



Minnesota 2019 Legislative Session and Special Session Summary Minnesota Pharmacy

Early in the morning Saturday, May 25th, a rare Memorial Day Weekend Special Session of the Minnesota legislature adjourned. The 10 remaining budget bills that make up the State's \$48.3 billion two-year budget were adopted during the 21-hour Special Session. The following budget bills and a pension bill were adopted:

- Health & Human Services
- Taxes
- E-12 Education
- Environment & Natural Resources
- Public Safety & Judiciary
- Jobs & Energy
- Transportation
- Agriculture & Housing
- State Government Finance & Veterans Affairs
- Legacy
- Pensions

The Global Budget Agreement reached between the Governor, Speaker of the House and Senate Majority Leader included passing a \$500 million Capital Investment or Bonding Bill, however, the bill was not brought forward for a vote in either body and died when the Special Session adjourned. While the initial response from the Minority Leaders in both bodies was to not provide the votes necessary to suspend the rules and allow for a quick overtime session, in the end private discussions led to non-public agreements with the minority that provided legislative leaders and the Governor with a path to the finish line. Minority members in both bodies did offer a handful of amendments to various bills. Those amendments were not adopted and the Legislature was able to meet the 7 am, Saturday morning, adjournment time agreed to with the Governor. Governor Walz has since signed all 10 budget bills, which included the Health and Human Services Budget, signed this past Thursday.

The new State budget goes into effect on July 1, 2019. In addition to the passage of the State's budget, there were 65 other bills passed and signed into law by Governor Walz. Of importance to Minnesota pharmacy, in addition to the many provisions included in the Health and Human Services budget legislation is both the PBM licensure – Patient's Fair Practices legislation and Opioid Stewardship bill, both signed into law the last week of session. The Legislature is not scheduled to return until noon, Tuesday, February 11, 2020. Numerous House and Senate committees have indicated an interest in conducting hearings or listening sessions over the interim. And bills introduced during the 2019 legislative session and not acted on will remain in introduced status heading into 2020.

Below we provide a specific report highlighting Minnesota Pharmacy Alliance's 2019-2020 Legislative Session priorities. There is also a summary of provisions relevant to Minnesota pharmacy that was enacted through the Health and Human Service Omnibus budget legislation passed during the brief Special Session ([SF12](#)). Specific legislative bill language is included in Appendix A.

Minnesota Pharmacy Alliance priorities, provisions and authorities enacted out of the 2019 Legislative Session (More detailed summaries and specific legislative language can be found in Appendix A):

- **Medication Administration for Minnesota Pharmacists** ([SF1959](#)) broad medication administration authority legislation was introduced this year by Senators Jensen, Klein, Wiklund and Chair Abeler. Representative Mann, Morrison and Baker among other House members, are all interested in introducing companion legislation in 2020 in the House of Representatives if MPA seeks to expand medication administration authorities for pharmacists next year. SF1959 did not receive a hearing in the Minnesota Senate in 2019. Limited medication administration authorities for Minnesota pharmacists were enacted as provisions in the Opioid Stewardship legislation ([HF400](#); ** see Appendix A for enacted HF400).

Adopted as part of the Opioid Stewardship legislation, HF 400 bill language adds authorities for Minnesota pharmacists to conduct **intramuscular and subcutaneous administration of medications for alcohol and opioid dependency; adds intramuscular and subcutaneous administration for mental illness treatment** as well. A pharmacist can only administer these injectable medications upon the order of a prescriber or according to a protocol or collaborative practice agreement with any changes reported by a pharmacist to the practitioner. A pharmacist must notify the prescriber when the administration of the prescription medication is complete.

- **Patient Fair Practices - PFP** ([HF728](#) Mann; [SF278](#) Jensen). The Legislature passed MPA priority legislation that will make Minnesota the 9th State in the US to license, regulate and hold pharmacy benefit managers (PBMs), which negotiate with drug makers and pharmacies on behalf of insurance plans and their beneficiaries, accountable. A bi-partisan effort to pass meaningful regulatory oversight and licensure, patient and pharmacy fair practices reform and greater drug pricing transparency, Senator Jensen, Benson, Representative Mann, Liebling and Hamilton and Governor Walz among other policy makers passed with almost complete support SF278. Creating an entire new

chapter in Minnesota insurance law. This statute puts in place the initial tracks to run the train of pharmacy benefits and contracting on.

