

2019 Legislation Affecting MN Board of Pharmacy Licensees and Registrants (June 6, 2019)

Executive Summary

This summary covers only major provisions – mostly involving issues directly under the authority of the Board. However, the full text of the relevant language passed by the Legislature is included after this summary. Some provisions are under the jurisdiction of the Departments of Human Services, Health or Commerce, rather than the Board of Pharmacy. Given that many bills related to drugs and pharmacy were passed this Session, it is possible that some provisions have been missed. However, Board staff will edit this document as necessary to include any important, missed items.

The Board's recommendations for the scheduling of controlled substances were not enacted.

The Board's scheduling bills died in committee for unknown reasons. That being the case, the Board will be engaging in rule-making to modify the controlled substance schedules. It is particularly important to permanently place fentanyl analogs into Schedule I and Epidiolex into Schedule V.

Opiate-related provisions

- Changes to certain application and registration fees:
 - The application and renewal registration fees for most drug manufacturers, medical gas manufacturers, drug wholesalers, medical gas wholesalers, and medical gas distributors will increase to at least \$5,260 effective July 1, 2019.
 - All drug and medical gas wholesalers: \$5,260
 - Drug manufacturers (except for opioid manufacturers) and medical gas manufacturers: \$5,260
 - Medical gas distributors: \$5,260
 - Opioid drug manufacturers: \$55,260 (Reduced to \$5,260 if the sunset provision kicks in).
 - Opioid manufacturers with sales within Minnesota of over 2,000,000 units per year will also have to pay an annual opiate product registration fee of \$250,000. (Repealed if the sunset provision kicks in). The fee must be paid annually by June 1st. There will be a mechanism through which manufacturers can dispute the fee.

The Board will use data reported to it to determine which opioid manufacturers must pay the fee. By March 1 of each year, beginning March 1, 2020:

- each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution within or into this state of any opiate that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted by section 151.37 to possess controlled substances for administration or dispensing to patients that occurred during the previous calendar year. Reporting must be in the automation of reports and consolidated orders system (ARCOS) format unless otherwise specified by the board. If a manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of \$500 per day. This penalty shall not be considered a form of disciplinary action. (Note that sales or distributions to wholesalers do not have to be reported).
- each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution into this state, of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the opiate, and the amount and date that the purchase occurred.
 - Some of the increased fee revenue is appropriated to the Board of Pharmacy for administrative costs associated with collecting the new fees. Most of the revenue is deposited into a new opiate epidemic response account for use by other state and local agencies.
- A sheriff may meet the requirements for collection of unwanted pharmaceuticals by providing public educational information and making an alternative method available to the public, at no charge, for safely destroying unwanted legend drugs, including at-home prescription drug deactivation and disposal products, so long as the alternative method meets the requirements of the Minnesota Pollution Control Agency, the United States Drug Enforcement Administration, and the Board of Pharmacy. Note it is the Board's understanding that currently available at-home prescription drug deactivation and disposal products do *not* meet the requirements of the MPCA or DEA. The Board of Pharmacy administers sections of statutes that require all collection of unwanted pharmaceutical waste to follow the requirements of the MPCA and DEA.

- Limits on opiate prescriptions (These provisions take effect July 1, 2019):
 - Limits on filling dates.
 - 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.
 - Limit on quantity of opiates prescribed.
 - (a) When used for the treatment of acute pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV in section 152.02 shall not exceed a seven-day supply for an adult and shall not exceed a five-day supply for a minor under 18 years of age.
 - (b) Notwithstanding paragraph (a), when used for the treatment of acute dental pain, including acute pain associated with wisdom teeth extraction surgery or acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 shall not exceed a four-day supply.
 - (c) For the purposes of this subdivision, "acute pain" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. Acute pain does not include chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.
 - (d) Notwithstanding paragraph (a) or (b), if, in the professional clinical judgment of a practitioner, more than the limit specified in paragraph (a) or (b) is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.
 - Identification requirement for controlled substance prescriptions. (Note that this is a change from current law that will require more frequent checks of IDs when controlled substances are dispensed).
 - No person may dispense a controlled substance included in Schedules II through V without requiring the person purchasing the controlled substance, who need not be the patient for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance is known to the

dispenser. A Doctor of Veterinary Medicine who dispenses a controlled substance must comply with this subdivision.

- This applies to all prescriptions, even those covered by insurance.
- Required use of the Prescription Monitoring Program (PMP) by Prescribers. Beginning January 1, 2021, a prescriber (or an agent or employee of the prescriber to whom the prescriber has delegated the task) will be required to check the PMP prior to issuing prescriptions for Schedule II through IV opiate controlled substances. There are several exceptions to that requirement.

Other provisions

- Pharmacist administration of certain injectable drugs. The definition of “practice of pharmacy” was amended to include the administration of additional types of drugs. Note that the language adopted for administration of mental health drugs mentions protocols or collaborative practice agreements with not only physicians and advanced practice registered nurses, but also with dentists, optometrists, podiatrists, and veterinarians. However, it would not be within the scope of practice of those other practitioners to prescribe and administer mental health drugs. That effectively means that collaborative practice agreements and protocols in this area will need to be with physicians or APRNs.
 - intramuscular and subcutaneous administration used for the treatment of alcohol or opioid dependence (e.g. Vivitrol)
 - 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.
- Medication Drug Repository. The Board is required to set up a medication drug repository program by January 1, 2020 - through which donors may donate a drug or medical supply for use by an individual who meets certain eligibility criteria. The board will contract with a central repository that meets certain requirements to implement and administer the prescription drug repository program.

- Syringe/needle access. Section 151.40 was amended to:
 - Clarify that a prescription is not necessary for the purchase of needles and syringes. That has been the Board’s long-standing interpretation of this section. However, in finding a defendant not guilty of illegally possessing syringes, a district court judge recently opined that prescriptions were required – unless one of several exceptions applied to the individual. New language was added that states (emphasis added): “a person who self-administers drugs pursuant to either the prescription *or the direction* of a practitioner, or a family member, caregiver, or other individual who is designated by such person to assist the person in obtaining and using needles and syringes for the administration of such drugs” may legally possess needles and syringes. This means that a practitioner may simply direct a patient to use needles and syringes to self-administer a drug, rather than having to issue a prescription.
 - Allow pharmacies that choose to sell up to ten needles and syringes, without the prescription or direction of a practitioner, to advertise that fact. Prior to this change pharmacies that sold up to ten syringes and needles, “no questions asked,” were not allowed to advertise that they sold syringes and needles in that manner.
 - Clarify that individuals who purchase up to ten needles and syringes from a pharmacy, despite not doing so based on the prescription or direction of a practitioner, can legally possess those needles and syringes.
- Emergency prescription refills. Pharmacists will be allowed to refill prescriptions, even if no refills remain, provided that:
 - the patient has been compliant with taking the medication and has consistently had the drug filled or refilled as demonstrated by records maintained by the pharmacy;
 - the pharmacy from which the legend drug is dispensed has record of a prescription drug order for the drug in the name of the patient who is requesting it, but the prescription drug order does not provide for a refill, or the time during which the refills were valid has elapsed;
 - the pharmacist has tried but is unable to contact the practitioner who issued the prescription drug order, or another practitioner responsible for the patient's care, to obtain authorization to refill the prescription;
 - the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition;
 - failure to dispense the drug to the patient would result in harm to the health of the patient; and
 - the drug is not a controlled substance listed in section 152.02, subdivisions 3 to 6, except for a controlled substance that has been specifically prescribed to treat a seizure disorder, in which case the pharmacist may dispense up to a 72-hour supply.

If those conditions are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed a 30-day supply, or the quantity originally prescribed, whichever

is less, except as provided for controlled substances. If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing.

A pharmacist can't dispense or sell the same drug to the same patient, as an emergency refill allowed under this new provision, more than one time in any 12-month period.

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

The record of a drug sold or dispensed under this section shall be maintained in the same manner required for any other refills.

Insurers and PBMs are required to pay for these emergency refills – even though there were no refills remaining.

- Information provision; sources of lower cost prescription drugs. The Board of Pharmacy will develop a page on its Web site that provides information to pharmacists, practitioners, and the public about sources of lower cost prescription drugs. The Board will also develop handouts, posters, and other documents with information about such sources. The documents will be available on the Board's Web site for download. The Board of Pharmacy and the boards that license prescribing will be required to inform their licensees of the availability of this information. Licensees are required to provide the information to patients.
- Certain payment arrangements between pharmacies and practitioners (with exceptions for veterinarians). Defines the following as an impermissible kickback: "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." But provides for this exception:
 - 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.

Effective July 1, 2019 any pharmacy licensed by the Board that has entered into any such arrangement with veterinarians who treat animals other than food-producing animals, must provide written notification about the arrangement with each prescription filled. The pharmacy is not required to provide *specific* information about the financial details of the arrangement. *However, the notification must explain that there is a **financial relationship between the pharmacy and the veterinarian.*** Also, nothing in this provision prevents the client from asking about the arrangement and the amount of money received by both the pharmacy and the veterinarian.

Note that the exceptions **ONLY** apply when the practitioner is a veterinarian. Such arrangements are never permitted when the practitioner is not a veterinarian. For example, a compounding pharmacy may not fill a prescription for a patient, send it to a practitioner's office and, in any manner, split the payment made by the patient with that practitioner. The patient should not pay more for the drug than the amount that the pharmacy will receive for the product.

- Receipt and processing of prescriptions outside of a licensed pharmacy. Prior to these changes, all prescriptions were required to be received and processed within a licensed pharmacy. These changes allow for the receipt and processing of prescriptions outside of a licensed pharmacy – but only for limited situations. Specifically, they:
 - Clarify that a licensed pharmacist or pharmacist intern working within a licensed hospital may receive a prescription drug order and access the hospital's pharmacy prescription processing system through secure and encrypted electronic means in order to process the prescription drug order, even when they are not in the actual licensed pharmacy. Technically, that hasn't been legal – though it has long been the standard of practice and the Board has never objected to it.
 - Allow a pharmacist, when that pharmacist is not present within a licensed pharmacy, to accept a written, verbal, or electronic prescription drug order from a practitioner – but only if certain conditions are met:
 - the prescription drug order is for an emergency situation where waiting for the pharmacist to travel to a licensed pharmacy to accept the prescription drug order would likely cause the patient to experience significant physical harm or discomfort;
 - the pharmacy from which the prescription drug order will be dispensed is closed for business;
 - ***the pharmacist has been designated to be on call*** for the licensed pharmacy that will fill the prescription drug order;
 - electronic prescription drug orders are received through secure and encrypted electronic means;
 - the pharmacist takes reasonable precautions to ensure that the prescription drug order will be handled in a manner consistent with federal and state statutes regarding the handling of protected health information; and

- the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.
 - Allow a pharmacist, when that pharmacist is not present within a licensed pharmacy, to access a pharmacy prescription processing system through secure and encrypted electronic means in order to process an emergency prescription accepted pursuant to subdivision 5 only if:
 - the pharmacy from which the prescription drug order will be dispensed is closed for business;
 - ***the pharmacist has been designated to be on call*** for the licensed pharmacy that will fill the prescription drug order;
 - ***the prescription drug order is for a patient of a long-term care facility or a county correctional facility***;
 - the prescription drug order is not being processed pursuant to section 151.58;
 - the prescription drug order is processed pursuant to Chapter 151 and the rules promulgated thereunder; and
 - the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.
- Compounding for veterinary office use. This change simply codifies the Board’s previously issued guidance document that allows a pharmacy to compound certain drugs, that are needed for urgent or emergency treatment of animals, and sell them to a veterinarian without first receiving a prescription.
- Drug wholesaler and third-party logistics provider provisions:
 - Conform state drug wholesaler licensing provisions with federal law (Drug Supply Chain Security Act - DSCSA).
 - Establish licensing requirements for third-party logistics providers that conform to the DSCSA.
 - Note that the DSCSA excludes from the definition of drug wholesaling “the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use.” Along with other exceptions that apply to hospitals, businesses under common ownership, and the sale of drugs for emergencies, pharmacies no longer need a drug wholesaler license to, for example, sell a couple of bottles of amoxicillin to the local dentist’s office. Therefore, effective July 1, 2020, any pharmacy that applies for a drug wholesaler license will be have to meet all the licensing requirements that any other drug wholesaler must meet, including payment of the new \$5,260 licensing fee. Pharmacies that have an active wholesale license on that date will have to meet the new requirements upon renewal of the license.

