MINNESOTA
BOARD OF PHARMACY

2025 Legislative Session

Overview

- The following highlights include relevant statutory changes passed by the Minnesota Legislature during the 2025 Regular and 2025 first Special Session. There are several provisions that will affect licensees and registrants of the Board of Pharmacy. The following highlights include relevant statutory changes.

- Revisions to Chapters 151, 152, 62D, 62J, 62Q, and 256B which may impact licensees are included; however, **this document is not inclusive of all revisions** to those chapters, and the reader is encouraged to further review 2025 Session law.

- Statutes are enacted by state representatives. While the board often works to propose legislation or is consulted by government committees on legislation introduced by other parties, the board is not involved in every bill introduced, reviewed, or passed.

- Per Minnesota Statute §645.02, "**Each act** (except appropriations), enacted finally at any session of the legislature **takes effect on August 1** next following its final enactment, unless a different date is specified in the act." The statute further states, "**An appropriation act** or an act having appropriation items enacted finally at any session of the legislature **takes effect at the beginning of the first day of July** next following its final enactment, unless a different date is specified in the act. Each act takes effect at 12:01 a.m. on the day it becomes effective, **unless a different time is specified in the act**."

Highlights

Pharmacy Interns

Effective July 1, 2025, portions of pharmacy intern rules from Chapter 6800.5100 and 6800.5400 were repealed, and revisions were placed in Minnesota Statutes 151.101.

Internship registration eligibility, fees, and terms have been revised. Internship limits considered for qualification for pharmacist licensure have also been revised.

- Internship will require annual review
- The initial registration fee is reduced from $75 to $25.
- Starting January 1, 2026, an $25 annual renewal fee will be charged.
- Interns who initially registered between May 1, 2024, and June 30, 2025, are exempt from the renewal fee for both the 2026 and 2027 registration cycles but must still renew their registration.
- Starting in 2026, intern registrations will expire annually on September 30 or upon the intern becoming a licensed pharmacist, whichever occurs first.
- Renewal applications and fees must be submitted by September 1 each year. Late renewals will incur a 50% late fee.
- Applications received within 90 days prior to expiration may be extended to the following September 30, with fees prorated accordingly.
- Eligibility for pharmacy intern registration to include individuals who are:
    - Enrolled in or progressing through an ACPE-accredited PharmD program and have completed orientation,
        - The fall of 2025 is the first time a first-year pharmacy student will be eligible for an intern registration pursuant to this statutory language
    - Graduates of an approved program gaining practical experience for licensure as a pharmacist,
    - Applicants awaiting exams for licensure,
    - Participating in a residency or fellowship (including those licensed in other states or PharmD graduates not yet registered in Minnesota), and
    - Foreign pharmacy graduates who have passed required equivalency exams and are seeking experience under Minnesota regulations.
- Intern registration will be terminated if the individual is no longer enrolled in an ACPE-accredited PharmD program.
- To maintain registration, interns must:
    - Keep internship employment notices current,
    - Submit intern hour progress reports by June 15 annually,
    - Meet all eligibility requirements, and
    - Demonstrate active progress toward earning a PharmD degree or completing a residency or fellowship.
- To apply for a pharmacist license, it is statutorily required for an intern to complete at least 1,600 intern hours under the direction and supervision of a pharmacist. Effective July 1, 2025, there is no longer a requirement for 800 of those hours to specifically be focused on traditional compounding, dispensing, and related patient counseling activities. Additional qualifiers regarding the 1,600 intern hours are below:

    - a maximum of 80 hours in the individual's first professional academic (PD1) year can be counted for a structured experience directed by the college of pharmacy that the individual attends and is overseen by college faculty, registered preceptors, or supervising licensed pharmacists (i.e., IPPE);
    - a maximum of 400 credit hours of concurrent time internship can be counted;
    - a maximum of 54 credit hours per week may be earned if an intern is employed at more than one site.
- With the legislative changes, a first-year pharmacy student is:
    - Eligible for an intern registration if they are enrolled in or progressing through an ACPE-accredited PharmD program and have completed orientation
    - Required to be registered as an intern prior to participating in Introductory Pharmacy Practice Experience Activities (IPPE) overseen by the College of Pharmacy.
    - Eligible to be employed and work as an intern during their first year of pharmacy school; however, the only hours that count toward the 1,600-intern hour requirement during the first year are limited to a maximum of 80 hours from IPPE. Once a first-year pharmacy student has completed their first academic year, hours worked as an intern in the summer can be counted toward the required 1,600.

Medication Repository Program

The standards and procedures for accepting donations of drugs and supplies was revised, allowing the central repository to purchase drugs from a licensed wholesaler for eligible prescriptions as revised in Minnesota Statutes 151.555.

- The central repository must use donated drugs to fill prescriptions whenever possible
- Central repository drug purchases may occur
    - From a wholesaler licensed by the board
    - For eligible patient prescriptions
    - When the repository does not have sufficient supply to fill the prescription.
- Purchased drugs remaining from the fill of an eligible prescription to fill other prescriptions
- A local repository that does not dispense donated drugs or supplies that are suitable for donation and dispensing must transfer them to the central repository. A local repository must dispose of drugs and supplies in its possession that are not suitable for donation or dispensing pursuant to subdivision 7.

Certified Midwife License Creation

The Board of Nursing is responsible for regulating Certified **Nurse** Midwives (CNM) which are a specialized Advanced Practice Registered Nurse. A newly established **Licensed Certified Midwife** credential designed for individuals without a nursing degree (BSN) was created by the legislature this session.

- This adds certified midwives to the list of practitioners authorized to prescribe medications
- Certified midwives may prescribe drugs appropriate to midwifery practice (must be licensed)
- Prescriptions may be oral or written
- Prescriptions must meet the standard definitions found in section 151.01
- Certified midwives may prescribe, procure, sign for, record or administer drugs which are over the counter, legend, controlled substances, and samples within their scope of practice
- Certified midwives must comply with all DEA requirements related to controlled substances and be registered to prescribe, procure, or administer controlled substances.

Nonopioid Directive (Minn. Stat. 145C)

Patients or their healthcare agents may request that instructions regarding opioid use—such as administration, dispensing, or prescribing—be entered into the patient's health record as a nonopioid directive. Healthcare providers are required to include this directive in the patient's record and must document any revocation.

- A patient with decision-making capacity or their healthcare agent may execute a nonopioid directive specifying that the patient must not be administered or prescribed opioids. This directive can be revoked at any time by the patient or, if executed by a healthcare agent, through a written and dated revocation notice provided to the healthcare provider.
- Providers must comply with valid nonopioid directives except in emergencies when the patient is treated in or outside a hospital, an opioid is medically necessary (for example, due to surgical complications), and the provider cannot reasonably access the patient's health record. In such cases, the patient must be informed about available substance use disorder services.
- Healthcare providers, facilities, and emergency medical personnel are protected from liability or disciplinary action for complying with, or under specific conditions deviating from, a nonopioid directive, provided their actions are taken in good faith and align with the standard of care.

- The Commissioner of Health is tasked with developing and publishing a standardized nonopioid directive form, which will include instructions on revocation and other relevant guidance for patients and healthcare agents.