The PFP legislation, which was signed into law by Governor Walz the last week of Session, requires that PBMs be licensed to do business in the State of Minnesota and gives the State authority to suspend, revoke or place a PBM on probation. PBMs must also disclose rebate and pricing information to both plan sponsors and the Minnesota Department of Commerce (DOC) and notify health plans if their activity or policies presents a conflict of interest or a practice does not comply with the law or rules promulgated by the DOC.

- **Patient and pharmacy fair practices provisions in SF278 include:**
 - Creates a new chapter in Minnesota insurance law - statute (62W).
 - Gives authority to the MN Department of Commerce/Commerce Commissioner to regulate Pharmacy Benefit Managers (PBMs) in Minnesota.
 - Transparency information provisions related to spread-pricing, rebates, claw backs and other related pricing variables are required to be made available annually to health plan sponsors.
 - Transparency information is required to be reported by PBMs to the DOC. The data provided to the DOC will be claims level data (see the bill language for the specific list of information to be reported).
 - Creates Specialty Pharmacy and Specialty Drugs definitions.
 - New network adequacy provisions are mandated. The bill references the Minnesota Department of Health Network Adequacy requirements found in Minnesota Statute, 62K.
 - Retroactive adjustments by PBMS after a claim is adjudicated are now prohibited.
 - Conflict of interest and ownership disclosures are required and the legislation includes additional PBM anti-steering provisions.
 - Any patient can ask the PBM to provide them with the price of their specialty or mail order medication to compare with a local retail pharmacy and shop for where a patient chooses to fill their prescription at the same or lower price (in network).
 - Includes gag order, copay claw back and medication synchronization prohibitions in PBM contracting with pharmacies.
 - Mandates PBMs to provide patients with the lowest cost of medication at the point of sale. UC/cash, in-network copay or the claims-reimbursement payment amount to the pharmacy establishes the lowest patient medication price.
 - Updates and moves over MAC list transparency provisions previously found in MN Board of Pharmacy, MN-151, authorities to the new chapter 62W.
 - Moves current PBM audit of pharmacies provisions, currently under the Minnesota Board of Pharmacy (MN Chapter 151), to DOC authorities under the new 62W.
 - The legislation does not contain “fiduciary duty” provisions that would have required a PBM to be a fiduciary to its client, the Health Carrier/HMO.

- **Prescribing Authority for Minnesota Pharmacists:**
Senator Jensen and Abler along with Representatives Mann and Morrison introduced prescribing authority for pharmacists in Minnesota legislation this year ([SF1960](#), [HF2635](#)) that would provide pharmacists with the authority to prescribe medications to patients, including an opioid antagonist-Naloxone, hormonal contraceptives and tobacco-nicotine cessation treatment medications. While the legislation did not receive a hearing and is considered strictly a policy – scope of practices - bill there is good indication that the legislation will receive hearings and be considered through the legislative process during the 2020 “Policy” legislative session.

Health care and other pharmacy related highlights of the 2019 legislature:

HHS Omnibus budget legislation for the 2020 and 2021 fiscal years – final, Special Session, adopted bill language and law ([HF14/SF12](#); * = MPA priority; ** see Appendix A for specific MPA and pharmacy related legislative/now MN Statute language).

