ARTICLE 8

PHARMACY BOARD AND PRACTICE

Section 1. Minnesota Statutes 2023 Supplement, section 62Q.46, subdivision 1, is amended to read:

Subdivision 1. Coverage for preventive items and services. (a) "Preventive items and services" has the meaning specified in the Affordable Care Act. Preventive items and services includes:

(1) evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved;

(2) immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved. For purposes of this clause, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after the recommendation has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if the recommendation is listed on the Immunization Schedules of the Centers for Disease Control and Prevention;

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(4) with respect to women, additional preventive care and screenings that are not listed with a rating of A or B by the United States Preventive Services Task Force but that are provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(5) all contraceptive methods established in guidelines published by the United States Food and Drug Administration;

(6) screenings for human immunodeficiency virus for:

(i) all individuals at least 15 years of age but less than 65 years of age; and

(ii) all other individuals with increased risk of human immunodeficiency virus infection according to guidance from the Centers for Disease Control;

(7) all preexposure prophylaxis when used for the prevention or treatment of human immunodeficiency virus, including but not limited to all preexposure prophylaxis, as defined in any guidance by the United States Preventive Services Task Force or the Centers for Disease Control, including the June 11, 2019, Preexposure Prophylaxis for the Prevention of this clause, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after the recommendation has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if the recommendation is listed on the Immunization Schedules of the Centers for Disease Control and Prevention;

(8) all other individuals with increased risk of human immunodeficiency virus infection according to guidance from the Centers for Disease Control;

(9) all preexposure prophylaxis when used for the prevention or treatment of human immunodeficiency virus, including but not limited to all preexposure prophylaxis, as defined in any guidance by the United States Preventive Services Task Force or the Centers for Disease Control, including the June 11, 2019, Preexposure Prophylaxis for the Prevention
206.5 of HIV Infection United States Preventive Services Task Force Recommendation Statement; and
206.6 (b) all postexposure prophylaxis when used for the prevention or treatment of human
206.7 immunodeficiency virus, including but not limited to all postexposure prophylaxis as defined
206.8 in any guidance by the United States Preventive Services Task Force or the Centers for
206.9 Disease Control.
206.10 (b) A health plan company must provide coverage for preventive items and services at
206.11 a participating provider without imposing cost-sharing requirements, including a deductible,
206.12 coinsurance, or co-payment. Nothing in this section prohibits a health plan company that
206.13 has a network of providers from excluding coverage or imposing cost-sharing requirements
206.14 for preventive items or services that are delivered by an out-of-network provider.
206.15 (c) A health plan company is not required to provide coverage for any items or services
206.16 specified in any recommendation or guideline described in paragraph (a) if the
206.17 recommendation or guideline is no longer included as a preventive item or service as defined
206.18 in paragraph (a). Annually, a health plan company must determine whether any additional
206.19 items or services must be covered without cost-sharing requirements or whether any items
206.20 or services are no longer required to be covered.
206.21 (d) Nothing in this section prevents a health plan company from using reasonable medical
206.22 management techniques to determine the frequency, method, treatment, or setting for a
206.23 preventive item or service to the extent not specified in the recommendation or guideline.
206.24 (e) A health plan shall not require prior authorization or step therapy for preexposure
206.25 prophylaxis or postexposure prophylaxis, except that if the United States Food and Drug
206.26 Administration has approved one or more therapeutic equivalents of a drug, device, or
206.27 product for the prevention of HIV, this paragraph does not require a health plan to cover
206.28 all of the therapeutically equivalent versions without prior authorization or step therapy, if
206.29 at least one therapeutically equivalent version is covered without prior authorization or step
206.30 therapy.
206.31 (g) This section does not apply to grandfathered plans.
206.32 (h) This section does not apply to plans offered by the Minnesota Comprehensive
206.33 Health Association.