Pharmacy Benefits

Effective January 1, 2026, health plans and pharmacy benefit managers have obligations and limitations on removing a drug from a formulary or placing it in a benefit category that increases an enrollee's costs. Legislators created 62Q.83 and changes also applied in 256B. Changes also affect pharmacy dispensing payments and contracts with the state pharmacy benefit manager.

Prescription Drug Price Transparency (Minn. Stat. 62J.84) Manufacturers

Since January 1, 2022, drug manufacturers have been required to report price increases and new prescription drug pricing on prescription drugs priced at $100 or more for a 30-day supply (or shorter treatment course).

- Additional price increase reporting applies to:
  - Brand-name drugs with price increases of 10% or more within the previous 12 months, or 16% or more within the previous 24 months, and
  - Generic or biosimilar drugs with price increases of 50% or more over the previous 12 months.
- Manufacturers must submit the required information to the commissioner within 60 days after the price increase takes effect.
- In 2025, the legislature expanded the reporting requirements to include:
  - The year the prescription drug was introduced for sale in the United States,
  - The number of units of the drug sold during the previous 12 months, and
  - The total rebate amount accrued for the drug during the previous 12 months.

Prescription Drug Price Transparency (Minn. Stat. 62J.84) Pharmacies

Since January 1, 2024, pharmacies have been required to report to the Minnesota Department of Health certain data regarding drugs identified as having "substantial public interest" and which are included in a report issued by the department. Pharmacies report on data elements specified in the statute. Changes for reporting pharmacies to be aware of included that pharmacies report:

- Only on drugs dispensed in Minnesota or mailed to a Minnesota address.
- Only for the period specified in the notification.

Prescription Drug Price Transparency (Minn. Stat. 62J.84) Wholesalers

Since January 1, 2024, wholesalers distributing prescription drugs must report certain data. Changes for reporting wholesalers to be aware of included:

- Only on drugs distributed within or into Minnesota.
- Only for the period specified in the notification.

Prescription Drug Price Transparency (Minn. Stat. 62J.84) All reporting entities

All reporting entities subject to the chapter are required to register. The change here is that there is also a duty to update existing registration information by January 30 of each year.

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151.101 Internship

Sec. 106. Minnesota Statutes 2024, section 151.01, subdivision 15, is amended to read:

Subd. 15. **Pharmacist intern or intern.** "Pharmacist intern" or "intern" means:

(1) a natural person who has completed college or school of pharmacy orientation or is otherwise enrolled in a doctor of pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) and is satisfactorily progressing toward the degree in pharmacy required for licensure~~, or~~;

(2) a graduate of ~~the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board,~~ a doctor of pharmacy program accredited by ACPE who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist~~, or~~;

(3) a qualified applicant awaiting examination for licensure~~.~~;

(4) a participant in a residency or fellowship program who is not licensed to practice pharmacy in Minnesota but is:

(i) licensed to practice pharmacy in another state; or

(ii) a graduate of a doctor of pharmacy program accredited by ACPE and not registered by the board under clause (2); or

(5) a foreign pharmacy graduate who:

(i) has passed the Foreign Pharmacy Graduate Equivalency Examination;

(ii) is certified by the Foreign Pharmacy Graduate Equivalency Commission; and

(iii) is seeking internship experience in accordance with Minnesota Rules, part 6800.1250.

Sec. 108. Minnesota Statutes 2024, 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, $225;

(2) pharmacist licensed by reciprocity, $300;

(3) pharmacy intern, ~~$75~~ $25;

(4) pharmacy technician, $60;

(5) pharmacy, $450;

(6) drug wholesaler, legend drugs only, $5,500;

(7) drug wholesaler, legend and nonlegend drugs, $5,500;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,500;

(9) drug wholesaler, medical gases, $5,500 for the first facility and $500 for each additional facility;

(10) third-party logistics provider, $300;

(11) drug manufacturer, nonopiate legend drugs only, $5,500;

(12) drug manufacturer, nonopiate legend and nonlegend drugs, $5,500;

(13) drug manufacturer, nonlegend or veterinary legend drugs, $5,500;

(14) drug manufacturer, medical gases, $5,500 for the first facility and $500 for each additional facility;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,500;

(16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,500;

(17) medical gas dispenser, $400;

(18) controlled substance researcher, $150; and

(19) pharmacy professional corporation, $150.

Sec. 109. Minnesota Statutes 2024, 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, $225;

(2) pharmacy technician, $60;

(3) beginning January 1, 2026, pharmacy intern, $25;

~~(3)~~ (4) pharmacy, $450;

~~(4)~~ (5) drug wholesaler, legend drugs only, $5,500;

~~(5)~~ (6) drug wholesaler, legend and nonlegend drugs, $5,500;

~~(6)~~ (7) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,500;

~~(7)~~ (8) drug wholesaler, medical gases, $5,500 for the first facility and $500 for each additional facility;

~~(8)~~ (9) third-party logistics provider, $300;

~~(9)~~ (10) drug manufacturer, nonopiate legend drugs only, $5,500;

~~(10)~~ (11) drug manufacturer, nonopiate legend and nonlegend drugs, $5,500;

~~(11)~~ (12) drug manufacturer, nonlegend, veterinary legend drugs, or both, $5,500;

~~(12)~~ (13) drug manufacturer, medical gases, $5,500 for the first facility and $500 for each additional facility;

~~(13)~~ (14) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,500;

~~(14)~~ (15) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,500;

~~(15)~~ (16) medical gas dispenser, $400;

~~(16)~~ (17) controlled substance researcher, $150; and

~~(17)~~ (18) pharmacy professional corporation, $150.

Sec. 110. Minnesota Statutes 2024, 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 $250.

(c) A pharmacy intern who has allowed the intern'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 $100.

~~(c)~~ (d) An owner of a pharmacy, a drug wholesaler, a drug manufacturer, third-party logistics provider, or a medical gas dispenser 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)~~ (e) 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)~~ (f) 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. 111. Minnesota Statutes 2024, section 151.101, is amended to read:

Subdivision 1. **Registration requirements.**

(a) Upon payment of the fee specified in section 151.065, the board may register as an intern any natural persons who have satisfied the board that they are of good moral character, not physically or mentally unfit, and who have successfully completed the educational requirements for intern registration prescribed by the board. ~~The board shall prescribe standards and requirements for interns, pharmacist-preceptors, and internship training but may not require more than one year of such training.~~

(b) The board in its discretion may accept internship experience obtained in another state provided the internship requirements in such other state are in the opinion of the board equivalent to those herein provided.

Subd. 2.

Renewal requirements.

(a) Beginning January 1, 2026, an intern registration expires on September 30 each year or when the intern receives a pharmacist license, whichever is earlier.

(b) To renew an intern registration, the intern must file an application for renewal and submit the fee established under section 151.065 on or before September 1 each year.

(c) If the board does not receive the intern's registration renewal application on or before September 1 each year, the intern is subject to a late filing fee equal to 50 percent of the renewal fee under section 151.065 in addition to the renewal fee.

(d) An individual who received an intern registration under the criteria in section 151.01, subdivision 15, clause (1), and paid $75 for the individual's application fee between May 1, 2024, and June 30, 2025, is not subject to the $25 renewal fee for the first two renewal cycles following the $75 fee payment.

(e) If an individual is no longer enrolled in a doctor of pharmacy program accredited by the Accreditation Council for Pharmacy Education, the board must terminate that individual's intern registration effective the last date the individual was enrolled in a qualifying program.