- **HHS Omnibus - HF14 Sections summary (link)**
https://www.senate.mn/committees/2019-2020/3095_Committee_on_Health_and_Human_Services_Finance_and_Policy/HHS%20Final%20Bill%20List.pdf
- **State of Minnesota’s Health and Human Services budget:**
 - \$17.1B in 2020-2021
 - \$19.2B in ‘22-‘23
- **Current Minnesota statute was repealed that would have sunset the Wholesaler/Provider Tax.**
 - The 2011 - government shutdown – Omnibus budget agreement created Minnesota law to sunset the Provider tax on December 31st of 2019.
 - The 2019 Omnibus Tax legislation ([SF11](#)) agreement repeals the statutory sunset language and calls for the 27 year-old health care transaction tax to be in place permanently, although at a reduced rate. This year’s agreement moves the tax rate from 2% to 1.8% per moving forward.
 - Provides \$872.6 million in revenue for health related programing and funding of the MNCare program in FY 20/21 and \$1.42 billion in revenue in FY 22/23
 - Invests \$35.2 million in FY 20/21 and \$76.7 million in FY 22/23 from the Health Care Access Fund into MDHS and MDH programing
- ***CMS-Outpatient Drug Rule implementation (MDHS fee-for-service MA/MNCare):**
 - Ingredient cost = NADAC + \$10.48 reimbursement rate (initial)
 - Wholesaler – Provider tax 1.8% fee-for-service reimbursement (New rate) to be paid by MDHS
 - Initial statewide Minnesota survey of pharmacy dispensing costs with a revised dispensing rate recommendation to the legislature in 20121. A statewide survey of Minnesota pharmacy’s dispensing costs and recommendation to the legislature to occur every 3 years following the initial survey.
- ***Minnesota Board of Pharmacy (MBOP) Conforming provisions** to comply with federal law and bring clarity to other subject areas adopted in SF12, the Special Session HHS Omnibus budget legislation. The MBOP language also includes manufacturer, wholesaler and pharmacy definitions and licensing fee amounts. Most of Representative Baker’s

[HF1718](#) – MBOP policy bill language was included in the final HHS Omnibus budget bill signed into law this Thursday, May 30th.

MBOP Provisions included in the 2019 HHS Omnibus budget legislation:

- Pharmacy, Wholesaler, Manufacturer and Third-Party-Administer definitions modified.
 - New licensing fees (increases).
 - Emergency prescribing for pharmacists, including mandated coverage.
 - Authority for Emergency Prescription Refills.
 - *Prescription Drug Repository Program - LTC PDs recycling program.
 - Recipient of Emergency Prescription Orders & Drug Coverage in Emergency Situations and payment.
 - Processing of prescriptions outside a Minnesota licensed pharmacy.
 - Step therapy override process; transparency modifications.
 - MBOP disciplinary action grounds clarified – fee splitting further defined and practitioners, pharmacists, and pharmacies business interactions prohibited and disclosure required.
 - Limit on quantity of opiates prescribed and limits on filling dates.
 - Identification requirement for controlled substance prescriptions.
 - PDMP:
 - Providers will be required to check the PMP prior to issuing prescriptions for Schedule II through IV opiate controlled substances.
 - Access modifications including 3-day purge of former employee access requirement.
 - Compounding requirements clarified; veterinary office use compounding allowed.
 - Manufacturer and wholesaler drug distribution provisions changed.
 - CBD sales legal for labeling and testing.
 - Syringe needle access without a prescription.
 - Central Service Pharmacy definition modified.
 - Prior authorization modifications.
 - And obsolete language repealed.
- None of Governor Walz' **OneCare proposal** language, that had been adopted in the House of Representatives, was included in the final HHS Omnibus budget legislation. One of the provisions in the Governor's OneCare proposal being monitored by MPA would have brought management of Medical Assistance (Medicaid) and Minnesota Care (ACA population) pharmacy and dental benefit coverage in-house, to be managed by the MN Department of Human Services (MDHS). The proposal would have also rescinded current MCO MA and MNCare prescription drug benefit and dental care contracts for management of approximately 80% of the MA/MNCare population.
 - Pharmacogenomics: **expanded pharmacogenomic clinical services** statewide was not passed during the 2019 Session and remains introduced.

- **Emergency insulin, prescription drug transparency ([HF485](#); [SF1098](#)):** Heading into final talks, Democrats in the House and Republicans in the Senate appeared to be in agreement on two proposals: giving diabetics access to an emergency supply of insulin if they cannot afford it and requiring drug makers to report price hikes and explain why they increased, prescription drug price transparency. The proposals were included in both the House and Senate HHS bills but did not make it into the final compromise. Since the legislature adjourned without including relief for diabetics, there has been a national outcry surrounding the issue of escalating, life-necessary, cost of prescription medications.