207.1 EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health
207.2 plans offered, issued, or renewed on or after that date.
207.3 Sec. 2. Minnesota Statutes 2022, section 151.01, subdivision 23, is amended to read:
207.4 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, licensed
advanced practice registered nurse, or licensed physician assistant. For purposes of sections
207.5 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision
207.6 of HIV Infection United States Preventive Services Task Force Recommendation Statement; and
207.7 (b) all postexposure prophylaxis when used for the prevention or treatment of human
207.8 immunodeficiency virus, including but not limited to all postexposure prophylaxis as defined
207.9 in any guidance by the United States Preventive Services Task Force or the Centers for
207.10 Disease Control.
207.11 (b) A health plan company must provide coverage for preventive items and services at
207.12 a participating provider without imposing cost-sharing requirements, including a deductible,
207.13 coinsurance, or co-payment. Nothing in this section prohibits a health plan company that
207.14 has a network of providers from excluding coverage or imposing cost-sharing requirements
207.15 for preventive items or services that are delivered by an out-of-network provider.
207.16 (c) A health plan company is not required to provide coverage for any items or services
207.17 specified in any recommendation or guideline described in paragraph (a) if the
207.18 recommendation or guideline is no longer included as a preventive item or service as defined
207.19 in paragraph (a). Annually, a health plan company must determine whether any additional
207.20 items or services must be covered without cost-sharing requirements or whether any items
207.21 or services are no longer required to be covered.
207.22 (d) Nothing in this section prevents a health plan company from using reasonable medical
207.23 management techniques to determine the frequency, method, treatment, or setting for a
207.24 preventive item or service to the extent not specified in the recommendation or guideline.
207.25 (e) A health plan shall not require prior authorization or step therapy for preexposure
207.26 prophylaxis, except that if the United States Food and Drug Administration has approved
207.27 one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV,
207.28 this paragraph does not require a health plan to cover all of the therapeutically equivalent
207.29 versions without prior authorization or step therapy, if at least one therapeutically equivalent
207.30 version is covered without prior authorization or step therapy.
207.31 (f) This section does not apply to grandfathered plans.
207.32 (g) This section does not apply to plans offered by the Minnesota Comprehensive
207.33 Health Association.

208.1 EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health
208.2 plans offered, issued, or renewed on or after that date.
208.3 Sec. 2. Minnesota Statutes 2022, section 151.01, subdivision 23, is amended to read:
208.4 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, licensed
advanced practice registered nurse, or licensed physician assistant. For purposes of sections
208.5 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision
208.6 of HIV Infection United States Preventive Services Task Force Recommendation Statement; and
208.7 (b) all postexposure prophylaxis when used for the prevention or treatment of human
208.8 immunodeficiency virus, including but not limited to all postexposure prophylaxis as defined
208.9 in any guidance by the United States Preventive Services Task Force or the Centers for
208.10 Disease Control.
208.11 (b) A health plan company must provide coverage for preventive items and services at
208.12 a participating provider without imposing cost-sharing requirements, including a deductible,
208.13 coinsurance, or co-payment. Nothing in this section prohibits a health plan company that
208.14 has a network of providers from excluding coverage or imposing cost-sharing requirements
208.15 for preventive items or services that are delivered by an out-of-network provider.
208.16 (c) A health plan company is not required to provide coverage for any items or services
208.17 specified in any recommendation or guideline described in paragraph (a) if the
208.18 recommendation or guideline is no longer included as a preventive item or service as defined
208.19 in paragraph (a). Annually, a health plan company must determine whether any additional
208.20 items or services must be covered without cost-sharing requirements or whether any items
208.21 or services are no longer required to be covered.
208.22 (d) Nothing in this section prevents a health plan company from using reasonable medical
208.23 management techniques to determine the frequency, method, treatment, or setting for a
208.24 preventive item or service to the extent not specified in the recommendation or guideline.
208.25 (e) A health plan shall not require prior authorization or step therapy for preexposure
208.26 prophylaxis, except that if the United States Food and Drug Administration has approved
208.27 one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV,
208.28 this paragraph does not require a health plan to cover all of the therapeutically equivalent
208.29 versions without prior authorization or step therapy, if at least one therapeutically equivalent
208.30 version is covered without prior authorization or step therapy.
208.31 (f) This section does not apply to grandfathered plans.
208.32 (g) This section does not apply to plans offered by the Minnesota Comprehensive
208.33 Health Association.

