufacturer or from any third-party payer.

(e) The pharmacy may collect a co-payment from the individual to cover the pharmacy's costs for processing and dispensing in an amount not to exceed \$50 for each 90-day supply if the insulin is sent to the pharmacy.

(f) The pharmacy may submit to a manufacturer a reorder for an individual if the individual's eligibility statement has not expired. Upon receipt of a reorder from a pharmacy, the manufacturer must send to the pharmacy an additional 90-day supply of the product, unless a lesser amount is requested, at no charge to the individual or pharmacy if the individual's eligibility statement has not expired.

(g) Notwithstanding paragraph (c), a manufacturer may send the insulin as ordered directly to the individual if the manufacturer provides a mail order service option.

Subd. 7. Board of Pharmacy and MNsure responsibilities. (a) The Board of Pharmacy shall develop an information sheet to post on its website and provide a link to the information sheet on the board's website for pharmacies, health care practitioners, hospital emergency departments, urgent care clinics, and community health clinics. The information sheet must contain:

(1) a description of the urgent-need insulin safety net program, including how to access the program;

(2) a description of each insulin manufacturer's patient assistance program and cost-sharing assistance program, including contact information on accessing the assistance programs for each manufacturer;

(3) information on how to contact a trained navigator for assistance in applying for medical assistance, MinnesotaCare, a qualified health plan, or an insulin manufacturer's patient assistance programs;

(4) information on how to contact the Board of Pharmacy if a manufacturer determines that an individual is not eligible for the manufacturer's patient assistance program; and

(5) notification that an individual in need of assistance may contact their local county social service department for more information or assistance in accessing ongoing affordable insulin options.

(b) The board shall also inform each individual who accesses urgent-need insulin through the insulin safety net program or accesses a manufacturer's patient assistance program that the individual may participate in a survey conducted by the Department of Health regarding satisfaction with the program. The board shall provide contact information for the individual to learn more about the survey and how to participate. This information may be included on the information sheet described in paragraph (a).

(c) MNsure, in consultation with the Board of Pharmacy and the commissioner of human services, shall develop a training program for navigators to provide navigators with information and resources necessary to assist individuals in accessing appropriate long-term insulin options.

(d) MNsure, in consultation with the Board of Pharmacy, shall compile a list of navigators who have completed the training program, and who are available to assist individuals in accessing affordable insulin coverage options. The list shall be made available through the board's website and to pharmacies and health care practitioners who dispense and prescribe insulin.

(e) If a navigator assists an individual in accessing an insulin manufacturer's patient assistance program, MNsure, within the available appropriation, shall pay the navigator a onetime application assistance bonus of no less than \$25. If a navigator receives a payment per enrollee of an assistance bonus under section 62V.05, subdivision 4, or 256.962, subdivision 5, the navigator shall not receive compensation under this paragraph.

Subd. 8. Dispute resolution. (a) If an individual disagrees with a manufacturer's determination of eligibility under subdivision 5, the individual may contact the Board of Pharmacy to request the use of a three-person panel to review eligibility. The panel shall be composed of three members of the board. The individual requesting the review shall submit to the board, with the request, all documents submitted by the individual to the manufacturer. The board shall provide the panel with the documents submitted by the individual. The panel shall render a decision within ten business days of receipt of all the necessary documents from the individual. The decision of the panel is final.

(b) If the panel determines that the individual is eligible, the manufacturer shall provide the individual with an eligibility statement in accordance with subdivision 5.

Subd. 9. Additional 30-day urgent-need insulin supply. (a) If an individual has applied for medical assistance or MinnesotaCare but has not been determined eligible or has been determined eligible but coverage has not become effective or the individual has been determined ineligible for the manufacturers' patient assistance program by the manufacturer and the individual has requested a review pursuant to subdivision 8 but the panel has not rendered a decision, the individual may access urgent-need insulin under subdivision 3 if the individual is in urgent need of insulin as defined under subdivision 2, paragraph (b).

(b) To access an additional 30-day supply of insulin, the individual must attest to the pharmacy that the individual meets the requirements of paragraph (a) and must comply with subdivision 3, paragraph (b).