(f) The board must not renew an intern registration unless the individual:

(1) has maintained current notices of employment for internship training with the board;

(2) submitted a progress report affidavit of the intern credit hours completed by June 15 each year;

(3) meets all other eligibility criteria for a pharmacist intern; and

(4) demonstrates to the board's satisfaction the individual is in good faith and with reasonable diligence pursuing a degree in pharmacy or is completing a pharmacy residency or fellowship.

(g) An intern whose registration has lapsed may renew the intern registration within one year of expiration, subject to the fees in paragraph (c). An intern whose registration has lapsed for more than one year must meet the registration requirements for an initial intern applicant in effect at the time the individual applies for reinstatement and pay any fees and late fees in arrears in accordance with section 151.065.

(h) If the board receives a late renewal, reinstatement, or initial intern application from an eligible individual within 90 days before September 30, the board may extend the registration expiration date for that applicant to September 30 of the subsequent calendar year and prorate the application fee accordingly.

Subd. 3.

Internship credit hour requirements.

(a) To apply for licensure as a pharmacist under section 151.10, an individual must complete at least 1,600 intern credit hours under the direction and supervision of a preceptor.

(b) Of the 1,600 credit hours required under this subdivision, an intern may earn:

(1) a maximum of 80 credit hours in the individual's first professional academic year for a structured experience directed by the college of pharmacy that the individual attends and is overseen by college faculty, registered preceptors, or supervising licensed pharmacists;

(2) a maximum of 400 credit hours of concurrent time internship; and

(3) a maximum of 54 credit hours per week that may be earned from more than one site.

151.555 Medication Repository Program

Sec. 112. Minnesota Statutes 2024, section 151.555, subdivision 6, is amended to read:

Subd. 6. **Standards and procedures for accepting donations of drugs and supplies and purchasing drugs from licensed wholesalers.** (a) Notwithstanding any other law or rule, a donor may donate 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 drug is eligible for donation under the medication repository program if the following requirements are met:

(1) 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;

(2) 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;

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

(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

(5) the drug is not a controlled substance.

(c) A medical supply is eligible for donation under the medication 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; and

(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.

(d) The board shall develop the medication repository donor form and make it available on the board's website. 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:

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

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

(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

(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.

(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 prior to dispensing. 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.

(g) The central repository may purchase a drug from a wholesaler licensed by the board to fill prescriptions for eligible patients when the repository does not have a sufficient supply of donated drugs to fill the prescription. The central repository may use any purchased drugs remaining after filling the prescriptions for which the drugs were initially purchased to fill other prescriptions. Whenever possible, the repository must use donated drugs to fill prescriptions.

Sec. 113. Minnesota Statutes 2024, section 151.555, subdivision 10, is amended to read:

Subd. 10. **Distribution of donated drugs and supplies.** (a) The central repository and local repositories may distribute drugs and supplies donated under the medication 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 that are suitable for donation and dispensing must transfer ~~all~~ those 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. A local repository must dispose of drugs and supplies in its possession that are not suitable for donation or dispensing pursuant to subdivision 7.

151.01 Licensed Certified Midwife

Sec. 107. Minnesota Statutes 2024, 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, licensed advanced practice registered nurse, licensed certified midwife, or licensed physician assistant. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A. For purposes of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists under section 151.37, subdivision 14, 15, or 16, or authorized to prescribe drugs to prevent the acquisition of human immunodeficiency virus (HIV) under section 151.37, subdivision 17.

Sec. 114. Minnesota Statutes 2024, section 152.12, subdivision 1, is amended to read:

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

Opioid Instructions Entered Health Record

Sec. 3. Minnesota Statutes 2024, section 145C.01, is amended by adding a subdivision to read:

Subd. 7b. **Nonopioid directive.** "Nonopioid directive" means a written instrument that includes one or more instructions that a patient must not be administered an opioid by a health professional or be offered a prescription for an opioid by a prescriber.

Sec. 5. Minnesota Statutes 2024, section 145C.17, is amended to read:

145C.17 OPIOID INSTRUCTIONS ENTERED INTO HEALTH RECORD.

At the request of the patient or health care agent, a health care provider shall enter into the patient's health care record any instructions relating to administering, dispensing, or prescribing an opioid. A health care provider presented with a nonopioid directive executed by or on behalf of a patient must include the nonopioid directive in the patient's health care record. A health care provider receiving notice of revocation of a patient's nonopioid directive must note the revocation in the patient's health care record.

Sec. 6. **[145C.18] NONOPIOID DIRECTIVE.**

Subdivision 1. **Execution.** A patient with the capacity to do so may execute a nonopioid directive on the patient's own behalf. A patient's health care agent may execute a nonopioid directive on behalf of the patient. A nonopioid directive must include one or more instructions that the patient must not be administered an opioid by a health professional or be offered a prescription for an opioid by a prescriber.

Subd. 2. **Revocation.** A patient who executed a nonopioid directive on the patient's own behalf may revoke the nonopioid directive at any time and in any manner in which the patient is able to communicate an intent to revoke the nonopioid directive. A patient's health care agent may revoke the nonopioid directive executed on behalf of a patient by executing a written, dated statement of revocation and by providing notice of the revocation to the patient's health care provider.

Subd. 3. **Compliance with nonopioid directive; exception.** (a) Except as specified in paragraph (b), prescribers and health professionals must comply with a nonopioid directive executed under this section.

(b) A prescriber or a health professional acting on the order of a prescriber may administer an opioid to a patient with a nonopioid directive if:

(1) the patient is being treated, in emergency circumstances, in a hospital setting or in a setting outside a hospital;

(2) in the prescriber's professional opinion, it is medically necessary to administer an opioid to the patient in order to treat the patient, including but not limited to during a surgical procedure when one or more complications arise; and

(3) it is not practical or feasible for the prescriber or health professional to access the patient's health care record.

If an opioid is administered according to this paragraph to a patient with a nonopioid directive, the prescriber must ensure that the patient is provided with information on substance use disorder services.

Subd. 4. **Immunities.** Except as otherwise provided by law, the following persons or entities are not subject to criminal prosecution, civil liability, or professional disciplinary action for failing to prescribe, administer, or dispense an opioid to a patient with a nonopioid directive; for the administration of an opioid in the circumstances in subdivision 3, paragraph (b), to a patient with a nonopioid directive; or for the inadvertent administration of an opioid to a patient with a nonopioid directive, if the act or failure to act was performed in good faith and in accordance with the applicable standard of care:

(1) a health professional whose scope of practice includes prescribing, administering, or dispensing a controlled substance;

(2) an employee of a health professional described in clause (1);

(3) a health care facility or an employee of a health care facility; or

(4) an emergency medical services provider.

Subd. 5. **Nonopioid directive form.** The commissioner of health must develop a nonopioid directive form for use by patients and health care agents to communicate to health professionals and prescribers that a patient with a nonopioid directive must not be administered an opioid or offered a prescription for an opioid. The commissioner must include on the nonopioid directive form instructions for how to revoke a nonopioid directive and other information the commissioner deems relevant. The commissioner must post the form on the Department of Health website.

62Q.83 Pharmacy Benefits

Section 1. **[62Q.83] FORMULARY CHANGES.**

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

(b) "Drug" has the meaning given in section 151.01, subdivision 5.

