MINNESOTA
BOARD OF PHARMACY

Summary of 2021 Legislation

Governor Tim Walz signed bills that were passed by the Minnesota Legislature during the 2021 Regular and Special Sessions. The bills have several provisions that will affect licensees and registrants of the Board. Some of the changes are described below. (Changes that are under the jurisdiction of the Minnesota Department of Human Services are not included, since DHS will most likely provide information to pharmacists and pharmacies about those changes). The relevant language from the bill is included in Appendix A.

Temperature monitoring for drug deliveries

In addition to complying with the requirements of Minnesota Rules, part 6800.3000, a mail order or specialty pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must ensure that the drug is delivered in compliance with temperature requirements established by the manufacturer of the drug. The pharmacy must develop written policies and procedures that are consistent with United States Pharmacopeia, chapters 1079 and 1118, and with nationally recognized standards issued by standard-setting or accreditation organizations recognized by the board through guidance. The policies and procedures must be provided to the board upon request.

The Board must also conduct a study to determine the appropriateness and feasibility of requiring mail order and specialty pharmacies to enclose in each medication's packaging a method by which the patient can easily detect improper storage or temperature variations that may have occurred during the delivery of a medication.

Issuance of prescriptions for drugs used for medication-assisted therapy

An in-person examination of a patient is not necessary for drugs used for medication-assisted therapy for a substance use disorder (i.e., buprenorphine used for MAT) as long as the prescribing practitioner has completed an examination of the patient via telehealth as defined in section 62A.673, subdivision 2, paragraph (h). Note that a prescription for buprenorphine issued for the treatment of pain does require that an in-person examination of the patient has occurred (see. Minn. Stats §151.37, subd. 2 for specifics).

Labeling of products that contain cannabinoids extracted from hemp

Minn. Stats. §151.72 was amended to allow the label of a product that contains a cannabinoid extracted from hemp to use a scannable bar code or QR code that links to the manufacturer's website. The website must still provide the following information:

(1) the name, location, contact phone number, and website of the manufacturer of the product;

(2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product; and

(3) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed.

The other requirements of Minn. Stats. §151.72 remain unchanged, including the testing requirements. Also, only those products that contain *non-intoxicating* cannabinoids that are *extracted directly* from hemp can be legally sold in Minnesota (provided that the product is not a food). The Board is aware that products containing Δ8-THC are being sold in Minnesota. Δ8-THC is intoxicating, and it is the Board's understanding that it can't be directly extracted from hemp in any significant quantity. Instead, it is produced by conversion from cannabidiol (CBD) that is extracted from hemp. Consequently, Minn. Stats. §151.72 does not allow for the sale of products containing Δ8-THC. That section applies to the sale of any product that contains nonintoxicating cannabinoids *extracted* (not indirectly derived) from hemp.

Provisions related to medical gases

The definition of "medical gases" found in Minn. Stats. §151.01 was amended and new definitions of medical gas manufacturer, medical gas wholesaler, and medical dispenser were added to that section. Minn. Stats. §151.191 was added to Chapter 151. It replaces Minn. Stats. §151.19, subd. 3 and creates licensing requirements for all types of medical gas facilities.

Medication repository

Minn. Stats. §151.555 was amended to allow RoundtableRx, Minnesota's Medication Repository, to accept the donation of over-the-counter (nonprescription) medications that meet the criteria established in that section for donations. Also, the central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

Pharmacy benefit manager gag clause

Minn. Stats. §62W.11, which is under the jurisdiction of the Minnesota Department of Commerce, was amended to make the following changes:

- A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount ~~and~~, the pharmacy's own usual and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug.

- A pharmacy benefit manager must not prohibit a pharmacist or pharmacy from discussing with a health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the pharmacy benefit manager or the pharmacy's acquisition cost for a prescription drug.

APPENDIX A

From Minnesota Session Law 2021, Regular Session, Chapter 30

Article 4, Sections 1 through 5. Medical gas facility licensing.