Subd. 10. Penalty. (a) If a manufacturer fails to comply with this section, the board may assess an administrative penalty of \$200,000 per month of noncompliance, with the penalty increasing to \$400,000 per month if the manufacturer continues to be in noncompliance after six months, and increasing to \$600,000 per month if the manufacturer continues to be in noncompliance after one year. The penalty shall remain at \$600,000 per month for as long as the manufacturer continues to be in noncompliance.

(b) In addition, a manufacturer is subject to the administrative penalties specified in paragraph (a) if the manufacturer fails to:

(1) provide a hotline for individuals to call or access between 8 a.m. and 10 p.m. on weekdays and between 10 a.m. and 6 p.m. on Saturdays; and

(2) list on the manufacturer's website the eligibility requirements for the manufacturer's patient assistance programs for Minnesota residents.

(c) Any penalty assessed under this subdivision shall be deposited in a separate insulin assistance account in the special revenue fund.

Subd. 11. Data. (a) Any data collected, created, received, maintained, or disseminated by the Board of Pharmacy, the legislative auditor, the commissioner of health, MNsure, or a trained navigator under this section related to an individual who is seeking to access urgent-need insulin or participate in a manufacturer's patient assistance program under this section is classified as private data on individuals as defined in section 13.02, subdivision 12, and may not be retained for longer than ten years.

(b) A manufacturer must maintain the privacy of all data received from any individual applying for the manufacturer's patient assistance program under this section and is prohibited from selling, sharing, or disseminating data received under this section unless required to under this section or the individual has provided the manufacturer with a signed authorization.

Subd. 12. State and federal anti-kickback provisions. (a) The conduct of any person or entity participating in or administering the insulin safety net program under this section is not subject to liability under section 62J.23, subdivisions 1 and 2.

(b) No person or entity, including but not limited to any drug manufacturer, pharmacy, pharmacist, or third-party administrator, as part of the person's or entity's participation in or administration of the insulin safety net program established under this section, shall request or seek, or cause another to request or seek, any reimbursement or other compensation for which payment may be made in whole or in part under a federal health care program, as defined in United States Code, title 42, section 1320a-7b(f).

Subd. 13. Reports. (a) By February 15 of each year, beginning February 15, 2021, each manufacturer shall report to the Board of Pharmacy the following:

(1) the number of Minnesota residents who accessed and received insulin on an urgent-need basis under this section in the preceding calendar year;

(2) the number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Minnesota residents who the manufacturer determined were ineligible for their patient assistance program; and

(3) the value of the insulin provided by the manufacturer under clauses (1) and (2).

For purposes of this paragraph, "value" means the wholesale acquisition cost of the insulin provided.

(b) By March 15 of each year, beginning March 15, 2021, the Board of Pharmacy shall submit the information reported in paragraph (a) to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The board shall also include in the report any administrative penalties assessed under subdivision 10, including the name of the manufacturer and amount of the penalty assessed.

Subd. 14. Program review; legislative auditor. (a) The legislative auditor is requested to conduct a program review to determine:

(1) whether the manufacturers are meeting the responsibilities required under this section, including but not limited to:

(i) reimbursing pharmacies for urgent-need insulin dispensed under subdivision 3;

(ii) determining eligibility in a timely manner and notifying the individuals as required under subdivision 5; and

(iii) providing pharmacies with insulin product under the manufacturers' patient assistance program; and

(2) whether the training program developed for navigators is adequate and easily accessible for navigators interested in becoming trained, and that there is a sufficient number of trained navigators to provide assistance to individuals in need of assistance.

(b) The legislative auditor may access application forms retained by pharmacies under subdivision 3, paragraph (g), to determine whether urgent-need insulin is being dispensed in accordance with this section.

Subd. 15. Program satisfaction; surveys. (a) The commissioner of health, in consultation with the Board of Pharmacy and individuals who are insulin-dependent, shall develop and conduct a survey of individuals who have accessed urgent-need insulin through the program and who are accessing or have accessed a manufacturers' patient assistance program since the commencement of the insulin safety net program; and a survey of pharmacies that have dispensed insulin on an urgent-need basis under the program and have participated in the manufacturers' patient assistance programs under this section.