- Prescription Monitoring Program. Several changes are meant to ensure that PMP access is for appropriate reasons. These changes were not requested by the Board. However, the Board will, of course, enforce them.
 - “A permissible user who has delegated the task of accessing the data in subdivision 4 to an agent or employee shall audit the use of the electronic system by delegated agents or employees on at least a quarterly basis to ensure compliance with permissible use as defined in this section. When a delegated agent or employee has been identified as inappropriately accessing data, the permissible user must immediately remove access for that individual and notify the board within seven days. The board shall notify all permissible users associated with the delegated agent or employee of the alleged violation.”
 - “A permissible user who delegates access to the data submitted under subdivision 4 to an agent or employee shall terminate that individual's access to the data within three business days of the agent or employee leaving employment with the permissible user. The board may conduct random audits to determine compliance with this requirement.”
 - “The board shall conduct random audits, on at least a quarterly basis, of electronic access by permissible users . . . to ensure compliance with permissible use as defined in this section. A permissible user whose account has been selected for a random audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted. Failure to respond may result in deactivation of access to the electronic system and referral to the appropriate health licensing board, or the commissioner of human services, for further action. The board shall report the results of random audits to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and government data practices.”
- Sale of cannabidiol (CBD) products. Sale of such products are currently illegal under state and federal law (at least to the extent that the intended use of the products is to prevent, cure or treat a disease or to alter the structure and function of human or animal bodies). However, effective January 1, 2020, the sale of CBD products that meet certain labeling and testing requirements will be permitted under state law. That being the case, the Board will no longer prohibit pharmacies from selling CBD products that meet the new requirements.

Appropriations and fee increases

- In addition to the fee increases for drug and medical gas manufacturers, drug and medical gas wholesalers, and medical gas distributors, the following fee increases were granted. The expected additional revenue is \$651,000 per year.
 - pharmacist, \$175; (increased from \$145)
 - pharmacist licensed by reciprocity (application fee), \$275 (increased from \$240)

- pharmacy intern, \$50 (increased from \$37.50)
- pharmacy technician, \$50; (increased from \$37.50)
- pharmacy, \$260; (increased from \$225)
- third party logistics provider, \$260; (newly established fee)
- pharmacy professional corporation (new), \$150; (increased from \$125)
- pharmacy professional corporation (renewal), \$100 (increased from \$75)
- Appropriations granted
 - General operating adjustment. FY 2020 - \$124,000; FY 2021 - \$126,000
 - PMP operating adjustment. FY 2020 - \$696,000; FY 2021 - \$699,000
 - Hire new pharmacy surveyor. FY 2020 - \$199,000; FY 2021 - \$190,000
 - Prescription drug repository program. FY 2020 - \$12,000; FY 2021 - \$13,000
 - Opioid registration fee/licensing fee one-time expenses. FY 2020 - \$244,000 (one-time appropriation from general fund).
 - Opioid registration fee collection. FY 2020 - \$126,000 (from general fund). FY 2021 - \$126,000 (from Opioid Response Account)

Provisions not under the Board's Authority

- Pharmacy benefit managers will be licensed and regulated by the Minnesota Department of Commerce.
- Changes have been made to the reimbursement that the Department of Human Services provides for pharmacy claims.

The following pieces of legislation that were enacted during the 2019 Regular or Special Sessions have language that will have an impact on the Board and it licenses or registrants. (For the Opioid Omnibus Bill, the most relevant language is highlighted in green).

CHAPTER 63--H.F. No. 400 (Opioid Omnibus Bill – as amended by HF 2414)

An act relating to health; establishing the opiate product registration fee and the Opiate Epidemic Response Advisory Council; modifying certain licensure and registration fees; modifying sections relating to prescription drugs and controlled substances; requiring reports; appropriating money; amending Minnesota Statutes 2018, sections 16A.151, subdivision 2; 145C.05, subdivision 2; 151.01, subdivision 27; 151.065, subdivisions 1, 3, by adding a subdivision; 151.252, subdivision 1; 151.37, subdivision 12; 152.105, subdivision 2; 152.11, subdivisions 1, 2d, 4; 152.126, subdivision 6; 214.12, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapters 145C; 151; 256.

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

**ARTICLE 1
OPIATE EPIDEMIC RESPONSE**

Section 1. Minnesota Statutes 2018, 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. 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 section 151.065, 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 account 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 3.

Sec. 2. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:

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

- (1) pharmacist licensed by examination, \$145;
- (2) pharmacist licensed by reciprocity, \$240;
- (3) pharmacy intern, \$37.50;

- (4) pharmacy technician, \$37.50;
- (5) pharmacy, \$225;
- (6) drug wholesaler, legend drugs only, ~~\$235~~ \$5,000;
- (7) drug wholesaler, legend and nonlegend drugs, ~~\$235~~ \$5,000;
- (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~\$210~~ \$5,000;
- (9) drug wholesaler, medical gases, ~~\$175~~ \$5,000;
- (10) drug wholesaler, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$5,000;
- (11) drug manufacturer, nonopiate legend drugs only, ~~\$235~~ \$5,000;
- (12) drug manufacturer, nonopiate legend and nonlegend drugs, ~~\$235~~ \$5,000;
- (13) drug manufacturer, nonlegend or veterinary legend drugs, ~~\$210~~ \$5,000;
- (14) drug manufacturer, medical gases, ~~\$185~~ \$5,000;
- (15) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$5,000;
- (16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, \$55,000;
- ~~(16)~~ (17) medical gas distributor, ~~\$110~~ \$5,000;
- ~~(17)~~ (18) controlled substance researcher, \$75; and
- ~~(18)~~ (19) pharmacy professional corporation, \$125.

EFFECTIVE DATE. This section is effective July 1, 2019, and applies to any license issued on or after that date.

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

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

- (1) pharmacist, \$145;
- (2) pharmacy technician, \$37.50;
- (3) pharmacy, \$225;
- (4) drug wholesaler, legend drugs only, ~~\$235~~ \$5,000;
- (5) drug wholesaler, legend and nonlegend drugs, ~~\$235~~ \$5,000;
- (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~\$210~~ \$5,000;
- (7) drug wholesaler, medical gases, ~~\$185~~ \$5,000;
- (8) drug wholesaler, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$5,000;
- (9) drug manufacturer, nonopiate legend drugs only, ~~\$235~~ \$5,000;
- (10) drug manufacturer, nonopiate legend and nonlegend drugs, ~~\$235~~ \$5,000;
- (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, ~~\$210~~ \$5,000;

- (12) drug manufacturer, medical gases, ~~\$185~~ \$5,000;
- (13) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$5,000;
- (14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, \$55,000;
- ~~(14)~~ (15) medical gas distributor, ~~\$110~~ \$5,000;
- ~~(15)~~ (16) controlled substance researcher, \$75; and
- ~~(16)~~ (17) pharmacy professional corporation, \$75.

EFFECTIVE DATE. This section is effective July 1, 2019, and applies to any license renewed on or after that date.

Sec. 4. Minnesota Statutes 2018, section 151.065, is amended by adding a subdivision 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 (15) and (17), and subdivision 3, clauses (4) 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.

Sec. 5. **[151.066] OPIATE PRODUCT REGISTRATION FEE.** **Subdivision 1. Definition.**

(a) For purposes of this section, the following terms have the meanings given to them in this subdivision.

(b) "Manufacturer" means a manufacturer licensed under section 151.252 that is engaged in the manufacturing of an opiate.

(c) "Opiate" means any opiate-containing controlled substance listed in section 152.02, subdivisions 3 to 5, that is distributed, delivered, sold, or dispensed into or within this state.

(d) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 that is engaged in the wholesale drug distribution of an opiate.

Subd. 2. Reporting requirements.

(a) By March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution within or into this state of any opiate that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted by section 151.37 to possess controlled substances for administration or dispensing to patients that occurred during the previous calendar year. Reporting must be in the automation of reports and consolidated orders system format unless otherwise specified by the board. If a manufacturer or wholesaler fails to provide information

required under this paragraph on a timely basis, the board may assess an administrative penalty of \$500 per day. This penalty shall not be considered a form of disciplinary action.

(b) By March 1 of each year, beginning March 1, 2020, each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution into this state, of any opiate, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the opiate, and the amount and date that the purchase occurred.

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

(c) 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) 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) 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) 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.

Subd. 4. Report. (a) The Board of Pharmacy shall evaluate the registration fee on drug manufacturers established under this section, and whether the registration fee and the increased licensure fees have impacted the prescribing practices of opiates by reducing the number of opiate prescriptions issued during calendar years 2021, 2022, and 2023, or creating any unintended consequences in the availability of opiates for the treatment of chronic or intractable pain to the extent the board has the ability to effectively identify a correlation. Notwithstanding

section 152.126, subdivision 6, the board may access the data reported under section 152.126, subdivision 4, to conduct this evaluation.

(b) The board shall submit the results of its evaluation to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by March 1, 2024.

Subd. 5. **Legislative review.** The legislature shall review the reports from the Opiate Epidemic Response Advisory Council under section 256.042, subdivision 5, paragraph (a), the reports from the commissioner of management and budget on the Results First evaluation activities under section 256.042, subdivision 5, paragraph (b), the report from the Board of Pharmacy under subdivision 4, and any other relevant report or information related to the opioid crisis in Minnesota, to make a determination about whether the opiate product registration fee assessed under this section should continue beyond July 1, 2024.

Sec. 6. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

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

(b) 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 established under section 256.043.

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

~~(c)~~ (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.

~~(d)~~ (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.

~~(e)~~ (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.

~~(f)~~ (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 151.065, subdivision 3, clause (14), for more than one facility.

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

Sec. 7. **[256.042] OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL.**

Subdivision 1. Establishment of the advisory council.

(a) The Opiate Epidemic Response Advisory Council is established to develop and implement a comprehensive and effective statewide effort to address the opioid addiction and overdose epidemic in Minnesota. The council shall focus on:

(1) prevention and education, including public education and awareness for adults and youth, prescriber education, the development and sustainability of opioid overdose prevention and education programs, the role of adult protective services in prevention and response, and providing financial support to local law enforcement agencies for opiate antagonist programs;

(2) training on the treatment of opioid addiction, including the use of all Food and Drug Administration approved opioid addiction medications, detoxification, relapse prevention, patient assessment, individual treatment planning, counseling, recovery supports, diversion control, and other best practices;

(3) the expansion and enhancement of a continuum of care for opioid-related substance use disorders, including primary prevention, early intervention, treatment, recovery, and aftercare services; and

(4) the development of measures to assess and protect the ability of cancer patients and survivors, persons battling life threatening illnesses, persons suffering from severe chronic pain, and persons at the end stages of life, who legitimately need prescription pain medications, to maintain their quality of life by accessing these pain medications without facing unnecessary barriers. The measures must also address the needs of individuals described in this clause who are elderly or who reside in underserved or rural areas of the state.

(b) The council shall:

(1) review local, state, and federal initiatives and activities related to education, prevention, treatment, and services for individuals and families experiencing and affected by opioid use disorder;

(2) establish priorities to address the state's opioid epidemic, for the purpose of recommending initiatives to fund;

(3) recommend to the commissioner of human services specific projects and initiatives to be funded;

(4) ensure that available funding is allocated to align with other state and federal funding, to achieve the greatest impact and ensure a coordinated state effort;

(5) consult with the commissioners of human services, health, and management and budget to develop measurable outcomes to determine the effectiveness of funds allocated; and

(6) develop recommendations for an administrative and organizational framework for the allocation, on a sustainable and ongoing basis, of any money deposited into the separate account under section 16A.151, subdivision 2, paragraph (f), in order to address the opioid abuse and overdose epidemic in Minnesota and the areas of focus specified in paragraph (a).

(c) The council, in consultation with the commissioner of management and budget, and within available appropriations, shall select from the awarded grants projects that include promising practices or theory-based activities for which the commissioner of management and budget shall conduct evaluations using experimental or quasi-experimental design. Grants awarded to proposals that include promising practices or theory-based activities and that are selected for an evaluation shall be administered to support the experimental or quasi-experimental evaluation and require grantees to collect and report information that is needed to complete the evaluation. The commissioner of management and budget, under section 15.08, may obtain additional relevant data to support the experimental or quasi-experimental evaluation studies.