(c) "Enrollee" has the meaning given in section 62Q.01, subdivision 2b.

(d) "Formulary" means a current list of covered prescription drug products that is subject to periodic review and update.

(e) "Health plan" has the meaning given in section 62Q.01, subdivision 3.

(f) "Pharmacy benefit manager" has the meaning given in section 62W.02, subdivision 15.

(g) "Prescription" has the meaning given in section 151.01, subdivision 16a.

Subd. 2. **Formulary changes.** (a) Except as provided in paragraphs (b) and (c), a health plan must not, with respect to an enrollee who was previously prescribed the drug during the plan year, remove a drug from the health plan's formulary or place a drug in a benefit category that increases the enrollee's cost for the duration of the enrollee's plan year.

(b) Paragraph (a) does not apply if a health plan changes the health plan's formulary:

(1) for a drug that has been deemed unsafe by the United States Food and Drug Administration (FDA);

(2) for a drug that has been withdrawn by the FDA or the drug manufacturer; or

(3) when an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes with respect to a drug's use for reasons related to previously unknown and imminent patient harm.

(c) Paragraph (a) does not apply if a health plan removes a brand name drug from the health plan's formulary or places a brand name drug in a benefit category that increases the enrollee's cost if the health plan:

(1) adds to the health plan's formulary a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book, a biologic drug rated as interchangeable according to the FDA Purple Book, or a biosimilar at the same or lower cost to the enrollee; and

(2) provides at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health plans offered, sold, issued, or renewed on or after that date.

256B Pharmacy Benefits Formulary

Sec. 2. Minnesota Statutes 2024, 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, a physician assistant, or an advanced practice registered nurse 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 or as provided in paragraph (h) or the drug appears on the 90-day supply list published by the commissioner. The 90-day supply list shall be published by the commissioner on the department's website. The commissioner may add to, delete from, and otherwise modify the 90-day supply list after providing public notice and the opportunity for a 15-day public comment period. The 90-day supply list may include cost-effective generic drugs and shall not include controlled substances.

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

(1) is not a therapeutic option for the patient;

(2) does not exist in the same combination of active ingredients in the same strengths as the compounded prescription; and

(3) cannot be used in place of the active pharmaceutical ingredient in the compounded prescription.

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

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

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

(g) Notwithstanding paragraph (a), medical assistance covers self-administered hormonal contraceptives prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 14; nicotine replacement medications prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 15; and opiate antagonists used for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 16.

(h) Medical assistance coverage for a prescription contraceptive must provide a 12-month supply for any prescription contraceptive if a 12-month supply is prescribed by the prescribing health care provider. The prescribing health care provider must determine the appropriate duration for which to prescribe the prescription contraceptives, up to 12 months. For purposes of this paragraph, "prescription contraceptive" means any drug or device that requires a prescription and is approved by the Food and Drug Administration to prevent pregnancy. Prescription contraceptive does not include an emergency contraceptive drug approved to prevent pregnancy when administered after sexual contact. For purposes of this paragraph, "health plan" has the meaning provided in section 62Q.01, subdivision 3.

(i) Notwithstanding a removal of a drug from the drug formulary under subdivision 13d, except as provided in paragraphs (j) and (k), medical assistance covers a drug, with respect to an enrollee who was previously prescribed the drug during the calendar year when the drug was on the formulary, at the same level until January 1 of the calendar year following the year in which the commissioner removed the drug from the formulary.

(j) Paragraph (i) does not apply if the commissioner changes the drug formulary:

(1) for a drug that has been deemed unsafe by the United States Food and Drug Administration (FDA);

(2) for a drug that has been withdrawn by the FDA or the drug manufacturer; or

(3) when an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes with respect to a drug's use for reasons related to previously unknown and imminent patient harm.

(k) Paragraph (i) does not apply when the commissioner removes a brand name drug from the formulary if the commissioner adds to the formulary a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book, or a biologic drug rated as interchangeable according to the FDA Purple Book, at the same or lower cost to the enrollee.

EFFECTIVE DATE. This section is effective January 1, 2026, or upon federal approval, whichever is later. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

Sec. 4. Minnesota Statutes 2024, section 256B.0625, subdivision 13d, is amended to read:

Subd. 13d. **Drug formulary.** (a) The commissioner shall establish a drug formulary. Its establishment and publication shall not be subject to the requirements of the Administrative Procedure Act, but the Formulary Committee shall review and comment on the formulary contents.

(b) The formulary shall not include:

(1) drugs, active pharmaceutical ingredients, or products for which there is no federal funding;

(2) over-the-counter drugs, except as provided in subdivision 13;

(3) drugs or active pharmaceutical ingredients when used for the treatment of impotence or erectile dysfunction;

(4) drugs or active pharmaceutical ingredients for which medical value has not been established;

(5) drugs from manufacturers who have not signed a rebate agreement with the Department of Health and Human Services pursuant to section 1927 of title XIX of the Social Security Act; and

(6) medical cannabis flower as defined in section 342.01, subdivision 54, or medical cannabinoid products as defined in section 342.01, subdivision 52.

(c) If a single-source drug used by at least two percent of the fee-for-service medical assistance recipients is removed from the formulary due to the failure of the manufacturer to sign a rebate agreement with the Department of Health and Human Services, the commissioner shall notify prescribing practitioners within 30 days of receiving notification from the Centers for Medicare and Medicaid Services (CMS) that a rebate agreement was not signed.

(d) Within ten calendar days of any commissioner determination to change the drug formulary, the commissioner must provide written notice to all enrollees, prescribers, and pharmacists affected by the change. The notice must include a description of the change, the reason for the change, and the date the change will become effective.

(e) By January 15, 2026, and annually thereafter, the commissioner of human services must provide a report with data and information related to the effects on enrollees of drug formulary changes made in the prior calendar year to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The report must include but is not limited to data and information on:

(1) the number of times the formulary was changed;

(2) the reasons for the formulary changes and how frequently the formulary was changed for each reason;

(3) the drugs that were removed from the formulary;

(4) for each drug that was removed from the formulary, the number of enrollees who were prescribed that drug when it was removed;

(5) for each drug that was removed from the formulary, whether a therapeutically equivalent drug was added;

(6) the drugs that were added to the formulary;

(7) the fiscal impacts to the Department of Human Services resulting from the changes to the formulary; and

(8) enrollee populations or medical conditions disproportionately affected by the formulary changes.