(b) The survey for individuals shall cover overall satisfaction with the program, including but not limited to:

(1) accessibility to urgent-need insulin;

(2) adequacy of the information sheet and list of navigators received from the pharmacy;

(3) whether the individual contacted a trained navigator and, if so, if the navigator was helpful and knowledgeable;

(4) whether the individual accessed the manufacturers' patient assistance program and, if so, how easy was it to access application forms, apply to the manufacturers' programs, and receive the insulin product from the pharmacy; and

(5) whether the individual is still in need of a long-term solution for affordable insulin.

(c) The survey for the pharmacies shall include, but is not limited to:

(1) timeliness of reimbursement from the manufacturers for urgent-need insulin dispensed by the pharmacy;

(2) ease in submitting insulin product orders to the manufacturers; and

(3) timeliness of receiving insulin orders from the manufacturers.

(d) The commissioner may contract with a nonprofit entity to develop and conduct the survey and to evaluate the survey results.

(e) By January 15, 2022, the commissioner shall submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance containing the results of the surveys.

Subd. 16. Legislative review; sunset. (a) The legislature shall review the reports from the Board of Pharmacy under subdivision 13, paragraph (b); the program review by the legislative auditor under subdivision 14; and the report from the commissioner of health on the survey results under subdivision 15, paragraph (e); and any other relevant information related to the cost, access, and affordability of insulin, and make a determination on whether there is a need for the continued implementation of the long-term safety net program described in subdivisions 4 to 6 to ensure that Minnesota residents have access to affordable emergency and long-term insulin or whether the market has sufficiently changed to where the continuation of this program is no longer needed past December 31, 2024, or whether there are more appropriate options available to ensure access to affordable insulin for all Minnesota residents.

(b) Subdivisions 4 to 6, 8, and 9 expire December 31, 2024, unless the legislature affirmatively determines the need for the continuation of the long-term safety net program described in subdivisions 4 to 6.

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

Sec. 5. Minnesota Statutes 2019 Supplement, section 214.122, is amended to read:

214.122 INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS. (a) The Board of Medical Practice and the Board of Nursing shall at least annually inform licensees who are authorized to prescribe prescription drugs of the availability of the Board of Pharmacy's website that contains information on resources and programs to assist patients with the cost of prescription drugs. The boards shall provide licensees with the website address established by the Board of Pharmacy under section [151.06, subdivision 6](#), and the materials described under section [151.06, subdivision 6](#), paragraph (b). The boards shall also ensure that licensees are provided with information on the insulin safety net program established in section 151.74, and a link to the Board of Pharmacy's information sheet on how patients can apply for the program.

(b) Licensees must make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established by the Board of Pharmacy under section [151.06, subdivision 6](#).

Sec. 6. **PUBLIC AWARENESS CAMPAIGN.** The Board of Directors of MNsure shall conduct a public awareness campaign to create awareness of the insulin safety net program established under Minnesota Statutes, section 151.74, including how to access insulin if an individual is in urgent need, and the availability of insulin manufacturers' patient assistance programs.

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

Sec. 7. **SEVERABILITY.** If any provision of this act is found to be unconstitutional or void, the remaining provisions of this act are valid.

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

Sec. 8. **APPROPRIATIONS.** (a) \$297,000 is appropriated in fiscal year 2020 from the health care access fund to the Board of Directors of MNsure to train navigators to assist individuals and provide compensation as required under Minnesota Statutes, section 151.74, subdivision 7. Of this appropriation, \$108,000 is for implementing the training requirements for navigators and \$189,000 is for application assistance bonus payments. This is a onetime appropriation and is available until December 31, 2024.

(b) \$250,000 is appropriated in fiscal year 2020 from the health care access fund to the Board of Directors of MNsure for a public awareness campaign for the insulin safety net program established under Minnesota Statutes, section 151.74. This is a onetime appropriation and is available until December 31, 2024.

(c) \$76,000 is appropriated in fiscal year 2021 from the health care access fund to the Board of Pharmacy to implement Minnesota Statutes, section 151.74. The base for this appropriation is \$76,000 in fiscal year 2022; \$76,000 in fiscal year 2023; \$76,000 in fiscal year 2024; \$38,000 in fiscal year 2025; and \$0 in fiscal year 2026.