(d) The council, in consultation with the commissioners of human services, health, public safety, and management and budget, shall establish goals related to addressing the opioid epidemic and determine a baseline against which progress shall be monitored and set measurable outcomes, including benchmarks. The goals established must include goals for prevention and public health, access to treatment, and multigenerational impacts. The council shall use existing measures and data collection systems to determine baseline data against which progress shall be measured. The council shall include the proposed goals, the measurable outcomes, and proposed benchmarks to meet these goals in its initial report to the legislature under subdivision 5, paragraph (a), due January 31, 2021.

Subd. 2. Membership. (a) The council shall consist of the following 19 voting members, appointed by the commissioner of human services except as otherwise specified, and three nonvoting members:

(1) two members of the house of representatives, appointed in the following sequence: the first from the majority party appointed by the speaker of the house and the second from the minority party appointed by the minority leader. Of these two members, one member must represent a district outside of the seven-county metropolitan area, and one member must represent a district that includes the seven-county metropolitan area. The appointment by the minority leader must ensure that this requirement for geographic diversity in appointments is met;

(2) two members of the senate, appointed in the following sequence: the first from the majority party appointed by the senate majority leader and the second from the minority party appointed by the senate minority leader. Of these two members, one member must represent a district outside of the seven-county metropolitan area and one member must represent a district

that includes the seven-county metropolitan area. The appointment by the minority leader must ensure that this requirement for geographic diversity in appointments is met;

(3) one member appointed by the Board of Pharmacy;

(4) one member who is a physician appointed by the Minnesota Medical Association;

(5) one member representing opioid treatment programs, sober living programs, or substance use disorder programs licensed under chapter 245G;

(6) one member appointed by the Minnesota Society of Addiction Medicine who is an addiction psychiatrist;

(7) one member representing professionals providing alternative pain management therapies, including, but not limited to, acupuncture, chiropractic, or massage therapy;

(8) one member representing nonprofit organizations conducting initiatives to address the opioid epidemic, with the commissioner's initial appointment being a member representing the Steve Rummeler Hope Network, and subsequent appointments representing this or other organizations;

(9) one member appointed by the Minnesota Ambulance Association, who is serving with an ambulance service as an emergency medical technician, advanced emergency medical technician, or paramedic;

(10) one member representing the Minnesota courts who is a judge or law enforcement officer;

(11) one public member who is a Minnesota resident and who is in opioid addiction recovery;

(12) two members representing Indian tribes, one representing the Ojibwe tribes and one representing the Dakota tribes;

(13) one public member who is a Minnesota resident and who is suffering from chronic pain, intractable pain, or a rare disease or condition;

(14) one mental health advocate representing persons with mental illness;

(15) one member representing the Minnesota Hospital Association;

(16) one member representing a local health department; and

(17) the commissioners of human services, health, and corrections, or their designees, who shall be ex officio nonvoting members of the council.

(b) The commissioner of human services shall coordinate the commissioner's appointments to provide geographic, racial, and gender diversity, and shall ensure that at least one-half of council members appointed by the commissioner reside outside of the seven-county metropolitan area. Of the members appointed by the commissioner, to the extent practicable, at least one member must represent a community of color disproportionately affected by the opioid epidemic.

(c) The council is governed by section 15.059, except that members of the council shall receive no compensation other than reimbursement for expenses. Notwithstanding section 15.059, subdivision 6, the council shall not expire.

(d) The chair shall convene the council at least quarterly, and may convene other meetings as necessary. The chair shall convene meetings at different locations in the state to provide geographic access, and shall ensure that at least one-half of the meetings are held at locations outside of the seven-county metropolitan area.

(e) The commissioner of human services shall provide staff and administrative services for the advisory council.

(f) The council is subject to chapter 13D.

Subd. 3. Conflict of interest. Advisory council members must disclose to the council, refrain from participating in discussions, and recuse themselves from voting on any matter before the council if the member has a conflict of interest. A conflict of interest means a financial association that has the potential to bias or have the appearance of biasing a council member's decision related to the opiate epidemic response grant decision process or other council activities under this section.

Subd. 4. Grants. (a) The commissioner of human services shall submit a report of the grants proposed by the advisory council to be awarded for the upcoming fiscal year to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, by March 1 of each year, beginning March 1, 2020.

(b) The commissioner of human services shall award grants from the opiate epidemic response account under section 256.043. The grants shall be awarded to proposals selected by the advisory council that address the priorities in subdivision 1, paragraph (a), clauses (1) to (4), unless otherwise appropriated by the legislature. No more than three percent of the grant amount may be used by a grantee for administration.

Subd. 5. Reports. (a) The advisory council shall report annually to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by January 31 of each year, beginning January 31, 2021. The report shall include information about the individual projects that receive grants and the overall role of the project in addressing the opioid addiction and overdose epidemic in Minnesota. The report must describe the grantees and the activities implemented, along with measurable outcomes as determined by the council in consultation with the commissioner of human services and the commissioner of management and budget. At a minimum, the report must include information about the number of individuals who received information or treatment, the outcomes the individuals achieved, and demographic information about the individuals participating in the project; an assessment of the progress toward achieving statewide access to qualified providers and comprehensive treatment and recovery services; and an update on the evaluations implemented by the commissioner of management and budget for the promising practices and theory-based projects that receive funding.

(b) The commissioner of management and budget, in consultation with the Opiate Epidemic Response Advisory Council, shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance when an evaluation study described in subdivision 1, paragraph (c), is complete on the promising practices or theory-based projects that are selected for evaluation activities. The report shall include demographic information; outcome information for the individuals in the program; the results for the program in promoting recovery, employment, family reunification, and reducing

involvement with the criminal justice system; and other relevant outcomes determined by the commissioner of management and budget that are specific to the projects that are evaluated. The report shall include information about the ability of grant programs to be scaled to achieve the statewide results that the grant project demonstrated.

(c) The advisory council, in its annual report to the legislature under paragraph (a) due by January 31, 2024, shall include recommendations on whether the appropriations to the specified entities under this act should be continued, adjusted, or discontinued; whether funding should be appropriated for other purposes related to opioid abuse prevention, education, and treatment; and on the appropriate level of funding for existing and new uses.

Sec. 8. [256.043] OPIATE EPIDEMIC RESPONSE ACCOUNT.

Subdivision 1. Establishment. The opiate epidemic response account is established in the special revenue fund in the state treasury. The registration fees assessed by the Board of Pharmacy under section 151.066 and the license fees identified in section 151.065, subdivision 7, paragraphs (b) and (c), shall be deposited into the account. Beginning in fiscal year 2021, for each fiscal year, the funds in the account shall be administered according to this section.

Subd. 2. Transfers from account to state agencies. (a) The commissioner shall transfer the following amounts to the agencies specified in this subdivision.

(b) \$126,000 to the Board of Pharmacy for the collection of the registration fees under section 151.066.

(c) \$672,000 to the commissioner of public safety for the Bureau of Criminal Apprehension. Of this amount, \$384,000 is for drug scientists and lab supplies and \$288,000 is for special agent positions focused on drug interdiction and drug trafficking.

Subd. 3. Appropriations from account. (a) After the transfers described in subdivision 2, and the appropriations in article 3, section 1, paragraphs (e), (f), (g), and (h) are made, \$249,000 is appropriated for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the administration of the grants awarded under paragraph (c).

(b) After the transfers in subdivision 2 and appropriations in paragraph (a) are made, 50 percent of the remaining amount is appropriated to the commissioner for distribution to county social service and tribal social service agencies to provide child protection services to children and families who are affected by addiction. The commissioner shall distribute this money proportionally to counties and tribal social service agencies based on out-of-home placement episodes where parental drug abuse is the primary reason for the out-of-home placement using data from the previous calendar year. County and tribal social service agencies receiving funds from the opiate epidemic response account must annually report to the commissioner on how the funds were used to provide child protection services, including measurable outcomes, as determined by the commissioner. County social service agencies and tribal social service agencies must not use funds received under this paragraph to supplant current state or local funding received for child protection services for children and families who are affected by addiction.

(c) After making the transfers in subdivision 2 and appropriations in paragraphs (a) and (b), the remaining funds in the account are appropriated to the commissioner to award grants as specified by the Opiate Epidemic Response Advisory Council in accordance with section 256.042, unless otherwise appropriated by the legislature.

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 section 151.065, subdivisions 1 and 3, and section 151.066, that are deposited into the opiate epidemic response account established in section 256.043, or from a combination of both, the fees specified in section 151.065, subdivision 1, clause (16), and section 151.065, subdivision 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.

Sec. 9. **OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL FIRST MEETING.** The commissioner of human services shall convene the first meeting of the Opiate Epidemic Response Advisory Council established under Minnesota Statutes, section 256.042, no later than October 1, 2019. The members shall elect a chair at the first meeting.

Sec. 10. **REVISOR INSTRUCTION.** The fee increases in Minnesota Statutes, section 151.065, subdivisions 1 and 3 in this act are in addition to any other fee increases in Minnesota Statutes, section 151.065, subdivisions 1 and 3, enacted in 2019 regular or special sessions. If multiple fees are enacted, the revisor of statutes shall add the fees together for publication in the 2020 Minnesota Statutes Supplement to effectuate the intent of the legislature.

ARTICLE 2

OTHER PROVISIONS

Section 1. Minnesota Statutes 2018, section 145C.05, subdivision 2, is amended to read:

Subd. 2. **Provisions that may be included.** (a) A health care directive may include provisions consistent with this chapter, including, but not limited to:

(1) the designation of one or more alternate health care agents to act if the named health care agent is not reasonably available to serve;

(2) directions to joint health care agents regarding the process or standards by which the health care agents are to reach a health care decision for the principal, and a statement whether joint health care agents may act independently of one another;

(3) limitations, if any, on the right of the health care agent or any alternate health care agents to receive, review, obtain copies of, and consent to the disclosure of the principal's medical records or to visit the principal when the principal is a patient in a health care facility;

(4) limitations, if any, on the nomination of the health care agent as guardian for purposes of sections [524.5-202](#), [524.5-211](#), [524.5-302](#), and [524.5-303](#);

(5) a document of gift for the purpose of making an anatomical gift, as set forth in chapter 525A, or an amendment to, revocation of, or refusal to make an anatomical gift;

(6) a declaration regarding intrusive mental health treatment under section [253B.03, subdivision 6d](#), or a statement that the health care agent is authorized to give consent for the principal under section [253B.04, subdivision 1a](#);

(7) a funeral directive as provided in section [149A.80, subdivision 2](#);

(8) limitations, if any, to the effect of dissolution or annulment of marriage or termination of domestic partnership on the appointment of a health care agent under section [145C.09, subdivision 2](#);

(9) specific reasons why a principal wants a health care provider or an employee of a health care provider attending the principal to be eligible to act as the principal's health care agent;

(10) health care instructions by a woman of child bearing age regarding how she would like her pregnancy, if any, to affect health care decisions made on her behalf; ~~and~~

(11) health care instructions regarding artificially administered nutrition or hydration; ~~and~~

(12) health care instructions to prohibit administering, dispensing, or prescribing an opioid, except that these instructions must not be construed to limit the administering, dispensing, or prescribing an opioid to treat substance abuse, opioid dependence, or an overdose, unless otherwise prohibited in the health care directive.

(b) A health care directive may include a statement of the circumstances under which the directive becomes effective other than upon the judgment of the principal's attending physician in the following situations:

(1) a principal who in good faith generally selects and depends upon spiritual means or prayer for the treatment or care of disease or remedial care and does not have an attending physician, may include a statement appointing an individual who may determine the principal's decision-making capacity; and

(2) a principal who in good faith does not generally select a physician or a health care facility for the principal's health care needs may include a statement appointing an individual who may determine the principal's decision-making capacity, provided that if the need to determine the principal's capacity arises when the principal is receiving care under the direction of an attending physician in a health care facility, the determination must be made by an attending physician after consultation with the appointed individual.

If a person appointed under clause (1) or (2) is not reasonably available and the principal is receiving care under the direction of an attending physician in a health care facility, an attending physician shall determine the principal's decision-making capacity.

(c) A health care directive may authorize a health care agent to make health care decisions for a principal even though the principal retains decision-making capacity.

Sec. 2. **145C.17 OPIOID INSTRUCTIONS ENTERED INTO HEALTH RECORD.**

At the request of the patient or health care agent, a health care provider shall enter into the patient's health care record any instructions relating to administering, dispensing, or prescribing an opioid.