256B Payment Rates

Sec. 5. Minnesota Statutes 2024, 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 ingredient costs of the drugs plus the 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, unless the prescription savings club or prescription discount club is one in which an individual pays a

recurring monthly access fee for unlimited access to a defined list of drugs for which the pharmacy does not bill the member or a payer on a per-standard-transaction basis. 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 professional dispensing fee shall be $11.55 for 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 that must be compounded by the pharmacist shall be $11.55 per claim. The professional dispensing fee for prescriptions filled with over-the-counter drugs meeting the definition of covered outpatient drugs shall be $11.55 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 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 ingredient cost for a drug is either: (1) the lower of the National Average Drug Acquisition Cost (NADAC) ~~shall be used to determine the ingredient cost of a drug.~~ or the Minnesota actual acquisition cost (MNAAC) under paragraph (i); (2) the maximum allowable cost, if a drug ingredient cost is unreported in the NADAC and the MNAAC; or (3) ~~for drugs for which a NADAC is not reported, the commissioner shall estimate the ingredient cost at~~ the wholesale acquisition cost minus two percent, if a drug ingredient cost is unreported in the NADAC and the MNAAC and a maximum allowable cost is unavailable. The ingredient cost of a drug for a provider participating in the federal 340B Drug Pricing Program ~~shall be~~ is either: (1) the lowest of the 340B ~~Drug Pricing Program~~ ceiling price established by the Health Resources and Services Administration ~~or,~~ the NADAC, ~~whichever is lower.~~ or the MNAAC; (2) the maximum allowable cost, if the 340B ceiling price is unknown and the drug ingredient cost is unreported in the NADAC and the MNAAC; or (3) the wholesale acquisition cost minus two percent, if the 340B ceiling price is unknown, the drug ingredient cost is unreported in the NADAC and the MNAAC, and the maximum allowable cost is unavailable. 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 the actual acquisition cost of the drug product ~~and~~

~~no higher than 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) 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) If a pharmacy dispenses a multisource drug, the ingredient cost ~~shall be the~~ is either: (1) the lower of the NADAC or the MNAAC of the generic product ~~or~~; (2) the maximum allowable cost, if the generic product ingredient cost is unreported in the NADAC and the MNAAC; or (3) the wholesale acquisition cost minus two percent of the generic product established by the commissioner, if the generic drug ingredient cost is unreported in the NADAC and the MNAAC and a maximum allowable cost is unavailable, 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. If prior authorization is granted, the ingredient cost is either: (1) the lower of the NADAC or the MNAAC of the brand name product; (2) the maximum allowable cost, if the drug ingredient cost is unreported in the NADAC and MNAAC; or (3) the wholesale acquisition cost minus two percent, if the drug ingredient cost is unreported in the NADAC and the MNAAC and the maximum allowable cost is unavailable. A generic product includes a generic drug, an authorized generic drug, and a biosimilar biological product as defined in Code of Federal Regulations, title 42, section 423.4. A brand name product includes a brand name drug, a brand name biological product, and an unbranded biological product as defined in Code of Federal Regulations, title 42, section 423.4.

(e) The basis for determining the amount of payment for drugs administered in an outpatient setting ~~shall be~~ is the ~~lower~~ lowest 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~~ MNAAC, or the maximum allowable cost set by the commissioner. If the

average sales price ~~is~~, the MNAAC, and the maximum allowable cost are unavailable, the amount of payment must be the lower of the usual and customary cost submitted by the provider~~;~~ or the wholesale acquisition cost~~, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner~~. The commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by 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 establish maximum allowable cost rates for specialty pharmacy products 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 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 maximum allowable cost to prevent access to care issues.~~

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

~~(h)~~ (g) 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 specialty prescription drugs and a single statewide cost of dispensing for nonspecialty prescription drugs 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 minority members of the legislative committees with jurisdiction over medical assistance pharmacy reimbursement. Notwithstanding section 256.01, subdivision 42, this paragraph does not expire.

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

(i) The commissioner shall contract with a vendor to create the MNAAC through a periodic survey of enrolled pharmacy providers. The initial MNAAC must be completed by January 1, 2027. Each pharmacy enrolled with the department to dispense outpatient prescription drugs must respond to the periodic surveys. The commissioner may sanction a pharmacy under section 256B.064 for failure to respond. The commissioner must exclude drug purchases under the federal 340B Drug Pricing Program and Federal Supply Schedule invoices from any measure and calculation of the MNAAC. The current MNAAC rates must be publicly available on the department's or vendor's website. The commissioner must require that the MNAAC is measured and calculated at least quarterly. The commissioner must ensure that the vendor has an appeal process available to providers for the time between the measurement and calculation of the periodically updated MNAAC rates if price fluctuations result in a MNAAC that is lower than the price at which enrolled providers can purchase a drug. Establishment of the MNAAC and survey reporting requirements are not subject to the requirements of the Administrative Procedure Act. Data provided by pharmacies for the measurement and calculation of the MNAAC are nonpublic data as defined in section 13.02, subdivision 9.

EFFECTIVE DATE. This section is effective January 1, 2027, or upon federal approval, whichever is later. The commissioner of human services must notify the revisor of statutes when federal approval is obtained.

256B Minnesota Drug Acquisition Cost Survey

Sec. 6. Minnesota Statutes 2024, section 256B.064, subdivision 1a, as amended by Laws 2025, chapter 38, article 5, section 28, is amended to read:

Subd. 1a. **Grounds for sanctions.** (a) The commissioner may impose sanctions against any individual or entity that receives payments from medical assistance or provides goods or services for which payment is made from medical assistance for any of the following:

(1) fraud, theft, or abuse in connection with the provision of goods and services to recipients of public assistance for which payment is made from medical assistance;

(2) a pattern of presentment of false or duplicate claims or claims for services not medically necessary;

(3) a pattern of making false statements of material facts for the purpose of obtaining greater compensation than that to which the individual or entity is legally entitled;

(4) suspension or termination as a Medicare vendor;

(5) refusal to grant the state agency access during regular business hours to examine all records necessary to disclose the extent of services provided to program recipients and appropriateness of claims for payment;

(6) failure to repay an overpayment or a fine finally established under this section;

(7) failure to correct errors in the maintenance of health service or financial records for which a fine was imposed or after issuance of a warning by the commissioner; and

(8) any reason for which an individual or entity could be excluded from participation in the Medicare program under section 1128, 1128A, or 1866(b)(2) of the Social Security Act.

(b) For the purposes of this section, goods or services for which payment is made from medical assistance includes but is not limited to care and services identified in section 256B.0625 or provided pursuant to any federally approved waiver.

(c) Regardless of the source of payment or other item of value, the commissioner may impose sanctions against any individual or entity that solicits, receives, pays, or offers to pay any illegal remuneration as described in section 142E.51, subdivision 6a, in violation of section 609.542, subdivision 2, or in violation of United States Code, title 42, section 1320a-7b(b)(1) or (2). No conviction is required before the commissioner can impose sanctions under this paragraph.

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

(e) The commissioner may impose sanctions against a pharmacy provider for failure to respond to a Minnesota drug acquisition cost survey under section 256B.0625, subdivision 13e, paragraph (i).

256B Directed Pharmacy Dispensing Payment

Sec. 8. Minnesota Statutes 2024, section 256B.69, is amended by adding a subdivision to read:

Subd. 6i. **Directed pharmacy dispensing payment.** (a) The commissioner shall provide a directed pharmacy dispensing payment of $4.50 per filled prescription to eligible outpatient retail pharmacies in Minnesota to improve and maintain access to pharmaceutical services in rural and underserved areas of Minnesota. Managed care and county-based purchasing plans delivering services under section 256B.69 or 256B.692, and any pharmacy benefit managers under contract with these entities, must pay the directed pharmacy dispensing payment to eligible outpatient retail pharmacies for drugs dispensed to medical assistance enrollees. The directed pharmacy dispensing payment is in addition to, and must not supplant or reduce, any other dispensing fee paid by these entities to the pharmacy. Entities paying the directed pharmacy dispensing payment must not reduce other payments to the pharmacy as a result of payment of the directed pharmacy dispensing payment.