209.1 EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health
209.2 plans offered, issued, or renewed on or after that date.
“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 ordering and performing 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 not modify, administration, and discontinuation of drug therapy is according to the protocol 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 drug administration under a prescription drug order; 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, physician assistant, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section 148.235. Any changes to prevent the acquisition of human immunodeficiency virus (HIV) under section 151.37, subdivision 17. This section is effective January 1, 2025.
in drug therapy or medication administration made pursuant to a protocol or collaborative
practice agreement must be documented by the pharmacist in the patient's medical record
or reported by the pharmacist to a practitioner responsible for the patient's care;

(6) participation in administration of influenza vaccines and initiating, ordering, and
administering influenza and COVID-19 or SARS-CoV-2 vaccines authorized or approved
by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2
to all eligible individuals six three years of age and older and all other United States Food
and Drug Administration-approved vaccines to patients 12 six years of age and older by
written protocol with a physician licensed under chapter 147A, a physician assistant authorized
to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized
to prescribe drugs under section 148.235, provided that according to the federal Advisory
Committee on Immunization Practices recommendation. A pharmacist may delegate the
authority to administer vaccines under this clause to a pharmacy technician or pharmacy
intern who has completed training in vaccine administration if:

(i) the protocol includes, at a minimum:

(A) the name, dose, and route of each vaccine that may be given;

(B) the patient population for whom the vaccine may be given;

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

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

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

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

(ii) the pharmacist utilizes and the pharmacy technician or pharmacy intern utilize
the Minnesota Immunization Information Connection to assess the immunization status of
individuals prior to the administration of vaccines, except when administering influenza
vaccines to individuals age nine three and older;

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

(iv) the pharmacist complies with guidelines for vaccines and immunizations established
by the federal Advisory Committee on Immunization Practices, except that a pharmacist

in drug therapy or medication administration made pursuant to a protocol or collaborative
practice agreement must be documented by the pharmacist in the patient's medical record
or reported by the pharmacist to a practitioner responsible for the patient's care;

(6) participation in administration of influenza vaccines and initiating, ordering, and
administering influenza and COVID-19 or SARS-CoV-2 vaccines authorized or approved
by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2
to all eligible individuals six three years of age and older and all other United States Food
and Drug Administration-approved vaccines to patients 12 six years of age and older by
written protocol with a physician licensed under chapter 147A, a physician assistant authorized
to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized
to prescribe drugs under section 148.235, provided that according to the federal Advisory
Committee on Immunization Practices recommendation. A pharmacist may delegate the
authority to administer vaccines under this clause to a pharmacy technician or pharmacy
intern who has completed training in vaccine administration if:

(i) the protocol includes, at a minimum:

(A) the name, dose, and route of each vaccine that may be given;

(B) the patient population for whom the vaccine may be given;

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

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

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

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

(ii) the pharmacist utilizes and the pharmacy technician or pharmacy intern utilize
the Minnesota Immunization Information Connection to assess the immunization status of
individuals prior to the administration of vaccines, except when administering influenza
vaccines to individuals age nine three and older;
does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147A, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section 148.235, provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine.

(iv) if the patient is 18 years of age or younger, the pharmacist, pharmacy technician, or pharmacy intern informs the patient and any adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider; and

(v) in the case of a pharmacy technician administering vaccinations while being supervised by a licensed pharmacist, which supervision must be in-person and must not be done through telehealth as defined under section 62A.673, subdivision 2;

(A) the pharmacy technician has completed a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education as part of the pharmacy technician's two-year continuing education schedule;

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

(i) one or more pharmacists and one or more optometrists, physicians, physician assistants, podiatrists, or veterinarians; or

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

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

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

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

(i) one or more pharmacists and one or more dentists, optometrists, physicians, physician assistants, podiatrists, or veterinarians; or