Sec. 3. Minnesota Statutes 2018, 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;

~~(5)~~ (6) participation in administration of influenza vaccines 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 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;
- ~~(6)~~ (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 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;
- ~~(7)~~ (8) participation in the storage of drugs and the maintenance of records;

~~(8)~~ (9) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices;

~~(9)~~ (10) offering or performing those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy; and

~~(10)~~ (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.

Sec. 4. Minnesota Statutes 2018, section 151.37, subdivision 12, is amended to read:

Subd. 12. **Administration of opiate antagonists for drug overdose.** (a) A licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section [148.235](#), or a licensed physician assistant authorized to prescribe drugs pursuant to section [147A.18](#) may authorize the following individuals to administer opiate antagonists, as defined in section [604A.04, subdivision 1](#):

(1) an emergency medical responder registered pursuant to section [144E.27](#);

(2) a peace officer as defined in section [626.84, subdivision 1](#), paragraphs (c) and (d); ~~and~~

(3) correctional employees of a state or local political subdivision;

~~(4)~~ staff of community-based health disease prevention or social service programs;

~~(5)~~ a volunteer firefighter; and

~~(6)~~ a licensed school nurse or certified public health nurse employed by, or under contract with, a school board under section 121A.21.

(b) For the purposes of this subdivision, opiate antagonists may be administered by one of these individuals only if:

(1) the licensed physician, licensed physician assistant, or licensed advanced practice registered nurse has issued a standing order to, or entered into a protocol with, the individual; and

(2) the individual has training in the recognition of signs of opiate overdose and the use of opiate antagonists as part of the emergency response to opiate overdose.

(c) Nothing in this section prohibits the possession and administration of naloxone pursuant to section [604A.04](#).

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

Sec. 5. Minnesota Statutes 2018, section 152.105, subdivision 2, is amended to read:

Subd. 2. Sheriff to maintain collection receptacle. (a) The sheriff of each county shall maintain or contract for the maintenance of at least one collection receptacle for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs, as permitted by federal law. For purposes of this section, "legend drug" has the meaning given in section [151.01, subdivision 17](#). The collection receptacle must comply with federal law. In maintaining and operating the collection receptacle, the sheriff shall follow all applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017.

(b) A sheriff may meet the requirements of paragraph (a) by providing public educational information and making an alternative method available to the public, at no charge, for safely destroying unwanted legend drugs, including an at-home prescription drug deactivation and disposal product, so long as the alternative method meets the requirements of the Minnesota Pollution Control Agency, the United States Drug Enforcement Administration, and the Board of Pharmacy.

Sec. 6. Minnesota Statutes 2018, 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.

Sec. 7. Minnesota Statutes 2018, section 152.11, subdivision 2d, is amended to read:

Subd. 2d. Identification requirement for ~~Schedule II or III~~ controlled substance prescriptions. ~~(a) No person may dispense a controlled substance included in Schedule II or III Schedules II through V without requiring the person purchasing the controlled substance, who need not be the person patient for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance, or if applicable the person for whom the controlled substance prescription is written, is known to the dispenser. A doctor of veterinary medicine who dispenses a controlled substance must comply with this subdivision.~~

~~(b) This subdivision applies only to purchases of controlled substances that are not covered, in whole or in part, by a health plan company or other third-party payor.~~

Sec. 8. Minnesota Statutes 2018, section 152.11, subdivision 4, is amended to read:

Subd. 4. Limit on quantity of opiates prescribed for acute dental and ophthalmic pain. (a) When used for the treatment of acute pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV in section 152.02 shall not exceed a seven-day supply for an adult and shall not exceed a five-day supply for a minor under 18 years of age.

~~(a) (b) Notwithstanding paragraph (a), when used for the treatment of acute dental pain, including acute pain associated with wisdom teeth extraction surgery or acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 shall not exceed a four-day supply. The quantity prescribed shall be consistent with the dosage listed in the professional labeling for the drug that has been approved by the United States Food and Drug Administration.~~

~~(b) (c) For the purposes of this subdivision, "acute pain" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. Acute pain does not include chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.~~

~~(c) Notwithstanding paragraph (a), if in the professional clinical judgment of a practitioner more than a four-day supply of a prescription listed in Schedules II through IV of section 152.02 is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat such acute pain.~~

(d) Notwithstanding paragraph (a) or (b), if, in the professional clinical judgment of a practitioner, more than the limit specified in paragraph (a) or (b) is required to treat a patient's

acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.

Sec. 9. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read:

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

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

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

- (i) prescribing or considering prescribing any controlled substance;
- (ii) providing emergency medical treatment for which access to the data may be necessary;
- (iii) providing care, and the prescriber has reason to believe, based on clinically valid indications, that the patient is potentially abusing a controlled substance; or
- (iv) providing other medical treatment for which access to the data may be necessary for a clinically valid purpose and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

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

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

(4) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or guardian of a minor, or health care agent of the individual acting under a health care directive under chapter 145C. For purposes of this clause, access by individuals includes persons in the definition of an individual under section 13.02;

(5) personnel or designees of a health-related licensing board listed in section [214.01, subdivision 2](#), or of the Emergency Medical Services Regulatory Board, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is impaired by use of a drug for which data is collected under subdivision 4, has engaged in

activity that would constitute a crime as defined in section [152.025](#), or has engaged in the behavior specified in subdivision 5, paragraph (a);

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

(7) authorized personnel of a vendor under contract with the state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

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

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

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

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

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

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

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

(d) Notwithstanding paragraph (b), beginning January 1, 2021, a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the

data, must access the data submitted under subdivision 4 to the extent the information relates specifically to the patient:

(1) before the prescriber issues an initial prescription order for a Schedules II through IV opiate controlled substance to the patient; and

(2) at least once every three months for patients receiving an opiate for treatment of chronic pain or participating in medically assisted treatment for an opioid addiction.

(e) Paragraph (d) does not apply if:

(1) the patient is receiving palliative care, or hospice or other end-of-life care;

(2) the patient is being treated for pain due to cancer or the treatment of cancer;

(3) the prescription order is for a number of doses that is intended to last the patient five days or less and is not subject to a refill;

(4) the prescriber and patient have a current or ongoing provider/patient relationship of a duration longer than one year;

(5) the prescription order is issued within 14 days following surgery or three days following oral surgery or follows the prescribing protocols established under the opioid prescribing improvement program under section 256B.0638;

(6) the controlled substance is prescribed or administered to a patient who is admitted to an inpatient hospital;

(7) the controlled substance is lawfully administered by injection, ingestion, or any other means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a prescriber and in the presence of the prescriber or pharmacist;

(8) due to a medical emergency, it is not possible for the prescriber to review the data before the prescriber issues the prescription order for the patient; or

(9) the prescriber is unable to access the data due to operational or other technological failure of the program so long as the prescriber reports the failure to the board.

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

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

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

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

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

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

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

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

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

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

Sec. 10. Minnesota Statutes 2018, section 214.12, is amended by adding a subdivision to read:

Subd. 6. Opioid and controlled substances prescribing. (a) The Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Optometry, and the Board of Podiatric Medicine shall require that licensees with the authority to prescribe controlled substances obtain at least two hours of continuing education credit on best practices in prescribing opioids and controlled substances, including nonpharmacological and implantable device alternatives for treatment of pain and ongoing pain management, as part of the continuing education requirements for licensure renewal. Licensees shall not be required to complete more than two credit hours of continuing education on best practices in prescribing opioids and controlled substances before this subdivision expires. Continuing education credit on best practices in prescribing opioids and controlled substances must meet board requirements.

(b) Paragraph (a) does not apply to any licensee who is participating in the opioid prescribing improvement program under section 256B.0638, unless the licensee has been terminated as a medical assistance provider under section 256B.0638, subdivision 5, paragraph (d).

(c) This subdivision expires January 1, 2023.

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

ARTICLE 3

APPROPRIATIONS

Section 1. **APPROPRIATIONS. (a) Board of Pharmacy; administration. \$244,000 in fiscal year 2020 is appropriated from the general fund to the Board of Pharmacy for onetime information technology and operating costs for administration of licensing activities under Minnesota Statutes, section 151.066. This is a onetime appropriation.**

(b) Commissioner of human services; administration. \$309,000 in fiscal year 2020 is appropriated from the general fund and \$60,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of human services for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the administration of the grants awarded under paragraphs (f), (g), and (h). The opiate epidemic response account base for this appropriation is \$60,000 in fiscal year 2022, \$60,000 in fiscal year 2023, \$60,000 in fiscal year 2024, and \$0 in fiscal year 2025.

(c) Board of Pharmacy; administration. \$126,000 in fiscal year 2020 is appropriated from the general fund to the Board of Pharmacy for the collection of the registration fees under section 151.066.

(d) Commissioner of public safety; enforcement activities. \$672,000 in fiscal year 2020 is appropriated from the general fund to the commissioner of public safety for the Bureau of Criminal Apprehension. Of this amount, \$384,000 is for drug scientists and lab supplies and \$288,000 is for special agent positions focused on drug interdiction and drug trafficking.

(e) Commissioner of management and budget; evaluation activities. \$300,000 in fiscal year 2020 is appropriated from the general fund and \$300,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of management and budget for evaluation activities under Minnesota Statutes, section 256.042, subdivision 1, paragraph (c). The opiate epidemic response account base for this appropriation is \$300,000 in fiscal year 2022, \$300,000 in fiscal year 2023, \$300,000 in fiscal year 2024, and \$0 in fiscal year 2025.

(f) Commissioner of human services; grants for Project ECHO. \$400,000 in fiscal year 2020 is appropriated from the general fund and \$400,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of human services for grants of \$200,000 to CHI St. Gabriel's Health Family Medical Center for the opioid-focused Project ECHO program and \$200,000 to Hennepin Health Care for the opioid-focused Project ECHO program. The opiate epidemic response account base for this appropriation is \$400,000 in fiscal year 2022, \$400,000 in fiscal year 2023, \$400,000 in fiscal year 2024, and \$0 in fiscal year 2025.

(g) Commissioner of human services; opioid overdose prevention grant. \$100,000 in fiscal year 2020 is appropriated from the general fund and \$100,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of human services for a grant to a nonprofit organization that has provided overdose prevention programs to the public in at least 60 counties within the state, for at least three years, has received federal funding before January 1, 2019, and is dedicated to addressing the opioid epidemic. The grant must be used for opioid overdose prevention, community asset mapping, education, and overdose antagonist distribution. The opiate epidemic response account base for this appropriation is \$100,000 in fiscal year 2022, \$100,000 in fiscal year 2023, \$100,000 in fiscal year 2024, and \$0 in fiscal year 2025.

(h) Commissioner of human services; traditional healing. \$2,000,000 in fiscal year 2020 is appropriated from the general fund and \$2,000,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of human services to award grants to tribal nations and five urban Indian communities for traditional healing practices to American Indians and to increase the capacity of culturally specific providers in the behavioral health workforce. The opiate epidemic response account base for this appropriation is \$2,000,000 in fiscal year 2022, \$2,000,000 in fiscal year 2023, \$2,000,000 in fiscal year 2024, and \$0 in fiscal year 2025.

(i) Board of Dentistry; continuing education. \$11,000 in fiscal year 2020 is appropriated from the state government special revenue fund to the Board of Dentistry to implement the continuing education requirements under Minnesota Statutes, section 214.12, subdivision 6.

(j) Board of Medical Practice; continuing education. \$17,000 in fiscal year 2020 is appropriated from the state government special revenue fund to the Board of Medical Practice to implement the continuing education requirements under Minnesota Statutes, section 214.12, subdivision 6.

(k) Board of Nursing; continuing education. \$17,000 in fiscal year 2020 is appropriated from the state government special revenue fund to the Board of Nursing to implement the continuing education requirements under Minnesota Statutes, section 214.12, subdivision 6.

(l) Board of Optometry; continuing education. \$5,000 in fiscal year 2020 is appropriated from the state government special revenue fund to the Board of Optometry to implement the continuing education requirements under Minnesota Statutes, section 214.12, subdivision 6.

(m) Board of Podiatric Medicine; continuing education. \$5,000 in fiscal year 2020 is appropriated from the state government special revenue fund to the Board of Podiatric Medicine to implement the continuing education requirements under Minnesota Statutes, section 214.12, subdivision 6.