Section 1. Minnesota Statutes 2020, section 151.01, subdivision 29, is amended to read:

Subd. 29. ~~**Legend**~~ **Medical gas.** "~~Legend~~ Medical gas" means ~~a liquid or gaseous substance used for medical purposes and that is required by federal law to be dispensed only pursuant to the prescription of a licensed practitioner~~ any gas or liquid manufactured or stored in a liquefied, nonliquefied, or cryogenic state that:

(1) has a chemical or physical action in or on the human body or animals or is used in conjunction with medical gas equipment; and

(2) is intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of disease.

Sec. 2. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 29a. **Medical gas manufacturer.** "Medical gas manufacturer" means any person:

(1) originally manufacturing a medical gas by chemical reaction, physical separation, compression of atmospheric air, purification, or other means;

(2) filling a medical gas into a dispensing container via gas to gas, liquid to gas, or liquid to liquid processes;

(3) combining two or more medical gases into a container to form a medically appropriate mixture; or

(4) filling a medical gas via liquid to liquid into a final use container at the point of use.

Sec. 3. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 29b. **Medical gas wholesaler.** "Medical gas wholesaler" means any person who sells a medical gas to another business or entity for the purpose of reselling or providing that medical gas to the ultimate consumer or patient.

Sec. 4. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 29c. **Medical gas dispenser.** "Medical gas dispenser" means any person, other than a licensed practitioner or pharmacy, who sells or provides a medical gas directly to the ultimate consumer or patient via a valid prescription.

Sec. 5. **[151.191] LICENSING MEDICAL GAS FACILITIES; FEES; PROHIBITIONS.**

Subdivision 1. **Medical gas manufacturers; requirements.** (a) No person shall act as a medical gas manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

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

(c) A license must not be issued or renewed for a medical gas manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) A license must not be issued or renewed for a medical gas 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 standards for the licensure of a medical gas manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(e) The board must require a separate license for each facility located within the state at which medical gas manufacturing occurs and for each facility located outside of the state at which medical gases that are shipped into the state are manufactured.

(f) Prior to the issuance of an initial or renewed license for a medical gas manufacturing facility, the board may require the facility to pass an inspection conducted by an authorized representative of the board. In the case of a medical gas 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, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(g) A duly licensed medical gas manufacturing facility may also wholesale or dispense any medical gas that is manufactured by the licensed facility, or manufactured or wholesaled by another properly licensed medical gas facility, without also obtaining a medical gas wholesaler license or medical gas dispenser registration.

(h) The filling of a medical gas into a final use container, at the point of use and by liquid to liquid transfer, is permitted as long as the facility used as the base of operations is duly licensed as a medical gas manufacturer.

Subd. 2. **Medical gas wholesalers; requirements.**

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

(b) Application for a medical gas wholesaler license under this section must be made in a manner specified by the board.

(c) A license must not be issued or renewed for a medical gas wholesaler unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) A license must not be issued or renewed for a medical gas wholesaler 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 standards for the licensure of a medical gas wholesaler that is not required to be licensed or registered by the state in which it is physically located.

(e) The board must require a separate license for each facility located within the state at which medical gas wholesaling occurs and for each facility located outside of the state from which medical gases that are shipped into the state are wholesaled.

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

(g) A duly licensed medical gas wholesaling facility may also dispense any medical gas that is manufactured or wholesaled by another properly licensed medical gas facility.

Subd. 3.

Medical gas dispensers; requirements. (a) A person or establishment not licensed as a pharmacy, practitioner, medical gas manufacturer, or medical gas dispenser must not engage in the dispensing of medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration must be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board.

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

(c) A registration must not be issued or renewed for a medical gas 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. A license must not be issued for a medical gas dispenser located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when dispensing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) A registration must not be issued or renewed for a medical gas 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 establish standards for the registration of a medical gas dispenser that is not required to be licensed or registered by the state in which it is physically located.