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

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

(9) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices;
224.31 (10) offering or performing those acts, services, operations, or transactions necessary
224.32 in the conduct, operation, management, and control of a pharmacy;
225.1 (11) participation in the initiation, management, modification, and discontinuation of
225.2 therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant to:
225.3 (i) a written protocol as allowed under clause (7); or
225.4 (ii) a written protocol with a community health board medical consultant or a practitioner
225.5 designated by the commissioner of health, as allowed under section 151.37, subdivision 13;
225.6 (12) prescribing self-administered hormonal contraceptives; nicotine replacement
225.7 medications; and opiate antagonists for the treatment of an acute opiate overdose pursuant
225.8 to section 151.37, subdivision 14, 15, or 16;
225.9 (13) participation in the placement of drug monitoring devices according to a prescription,
225.10 protocol, or collaborative practice agreement;

NEW CLAUSES (14) AND (15) WERE MOVED DOWN TO MATCH WITH
THE DUPLICATE SENATE SECTION AMENDING SECTION 151.01, SUBDIVISION 27 (SENATE ARTICLE 9, SECTION 4)

225.17 EFFECTIVE DATE. This section is effective July 1, 2024, except that clauses (14)
225.18 and (15) are effective January 1, 2026.

May 10, 2024 01:12 PM
House Language UES4699-2

Sec. 4. Minnesota Statutes 2022, 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 drug administration under
a prescription drug order; 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, physician assistant, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy or medication administration made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

(6) participation in administration of influenza vaccines and vaccines approved by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2 to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older by written protocol with a physician licensed under chapter 147; a physician assistant authorized to prescribe drugs under chapter 147A; or an advanced practice registered nurse authorized to prescribe drugs under section 148.235, provided that:

(i) the protocol includes, at a minimum:

(A) the name, dose, and route of each vaccine that may be given;

(B) the patient population for whom the vaccine may be given;

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

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

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

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

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

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

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

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

(i) one or more pharmacists and one or more dentists, optometrists, physicians, physician assistants, podiatrists, or veterinarians; or

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

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

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

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

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

(i) a written protocol as allowed under clause (7); or

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

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

212.48 (13) participation in the placement of drug monitoring devices according to a prescription, protocol, or collaborative practice agreement;
AMENDING SECTION 151.01, SUBDIVISION 27 (SENATE ARTICLE 8, SECTION 3).

(14) prescribing, dispensing, and administering drugs for preventing the acquisition of human immunodeficiency virus (HIV) if the pharmacist meets the requirements in section 151.37, subdivision 17; and

(15) ordering, conducting, and interpreting laboratory tests necessary for therapies that use drugs for preventing the acquisition of HIV, if the pharmacist meets the requirements in section 151.37, subdivision 17.

EFFECTIVE DATE. This section is effective January 1, 2025.

Sec. 5. Minnesota Statutes 2022, section 151.065, is amended by adding a subdivision to read:

Subd. 4a. Application and fee; relocation. A person who is registered with or licensed by the board must submit a new application to the board before relocating the physical location of the person's business. An application must be submitted for each affected license. The application must set forth the proposed change of location on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the relocation application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (11) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the full application fee provided in subdivision 1. Upon approval of an application for a relocation, the board shall issue a new license or registration.

Sec. 6. Minnesota Statutes 2022, section 151.065, is amended by adding a subdivision to read:

Subd. 4b. Application and fee; change of ownership. A person who is registered with or licensed by the board must submit a new application to the board before changing the ownership of the licensee or registrant. An application must be submitted for each affected license. The application must set forth the proposed change of ownership on a form established by the board. If the licensee or registrant remitted payment for the full amount during the state's fiscal year, the application fee is the same as the application fee in subdivision 1, except that the fees in clauses (6) to (9) and (11) to (16) are reduced by $5,000 and the fee in clause (16) is reduced by $55,000. If the application is made within 60 days before the date of the original license or registration expiration, the applicant must pay the full application fee provided in subdivision 1. Upon approval of an application for a change of ownership, the board shall issue a new license or registration.
Sec. 7. Minnesota Statutes 2022, section 151.065, is amended by adding a subdivision to read:

Subd. 8. Transfer of licenses. Licenses and registrations granted by the board are not transferable.

Sec. 8. Minnesota Statutes 2022, section 151.066; subdivision 1, is amended to read:

Subdivision 1. Definitions. (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, excluding those exclusively licensed to manufacture medical gas.

(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) "Third-party logistics provider" means a third-party logistics provider licensed under section 151.471.