(n) Commissioner of health; nonnarcotic pain management and wellness. \$1,250,000 is appropriated in fiscal year 2020 from the general fund to the commissioner of health, to provide funding for:

(1) statewide mapping and assessment of community-based nonnarcotic pain management and wellness resources; and

(2) up to five demonstration projects in different geographic areas of the state to provide community-based nonnarcotic pain management and wellness resources to patients and consumers.

The demonstration projects must include an evaluation component and scalability analysis. The commissioner shall award the grant for the statewide mapping and assessment, and the demonstration project grants, through a competitive request for proposal process. Grants for statewide mapping and assessment and demonstration projects may be awarded simultaneously. In awarding demonstration project grants, the commissioner shall give preference to proposals that incorporate innovative community partnerships, are informed and led by people in the community where the project is taking place, and are culturally relevant and delivered by culturally competent providers. This is a onetime appropriation.

(o) Commissioner of health; administration. \$38,000 in fiscal year 2020 is appropriated from the general fund to the commissioner of health for the administration of the grants awarded in paragraph (n).

Sec. 2. **TRANSFER.** By June 30, 2021, the commissioner of human services shall transfer \$5,439,000 from the opiate epidemic response account to the general fund. This is a onetime transfer.

Sec. 3. **EXPIRATION OF UNCODIFIED LANGUAGE.** The uncodified language in this article shall not expire on June 30, 2021.

Presented to the governor May 22, 2019

Signed by the governor May 22, 2019, 1:51 p.m.

HHS Omnibus Policy and Finance Bill (2019 Special Session Law, Chapter 12)

Article 9, Sec. 2. **[62Q.528] DRUG COVERAGE IN EMERGENCY SITUATIONS.**

A health plan that provides prescription drug coverage must provide coverage for a prescription drug dispensed by a pharmacist under section 151.211, subdivision 3, under the terms of coverage that would apply had the prescription drug been dispensed according to a prescription.

Article 9, Sec. 3. Minnesota Statutes 2018, 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), (e), and (f); and [151.461](#), "practitioner" also means a 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

Article 9, Sec. 4. Minnesota Statutes 2018, section 151.06, is amended by adding a subdivision 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 prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(3) 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) 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) 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) 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).

Article 9, Sec. 5. Minnesota Statutes 2018, section 151.211, subdivision 2, is amended to read:

Subd. 2. Refill requirements. Except as provided in subdivision 3, a prescription drug order may be refilled only with the written, electronic, or verbal consent of the prescriber and in accordance with the requirements of this chapter, the rules of the board, and where applicable, section [152.11](#). The date of such refill must be recorded and initialed upon the original prescription drug order, or within the electronically maintained record of the original prescription drug order, by the pharmacist, pharmacist intern, or practitioner who refills the prescription.

Article 9, Sec. 6. Minnesota Statutes 2018, section 151.211, is amended by adding a subdivision to read:

Subd. 3. Emergency prescription refills.

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

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

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

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

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

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

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

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

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

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

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

Article 9, Sec. 7 [151.555] PRESCRIPTION DRUG REPOSITORY PROGRAM.

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. 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 supply 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.

Subd. 2. Establishment. By January 1, 2020, the Board of Pharmacy shall establish a drug repository program, through which donors may donate a drug or medical supply for use by an individual who meets the eligibility criteria specified under subdivision 5. The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the prescription drug repository program.

Subd. 3. Central repository requirements. (a) The board shall 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 shall follow all applicable state procurement procedures in the selection process.

(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.

Subd. 4. Local repository requirements. (a) To be eligible for participation in the drug repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the drug repository program, drug storage, and

dispensing. The facility must also agree to maintain in good standing any required state license or registration that may apply to the facility.

(b) A local repository may elect to participate in the program by submitting the following information to the central repository on a form developed by the board and made available on the board's website:

(1) the name, street address, and telephone number of the health care facility and any state-issued license or registration number issued to the facility, including the issuing state agency;

(2) the name and telephone number of a responsible pharmacist or practitioner who is employed by or under contract with the health care facility; and

(3) a statement signed and dated by the responsible pharmacist or practitioner indicating that the health care facility meets the eligibility requirements under this section and agrees to comply with this section.

(c) Participation in the drug repository program is voluntary. A local repository may withdraw from participation in the drug repository program at any time by providing written notice to the central repository on a form developed by the board and made available on the board's website. The central repository shall provide the board with a copy of the withdrawal notice within ten business days from the date of receipt of the withdrawal notice.

Subd. 5. Individual eligibility and application requirements. (a) To be eligible for the drug repository program, an individual must submit to a local repository an intake application form that is signed by the individual and attests that the individual:

(1) is a resident of Minnesota;

(2) is uninsured and is not enrolled in the medical assistance program under chapter 256B or the MinnesotaCare program under chapter 256L, has no prescription drug coverage, or is underinsured;

(3) acknowledges that the drugs or medical supplies to be received through the program may have been donated; and

(4) consents to a waiver of the child-resistant packaging requirements of the federal Poison Prevention Packaging Act.

(b) Upon determining that an individual is eligible for the program, the local repository shall furnish the individual with an identification card. The card shall be valid for one year from the date of issuance and may be used at any local repository. A new identification card may be issued upon expiration once the individual submits a new application form.

(c) The local repository shall send a copy of the intake application form to the central repository by regular mail, facsimile, or secured e-mail within ten days from the date the application is approved by the local repository.

(d) The board shall develop and make available on the board's website an application form and the format for the identification card.

Subd. 6. Standards and procedures for accepting donations of drugs and supplies. (a) A donor may donate prescription drugs or medical supplies to the central repository or a local repository if the drug or supply meets the requirements of this section as determined by a pharmacist or practitioner who is employed by or under contract with the central repository or a local repository.

(b) A prescription drug is eligible for donation under the drug repository program if the following requirements are met:

(1) the donation is accompanied by a drug repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d);

(2) the drug's expiration date is at least six months after the date the drug was donated. If a donated drug bears an expiration date that is less than six months from the donation date, the drug may be accepted and distributed if the drug is in high demand and can be dispensed for use by a patient before the drug's expiration date;

(3) the drug is in its original, sealed, unopened, tamper-evident packaging that includes the expiration date. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened;

(4) the drug or the packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

(5) the drug does not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, unless the drug is being donated directly by its manufacturer, a wholesale drug distributor, or a pharmacy located in Minnesota; and

(6) the prescription drug is not a controlled substance.

(c) A medical supply is eligible for donation under the drug repository program if the following requirements are met:

(1) the supply has no physical signs of tampering, misbranding, or alteration and there is no reason to believe it has been adulterated, tampered with, or misbranded;

(2) the supply is in its original, unopened, sealed packaging;

(3) the donation is accompanied by a drug repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d); and

(4) if the supply bears an expiration date, the date is at least six months later than the date the supply was donated. If the donated supply bears an expiration date that is less than six months from the date the supply was donated, the supply may be accepted and distributed if the supply is in high demand and can be dispensed for use by a patient before the supply's expiration date.

(d) The board shall develop the drug repository donor form and make it available on the board's website. The form must state that to the best of the donor's knowledge the donated drug or supply has been properly stored under appropriate temperature and humidity conditions, and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded.

(e) Donated drugs and supplies may be shipped or delivered to the premises of the central repository or a local repository, and shall be inspected by a pharmacist or an authorized practitioner who is employed by or under contract with the repository and who has been designated by the repository to accept donations. A drop box must not be used to deliver or accept donations.

(f) The central repository and local repository shall inventory all drugs and supplies donated to the repository. For each drug, the inventory must include the drug's name, strength, quantity, manufacturer, expiration date, and the date the drug was donated. For each medical supply, the inventory must include a description of the supply, its manufacturer, the date the supply was donated, and, if applicable, the supply's brand name and expiration date.

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 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.

Subd. 8. Dispensing requirements. (a) Donated drugs and supplies may be dispensed if the drugs or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist or practitioner. A repository shall dispense drugs and supplies to eligible individuals in the following priority order: (1) individuals who are uninsured; (2) individuals with no prescription drug coverage; and (3) individuals who are underinsured. A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(b) Before dispensing or administering a drug or supply, the pharmacist or practitioner shall visually inspect the drug or supply for adulteration, misbranding, tampering, and date of expiration. Drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way must not be dispensed or administered.

(c) Before a drug or supply is dispensed or administered to an individual, the individual must sign a drug repository recipient form acknowledging that the individual understands the

information stated on the form. The board shall develop the form and make it available on the board's website. The form must include the following information:

(1) that the drug or supply being dispensed or administered has been donated and may have been previously dispensed;

(2) that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the drug or supply has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging; and

(3) that the dispensing pharmacist, the dispensing or administering practitioner, the central repository or local repository, the Board of Pharmacy, and any other participant of the drug repository program cannot guarantee the safety of the drug or medical supply being dispensed or administered and that the pharmacist or practitioner has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or medical supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

Subd. 9. **Handling fees.** (a) The central or local repository may charge the individual receiving a drug or supply a handling fee of no more than 250 percent of the medical assistance program dispensing fee for each drug or medical supply dispensed or administered by that repository.

(b) A repository that dispenses or administers a drug or medical supply through the drug repository program shall not receive reimbursement under the medical assistance program or the MinnesotaCare program for that dispensed or administered drug or supply.

Subd. 10. **Distribution of donated drugs and supplies.** (a) The central repository and local repositories may distribute drugs and supplies donated under the drug repository program to other participating repositories for use pursuant to this program.

(b) A local repository that elects not to dispense donated drugs or supplies must transfer all donated drugs and supplies to the central repository. A copy of the donor form that was completed by the original donor under subdivision 6 must be provided to the central repository at the time of transfer.

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 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.

Subd. 12. Liability. (a) The manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or to property for causes of action described in clauses (1) and (2). A manufacturer is not liable for:

(1) the intentional or unintentional alteration of the drug or supply by a party not under the control of the manufacturer; or

(2) the failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

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

Subd. 13. Drug returned for credit. Nothing in this section allows a long-term care facility to donate a drug to a central or local repository when federal or state law requires the drug to be returned to the pharmacy that initially dispensed it, so that the pharmacy can credit the payer for the amount of the drug returned.

Article 9, Sec. 8. **[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).

(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.

Article 10, Sec. 24. Minnesota Statutes 2018, section 151.01, subdivision 31, is amended to read:

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

Article 10, Sec. 25. Minnesota Statutes 2018, section 151.01, subdivision 35, is amended to read:

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

Article 10, Sec. 26. (Note that these fee increases are combined with the fee increases made in the Opioid Omnibus Bill). Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:

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

- (1) pharmacist licensed by examination, ~~\$145~~ \$175;
- (2) pharmacist licensed by reciprocity, ~~\$240~~ \$275;
- (3) pharmacy intern, ~~\$37.50~~ \$50;
- (4) pharmacy technician, ~~\$37.50~~ \$50;
- (5) pharmacy, ~~\$225~~ \$260;
- (6) drug wholesaler, legend drugs only, ~~\$235~~ \$260;
- (7) drug wholesaler, legend and nonlegend drugs, ~~\$235~~ \$260;
- (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~\$210~~ \$260;
- (9) drug wholesaler, medical gases, ~~\$175~~ \$260;
- (10) ~~drug wholesaler, also licensed as a pharmacy in Minnesota,~~ \$150 third-party logistics provider, \$260;
- (11) drug manufacturer, legend drugs only, ~~\$235~~ \$260;
- (12) drug manufacturer, legend and nonlegend drugs, ~~\$235~~ \$260;
- (13) drug manufacturer, nonlegend or veterinary legend drugs, ~~\$210~~ \$260;
- (14) drug manufacturer, medical gases, ~~\$185~~ \$260;
- (15) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$260;
- (16) medical gas distributor, ~~\$110~~ \$260;
- (17) controlled substance researcher, \$75; and
- (18) pharmacy professional corporation, ~~\$125~~ \$150.