(b) For purposes of this subdivision, "eligible outpatient retail pharmacy" means an outpatient retail pharmacy licensed under chapter 151 that is not owned, either directly or indirectly or through an affiliate or subsidiary, by a pharmacy benefit manager licensed under chapter 62W or a health carrier, as defined in section 62A.011, subdivision 2, and that:

(1) is located in a medically underserved area or primarily serves a medically underserved population, as defined by the United States Department of Health and Human Services Health Resources and Services Administration under United States Code, title 42, section 254; or

(2) shares common ownership with 13 or fewer Minnesota pharmacies.

(c) In order to receive the directed pharmacy dispensing payment, a pharmacy must submit to the commissioner a form, developed by the commissioner, attesting that the pharmacy meets the requirements of paragraph (b).

(d) Managed care and county-based purchasing plans, and any pharmacy benefit managers under contract with these entities, shall pay the directed pharmacy dispensing payment to eligible outpatient retail pharmacies. The commissioner shall monitor the effect of this requirement on access to pharmaceutical services in rural and underserved areas of Minnesota. If, for any contract year, federal approval is not received for this subdivision, the commissioner must adjust the capitation rates paid to managed care plans and county-based purchasing plans for that contract year to reflect removal of this subdivision. Contracts between managed care plans and county-based purchasing plans, and any pharmacy benefit managers under contract with these entities, and providers to whom this subdivision applies must allow recovery of payments from those providers if capitation rates are adjusted in accordance with this paragraph. Payment recoveries must not exceed the amount equal to any increase in rates that results from this

subdivision. This subdivision expires if federal approval is not received for this subdivision at any time.

(e) This subdivision expires on December 31, 2026.

EFFECTIVE DATE. This section is effective July 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.

256B State Pharmacy Benefit Manager

Sec. 9. **[256B.696] PRESCRIPTION DRUGS; STATE PHARMACY BENEFIT MANAGER.**

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

(b) "Managed care enrollees" means medical assistance and MinnesotaCare enrollees receiving coverage from managed care plans.

(c) "Managed care organizations" means health plan companies and county-based purchasing organizations providing coverage to medical assistance and MinnesotaCare enrollees under the managed care delivery system.

(d) "State pharmacy benefit manager" means the pharmacy benefit manager selected pursuant to the procurement process in subdivision 2.

Subd. 2. **Procurement process.** (a) The commissioner must, through a competitive procurement process in compliance with paragraph (b), select a state pharmacy benefit manager to comply with the requirements set forth in subdivision 3. The state pharmacy benefit manager selected under this subdivision must be a prepaid ambulatory health plan, as defined in Code of Federal Regulations, title 42, section 438.2.

(b) When selecting the state pharmacy benefit manager, the commissioner must:

(1) accept applications for entities seeking to become the state pharmacy benefit manager;

(2) establish eligibility criteria an entity must meet in order to become the state pharmacy benefit manager; and

(3) enter into a master contract with a single pharmacy benefit manager.

(c) Applicants for the state pharmacy benefit manager must disclose to the commissioner the following during the procurement process:

(1) any activity, policy, practice, contract, or arrangement of the pharmacy benefit manager that may directly or indirectly present any conflict of interest with the pharmacy benefit manager's relationship with or obligation to the Department of Human Services or a managed care organization;

(2) all common ownership, members of a board of directors, managers, or other control of the pharmacy benefit manager or any of the pharmacy benefit manager's affiliated companies with:

(i) a managed care organization administering medical assistance or MinnesotaCare benefits in Minnesota or an affiliate of the managed care organization;

(ii) an entity that contracts on behalf of a pharmacy or any pharmacy services administration organization and its affiliates;

(iii) a drug wholesaler or distributor and its affiliates;

(vi) a third-party payer and its affiliates; or

(v) a pharmacy and its affiliates;

(3) any direct or indirect fees, charges, or any kind of assessments imposed by the pharmacy benefit manager on pharmacies licensed in the state with which the pharmacy benefit manager shares common ownership, management, or control, or that are owned, managed, or controlled by any of the pharmacy benefit manager's affiliated companies;

(4) any direct or indirect fees, charges, or any kind of assessments imposed by the pharmacy benefit manager on pharmacies licensed in the state; and

(5) any financial terms and arrangements between the pharmacy benefit manager and a prescription drug manufacturer or labeler, including formulary management, drug substitution programs, educational support claims processing, or data sales fees.

Subd. 3. **Contract requirements.** The master contract required under subdivision 2, paragraph (b), clause (3), must include provisions that prohibit the state pharmacy benefit manager from:

(1) requiring, enticing, or coercing an enrollee to obtain pharmacy services, including a prescription drug, from a pharmacy owned or otherwise affiliated with the state pharmacy benefit manager;

(2) communicating to an enrollee, in any manner, that the enrollee is required to obtain pharmacy services or have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy owned or affiliated with the state pharmacy benefit manager if there are other nonaffiliated pharmacies that have the ability to dispense the medication or provide the services and are also in network;

(3) requiring an enrollee to obtain pharmacy services, including a prescription drug, exclusively through a mail order pharmacy;

(4) directly or indirectly retroactively denying or reducing a claim or aggregate of claims for pharmacy services, including prescription drugs, after adjudication of the claim or aggregation of claims; and

(5) paying a rate for pharmacy services, including the prescription drug, that is less than the sum of the following:

(i) the amount of the professional dispensing fee if it were determined pursuant to section 256B.0625, subdivision 13e; and

(ii) either:

(A) the lower of the national average drug acquisition cost or the Minnesota actual acquisition cost under section 256B.0625, subdivision 13e, paragraph (i);

(B) the maximum allowable cost, as described in section 62W.08, if the national average drug acquisition cost and the Minnesota actual acquisition cost are unreported; or

(C) the wholesale acquisition cost minus two percent at the time the drug is administered or dispensed if the costs of subitems (A) and (B) are unreported or unavailable.

Subd. 4. **Prescription drug coverage requirements.** (a) The state pharmacy benefit manager is responsible for processing all point of sale outpatient pharmacy claims under the managed care delivery system. Managed care and county-based purchasing plans must use the state pharmacy benefit manager pursuant to the terms of the master contract required under subdivision 2, paragraph (b), clause (3). The state pharmacy benefit manager selected is the exclusive pharmacy benefit manager used by managed care and county-based purchasing plans when providing coverage to enrollees. The commissioner may require the managed care and county-based purchasing plans and state pharmacy benefit manager to directly exchange data and files for members enrolled with the plans.

(b) The commissioner may require the state pharmacy benefit manager to modify utilization review limitations, requirements, and strategies imposed on prescription drug coverage.

(c) All payment arrangements between the Department of Human Services, managed care plans, county-based purchasing plans, and the state pharmacy benefit manager must comply with state and federal statutes, regulations adopted by the Centers for Medicare and Medicaid Services, and any other agreement between the department and the Centers for Medicare and Medicaid Services. The commissioner may change a payment arrangement to comply with this paragraph.

(d) The commissioner must administer and oversee this section to:

(1) ensure proper administration of prescription drug benefits for managed care enrollees; and

(2) increase the transparency of prescription drug prices and other information for the benefit of pharmacies.

Subd. 5. **Reporting requirements.** (a) The state pharmacy benefit manager must, on request from the commissioner, disclose to the commissioner all sources of payment the state pharmacy benefit manager receives for prescribed drugs, including drug rebates, discounts, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other financial benefits or payments related to services provided for a managed care or county-based purchasing plan.