(e) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 that is engaged in the wholesale drug distribution of an opiate, excluding those exclusively licensed to distribute medical gas.

Sec. 9. Minnesota Statutes 2022, section 151.066; subdivision 2, is amended to read:

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 no reportable distributions occurred for a given year, notification must be provided to the board in a manner 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.
By March 1 of each year, beginning March 1, 2025, each third-party logistics provider must report to the board any 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 or manufacturer. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year.

Sec. 10. Minnesota Statutes 2022, section 151.066, subdivision 3, is amended to read:

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

(b) For purposes of assessing the annual registration fee under this section and determining the number of opiate units a manufacturer sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for substance use disorder treatment with medications for opioid use disorder.

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

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

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

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

(g) For purposes of this subdivision, a unit means the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or gram.
(h) For the purposes of this subdivision, an opiate's units will be assigned to the manufacturer holding the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), as listed by the United States Food and Drug Administration.

Sec. 11. Minnesota Statutes 2022, section 151.212, is amended by adding a subdivision to read:

Subd. 4. Accessible prescription drug container labels. (a) A pharmacy must inform each patient for whom a prescription drug is dispensed that an accessible prescription drug container label is available to any patient who identifies as a person who is blind, visually impaired, or otherwise disabled, upon request of the patient or the patient's representative, at no additional cost.

(b) If a patient requests an accessible container label, the pharmacy shall provide the patient with an audible, large print, or braille prescription drug container label depending on the need and preference of the patient.

(c) The accessible container label must:
   (1) be affixed on the container;
   (2) be available in a timely manner comparable to other patient wait time;
   (3) last for at least the duration of the prescription;
   (4) conform with the format-specific best practices established by the United States Access Board;
   (5) contain the information required under subdivisions 1 and 2; and
   (6) be compatible with a prescription reader if a reader is provided.

(d) This subdivision does not apply to prescription drugs dispensed and administered by a correctional institution.

(e) For purposes of this subdivision, “prescription reader” means a device that is designed to audibly convey the information contained on the label of a prescription drug container.

Sec. 12. Minnesota Statutes 2022, section 151.37, is amended by adding a subdivision to read:

Subd. 17. Drugs for preventing the acquisition of HIV. (a) A pharmacist is authorized to prescribe and administer drugs to prevent the acquisition of human immunodeficiency virus (HIV) in accordance with this subdivision.

(b) By January 1, 2025, the Board of Pharmacy shall develop a standardized protocol for a pharmacist to follow in prescribing the drugs described in paragraph (a). In developing the protocol, the board may consult with community health advocacy groups, the Board of Medical Practice, the Board of Nursing, the commissioner of health, professional pharmacy...
associations, and professional associations for physicians, physician assistants, and advanced
practice registered nurses.

Subdivision 1.
(c) Before a pharmacist is authorized to prescribe a drug described in paragraph (a), the
pharmacist must successfully complete a training program specifically developed for
prescribing drugs for preventing the acquisition of HIV that is offered by a college of
pharmacy, a continuing education provider that is accredited by the Accreditation Council
for Pharmacy Education, or a program approved by the board. To maintain authorization
to prescribe, the pharmacist shall complete continuing education requirements as specified
by the board.

(d) Before prescribing a drug described in paragraph (a), the pharmacist shall follow the
appropriate standardized protocol developed under paragraph (b) and, if appropriate, may
dispose to a patient a drug described in paragraph (a).

(e) Before dispensing a drug described in paragraph (a) that is prescribed by the
pharmacist, the pharmacist must provide counseling to the patient on the use of the drugs
and must provide the patient with a fact sheet that includes the indications and
contraindications for the use of these drugs, the appropriate method for using these drugs,
the need for medical follow up, and any additional information listed in Minnesota Rules,
part 6000.0910, subpart 2, that is required to be provided to a patient during the counseling
process.

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

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

EFFECTIVE DATE. This section is effective January 1, 2025, except that paragraph
(b) is effective the day following final enactment.

Sec. 13. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 1, is amended
to read:

Subdivision 1. Definitions. (a) For the purposes of this section, the terms defined in this
subdivision have the meanings given.