Article 10, Sec. 27 (Note that these fee increases are combined with the fee increases made in the Opioid Omnibus Bill). Minnesota Statutes 2018, section 151.065, subdivision 2, is amended to read:

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

Article 10, Sec. 28. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:

Subd. 3. **Annual renewal fees.**

Annual licensure and registration renewal fees are as follows:

- (1) pharmacist, ~~\$145~~ \$175;
- (2) pharmacy technician, ~~\$37.50~~ \$50;

- (3) pharmacy, ~~\$225~~ \$260;
- (4) drug wholesaler, legend drugs only, ~~\$235~~ \$260;
- (5) drug wholesaler, legend and nonlegend drugs, ~~\$235~~ \$260;
- (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~\$210~~ \$260;
- (7) drug wholesaler, medical gases, ~~\$185~~ \$260;
- (8) ~~drug wholesaler, also licensed as a pharmacy in Minnesota, \$150~~ third-party logistics provider, \$260;
- (9) drug manufacturer, legend drugs only, ~~\$235~~ \$260;
- (10) drug manufacturer, legend and nonlegend drugs, ~~\$235~~ \$260;
- (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, ~~\$210~~ \$260;
- (12) drug manufacturer, medical gases, ~~\$185~~ \$260;
- (13) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~\$150~~ \$260;
- (14) medical gas distributor, ~~\$110~~ \$260;
- (15) controlled substance researcher, \$75; and
- (16) pharmacy professional corporation, ~~\$75~~ \$100.

Article 10, Sec. 29. Minnesota Statutes 2018, section 151.065, subdivision 6, is amended to read:

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

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

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

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

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

Article 10, Sec. 30 Minnesota Statutes 2018, section 151.071, subdivision 2, is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) fee splitting, including without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 10, Sec. 31. Minnesota Statutes 2018, section 151.15, subdivision 1, is amended to read:

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

Article 10, Sec. 32. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Article 10, Sec. 33. Minnesota Statutes 2018, section 151.15, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Article 10, Sec. 34. Minnesota Statutes 2018, section 151.19, subdivision 1, is amended to read:

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

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

(c) No license shall be issued or renewed for a pharmacy located within the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal and state

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 10, Sec. 35. Minnesota Statutes 2018, section 151.19, subdivision 3, is amended to read:

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

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

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

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

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

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

Article 10, Sec. 36. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

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

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

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

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

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

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

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

Article 10, Sec. 37. Minnesota Statutes 2018, section 151.252, subdivision 1a, is amended to read:

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

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

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

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

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

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

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

Article 10, Sec. 38. Minnesota Statutes 2018, section 151.252, subdivision 3, is amended to read:

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

Article 10, Sec. 39. Minnesota Statutes 2018, section 151.253, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

Article 10, Sec. 40. Minnesota Statutes 2018, section 151.32, is amended to read:

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

Article 10, Sec. 41. Minnesota Statutes 2018, section 151.40, subdivision 1, is amended to read:

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

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

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

(ii) licensed pharmacies and their employees or agents;

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

(iv) registered nurses, and licensed practical nurses;

(v) registered medical technologists;

(vi) medical interns, and residents;

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

(viii) licensed hospitals;

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

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

(xi) licensed morticians;

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

(xiii) persons engaged in animal husbandry;

(xiv) clinical laboratories and their employees;

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

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

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

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

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

Article 10, Sec. 42. Minnesota Statutes 2018, section 151.40, subdivision 2, is amended to read:

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

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

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

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

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

Article 10, Sec. 43. Minnesota Statutes 2018, section 151.43, is amended to read:

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

Article 10, Sec. 44. [151.441] DEFINITIONS. Subdivision 1. Scope. As used in sections 151.43 to 151.51, the following terms have the meanings given in this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

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

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

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

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

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

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

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

Article 10, Sec. 45. Minnesota Statutes 2018, section 151.46, is amended to read:

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

Article 10, Sec. 46. Minnesota Statutes 2018, section 151.47, subdivision 1, is amended to read:

Subdivision 1. ~~Requirements~~ **Generally.** ~~(a) All wholesale drug distributors are subject to the requirements of this subdivision.~~ Each manufacturer, repackager, wholesale distributor, and

dispenser shall comply with the requirements set forth in United States Code, title 21, section 360eee-1, with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving a product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in United States Code, title 21, section 360eee-1, but shall not be required to duplicate requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 10, Sec. 47. Minnesota Statutes 2018, section 151.47, is amended by adding a subdivision to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 10, Sec. 48. **[151.471] THIRD-PARTY LOGISTICS PROVIDER**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) will develop and, as necessary, update written policies and procedures that ensure reasonable preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government

emergency, inventory inaccuracies or drug shipping and receiving, outdated drug, appropriate handling of returned goods, and drug recalls;

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

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

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

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

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

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

Article 10, Sec. 49. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read:

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

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

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

(i) prescribing or considering prescribing any controlled substance;

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

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

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

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

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

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

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

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

(7) authorized personnel of a vendor under contract with the state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(k) The board shall conduct random audits, on at least a quarterly basis, of electronic access by permissible users, as identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), to the data in subdivision 4, to ensure compliance with permissible use as defined in this section. A permissible user whose account has been selected for a random audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being

conducted. Failure to respond may result in deactivation of access to the electronic system and referral to the appropriate health licensing board, or the commissioner of human services, for further action. The board shall report the results of random audits to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and government data practices.

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

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

Article 10, Sec. 50. Minnesota Statutes 2018, section 152.126, subdivision 7, is amended to read:

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

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

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

Article 10, Sec. 51. Minnesota Statutes 2018, section 152.126, is amended by adding a subdivision to read:

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

Article 10, Sec. 52. **REVISOR INSTRUCTION.** The fee increases in Minnesota Statutes, section 151.065, subdivisions 1 and 3, in this article are in addition to any other fee increases in

Minnesota Statutes, section 151.065, subdivisions 1 and 3, enacted in 2019 regular or special sessions. If multiple fees are enacted, the revisor of statutes shall add the fees together for publication in the 2019 Minnesota Statutes Supplement to effectuate the intent of the legislature.

Sec. 53. **REPEALER.** (a) Minnesota Statutes 2018, sections 151.42; 151.44; 151.49; 151.50; 151.51; and 151.55, are repealed.

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

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

Article 11, Sec. 76. [151.72] SALE OF CERTAIN CANNABINOID PRODUCTS.

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(b) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 3.

(c) "Labeling" means all labels and other written, printed, or graphic matter that are:

(1) affixed to the immediate container in which a product regulated under this section is sold; or

(2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets.

Subd. 2. **Scope.** (a) This section applies to the sale of any product that contains nonintoxicating cannabinoids extracted from hemp other than food that is intended for human or animal consumption by any route of administration.

(b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.

Subd. 3. **Sale of cannabinoids derived from hemp.** Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids may be sold for human or animal consumption if all of the requirements of this section are met.

Subd. 4. **Testing requirements.** (a) A manufacturer of a product regulated under this section must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and at a minimum, the testing must confirm that the product:

(1) contains the amount or percentage of cannabinoids that is stated on the label of the product;

(2) does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals; and

(3) does not contain a delta-9 tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in section 18K.02, subdivision 3.

(b) Upon the request of the board, the manufacturer of the product must provide the board with the results of the testing required in this section.

Subd. 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:

(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;

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

(4) a statement stating that this product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

(b) The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.

(c) The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Subd. 6. **Enforcement.** (a) A product sold under this section shall be considered an adulterated drug if:

(1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;

(2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;

(3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(4) it contains any color additives or excipients that have been found by the FDA to be unsafe for human or animal consumption; or

(5) it contains an amount or percentage of cannabinoids that is different than the amount or percentage stated on the label.

(b) A product sold under this section shall be considered a misbranded drug if the product's labeling is false or misleading in any manner or in violation of the requirements of this section.

(c) The board's authority to issue cease and desist orders under section 151.06; to embargo adulterated and misbranded drugs under section 151.38; and to seek injunctive relief under section 214.11, extends to any violation of this section.

EFFECTIVE DATE. This section is effective January 1, 2020, and applies to any product sold in Minnesota on or after that date.

Article 11, Sec. 110. **SALE OF CERTAIN CANNABINOID PRODUCTS WORKGROUP.**

(a) The commissioner of health, in consultation with the commissioners of commerce, agriculture, and public safety, and the executive director of the Board of Pharmacy, shall convene a workgroup to advise the legislature on how to regulate products that contain cannabinoids extracted from hemp. For purposes of this section, "hemp" has the meaning given to "industrial hemp" in Minnesota Statutes, section 18K.02, subdivision 3.

(b) The commissioner shall assess the public health and consumer safety impact on the sale of cannabinoids derived from hemp and shall develop a regulatory framework of what the legislature would need to consider including, but not limited to:

(1) cultivation standards for industrial hemp if the hemp is used for any product intended for human or animal consumption;

(2) labeling requirements for products containing cannabidiol extracted from hemp, including the amount and percentage of cannabidiol in the product, the name of the manufacturer of the product, and the ingredients contained in the product;

(3) possible restrictions of advertising and marketing of the cannabidiol product;

(4) restrictions of false, misleading, or unsubstantiated health claims;

(5) requirements for the independent testing of cannabidiol products, including quality control and chemical identification;

(6) safety standards for edible products containing cannabinoids extracted from hemp, including container and packaging requirements; and

(7) any other requirement or procedure the commissioner deems necessary.

(c) By January 15, 2020, the commissioner of health shall submit the results of the workgroup to the chairs and ranking minority members of the legislative committees with jurisdiction over public health, consumer protection, public safety, and agriculture.

CHAPTER 49--H.F.No. 637

An act relating to health; modifying temporary license suspensions and background checks for certain health-related professions; amending Minnesota Statutes 2018, sections 214.075, subdivisions 1, 4, 5, 6; 214.077; 214.10, subdivision 8; repealing Minnesota Statutes 2018, section 214.075, subdivision 8.

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

Section 1. Minnesota Statutes 2018, section 214.075, subdivision 1, is amended to read:

Subdivision 1. **Applications.** (a) ~~By January 1, 2018,~~ Each health-related licensing board, as defined in section [214.01, subdivision 2](#), shall require applicants for initial licensure, licensure

~~by endorsement, or reinstatement or other relicensure after a lapse in licensure, as defined by the individual health-related licensing boards, the following individuals to submit to a criminal history records check of state data completed by the Bureau of Criminal Apprehension (BCA) and a national criminal history records check, including a search of the records of the Federal Bureau of Investigation (FBI):~~

(1) applicants for initial licensure or licensure by endorsement. An applicant is exempt from this paragraph if the applicant submitted to a state and national criminal history records check as described in this paragraph for a license issued by the same board;

(2) applicants seeking reinstatement or relicensure, as defined by the individual health-related licensing board, if more than one year has elapsed since the applicant's license or registration expiration date; or

(3) licensees applying for eligibility to participate in an interstate licensure compact.

(b) An applicant must complete a criminal background check if more than one year has elapsed since the applicant last submitted a background check to the board. An applicant's criminal background check results are valid for one year from the date the background check results were received by the board. If more than one year has elapsed since the results were received by the board, then an applicant who has not completed the licensure, reinstatement, or relicensure process must complete a new background check.

Sec. 2. Minnesota Statutes 2018, section 214.075, subdivision 4, is amended to read:

Subd. 4. Refusal to consent. (a) The health-related licensing boards shall not issue a license to any applicant who refuses to consent to a criminal background check or fails to submit fingerprints ~~within 90 days~~ after submission of an application for licensure. Any fees paid by the applicant to the board shall be forfeited if the applicant refuses to consent to the criminal background check or fails to submit the required fingerprints.

(b) The failure of a licensee to submit to a criminal background check as provided in subdivision 3 is grounds for disciplinary action by the respective health-related licensing board.

Sec. 3. Minnesota Statutes 2018, section 214.075, subdivision 5, is amended to read:

Subd. 5. Submission of fingerprints to the Bureau of Criminal Apprehension.

The health-related licensing board or designee shall submit applicant or licensee fingerprints to the BCA. The BCA shall perform a check for state criminal justice information and shall forward the applicant's or licensee's fingerprints to the FBI to perform a check for national criminal justice information regarding the applicant or licensee. The BCA shall report to the board the results of the state and national criminal ~~justice information~~ history records checks.

Sec. 4. Minnesota Statutes 2018, section 214.075, subdivision 6, is amended to read:

Subd. 6. Alternatives to fingerprint-based criminal background checks.

The health-related licensing board may require an alternative method of criminal history checks for an applicant or licensee who has submitted at least ~~three~~ two sets of fingerprints in accordance with this section that have been unreadable by the BCA or the FBI.