Opioid Stewardship legislation ([HF400](#): **see Appendix A for specific legislative language): On the last day of the regular legislative session, lawmakers agreed to raise fees on Opioid drug manufacturers and wholesalers to invest money into addiction treatment and prevention services – opioid stewardship grants and other community funding. The legislation is the first in the nation to require manufacturers and wholesalers to pay higher fees to a State based on volume/dosage of opioids sold. Manufacturers and drug wholesalers in Minnesota will pay the majority of new, higher, licensing fees.

The State will now collect about \$20 million per year from registration fees imposed on opioid manufacturers and distributors. Much of the proceeds will fund prevention strategies aimed at reducing opioid deaths, overdoses and addictions. Additional funds derived from the assessment will reimburse Minnesota counties for child protection costs related to families harmed by the opioid epidemic and other drug addictions.

APENDIX A
2019 Legislative Session

Minnesota Pharmacy Alliance priority and other pharmacy relevant enacted legislation:

Minnesota Patients Fair Practices Act. *CLICK* on bill link: [SF278](#) for the entire enacted legislative language.

Medication Administration provisions included in the final Opioid Stewardship legislation that was passed and signed into law this past May, ([HF400](#)) [Additional HF400 provisions found on page 22]:

Article 2

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;

Omnibus Tax bill ([SF11](#)):

Includes the repeal of Minnesota law that would have sunset the Wholesaler/Provider Tax that was set to sunset on December 31st of 2019.

- The agreement language calls for the 27 year-old health care transaction tax to be reduced from 2% to 1.8% permanent tax moving forward.
 - Provides \$872.6 million in revenue for health related programing and funding of the MNCare program in FY 20/21 and \$1.42 billion in revenue in FY 22/23
 - Invests \$35.2 million in FY 20/21 and \$76.7 million in FY 22/23 from the Health Care Access Fund into MDHS and MDH programing

Article 9 – MNCare Taxes

Section 1.

Minnesota Statutes 2018, section 295.51, subdivision 1a, is amended to read:

Subd. 1a.

Nexus in Minnesota.

(a) To the extent allowed by the United States Constitution and the laws of the United States, a person who is a wholesale drug distributor has nexus in Minnesota if its contacts with or presence in Minnesota is sufficient to satisfy the requirements of the United States Constitution, a person subject to tax under section 295.52, subdivision 4, or a person who sells or repairs hearing aids and related equipment or prescription eyewear is subject to the taxes imposed by this chapter if the person:

(1) has or maintains within this state, directly or by a subsidiary or an affiliate, an office, place of distribution, sales, storage, or sample room or place, warehouse, or other place of business, including the employment of a resident of this state who works from a home office in this state;

(2) has a representative, including but not limited to an employee, affiliate, agent, salesperson, canvasser, solicitor, independent contractor, or other third party operating in this state under the person's authority or the authority of the person's subsidiary, for any purpose, including the repairing, selling, delivering, installing, facilitating sales, processing sales, or soliciting of orders for the person's goods or services, or the leasing of tangible personal property located in this state, whether the place of business or the agent, representative, affiliate, salesperson, canvasser, or solicitor is located in the state permanently or temporarily, or whether or not the person, subsidiary, or affiliate is authorized to do business in this state;

(3) owns or leases real property that is located in this state; or

(4) owns or leases tangible personal property that is present in this state, including but not limited to mobile property.

(b) To the extent allowed by the United States Constitution and the laws of the United States, a person who is a wholesale drug distributor, or a person who is subject to tax under section 295.52, subdivision 4, is subject to the taxes imposed by this chapter if the person:

(1) conducts a trade or business not described in paragraph (a) and sells, delivers, or distributes legend drugs from outside this state to a destination within this state by common carrier or otherwise; and

(2) meets one of the following thresholds:

(i) makes 200 or more sales, deliveries, or distributions described in clause (1) during any taxable year;

(ii) the gross revenues of a wholesale drug distributor that sells, delivers, or distributes legend drugs as described in clause (1) totals more than \$100,000 during any taxable year; or

(iii) the price paid by a person who is subject to tax under section 295.52, subdivision 4, totals more than \$100,000 for legend drugs that the person sells, delivers, or distributes as described in clause (1) during any taxable year.