(b) "Central repository" means a wholesale distributor that meets the requirements under
subdivision 3 and enters into a contract with the Board of Pharmacy in accordance with this
section.
(c) "Distribute" means to deliver, other than by administering or dispensing.

(d) "Donor" means:

1. a health care facility as defined in this subdivision, 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; or

2. a skilled nursing facility licensed under chapter 144A, any entity legally authorized to possess medicine with a license or permit in good standing in the state in which it is located, without further restrictions, including but not limited to a health care facility, skilled nursing facility, assisted living facility, pharmacy, wholesaler, and drug manufacturer; or

3. an assisted living facility licensed under chapter 144G; or

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

5. a drug wholesaler licensed under section 151.47; or

6. a drug manufacturer licensed under section 151.252; or

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

(e) "Drug" means any prescription drug that has been approved for medical use in the United States, is listed in the United States Pharmacopoeia or National Formulary, and

meets the criteria established under this section for donation; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

(f) "Health care facility" means:

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

2. a hospital licensed under section 144.50;

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

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

(g) "Local repository" means a health care facility that elects to accept donated drugs and medical supplies and meets the requirements of subdivision 4.
To be eligible for participation in the medication repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the medication 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.

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

Subd. 5. Individual eligibility and application requirements. (a) To be eligible for participation in the medication repository program at the time of or before receiving donated drugs or supplies needed to administer a drug, the health care facility must meet the eligibility requirements under this section and agrees to provide written notice 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.

Participation in the medication repository program is voluntary. A local repository may withdraw from participation in the medication 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.

Sec. 15. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 5, is amended to read:

Sec. 16. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 4, is amended to read: (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.

Participation in the medication repository program is voluntary. A local repository may withdraw from participation in the medication 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.

Sec. 17. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 4, is amended to read: (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.

Participation in the medication repository program is voluntary. A local repository may withdraw from participation in the medication 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. Sec. 18. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 5, is amended to read:

Sec. 19. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 4, is amended to read: (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.

Participation in the medication repository program is voluntary. A local repository may withdraw from participation in the medication 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.
Standing by Attorney General's Email for Section 16 of Senate Bill 6999.

**Senate Language S4699-3**

221.14 supplies as a new eligible patient, an individual must submit to a local repository an electronic
221.15 or physical intake application form that is signed by the individual and attests that the
221.16 individual:
221.17 (1) is a resident of Minnesota;
221.18 (2) is uninsured and is not enrolled in the medical assistance program under chapter
221.19 256L or the MinnesotaCare program under chapter 256d, has no prescription drug coverage,
221.20 or is underinsured;
221.21 (3) acknowledges that the drugs or medical supplies to be received through the program
221.22 may have been donated; and
221.23 (4) consents to a waiver of the child-resistant packaging requirements of the federal
221.24 Poison Prevention Packaging Act.
221.25 (b) Upon determining that an individual is eligible for the program, the local repository
221.26 shall furnish the individual with an identification card. The card shall be valid for one year
221.27 from the date of issuance and may be used at any local repository. A new identification card
221.28 may be issued upon expiration once the individual submits a new application form.
221.29 (c) The local repository shall send a copy of the intake application form to the central
221.30 repository by regular mail, facsimile, or secured email within ten days from the date the
221.31 application is approved by the local repository.
221.32 (d) The board shall develop and make available on the board's website an application
221.33 form and the format for the identification card.

**Sec. 16. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 6, is amended**

222.17 (c) to read:
222.18 Subd. 6. Standards and procedures for accepting donations of drugs and supplies. (a)
222.19 Notwithstanding any other law or rule, a donor may donate drugs or medical supplies to
222.20 the central repository or a local repository if the drug or supply meets the requirements of
222.21 this section as determined by a pharmacist or practitioner who is employed by or under
222.22 contract with the central repository or a local repository.
222.23 (b) A drug is eligible for donation under the medication repository program if the
222.24 following requirements are met:
222.25 (1) the donation is accompanied by a medication repository donor form described under
222.26 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);
222.27 (2) the drug's expiration date is at least six months after the date the drug was donated.
222.28 If a donated drug bears an expiration date that is less than six months from the donation
222.29 date, the drug may be accepted and distributed if the drug is in high demand and can be
222.30 dispensed for use by a patient before the drug's expiration date;
the expiration date. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened;

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

222.24 (4) 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

222.28 (5) the drug is not a controlled substance.