Sec. 5. Minnesota Statutes 2018, section 214.077, is amended to read:

214.077 TEMPORARY LICENSE SUSPENSION; IMMINENT RISK OF SERIOUS HARM.

(a) Notwithstanding any provision of a health-related professional practice act, when a health-related licensing board receives a complaint regarding a regulated person and has probable cause to believe that the regulated person has violated a statute or rule that the health-related licensing board is empowered to enforce, and continued practice by the regulated person presents an imminent risk of serious harm, the health-related licensing board shall issue an order temporarily suspending the regulated person's authority to practice. The temporary suspension order shall specify the reason for the suspension, including the statute or rule alleged to have been violated. The temporary suspension order shall take effect upon personal service on the regulated person or the regulated person's attorney, or upon the third calendar day after the order is served by first class mail to the most recent address provided to the health-related licensing board for the regulated person or the regulated person's attorney.

(b) The temporary suspension shall remain in effect until the health-related licensing board or the commissioner completes an investigation, holds a contested case hearing pursuant to the Administrative Procedure Act, and issues a final order in the matter as provided for in this section.

(c) At the time it issues the temporary suspension order, the health-related licensing board shall schedule a contested case hearing, on the merits of whether discipline is warranted, to be held pursuant to the Administrative Procedure Act. The regulated person shall be provided with at least ten days' notice of any contested case hearing held pursuant to this section. The contested case hearing shall be scheduled to begin no later than 30 days after the effective service of the temporary suspension order.

(d) The administrative law judge presiding over the contested case hearing shall issue a report and recommendation to the health-related licensing board no later than 30 days after the final day of the contested case hearing. If the administrative law judge's report and recommendations are for no action, the health-related licensing board shall issue a final order pursuant to sections [14.61](#) and [14.62](#) within 30 days of receipt of the administrative law judge's report and recommendations. If the administrative law judge's report and recommendations are for action, the health-related licensing board shall issue a final order pursuant to sections [14.61](#) and [14.62](#) within 60 days of receipt of the administrative law judge's report and recommendations. Except as provided in paragraph (e), if the health-related licensing board has not issued a final order pursuant to sections [14.61](#) and [14.62](#) within 30 days of receipt of the administrative law judge's report and recommendations for no action or within 60 days of receipt of the administrative law judge's report and recommendations for action, the temporary suspension shall be lifted.

(e) If the regulated person requests a delay in the contested case proceedings provided for in paragraphs (c) and (d) for any reason, the temporary suspension shall remain in effect until the health-related licensing board issues a final order pursuant to sections [14.61](#) and [14.62](#).

(f) This section shall not apply to the Office of Unlicensed Complementary and Alternative Health Practice established under section [146A.02](#). The commissioner of health shall

conduct temporary suspensions for complementary and alternative health care practitioners in accordance with section [146A.09](#).

Sec. 6. Minnesota Statutes 2018, section 214.10, subdivision 8, is amended to read:

Subd. 8. Special requirements for health-related licensing boards. In addition to the provisions of this section that apply to all examining and licensing boards, the requirements in this subdivision apply to all health-related licensing boards, except the Board of Veterinary Medicine.

(a) If the executive director or consulted board member determines that a communication received alleges a violation of statute or rule that involves sexual contact with a patient or client, the communication shall be forwarded to the designee of the attorney general for an investigation of the facts alleged in the communication. If, after an investigation it is the opinion of the executive director or consulted board member that there is sufficient evidence to justify disciplinary action, the board shall conduct a disciplinary conference or hearing. If, after a hearing or disciplinary conference the board determines that misconduct involving sexual contact with a patient or client occurred, the board shall take disciplinary action. Notwithstanding subdivision 2, a board may not attempt to correct improper activities or redress grievances through education, conciliation, and persuasion, unless in the opinion of the executive director or consulted board member there is insufficient evidence to justify disciplinary action. The board may settle a case by stipulation prior to, or during, a hearing if the stipulation provides for disciplinary action.

(b) A board member who has a direct current or former financial connection or professional relationship to a person who is the subject of board disciplinary activities must not participate in board activities relating to that case.

(c) Each health-related licensing board shall establish procedures for exchanging information with other Minnesota state boards, agencies, and departments responsible for regulating health-related occupations, facilities, and programs, and for coordinating investigations involving matters within the jurisdiction of more than one regulatory body. The procedures must provide for the forwarding to other regulatory bodies of all information and evidence, including the results of investigations, that are relevant to matters within that licensing body's regulatory jurisdiction. Each health-related licensing board shall have access to any data of the Department of Human Services relating to a person subject to the jurisdiction of the licensing board. The data shall have the same classification under chapter 13, the Minnesota Government Data Practices Act, in the hands of the agency receiving the data as it had in the hands of the Department of Human Services.

(d) Each health-related licensing board shall establish procedures for exchanging information with other states regarding disciplinary actions against licensees. The procedures must provide for the collection of information from other states about disciplinary actions taken against persons who are licensed to practice in Minnesota or who have applied to be licensed in this state and the dissemination of information to other states regarding disciplinary actions taken in Minnesota. In addition to any authority in chapter 13 permitting the dissemination of data, the board may, in its discretion, disseminate data to other states regardless of its classification under chapter 13. Criminal history record information shall not be exchanged. Before transferring any

data that is not public, the board shall obtain reasonable assurances from the receiving state that the data will not be made public.

Sec. 7. **REPEALER.** Minnesota Statutes 2018, section 214.075, subdivision 8, is repealed.

Sec. 8. **EFFECTIVE DATE.** Sections 1 to 7 are effective the day following final enactment.

Presented to the governor May 22, 2019

Signed by the governor May 22, 2019, 1:45 p.m.

While not under the jurisdiction of the Board of Pharmacy, the following legislation that was enacted during the 2019 Session may have an impact on the Board and/or its licensees and registrants.

HHS Omnibus Policy and Finance Bill (2019 Special Session Law, Chapter 12)

Article 11, Sec. 1. Minnesota Statutes 2018, section 18K.03, is amended to read:

18K.03 AGRICULTURAL CROP; POSSESSION AUTHORIZED.

Subdivision 1. Industrial hemp.

Industrial hemp is an agricultural crop in this state. A person may possess, transport, process, sell, or buy industrial hemp that is grown pursuant to this chapter.

Subd. 2. Sale to medical cannabis manufacturers. A licensee under this chapter may sell hemp products derived from industrial hemp grown in this state to medical cannabis manufacturers as authorized under sections 152.22 to 152.37.

S.F. 1 (Agriculture Policy and Finance Bill)

Sec. 10. Minnesota Statutes 2018, section 18K.02, subdivision 3, is amended to read:

Subd. 3. **Industrial hemp.** "Industrial hemp" means the plant *Cannabis sativa* L. and any part of the plant, whether growing or not, including the plant's seeds, and all the plant's derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Industrial hemp is not marijuana as defined in section [152.01, subdivision 9](#).

Sec. 11. Minnesota Statutes 2018, section 18K.03, is amended to read:

18K.03 AGRICULTURAL CROP; POSSESSION AUTHORIZED. Industrial hemp is an agricultural crop in this state. A person may possess, transport, process, sell, or buy industrial hemp that is grown pursuant to this chapter or lawfully grown in another state.

HHS Omnibus Policy and Finance Bill (2019 Special Session Law, Chapter 12)

Article 7, Sec. 4. Minnesota Statutes 2018, section 62Q.184, subdivision 3, is amended to read:

Subd. 3. Step therapy override process; transparency. (a) When coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health plan company through the use of a step therapy protocol, enrollees and prescribing health care providers shall have access to a clear, readily accessible, and convenient process to request a step therapy override. The process shall be made easily accessible on the health plan company's website. A health plan company may use its existing medical exceptions process to satisfy this requirement. A health plan company shall grant an override to the step therapy protocol if at least one of the following conditions exist:

(1) the prescription drug required under the step therapy protocol is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

- (i) cause an adverse reaction to the enrollee;
- (ii) decrease the ability of the enrollee to achieve or maintain reasonable functional ability in performing daily activities; or
- (iii) cause physical or mental harm to the enrollee;

(2) the enrollee has had a trial of the required prescription drug covered by their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and was adherent during such trial for a period of time sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the enrollee's health care provider due to lack of effectiveness, or an adverse event. This clause does not prohibit a health plan company from requiring an enrollee to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice guideline, Food and Drug Administration label, or pharmaceutical manufacturer's prescribing information. This clause does not apply to the commissioner of human services or a managed care plan, county-based purchasing plan, or integrated health partnership administering a pharmacy benefit under chapter 256B or 256L; or

(3) for the fee-for-service system administered by the commissioner of human services, or a managed care plan, county-based purchasing plan, or integrated health partnership administering a pharmacy benefit under chapter 256B or 256L, the enrollee has had a trial of the required prescription drug covered by their current or previous health plan, or a drug in the same pharmacological class with the same mechanism of action, and was adherent during such trial for

a period of time sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the enrollee's health care provider due to lack of effectiveness, or an adverse event, or the prescriber submits an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested drug over the required prescription drug. This clause does not prohibit a managed care plan, county-based purchasing plan, or integrated health partnership from requiring an enrollee to try another drug in the same pharmacologic class with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice guideline, Food and Drug Administration label, or pharmaceutical manufacturer's prescribing information; or

~~(3)~~(4) the enrollee is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on their current health plan or the immediately preceding health plan, the enrollee received coverage for the prescription drug and the enrollee's prescribing health care provider gives documentation to the health plan company that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the enrollee based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

(b) Upon granting a step therapy override, a health plan company shall authorize coverage for the prescription drug if the prescription drug is a covered prescription drug under the enrollee's health plan.

(c) The enrollee, or the prescribing health care provider if designated by the enrollee, may appeal the denial of a step therapy override by a health plan company using the complaint procedure under sections [62Q.68](#) to [62Q.73](#) or [256.045](#).

(d) In a denial of an override request and any subsequent appeal, a health plan company's decision must specifically state why the step therapy override request did not meet the condition under paragraph (a) cited by the prescribing health care provider in requesting the step therapy override and information regarding the procedure to request external review of the denial pursuant to section [62Q.73](#). A denial of a request for a step therapy override that is upheld on appeal is a final adverse determination for purposes of section [62Q.73](#) and is eligible for a request for external review by an enrollee pursuant to section [62Q.73](#).

(e) A health plan company shall respond to a step therapy override request or an appeal within five days of receipt of a complete request. In cases where exigent circumstances exist, a health plan company shall respond within 72 hours of receipt of a complete request. If a health plan company does not send a response to the enrollee or prescribing health care provider if designated by the enrollee within the time allotted, the override request or appeal is granted and binding on the health plan company.

(f) Step therapy override requests must be accessible to and submitted by health care providers, and accepted by group purchasers electronically through secure electronic transmission, as described under section [62J.497, subdivision 5](#).

(g) Nothing in this section prohibits a health plan company from:

(1) requesting relevant documentation from an enrollee's medical record in support of a step therapy override request; or

(2) requiring an enrollee to try a generic equivalent drug pursuant to section [151.21](#), or a biosimilar, as defined under United States Code, chapter [42](#), section 262(i)(2), prior to providing coverage for the equivalent branded prescription drug.

(h) This section shall not be construed to allow the use of a pharmaceutical sample for the primary purpose of meeting the requirements for a step therapy override.

Sec. 24. Minnesota Statutes 2018, 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. ~~Over the counter medications must be dispensed in a quantity that is~~

~~the lowest of: (1) the number of dosage units contained in the manufacturer's original package; (2) the number of dosage units required to complete the patient's course of therapy; or (3) if applicable, the number of dosage units dispensed from a system using retrospective billing, as provided under subdivision 13e, paragraph (b).~~

(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.

EFFECTIVE DATE.