(c) To the extent allowed by the United States Constitution and the laws of the United States, a person who sells or repairs hearing aids and related equipment or prescription eyewear is subject to the taxes imposed by this chapter if the person:

(1) conducts a trade or business not described in paragraph (a) and:

(i) sells, delivers, or distributes hearing aids and related equipment or prescription eyewear from outside of this state to a destination within this state by common carrier or otherwise; or

(ii) repairs hearing aids and related equipment or prescription eyewear outside of this state and delivers or distributes the hearing aids and related equipment or prescription eyewear to a destination within this state by common carrier or otherwise; and

(2) meets one of the following thresholds:

(i) makes 200 or more sales, deliveries, distributions, or repairs described in clause (1) during any taxable year; or

(ii) the gross revenues of the person who sells, delivers, distributes, or repairs hearing aids and related equipment or prescription eyewear described in clause (1) totals more than \$100,000 during any taxable year.

(d) Once a taxpayer has established nexus with Minnesota under paragraph (b) or (c), the taxpayer must continue to file an annual return and remit taxes for subsequent years. A taxpayer who has established nexus under paragraph (b) or (c) is no longer required to file an annual return and remit taxes if the taxpayer:

(1) ceases to engage in the activities or no longer meets any of the applicable thresholds in paragraph (b) or (c) for an entire taxable year; and

(2) notifies the commissioner by March 15 of the following calendar year, in a manner prescribed by the commissioner, that the taxpayer no longer engages in any of the activities or no longer meets any of the applicable thresholds in paragraph (b) or (c).

(e) If, after notifying the commissioner pursuant to paragraph (d), the taxpayer subsequently engages in any of the activities and meets any of the applicable thresholds in paragraph (b) or (c), the taxpayer shall again comply with the applicable requirements of paragraphs (b) to (d).

EFFECTIVE DATE; APPLICATION.

(a) This section is effective the day following final enactment.

(b) In enacting this section, the legislature confirms that the United States Supreme Court decision in South Dakota v. Wayfair, Inc. et al., Dkt. No. 17-494 (June 21, 2018); 138 S. Ct. 2080 (2018), applied upon the date of that decision to provide Minnesota with jurisdiction over persons described in Minnesota Statutes, section 295.51, subdivision 1a, paragraphs

(b) and (c), for purposes of imposing tax under Minnesota Statutes, chapter 295, to the extent allowed by the United States Constitution and the laws of the United States.

Sec. 2.

Minnesota Statutes 2018, section 295.52, subdivision 1, is amended to read:

Subdivision 1.

Hospital tax.

A tax is imposed on each hospital equal to ~~two~~ 1.8 percent of its gross revenues.

EFFECTIVE DATE.

This section is effective for gross revenues received after December 31, 2019.

Sec. 3.

Minnesota Statutes 2018, section 295.52, subdivision 1a, is amended to read:

Subd. 1a.

Surgical center tax.

A tax is imposed on each surgical center equal to ~~two~~ 1.8 percent of its gross revenues.

EFFECTIVE DATE.

This section is effective for gross revenues received after December 31, 2019.

Sec. 4.

Minnesota Statutes 2018, section 295.52, subdivision 2, is amended to read:

Subd. 2.

Provider tax.

A tax is imposed on each health care provider equal to ~~two~~ 1.8 percent of its gross revenues.

EFFECTIVE DATE.

This section is effective for gross revenues received after December 31, 2019.

Sec. 5.

Minnesota Statutes 2018, section 295.52, subdivision 3, is amended to read:

Subd. 3.

Wholesale drug distributor tax.

A tax is imposed on each wholesale drug distributor equal to ~~two~~ 1.8 percent of its gross revenues.