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

222.31 (1) the 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;

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

223.2 (3) the donation is accompanied by a medication 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

223.5 (3) 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.

223.10 (d) The board shall develop the medication 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. Prior to the first donation from a new donor, a central repository or local repository shall verify and record the following information on the donor form:

223.16 (1) the donor's name, address, phone number, and license number, if applicable;

223.17 (2) that the donor will only make donations in accordance with the program;

223.18 (3) to the best of the donor's knowledge, only drugs or supplies that have been properly stored under appropriate temperature and humidity conditions will be donated; and

223.20 (4) to the best of the donor's knowledge, only drugs or supplies that have never been opened, used, tampered with, adulterated, or misbranded will be donated.

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(e) Notwithstanding any other law or rule, a central repository or a local repository may receive donated drugs from donors. 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 inspect and store drugs or supplies. A drop box must not be used to deliver or accept donations.

(f) The central repository and local repository shall maintain a written or electronic inventory of all drugs and supplies donated to the repository upon acceptance of each drug or supply. 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. The board may waive the requirement under this paragraph if an entity is under common ownership or control with a central repository or local repository and either the entity or the repository maintains an inventory containing all the information required under this paragraph.

Sec. 17. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 7, is amended to read:

Subd. 7. Standards and procedures for inspecting and storing donated 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 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 and 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 drug or supply 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.

(c) The central repository and local repositories shall dispose of all 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 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) Notwithstanding any other law or rule, a central repository or a local repository may receive donated drugs from donors. 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 inspect and store drugs or supplies. A drop box must not be used to deliver or accept donations.
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 record of destruction shall be maintained by the repository for at least two years. For each drug or supply destroyed, the record shall include the following information:

1. the date of destruction;
2. the name, strength, and quantity of the drug destroyed; and
3. the name of the person or firm that destroyed the drug.

No other record of destruction is required.

Subd. 8. Dispensing requirements. (a) Donated prescription 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 drugs in compliance with applicable federal and state laws and regulations for dispensing 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. A record of destruction 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.

(c) Before a first drug or supply is dispensed or administered to an individual, the individual must sign an electronic or physical 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;
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 medication 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 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) medication repository donor form described under subdivision 6;
(5) record of destruction form described under subdivision 7; and
(6) medication repository recipient form described under subdivision 8.

Participants may use substantively similar electronic or physical forms.

Sec. 14. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 11, is amended to read:

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

(1) intake application form described under subdivision 5;
(2) local repository participation form described under subdivision 4;
(3) local repository withdrawal form described under subdivision 4;
(4) medication repository donor form described under subdivision 6;
(5) record of destruction form described under subdivision 7; and
(6) medication repository recipient form described under subdivision 8.

Participants may use substantively similar electronic or physical forms.
(b) All records, including drug inventory, inspection, and disposal of donated drugs and medical supplies, must be maintained by a repository for a minimum of two years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

(c) Data collected by the medication 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.

Sec. 21. Minnesota Statutes 2023 Supplement, section 151.555, subdivision 12, is amended to read:

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 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, a donor of a drug or medical supply, or a person or entity that facilitates any of the above 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 person or entity 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.

Sec. 22. Minnesota Statutes 2023 Supplement, 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 commissioner:

(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, a donor of a drug or medical supply, or a person or entity that facilitates any of the above 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 person or entity 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.

Sec. 5. Minnesota Statutes 2023 Supplement, 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 commissioner:

(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.
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.

(i) 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 must not be required for liquid methadone if only one version of liquid methadone is available. If more than one version of liquid methadone is available, the commissioner shall ensure that at least one version of liquid methadone is available without prior authorization.