This section is effective July 1, 2019, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

Article 7, Sec. 25. Minnesota Statutes 2018, section 256B.0625, subdivision 13e, is amended to read:

Subd. 13e. **Payment rates.** (a) The basis for determining the amount of payment shall be the lower of the ~~actual acquisition~~ ingredient costs of the drugs ~~or the maximum allowable cost by the commissioner~~ plus the ~~fixed~~ professional dispensing fee; or the usual and customary price charged to the public. The usual and customary price means the lowest price charged by the provider to a patient who pays for the prescription by cash, check, or charge account and includes prices the pharmacy charges to a patient enrolled in a prescription savings club or prescription discount club administered by the pharmacy or pharmacy chain. The amount of payment basis must be reduced to reflect all discount amounts applied to the charge by any third-party provider/insurer agreement or contract for submitted charges to medical assistance programs. The net submitted charge may not be greater than the patient liability for the service. The ~~pharmacy~~ professional dispensing fee shall be ~~\$3.65~~ \$10.48 for ~~legend prescription drugs, except that prescriptions filled with legend drugs meeting the definition of "covered outpatient drugs" according to United States Code, title 42, section 1396r-8(k)(2).~~ The dispensing fee for intravenous solutions ~~which that~~ must be compounded by the pharmacist shall be ~~\$8~~ \$10.48 per bag, ~~\$14 per bag for cancer chemotherapy products, and \$30 per bag for total parenteral nutritional products dispensed in one liter quantities, or \$44 per bag for total parenteral nutritional products dispensed in quantities greater than one liter.~~ The professional dispensing fee for prescriptions filled with over-the-counter drugs meeting the definition of covered outpatient drugs shall be \$10.48 for dispensed quantities equal to or greater than the number of units

contained in the manufacturer's original package. The professional dispensing fee shall be prorated based on the percentage of the package dispensed when the pharmacy dispenses a quantity less than the number of units contained in the manufacturer's original package. The pharmacy dispensing fee for prescribed over-the-counter drugs not meeting the definition of covered outpatient drugs shall be \$3.65, except that the fee shall be \$1.31 for retrospectively billing pharmacies when billing for quantities less than the number of units contained in the manufacturer's original package. Actual acquisition cost includes quantity and other special discounts except time and cash discounts. The actual acquisition cost of a drug shall be estimated by the commissioner at wholesale acquisition cost plus four percent for independently owned pharmacies located in a designated rural area within Minnesota, and at wholesale acquisition cost plus two percent for all other pharmacies. A pharmacy is "independently owned" if it is one of four or fewer pharmacies under the same ownership nationally. A "designated rural area" means an area defined as a small rural area or isolated rural area according to the four category classification of the Rural Urban Commuting Area system developed for the United States Health Resources and Services Administration. Effective January 1, 2014, the actual acquisition for quantities equal to or greater than the number of units contained in the manufacturer's original package and shall be prorated based on the percentage of the package dispensed when the pharmacy dispenses a quantity less than the number of units contained in the manufacturer's original package. The National Average Drug Acquisition Cost (NADAC) shall be used to determine the ingredient cost of a drug. For drugs for which a NADAC is not reported, the commissioner shall estimate the ingredient cost at the wholesale acquisition cost minus two percent. The ingredient cost of a drug acquired through for a provider participating in the federal 340B Drug Pricing Program shall be estimated by the commissioner at wholesale acquisition cost minus 40 percent either the 340B Drug Pricing Program ceiling price established by the Health Resources and Services Administration or NADAC, whichever is lower. Wholesale acquisition cost is defined as the manufacturer's list price for a drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. The maximum allowable cost of a multisource drug may be set by the commissioner and it shall be comparable to, but the actual acquisition cost of the drug product and no higher than, the maximum amount paid by other third party payors in this state who have maximum allowable cost programs the NADAC of the generic product. Establishment of the amount of payment for drugs shall not be subject to the requirements of the Administrative Procedure Act.

(b) Pharmacies dispensing prescriptions to residents of long-term care facilities using an automated drug distribution system meeting the requirements of section [151.58](#), or a packaging system meeting the packaging standards set forth in Minnesota Rules, part [6800.2700](#), that govern the return of unused drugs to the pharmacy for reuse, may employ retrospective billing for prescription drugs dispensed to long-term care facility residents. A retrospectively billing pharmacy must submit a claim only for the quantity of medication used by the enrolled recipient during the defined billing period. A retrospectively billing pharmacy must use a billing period not less than one calendar month or 30 days.

(c) ~~An additional dispensing fee of \$.30 may be added to the dispensing fee paid to pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities when a unit dose blister card system, approved by the department, is used. Under this type of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National Drug~~

Code (NDC) from the drug container used to fill the blister card must be identified on the claim to the department. The unit dose blister card containing the drug must meet the packaging standards set forth in Minnesota Rules, part ~~6800.2700~~, that govern the return of unused drugs to the pharmacy for reuse. A pharmacy provider using packaging that meets the standards set forth in Minnesota Rules, part 6800.2700, is required to credit the department for the actual acquisition cost of all unused drugs that are eligible for reuse, unless the pharmacy is using retrospective billing. The commissioner may permit the drug clozapine to be dispensed in a quantity that is less than a 30-day supply.

(d) ~~Whenever a maximum allowable cost has been set for~~ If a pharmacy dispenses a multisource drug, payment shall be the lower of the usual and customary price charged to the public or the ingredient cost shall be the NADAC of the generic product or the maximum allowable cost established by the commissioner unless prior authorization for the brand name product has been granted according to the criteria established by the Drug Formulary Committee as required by subdivision 13f, paragraph (a), and the prescriber has indicated "dispense as written" on the prescription in a manner consistent with section 151.21, subdivision 2.

(e) The basis for determining the amount of payment for drugs administered in an outpatient setting shall be the lower of the usual and customary cost submitted by the provider, 106 percent of the average sales price as determined by the United States Department of Health and Human Services pursuant to title XVIII, section 1847a of the federal Social Security Act, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. If average sales price is unavailable, the amount of payment must be lower of the usual and customary cost submitted by the provider, the wholesale acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. ~~Effective January 1, 2014,~~ The commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by ~~20~~ 28.6 percent. The payment for drugs administered in an outpatient setting shall be made to the administering facility or practitioner. A retail or specialty pharmacy dispensing a drug for administration in an outpatient setting is not eligible for direct reimbursement.

(f) The commissioner may ~~negotiate lower reimbursement~~ establish maximum allowable cost rates for specialty pharmacy products than the rates that are lower than the ingredient cost formulas specified in paragraph (a). The commissioner may require individuals enrolled in the health care programs administered by the department to obtain specialty pharmacy products from providers with whom the commissioner has negotiated lower reimbursement rates. Specialty pharmacy products are defined as those used by a small number of recipients or recipients with complex and chronic diseases that require expensive and challenging drug regimens. Examples of these conditions include, but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis C, growth hormone deficiency, Crohn's Disease, rheumatoid arthritis, and certain forms of cancer. Specialty pharmaceutical products include injectable and infusion therapies, biotechnology drugs, antihemophilic factor products, high-cost therapies, and therapies that require complex care. The commissioner shall consult with the Formulary Committee to develop a list of specialty pharmacy products subject to ~~this paragraph~~ maximum allowable cost reimbursement. In consulting with the Formulary Committee in developing this list, the commissioner shall take into consideration the population served by specialty pharmacy products, the current delivery system and standard of care in the state, and access to care issues. The commissioner shall have the discretion to adjust the ~~reimbursement rate~~ maximum allowable cost to prevent access to care issues.

(g) Home infusion therapy services provided by home infusion therapy pharmacies must be paid at rates according to subdivision 8d.

(h) The commissioner shall contract with a vendor to conduct a cost of dispensing survey for all pharmacies that are physically located in the state of Minnesota that dispense outpatient drugs under medical assistance. The commissioner shall ensure that the vendor has prior experience in conducting cost of dispensing surveys. Each pharmacy enrolled with the department to dispense outpatient prescription drugs to fee-for-service members must respond to the cost of dispensing survey. The commissioner may sanction a pharmacy under section 256B.064 for failure to respond. The commissioner shall require the vendor to measure a single statewide cost of dispensing for all responding pharmacies to measure the mean, mean weighted by total prescription volume, mean weighted by medical assistance prescription volume, median, median weighted by total prescription volume, and median weighted by total medical assistance prescription volume. The commissioner shall post a copy of the final cost of dispensing survey report on the department's website. The initial survey must be completed no later than January 1, 2021, and repeated every three years. The commissioner shall provide a summary of the results of each cost of dispensing survey and provide recommendations for any changes to the dispensing fee to the chairs and ranking members of the legislative committees with jurisdiction over medical assistance pharmacy reimbursement.

(i) The commissioner shall increase the ingredient cost reimbursement calculated in paragraphs (a) and (f) by 1.8 percent for prescription and nonprescription drugs subject to the wholesale drug distributor tax under section 295.52.

EFFECTIVE DATE. This section is effective July 1, 2019, or upon federal approval, whichever is later. Paragraph (i) expires if federal approval is denied. The commissioner of human services shall inform the revisor of statutes when federal approval is obtained or denied.

Article 7, Sec. 26. Minnesota Statutes 2018, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

- (1) there is no generically equivalent drug available; and
- (2) the drug was initially prescribed for the recipient prior to July 1, 2003; or
- (3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

~~(d) Prior authorization shall not be required or utilized for any antihemophilic factor drug prescribed for the treatment of hemophilia and blood disorders where there is no generically equivalent drug available if the prior authorization is used in conjunction with any supplemental drug rebate program or multistate preferred drug list established or administered by the commissioner.~~

~~(e)~~ (d) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section [151.21, subdivision 2](#).

~~(f)~~ (e) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

(f) Prior authorization under this subdivision shall comply with section 62Q.184.

EFFECTIVE DATE. This section is effective the day following final enactment, except that paragraph (f) is effective July 1, 2019.

Article 7, Sec. 32. Minnesota Statutes 2018, section 256B.064, subdivision 1a, is amended to read:

Subd. 1a. Grounds for sanctions against vendors.

(a) The commissioner may impose sanctions against a vendor of medical care for any of the following: (1) fraud, theft, or abuse in connection with the provision of medical care to recipients of public assistance; (2) a pattern of presentment of false or duplicate claims or claims for services not medically necessary; (3) a pattern of making false statements of material facts for the purpose of obtaining greater compensation than that to which the vendor is legally entitled; (4) suspension or termination as a Medicare vendor; (5) refusal to grant the state agency access during regular business hours to examine all records necessary to disclose the extent of services provided to program recipients and appropriateness of claims for payment; (6) failure to repay an overpayment or a fine finally established under this section; (7) failure to correct errors in the maintenance of health service or financial records for which a fine was imposed or after issuance of a warning by the commissioner; and (8) any reason for which a vendor could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(2) of the Social Security Act.

(b) The commissioner may impose sanctions against a pharmacy provider for failure to respond to a cost of dispensing survey under section 256B.0625, subdivision 13e, paragraph (h).

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

Sec. 30. Minnesota Statutes 2018, section 245G.22, subdivision 1, is amended to read:
Subdivision 1. *(Note – this concerns opioid treatment programs).*

Additional requirements. (a) An opioid treatment program licensed under this chapter must also: (1) comply with the requirements of this section and Code of Federal Regulations, title 42, part 8. ~~When federal guidance or interpretations are issued on federal standards or requirements also required under this section, the federal guidance or interpretations shall apply.~~; (2) be registered as a narcotic treatment program with the Drug Enforcement Administration; (3) be accredited through an accreditation body approved by the Division of Pharmacologic Therapy of the Center for Substance Abuse Treatment; (4) be certified through the Division of Pharmacologic Therapy of the Center for Substance Abuse Treatment; and (5) hold a license from the Minnesota Board of Pharmacy or equivalent agency.

(b) Where a standard in this section differs from a standard in an otherwise applicable administrative rule or statute, the standard of this section applies.

Article 8, Sec. 15. **[62Q.48] COST-SHARING IN PRESCRIPTION INSULIN DRUGS.**

Subdivision 1. Scope of coverage. This section applies to all health plans issued or renewed to a Minnesota resident.

Subd. 2. Definitions. (a) For the purposes of this section, the terms defined in this subdivision have the meanings given them.

(b) "Cost-sharing" means a deductible payment, co-payment, or coinsurance amount imposed on an enrollee for a covered prescription drug in accordance with the terms and conditions of the enrollee's health plan.

(c) "Legend drug" has the same meaning as in section 151.01, subdivision 17.

(d) "Prescription insulin drug" means a legend drug that contains insulin and is used to treat diabetes.

(e) "Net price" means the health plan company's cost for a prescription insulin drug, including any rebates or discounts received by or accrued directly or indirectly to the health plan company from a drug manufacturer or pharmacy benefit manager.

Subd. 3. Cost-sharing limits. (a) A health plan that imposes a cost-sharing requirement on the coverage of a prescription insulin drug shall limit the total amount of cost-sharing that an enrollee is required to pay at point of sale, including deductible payments and the cost-sharing amounts charged once the deductible is met at an amount that does not exceed the net price of the prescription insulin drug.

(b) Nothing in this section shall prevent a health plan company from imposing a cost-sharing requirement that is less than the amount specified in paragraph (a).

EFFECTIVE DATE.

This section is effective for health plans issued or renewed on or after January 1, 2020.