(b) Each managed care and county-based purchasing plan must disclose to the commissioner, in the format specified by the commissioner, the entity's administrative costs associated with providing pharmacy services under the managed care delivery system.

(c) The state pharmacy benefit manager must provide a written quarterly report to the commissioner containing the following information from the immediately preceding quarter:

(1) the prices the state pharmacy benefit manager negotiated for prescribed drugs under the managed care delivery system. The prices must include any rebates the state pharmacy benefit manager received from drug manufacturers;

(2) unredacted copies of contracts between the state pharmacy benefit manager and enrolled pharmacies;

(3) any rebate amounts the state pharmacy benefit manager passed on to individual pharmacies;

(4) any changes to the information previously disclosed in accordance with subdivision 2, paragraph (c); and

(5) any other information required by the commissioner.

(d) Data submitted pursuant to paragraph (c), clause (3), are nonpublic data, as defined in section 13.02, subdivision 9.

(e) The commissioner may request and collect additional information and clinical data from the state pharmacy benefit manager.

(f) At the time of contract execution, renewal, or modification, the commissioner must modify the reporting requirements under its managed care contracts as necessary to meet the requirements of this subdivision.

Subd. 6. **Commissioner's program authority.** (a) To accomplish the requirements of subdivision 4, paragraph (d), the commissioner, in consultation with the Formulary Committee established under section 256B.0625, subdivision 13c, has the authority to:

(1) adopt or develop a preferred drug list for managed care plans;

(2) at the commissioner's discretion, engage in price negotiations with prescription drug manufacturers, wholesalers, or group purchasing organizations in place of the state pharmacy benefit manager to obtain price discounts and rebates for prescription drugs for managed care enrollees; and

(3) develop and manage a drug formulary for managed care and county-based purchasing plans.

(b) The commissioner may contract with one or more entities to perform any of the functions described in paragraph (a).

Subd. 7. **Contracts with pharmacies.** (a) The commissioner may review contracts between the state pharmacy benefit manager and pharmacies for compliance with this section and the master contract required under subdivision 2, paragraph (b), clause (3). The commissioner may amend any term or condition of a contract that does not comply with this section or the master contract.

(b) A master contract and a contract between a state pharmacy benefit manager and a pharmacy are nonpublic data, as defined in section 13.02, subdivision 9.

Subd. 8. **Federal approval.** (a) The commissioner must seek any necessary federal approval to implement this section.

(b) The commissioner shall monitor the effect of state directed payments under this section on access to pharmaceutical services in rural and underserved areas of Minnesota. If, for any contract year, federal approval is not received for a state directed payment under this section, the commissioner must adjust payments made to the managed care entity for that contract year to reflect removal of the payment. Contracts between the state pharmacy benefit manager and providers to whom this section applies must allow recovery of payments from those providers if rates are adjusted in accordance with this paragraph. Payment recoveries must not exceed the amount equal to any increase in rates that results from state directed payments under this section. This paragraph expires if federal approval is not received for state directed payments under this section at any time.

EFFECTIVE DATE. This section is effective January 1, 2027, or upon federal approval, whichever is later, except that subdivision 8 is effective the day following final enactment. The commissioner of human services shall notify the revisor of statutes when federal approval is obtained.

Prescription Drug Transparency

Sec. 7. Minnesota Statutes 2024, section 62J.84, subdivision 3, is amended to read:

Subd. 3. **Prescription drug price increases reporting.** (a) Beginning January 1, 2022, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:

(1) for brand name drugs where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in the price over the previous 24-month period; and

(2) for generic or biosimilar drugs where there is an increase of 50 percent or greater in the price over the previous 12-month period.

(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the price increase goes into effect, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the description and price of the drug and the net increase, expressed as a percentage, with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the factors that contributed to the price increase;

(3) the name of any generic version of the prescription drug available on the market;

(4) the year the prescription drug was introduced for sale in the United States;

~~(4)~~ (5) the introductory price of the prescription drug when it was introduced for sale in the United States and the price of the drug on the last day of each of the five calendar years preceding the price increase;

~~(5)~~ (6) the direct costs incurred during the previous 12-month period by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs; and

(iii) to distribute the prescription drug;

(7) the number of units of the prescription drug sold during the previous 12-month period;

~~(6)~~ (8) the total sales revenue for the prescription drug during the previous 12-month period;

(9) the total rebate payable amount accrued for the prescription drug during the previous 12-month period;

~~(7)~~ (10) the manufacturer's net profit attributable to the prescription drug during the previous 12-month period;

~~(8)~~ (11) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the previous 12-month period, if applicable;

~~(9)~~ (12) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

~~(10)~~ (13) the patent expiration date of the prescription drug if it is under patent;

~~(11)~~ (14) the name and location of the company that manufactured the drug;

~~(12)~~ (15) if a brand name prescription drug, the highest price paid for the prescription drug during the previous calendar year in the ten countries, excluding the United States, that charged the highest single price for the prescription drug; and

~~(13)~~ (16) if the prescription drug was acquired by the manufacturer during the previous 12-month period, all of the following information:

(i) price at acquisition;

(ii) price in the calendar year prior to acquisition;

(iii) name of the company from which the drug was acquired;

(iv) date of acquisition; and

(v) acquisition price.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Drug Price Transparency—Public Posting

Sec. 8. Minnesota Statutes 2024, section 62J.84, subdivision 6, is amended to read:

Subd. 6. **Public posting of prescription drug price information.** (a) The commissioner shall post on the department's website, or may contract with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the following information:

(1) a list of the prescription drugs reported under subdivisions 3, 4, and 11 to 14 and the manufacturers of those prescription drugs; ~~and~~

(2) a list of reporting entities that reported prescription drug price information under subdivisions 3, 4, and 11 to 14; and

~~(2)~~ (3) information reported to the commissioner under subdivisions 3, 4, and 11 to 14, aggregated on a per-drug basis in a manner that does not allow the identification of a reporting entity that is not the manufacturer of the drug.

(b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated in a manner that prevents the identification of the prescription drug.

(c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or is trade secret information under section 13.37, subdivision 1, paragraph (b); or is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. If a reporting entity believes information should be withheld from public disclosure pursuant to this paragraph, the reporting entity must clearly and specifically identify that information and describe the legal basis in writing when the reporting entity submits the information under this section. If the commissioner disagrees with the reporting entity's request to withhold information from public disclosure, the commissioner shall provide the reporting entity written notice that the information will be publicly posted 30 days after the date of the notice.

(d) If the commissioner withholds any information from public disclosure pursuant to this subdivision, the commissioner shall post to the department's website a report describing the nature of the information and the commissioner's basis for withholding the information from disclosure.

(e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.

Prescription Drug Transparency –Quarterly posting drugs of interest

Sec. 9. Minnesota Statutes 2024, section 62J.84, subdivision 10, is amended to read:

Subd. 10. **Notice of prescription drugs of substantial public interest.** (a) No later than January 31, 2024, and quarterly thereafter, the commissioner shall produce and post on the department's website a list of prescription drugs that the commissioner determines to represent a substantial public interest and for which the commissioner intends to request data under subdivisions 11 to 14, subject to paragraph (c). The commissioner shall base its inclusion of prescription drugs on any information the commissioner determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state, and the commissioner shall consider drug product families that include prescription drugs:

(1) that triggered reporting under subdivision 3 or 4 during the previous calendar quarter;

(2) for which average claims paid amounts exceeded 125 percent of the price as of the claim incurred date during the most recent calendar quarter for which claims paid amounts are available; or

(3) that are identified by members of the public during a public comment process.