(e) Prior authorization may be required for an oral liquid form of a drug, except as described in paragraph (d). A prior authorization request under this paragraph must be automatically approved within 24 hours if the drug is being prescribed for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration, even if the patient has current or prior claims for pills for that condition. If more than one version of the oral liquid form of a drug is available, the commissioner may select the version that is able to be approved for a Food and Drug Administration-approved condition for a patient who utilizes an enteral tube for feedings or medication administration. This paragraph applies to any multistate preferred drug list.
228.16 or supplemental drug rebate program established or administered by the commissioner. The commissioner shall design and implement a streamlined prior authorization form for patients who utilize an enteral tube for feedings or medication administration and are prescribed an oral liquid form of a drug. 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.

228.23 (f) 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.

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

228.32 (h) Any step therapy protocol requirements established by the commissioner must comply with section 62Q.1841.

228.4 (i) Notwithstanding any law to the contrary, prior authorization or step therapy shall not be required or utilized for any class of drugs that is approved by the United States Food and Drug Administration for the treatment or prevention of HIV and AIDS.

228.5 Sec. 23. Minnesota Statutes 2022, section 256B.0625, is amended by adding a subdivision to read:

Subd. 13j. Vaccines and laboratory tests provided by pharmacists. (a) Medical assistance covers vaccines initiated, ordered, or administered by a licensed pharmacist, according to the requirements of section 151.01, subdivision 2, clause (6), at no less than the rate for which the same services are covered when provided by any other licensed practitioner.

(b) Medical assistance covers laboratory tests ordered and performed by a licensed pharmacist, according to the requirements of section 151.01, subdivision 27, clause (3), at no less than the rate for which the same services are covered when provided by any other licensed practitioner.

EFFECTIVE DATE. This section is effective January 1, 2025, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

228.7 or supplemental drug rebate program established or administered by the commissioner. The commissioner shall design and implement a streamlined prior authorization form for patients who utilize an enteral tube for feedings or medication administration and are prescribed an oral liquid form of a drug. 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.

228.14 (f) 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.

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

228.23 (h) Any step therapy protocol requirements established by the commissioner must comply with section 62Q.1841.

228.25 (i) Notwithstanding any law to the contrary, prior authorization or step therapy shall not be required or utilized for any class of drugs that is approved by the United States Food and Drug Administration for preexposure prophylaxis of HIV and AIDS, except under the conditions specified in section 62Q.46, subdivision 1, paragraph (e).

EFFECTIVE DATE. This section is effective January 1, 2026.

228.30 Sec. 6. Minnesota Statutes 2022, section 256B.0625, is amended by adding a subdivision to read:

Subd. 13j. Vaccines and laboratory tests provided by pharmacists. (a) Medical assistance covers vaccines initiated, ordered, or administered by a licensed pharmacist, according to the requirements of section 151.01, subdivision 2, clause (6), at no less than the rate for which the same services are covered when provided by any other licensed practitioner.

(b) Medical assistance covers laboratory tests ordered and performed by a licensed pharmacist, according to the requirements of section 151.01, subdivision 27, clause (3), at no less than the rate for which the same services are covered when provided by any other licensed practitioner.

EFFECTIVE DATE. This section is effective January 1, 2025, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

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REVISOR FULL-TEXT SIDE-BY-SIDE
Sec. 24. Minnesota Statutes 2022, section 256B.0625, subdivision 39, is amended to read:

Subd. 39. Childhood immunizations. Providers who administer pediatric vaccines within the scope of their licensure, and who are enrolled as a medical assistance provider, must enroll in the pediatric vaccine administration program established by section 13631 of the Omnibus Budget Reconciliation Act of 1993. Medical assistance shall pay for administration of the vaccine to children eligible for medical assistance. Medical assistance does not pay for vaccines that are available at no cost from the pediatric vaccine administration program unless the vaccines qualify for 100 percent federal funding or are mandated by the Centers for Medicare and Medicaid Services to be covered outside of the Vaccines for Children program.

Sec. 25. RULEMAKING; BOARD OF PHARMACY.

The Board of Pharmacy must amend Minnesota Rules, part 6800.3400, to permit and promote the inclusion of the following on a prescription label:

1. the complete and unabbreviated generic name of the drug; and
2. instructions written in plain language explaining the patient-specific indications for the drug if the patient-specific indications are indicated on the prescription.

The Board of Pharmacy must comply with Minnesota Statutes, section 14.389, in adopting the amendment to the rule.

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