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

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

(g) A facility holding a medical gas dispenser registration must not engage in the manufacturing or wholesaling of medical gases, except that a medical gas dispenser may transfer medical gases from one of its duly registered facilities to other duly registered medical gas manufacturing, wholesaling, or dispensing facilities owned or operated by that same company, without requiring a medical gas wholesaler license.

Sec. 6. **REPEALER.** Minnesota Statutes 2020, section 151.19, subdivision 3, is repealed.

Article 5, Section 1. Gag Clause Prohibition

Section 1. Minnesota Statutes 2020, section 62W.11, is amended to read:

62W.11 GAG CLAUSE PROHIBITION. (a) No contract between a pharmacy benefit manager or health carrier and a pharmacy or pharmacist shall prohibit, restrict, or penalize a pharmacy or pharmacist from disclosing to an enrollee any health care information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment; the risks or alternatives; the availability of alternative therapies, consultations, or tests; the decision of utilization reviewers or similar persons to authorize or deny services; the process that is used to authorize or deny health care services or benefits; or information on financial incentives and structures used by the health carrier or pharmacy benefit manager.

(b) A pharmacy or pharmacist must provide to an enrollee information regarding the enrollee's total cost for each prescription drug dispensed where part or all of the cost of the prescription is being paid or reimbursed by the employer-sponsored plan or by a health carrier or pharmacy benefit manager, in accordance with section 151.214, subdivision 1.

(c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount ~~and~~, the pharmacy's own usual and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug.

(d) A pharmacy benefit manager must not prohibit a pharmacist or pharmacy from discussing with a health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the pharmacy benefit manager or the pharmacy's acquisition cost for a prescription drug.

~~(d)~~ (e) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy's usual and customary price when that amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee's health plan.

Article 5, Sections 2 – 4. Medication Repository

Sec. 2.
Minnesota Statutes 2020, section 151.555, subdivision 1, is amended to read:
Subdivision 1. **Definitions.** (a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Central repository" means a wholesale distributor that meets the requirements under subdivision 3 and enters into a contract with the Board of Pharmacy in accordance with this section.

(c) "Distribute" means to deliver, other than by administering or dispensing.

(d) "Donor" means:

(1) a health care facility as defined in this subdivision;

(2) a skilled nursing facility licensed under chapter 144A;

(3) an assisted living facility registered under chapter 144D where there is centralized storage of drugs and 24-hour on-site licensed nursing coverage provided seven days a week;

(4) a pharmacy licensed under section 151.19, and located either in the state or outside the state;

(5) a drug wholesaler licensed under section 151.47;

(6) a drug manufacturer licensed under section 151.252; or

(7) an individual at least 18 years of age, provided that the drug or medical supply that is donated was obtained legally and meets the requirements of this section for donation.

(e) "Drug" means any prescription drug that has been approved for medical use in the United States, is listed in the United States Pharmacopoeia or National Formulary, and meets the criteria established under this section for donation; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

(f) "Health care facility" means:

(1) a physician's office or health care clinic where licensed practitioners provide health care to patients;

(2) a hospital licensed under section 144.50;

(3) a pharmacy licensed under section 151.19 and located in Minnesota; or

(4) a nonprofit community clinic, including a federally qualified health center; a rural health clinic; public health clinic; or other community clinic that provides health care utilizing a sliding fee scale to patients who are low-income, uninsured, or underinsured.

(g) "Local repository" means a health care facility that elects to accept donated drugs and medical supplies and meets the requirements of subdivision 4.

(h) "Medical supplies" or "supplies" means any prescription and nonprescription medical supplies needed to administer a prescription drug.

(i) "Original, sealed, unopened, tamper-evident packaging" means packaging that is sealed, unopened, and tamper-evident, including a manufacturer's original unit dose or unit-of-use container, a repackager's original unit dose or unit-of-use container, or unit-dose packaging prepared by a licensed pharmacy according to the standards of Minnesota Rules, part 6800.3750.