(b) Not sooner than 30 days after publicly posting the list of prescription drugs under paragraph (a), the department shall notify, via email, reporting entities registered with the department of:

(1) the requirement to report under subdivisions 11 to 14.; and

(2) the reporting period for which data must be provided.

(c) The commissioner must not designate more than 500 prescription drugs as having a substantial public interest in any one notice.

(d) Notwithstanding subdivision 16, the commissioner is exempt from chapter 14, including section 14.386, in implementing this subdivision.

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

Prescription Drug Transparency –Manufacturer reporting

Sec. 10. Minnesota Statutes 2024, section 62J.84, subdivision 11, is amended to read:

Subd. 11. **Manufacturer prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a manufacturer must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the manufacturer by the department under subdivision 10;

(2) which the manufacturer manufactures or repackages;

(3) for which the manufacturer sets the wholesale acquisition cost; and

(4) for which the manufacturer has not submitted data under subdivision 3 during the 120-day period prior to the date of the notification to report.

(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the price of the drug product on the later of:

(i) the day one year prior to the date of the notification to report;

(ii) the introduced to market date; or

(iii) the acquisition date;

(3) the price of the drug product on the date of the notification to report;

(4) the year the prescription drug was introduced for sale in the United States;

~~(4)~~ (5) the introductory price of the prescription drug when it was introduced for sale in the United States and the price of the drug on the last day of each of the five calendar years preceding the date of the notification to report;

~~(5)~~ (6) the direct costs incurred during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report by the manufacturers that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs; and

(iii) to distribute the prescription drug;

~~(6)~~ (7) the number of units of the prescription drug sold during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

~~(7)~~ (8) the total sales revenue for the prescription drug during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

~~(8)~~ (9) the total rebate payable amount accrued for the prescription drug during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

~~(9)~~ (10) the manufacturer's net profit attributable to the prescription drug during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

~~(10)~~ (11) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report, if applicable;

~~(11)~~ (12) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

~~(12)~~ (13) the patent expiration date of the prescription drug if the prescription drug is under patent;

~~(13)~~ (14) the name and location of the company that manufactured the drug;

~~(14)~~ (15) if the prescription drug is a brand name prescription drug, the ten countries other than the United States that paid the highest prices for the prescription drug during the previous calendar year and their prices; and

~~(15)~~ (16) if the prescription drug was acquired by the manufacturer within ~~a 12-month period prior to the date of~~ the reporting period specified in the notification to report, all of the following information:

(i) the price at acquisition;

(ii) the price in the calendar year prior to acquisition;

(iii) the name of the company from which the drug was acquired;

(iv) the date of acquisition; and

(v) the acquisition price.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Prescription Drug Transparency –pharmacy reporting

Sec. 11. Minnesota Statutes 2024, section 62J.84, subdivision 12, is amended to read:

Subd. 12. **Pharmacy prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a pharmacy must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the pharmacy by the department under subdivision 10.; and

(2) that the pharmacy dispensed in Minnesota or mailed to a Minnesota address.

(b) For each of the drugs described in paragraph (a), the pharmacy shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug acquired during the 12-month period prior to the date of reporting period specified in the notification to report;

(3) the total spent before rebates by the pharmacy to acquire the drug during the 12-month period prior to the date of reporting period specified in the notification to report;

(4) the total rebate receivable amount accrued by the pharmacy for the drug during the 12-month period prior to the date of reporting period specified in the notification to report;

(5) the number of pricing units of the drug dispensed by the pharmacy during the 12-month period prior to the date of reporting period specified in the notification to report;

(6) the total payment receivable by the pharmacy for dispensing the drug including ingredient cost, dispensing fee, and administrative fees during the 12-month period prior to the date of reporting period specified in the notification to report;

(7) the total rebate payable amount accrued by the pharmacy for the drug during the 12-month period prior to the date of reporting period specified in the notification to report; and

(8) the average cash price paid by consumers per pricing unit for prescriptions dispensed where no claim was submitted to a health care service plan or health insurer during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report.

(c) The pharmacy may submit any documentation necessary to support the information reported under this subdivision.

(d) The commissioner may grant extensions, exemptions, or both to compliance with the requirements of paragraphs (a) and (b) by small or independent pharmacies, if compliance with paragraphs (a) and (b) would represent a hardship or undue burden to the pharmacy. The commissioner may establish procedures for small or independent pharmacies to request extensions or exemptions under this paragraph.

Prescription Drug Transparency –PBM reporting

Sec. 12. Minnesota Statutes 2024, section 62J.84, subdivision 13, is amended to read:

Subd. 13. **PBM prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a PBM must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the PBM by the department under subdivision 10~~.~~; and

(2) for which the PBM fulfilled pharmacy benefit management duties for Minnesota residents.

(b) For each of the drugs described in paragraph (a), the PBM shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of pricing units of the drug product filled ~~for which the PBM administered claims~~ during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(3) the total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled ~~for which the PBM administered claims~~ during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(4) the total reimbursement ~~or administrative fee~~ amount~~, or both,~~ accrued and receivable from payers for pricing units of the drug product filled ~~for which the PBM administered claims~~ during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(5) the total administrative fee amount accrued and receivable from payers for pricing units of the drug product filled during the reporting period specified in the notification to report;

~~(5)~~ (6) the total rebate receivable amount accrued by the PBM for the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report; and

~~(6)~~ (7) the total rebate payable amount accrued by the PBM for the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report.

(c) The PBM may submit any documentation necessary to support the information reported under this subdivision.

Prescription Drug Transparency –Wholesaler reporting

Sec. 13. Minnesota Statutes 2024, section 62J.84, subdivision 14, is amended to read:

Subd. 14. **Wholesale drug distributor prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a wholesale drug distributor that distributes prescription drugs, for which it is not the manufacturer, to persons or entities, or both, other than a consumer or patient in the state, must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the wholesale drug distributor by the department under subdivision 10~~.~~; and

(2) that the wholesale drug distributor distributed within or into Minnesota.

(b) For each of the drugs described in paragraph (a), the wholesale drug distributor shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug product acquired by the wholesale drug distributor during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(3) the total spent before rebates by the wholesale drug distributor to acquire the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(4) the total rebate receivable amount accrued by the wholesale drug distributor for the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(5) the number of units of the drug product sold by the wholesale drug distributor during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report;

(6) gross revenue from sales in the United States generated by the wholesale drug distributor for ~~this~~ the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report; and

(7) total rebate payable amount accrued by the wholesale drug distributor for the drug product during the ~~12-month period prior to the date of~~ reporting period specified in the notification to report.

(c) The wholesale drug distributor may submit any documentation necessary to support the information reported under this subdivision.

Prescription Drug Transparency –Registration and Reporting

Sec. 14. Minnesota Statutes 2024, section 62J.84, subdivision 15, is amended to read:

Subd. 15. **Registration requirements.** ~~Beginning January 1, 2024,~~ A reporting entity subject to this chapter shall register, or update existing registration information, with the department in a form and manner prescribed by the commissioner by January 30 each year.

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