(d) \$136,000 in fiscal year 2021 is appropriated from the health care access fund to the commissioner of health to implement the survey to assess program satisfaction in Minnesota Statutes, section 151.74, subdivision 12. The base for this appropriation is \$80,000 in fiscal year 2022 and \$0 in fiscal year 2023. This is a onetime appropriation.

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

Presented to the governor April 14, 2020

Signed by the governor April 15, 2020, 11:58 a.m.

Changes related to the fees paid by medical gas facilities, which have been reduced:

CHAPTER 71--H.F. No. 4531 ARTICLE 2

Sec. 5. Minnesota Statutes 2019 Supplement, 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, \$175;
- (2) pharmacist licensed by reciprocity, \$275;
- (3) pharmacy intern, \$50;
- (4) pharmacy technician, \$50;
- (5) pharmacy, \$260;
- (6) drug wholesaler, legend drugs only, \$5,260;
- (7) drug wholesaler, legend and nonlegend drugs, \$5,260;
- (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260;
- (9) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (10) third-party logistics provider, \$260;
- (11) drug manufacturer, nonopiate legend drugs only, \$5,260;
- (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;
- (13) drug manufacturer, nonlegend or veterinary legend drugs, \$5,260;
- (14) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (15) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;
- (16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, \$55,000;
- (17) medical gas distributor, ~~\$5,260~~ \$260;
- (18) controlled substance researcher, \$75; and
- (19) pharmacy professional corporation, \$150.

EFFECTIVE DATE. This section is effective June 1, 2020 and applies to any license issued on or after that date.

Sec. 6. Minnesota Statutes 2019 Supplement, 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, \$175;
- (2) pharmacy technician, \$50;
- (3) pharmacy, \$260;
- (4) drug wholesaler, legend drugs only, \$5,260;

- (5) drug wholesaler, legend and nonlegend drugs, \$5,260;
- (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260;
- (7) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (8) third-party logistics provider, \$260;
- (9) drug manufacturer, nonopiate legend drugs only, \$5,260;
- (10) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;
- (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$5,260;
- (12) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each additional facility;
- (13) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;
- (14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, \$55,000;
- (15) medical gas distributor, ~~\$5,260~~ \$260;
- (16) controlled substance researcher, \$75; and
- (17) pharmacy professional corporation, \$100.

EFFECTIVE DATE. This section is effective June 1, 2020 and applies to any license renewed on or after that date.

Sec. 7. Minnesota Statutes 2019 Supplement, section 151.065, subdivision 7, is amended to read:

Subd. 7. Deposit of fees. (a) The license fees collected under this section, with the exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state government special revenue fund.

(b) \$5,000 of each fee collected under subdivision 1, clauses (6) to (9), and (11) to (15) ~~and (17)~~, and subdivision 3, clauses (4) to (7), and (9) to (13) ~~and (15)~~, and the fees collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response account established in section 256.043.

(c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14), are reduced, \$5,000 of the reduced fee shall be deposited in the opiate epidemic response account in section 256.043.

EFFECTIVE DATE. This section is effective June 1, 2020.

CHAPTER 71--H.F. No. 4531

Changes removing the time limits for the filling of opiate prescriptions:

Sec. 8. Minnesota Statutes 2019 Supplement, section 152.11, subdivision 1, is amended to read:

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

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

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

(d) Every licensed pharmacy that dispenses a controlled substance prescription shall retain the original prescription in a file for a period of not less than two years, open to inspection by any officer of the state, county, or municipal government whose duty it is to aid and assist with the enforcement of this chapter. An original electronic or facsimile prescription may be stored in an electronic database, provided that the database provides a means by which original prescriptions can be retrieved, as transmitted to the pharmacy, for a period of not less than two years.

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

~~(f) No prescription for an opiate or narcotic pain reliever listed in Schedules II through IV of section [152.02](#) may be initially dispensed more than 30 days after the date on which the prescription was issued. No subsequent refills indicated on a prescription for a Schedule III or IV~~

~~opiate or narcotic pain reliever may be dispensed more than 30 days after the previous date on which the prescription was initially filled or refilled. After the authorized refills for Schedule III or IV opiate or narcotic pain relievers have been used up or are expired, no additional authorizations may be accepted for that prescription. If continued therapy is necessary, a new prescription must be issued by the prescriber.~~

EFFECTIVE DATE. This section is effective the day following enactment