(j) "Practitioner" has the meaning given in section 151.01, subdivision 23, except that it does not include a veterinarian.

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

Sec. 3. Minnesota Statutes 2020, section 151.555, subdivision 7, is amended to read:

Subd. 7. **Standards and procedures for inspecting and storing donated prescription drugs and supplies.**

(a) A pharmacist or authorized practitioner who is employed by or under contract with the central repository or a local repository shall inspect all donated prescription drugs and supplies before the drug or supply is dispensed to determine, to the extent reasonably possible in the professional judgment of the pharmacist or practitioner, that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe and suitable for dispensing, has not been subject to a recall, and meets the requirements for donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an inspection record stating that the requirements for donation have been met. If a local repository receives drugs and supplies from the central repository, the local repository does not need to reinspect the drugs and supplies.

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory. ~~If donated drugs or supplies are not inspected immediately upon receipt, a repository must quarantine the donated drugs or supplies separately from all dispensing stock until the donated drugs or supplies have been inspected and (1) approved for dispensing under the program; (2) disposed of pursuant to paragraph (c); or (3) returned to the donor pursuant to paragraph (d).~~

(c) The central repository and local repositories shall dispose of all prescription drugs and medical supplies that are not suitable for donation in compliance with applicable federal and state statutes, regulations, and rules concerning hazardous waste.

(d) In the event that controlled substances or prescription drugs that can only be dispensed to a patient registered with the drug's manufacturer are shipped or delivered to a central or local repository for donation, the shipment delivery must be documented by the

repository and returned immediately to the donor or the donor's representative that provided the drugs.

(e) Each repository must develop drug and medical supply recall policies and procedures. If a repository receives a recall notification, the repository shall destroy all of the drug or medical supply in its inventory that is the subject of the recall and complete a record of destruction form in accordance with paragraph (f). If a drug or medical supply that is the subject of a Class I or Class II recall has been dispensed, the repository shall immediately notify the recipient of the recalled drug or medical supply. A drug that potentially is subject to a recall need not be destroyed if its packaging bears a lot number and that lot of the drug is not subject to the recall. If no lot number is on the drug's packaging, it must be destroyed.

(f) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 8, are subject to a recall under paragraph (e), or are not suitable for donation shall be maintained by the repository for at least ~~five~~ two years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

(2) the name, strength, and quantity of the drug destroyed; and

(3) the name of the person or firm that destroyed the drug.

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

Sec. 4. Minnesota Statutes 2020, section 151.555, subdivision 11, is amended to read:

Subd. 11. **Forms and record-keeping requirements.** (a) The following forms developed for the administration of this program shall be utilized by the participants of the program and shall be available on the board's website:

(1) intake application form described under subdivision 5;

(2) local repository participation form described under subdivision 4;

(3) local repository withdrawal form described under subdivision 4;

(4) drug repository donor form described under subdivision 6;

(5) record of destruction form described under subdivision 7; and

(6) drug repository recipient form described under subdivision 8.

(b) All records, including drug inventory, inspection, and disposal of donated prescription drugs and medical supplies, must be maintained by a repository for a minimum of ~~five~~ two years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

(c) Data collected by the drug repository program from all local repositories shall be submitted quarterly or upon request to the central repository. Data collected may consist of the information, records, and forms required to be collected under this section.

(d) The central repository shall submit reports to the board as required by the contract or upon request of the board.

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

Sec. 5. Minnesota Statutes 2020, section 151.555, is amended by adding a subdivision to read:

Subd. 14. **Cooperation.** The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

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

From Minnesota Session Law 2021, Special Session, Chapter 7

Article 5, Sections 1, 2, 4, and 6. Opiate Product Registration Fee Program.