EFFECTIVE DATE.

This section is effective for gross revenues received after December 31, 2019.

Sec. 6.

Minnesota Statutes 2018, section 295.52, subdivision 4, is amended to read:

Subd. 4.

Use tax; legend drugs.

(a) A person that receives legend drugs for resale or use in Minnesota, other than from a wholesale drug distributor that is subject to tax under subdivision 3, is subject to a tax equal to the price paid for the legend drugs multiplied by ~~the tax percentage specified in this section~~ 1.8 percent. Liability for the tax is incurred when legend drugs are received or delivered in Minnesota by the person.

(b) A tax imposed under this subdivision does not apply to purchases by an individual for personal consumption.

EFFECTIVE DATE.

This section is effective for legend drugs received or delivered in Minnesota after December 31, 2019.

Sec. 7.

Minnesota Statutes 2018, section 295.52, subdivision 8, is amended to read:

Subd. 8.

Contingent reduction in tax rate.

(a) By December 1 of each year, beginning in 2011, the commissioner of management and budget shall determine the projected balance in the health care access fund for the biennium.

(b) If the commissioner of management and budget determines that the projected balance in the health care access fund for the biennium reflects a ratio of revenues to expenditures and transfers greater than 125 percent, and if the actual cash balance in the fund is adequate, as determined by the commissioner of management and budget, the commissioner, in consultation with the commissioner of revenue, shall reduce the tax rates levied under subdivisions 1, 1a, 2, 3, and 4, for the subsequent calendar year sufficient to reduce the structural balance in the fund. The rate may be reduced to the extent that the projected revenues for the biennium do not exceed 125 percent of expenditures and transfers. The new rate shall be rounded to the nearest one-tenth of one percent. The rate reduction under this paragraph expires at the end of each calendar year and is subject to an annual redetermination by the commissioner of management and budget.

(c) For purposes of the analysis defined in paragraph (b), the commissioner of management and budget shall include projected revenues, ~~notwithstanding the repeal of the tax imposed under this section effective January 1, 2020.~~

EFFECTIVE DATE.

This section is effective the day following final enactment.

Sec. 8.

Minnesota Statutes 2018, section 295.57, subdivision 3, is amended to read:

Subd. 3.

Interest on overpayments.

Interest must be paid on an overpayment refunded or credited to the taxpayer ~~from the date of payment of the tax until the date the refund is paid or credited. For purposes of this subdivision, the date of payment is the due date of the return or the date of actual payment of the tax, whichever is later~~ in the manner provided in section 289A.56, subdivision 2.

EFFECTIVE DATE.

This section is effective for overpayments made on or after January 1, 2020.

Pharmacy related provisions contained in **the HHS Omnibus budget legislation ([HF14/SF12](#)) – now law that will take effect, July 1st, 2019:**

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

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.

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 ~~29.28.6~~ 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.

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 9 Prescription Drugs

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.

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.

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).

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.

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.

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.

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 – Health-Related Licensing Boards

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.

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.

Sec. 26.

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,~~ 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.

Sec. 27.

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

Subd. 2.

Original license fee.

The pharmacist original licensure fee, ~~\$145~~ \$175.

Sec. 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.

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.

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)...(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;...

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.~~

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.

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.

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](#)...

...~~(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.

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.

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.

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.

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.

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.

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.

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.

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 of the board, or is accredited by an accreditation program approved by the board. In the case of a drug wholesale distributor facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section [151.065](#), unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board, or furnishes the board with proof of current accreditation. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

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

(1) adequate storage conditions and facilities;

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

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

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

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

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

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

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

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

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

Sec. 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.

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.

Opioid crisis legislation (HF400):

The State will collect just over \$20 million per year from registration fees imposed on opioid medication manufacturers and distributors. Here is the new licensing fee schedule, definitions and reporting requirements for manufacturers, wholesalers and pharmacies working with opioid prescription drugs:

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, ~~\$240~~ \$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.

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.

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.

ARTICLE 2

OTHER PROVISIONS

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;

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.

~~(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.