Section 1. Minnesota Statutes 2020, section 16A.151, subdivision 2, is amended to read:

Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific injured persons or entities, this section does not prohibit distribution of money to the specific injured persons or entities on whose behalf the litigation or settlement efforts were initiated. If money recovered on behalf of injured persons or entities cannot reasonably be distributed to those persons or entities because they cannot readily be located or identified or because the cost of distributing the money would outweigh the benefit to the persons or entities, the money must be paid into the general fund.

(b) Money recovered on behalf of a fund in the state treasury other than the general fund may be deposited in that fund.

(c) This section does not prohibit a state official from distributing money to a person or entity other than the state in litigation or potential litigation in which the state is a defendant or potential defendant.

(d) State agencies may accept funds as directed by a federal court for any restitution or monetary penalty under United States Code, title 18, section 3663(a)(3), or United States Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue account and are appropriated to the commissioner of the agency for the purpose as directed by the federal court.

(e) Tobacco settlement revenues as defined in section 16A.98, subdivision 1, paragraph (t), may be deposited as provided in section 16A.98, subdivision 12.

(f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, ~~against one or more opioid manufacturers or opioid wholesale drug distributors~~ related

to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall notify the chairs and ranking minority members of the Finance Committee in the senate and the Ways and Means Committee in the house of representatives that an account has been created. Notwithstanding section 11A.20, all investment income and all investment losses attributable to the investment of this account shall be credited to the account. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section 151.065, subdivision 1, clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response fund under section 256.043 an amount that ensures that $20,940,000 each fiscal year is available for distribution in accordance with section 256.043, ~~subdivisions 2 and~~ subdivision 3.

(g) Notwithstanding paragraph (f), if money is received from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state or a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency against a consulting firm working for an opioid manufacturer or opioid wholesale drug distributor and deposited into the separate account created under paragraph (f), the commissioner shall annually transfer from the separate account to the opiate epidemic response fund under section 256.043 an amount equal to the estimated amount submitted to the commissioner by the Board of Pharmacy in accordance with section 151.066, subdivision 3, paragraph (b). The amount transferred shall be included in the amount available for distribution in accordance with section 256.043, subdivision 3. This transfer shall occur each year until the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, or the money deposited in the account in accordance with this paragraph has been transferred, whichever occurs first.

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

Sec. 2. Minnesota Statutes 2020, section 151.066, subdivision 3, is amended to read:

Subd. 3. **Determination of an opiate product registration fee.** (a) The board shall annually assess an opiate product registration fee on any manufacturer of an opiate that annually sells, delivers, or distributes an opiate within or into the state 2,000,000 or more units as reported to the board under subdivision 2.

(b) For purposes of assessing the annual registration fee under this section and determining the number of opiate units a manufacturer sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for medication-assisted therapy for substance use disorders. If there is money deposited into the separate account as described in section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner of management and budget an estimate of the difference in the annual fee revenue collected under this section due to this exception.

(c) The annual registration fee for each manufacturer meeting the requirement under paragraph (a) is $250,000.

~~(c)~~ (d) In conjunction with the data reported under this section, and notwithstanding section 152.126, subdivision 6, the board may use the data reported under section 152.126, subdivision 4, to determine which manufacturers meet the requirement under paragraph (a) and are required to pay the registration fees under this subdivision.

~~(d)~~ (e) By April 1 of each year, beginning April 1, 2020, the board shall notify a manufacturer that the manufacturer meets the requirement in paragraph (a) and is required to pay the annual registration fee in accordance with section 151.252, subdivision 1, paragraph (b).

~~(e)~~ (f) A manufacturer may dispute the board's determination that the manufacturer must pay the registration fee no later than 30 days after the date of notification. However, the manufacturer must still remit the fee as required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the assessment of the registration fee was incorrect. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the fee was incorrectly assessed, the board must refund the amount paid in error.

~~(f)~~ (g) For purposes of this subdivision, a unit means the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or gram.

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

Sec. 4. Minnesota Statutes 2020, section 256.043, subdivision 4, is amended to read:

Subd. 4. **Settlement; sunset.** (a) If the state receives a total sum of $250,000,000 either as a result of a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or resulting from a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency~~, against one or more opioid manufacturers or opioid wholesale drug distributors~~ related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state, or other alleged illegal actions that contributed to the excessive use of opioids, or from the fees collected under sections 151.065, subdivisions 1 and 3, and 151.066, that are deposited into the opiate epidemic response fund established in this section, or from a combination of both, the fees specified in section 151.065, subdivisions 1, clause (16), and 3, clause (14), shall be reduced to $5,260, and the opiate registration fee in section 151.066, subdivision 3, shall be repealed.

(b) The commissioner of management and budget shall inform the Board of Pharmacy, the governor, and the legislature when the amount specified in paragraph (a) has been reached. The board shall apply the reduced license fee for the next licensure period.

(c) Notwithstanding paragraph (a), the reduction of the license fee in section 151.065, subdivisions 1 and 3, and the repeal of the registration fee in section 151.066 shall not occur before July 1, 2024.

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

Sec. 6. **OPIATE REGISTRATION FEE REDUCTION.** (a) For purposes of assessing the opiate registration fee under Minnesota Statutes, section 151.066, subdivision 3, that is required to be paid on June 1, 2021, in accordance with Minnesota Statutes, section 151.252, subdivision 1, paragraph (b), the Board of Pharmacy shall not consider any injectable opiate product distributed to a hospital or hospital pharmacy. If there is money deposited into the separate account as described in Minnesota Statutes, section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner of management and budget an estimate of the difference in the annual opiate registration fee revenue collected under Minnesota Statutes, section 151.066, due to the exception described in this paragraph.

(b) Any estimated loss to the opiate registration fee revenue attributable to paragraph (a) must be included in any transfer that occurs under Minnesota Statutes, section 16A.151, subdivision 2, paragraph (g), in calendar year 2021.

(c) If a manufacturer has already paid the opiate registration fee due on June 1, 2021, the Board of Pharmacy shall return the amount of the fee to the manufacturer if the manufacturer would not have been required to pay the fee after the calculations described in paragraph (a) were made.

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

Article 5, Sections 3 and 5. Temperature monitoring for drug deliveries.

Sec. 3. **[151.335] DELIVERY THROUGH COMMON CARRIER; COMPLIANCE WITH TEMPERATURE REQUIREMENTS.** In addition to complying with the requirements of Minnesota Rules, part 6800.3000, a mail order or specialty pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must ensure that the drug is delivered in compliance with temperature requirements established by the manufacturer of the drug. The pharmacy must develop written policies and procedures that are consistent with United States Pharmacopeia, chapters 1079 and 1118, and with nationally recognized standards issued by standard-setting or accreditation organizations recognized by the board through guidance. The policies and procedures must be provided to the board upon request.

Sec. 5. **STUDY OF TEMPERATURE MONITORING.** The Board of Pharmacy shall conduct a study to determine the appropriateness and feasibility of requiring mail order and specialty pharmacies to enclose in each medication's packaging a method by which the patient can easily detect improper storage or temperature variations that may have occurred during the delivery of a medication. The board shall report the results of the study by January 15, 2022, to the chairs and ranking minority members of the legislative committees with jurisdiction over health finance and policy.

Article 6 Telehealth

Sec. 3. ***Minnesota Statutes 2020, 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~~ sections 147A.02 and 147A.09.

(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:

(1) an in-person examination has been completed in any of the following circumstances:

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

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

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

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

~~(5)~~ (v) 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~~.~~; or

(2) the prescription order is for a drug listed in paragraph (d), clause (6), or for medication assisted therapy for a substance use disorder, and the prescribing practitioner has completed an examination of the patient via telehealth as defined in section 62A.673, subdivision 2, paragraph (h).

(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.