ARTICLE 10

PRESCRIPTION DRUGS

Section 1. Minnesota Statutes 2018, section 8.31, subdivision 1, is amended to read:

Subdivision 1. **Investigate offenses against provisions of certain designated sections; assist in enforcement.** The attorney general shall investigate violations of the law of this state respecting unfair, discriminatory, and other unlawful practices in business, commerce, or trade, and specifically, but not exclusively, the Prohibition Against Charging Unconscionable Prices for Prescription Drugs (section 151.462), the Nonprofit Corporation Act (sections 317A.001 to 317A.909), the Act Against Unfair Discrimination and Competition (sections 325D.01 to 325D.07), the Unlawful Trade Practices Act (sections 325D.09 to 325D.16), the Antitrust Act (sections 325D.49 to 325D.66), section 325F.67 and other laws against false or fraudulent advertising, the antidiscrimination acts contained in section 325D.67, the act against monopolization of food products (section 325D.68), the act regulating telephone advertising services (section 325E.39), the Prevention of Consumer Fraud Act (sections 325F.68 to 325F.70), and chapter 53A regulating currency exchanges and assist in the enforcement of those laws as in this section provided.

Sec. 2. Minnesota Statutes 2018, section 62J.23, subdivision 2, is amended to read:

Subd. 2. **Restrictions.** (a) From July 1, 1992, until rules are adopted by the commissioner under this section, the restrictions in the federal Medicare antikickback statutes in section 1128B(b) of the Social Security Act, United States Code, title 42, section 1320a-7b(b), and rules adopted under the federal statutes, apply to all persons in the state, regardless of whether the person participates in any state health care program.

(b) Nothing in paragraph (a) shall be construed to prohibit an individual from receiving a discount or other reduction in price or a limited-time free supply or samples of a prescription drug, medical supply, or medical equipment offered by a pharmaceutical manufacturer, medical supply or device manufacturer, health plan company, or pharmacy benefit manager, so long as:

(1) the discount or reduction in price is provided to the individual in connection with the purchase of a prescription drug, medical supply, or medical equipment prescribed for that individual;

(2) it otherwise complies with the requirements of state and federal law applicable to enrollees of state and federal public health care programs;

(3) the discount or reduction in price does not exceed the amount paid directly by the individual for the prescription drug, medical supply, or medical equipment; and

(4) the limited-time free supply or samples are provided by a physician or pharmacist, as provided by the federal Prescription Drug Marketing Act.

For purposes of this paragraph, "prescription drug" includes prescription drugs that are administered through infusion, and related services and supplies.

(c) No benefit, reward, remuneration, or incentive for continued product use may be provided to an individual or an individual's family by a pharmaceutical manufacturer, medical supply or device manufacturer, or pharmacy benefit manager, except that this prohibition does not apply to:

(1) activities permitted under paragraph (b);

(2) a pharmaceutical manufacturer, medical supply or device manufacturer, health plan company, or pharmacy benefit manager providing to a patient, at a discount or reduced price or free of charge, ancillary products necessary for treatment of the medical condition for which the prescription drug, medical supply, or medical equipment was prescribed or provided; and

(3) a pharmaceutical manufacturer, medical supply or device manufacturer, health plan company, or pharmacy benefit manager providing to a patient a trinket or memento of insignificant value.

(d) Nothing in this subdivision shall be construed to prohibit a health plan company from offering a tiered formulary with different co-payment or cost-sharing amounts for different drugs.

Sec. 3. [62Q.528] DRUG COVERAGE IN EMERGENCY SITUATIONS.

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

Sec. 4. [62Q.83] PRESCRIPTIONS FOR SPECIALTY DRUGS.

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

(b) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, but also includes a county-based purchasing plan participating in a public program under chapter 256B or 256L, and in integrated health partnership under section 256B.0755.

(c) "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, fax, or through electronic submissions, dispense prescription drugs to enrollees through the use of United States mail or other common carrier services, and provide consultation with patients by telephone or electronically rather than face-to-face.

ARTICLE 12:

Sec. 8. [62Q.528] DRUG COVERAGE IN EMERGENCY SITUATIONS.

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

(d) "Pharmacy benefit manager" has the meaning provided in section 151.71, subdivision 1, paragraph (c).

(e) "Retail pharmacy" means a chain pharmacy, a supermarket pharmacy, an independent pharmacy, or a network of independent pharmacies, licensed under chapter 151, that dispenses prescription drugs to the public.

(f) "Specialty drug" means a prescription drug that:

(1) is not routinely made available to enrollees of a health plan company or its contracted pharmacy benefit manager through dispensing by a retail pharmacy, regardless if the drug is meant to be self-administered;

(2) must usually be obtained from specialty or mail order pharmacies; and

(3) has special storage, handling, or distribution requirements that typically cannot be met by a retail pharmacy.

Subd. 2. **Prompt filling of specialty drug prescriptions.** A health plan company or its contracted pharmacy benefit manager that requires or provides financial incentives for enrollees to use a mail order pharmacy to fill a prescription for a specialty drug must ensure through contract and other means that the mail order pharmacy dispenses the prescription drug to the enrollee in a timely manner, such that the enrollee receives the filled prescription within five business days of the date of transmittal to the mail order pharmacy. The health plan company or contracted pharmacy benefit manager may grant an exemption from this requirement if the mail order pharmacy can document that the specialty drug was out of stock due to a delay in shipment by the specialty drug manufacturer or prescription drug wholesaler. If an exemption is granted, the health plan company or pharmacy benefit manager shall notify the enrollee within 24 hours of granting the exemption and, if medically necessary, shall provide the enrollee with an emergency supply of the specialty drug.

EFFECTIVE DATE. This section is effective January 1, 2020, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 5. [62Q.84] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.

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

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

(c) "Enrollee contract term" means the 12-month term during which benefits associated with health plan company products are in effect. For managed care plans and county-based purchasing plans under section 256B.69 and chapter 256L, it means a single calendar quarter.

(d) "Formulary" means a list of prescription drugs that have been developed by clinical and pharmacy experts and represents the health plan company's medically appropriate and cost-effective prescription drugs approved for use.

(e) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, and includes an entity that performs pharmacy benefits management for the health plan company. For purposes of this definition, "pharmacy benefits management" means the administration or management of prescription drug benefits provided by the health plan company for the benefit of its enrollees and may include but is not limited to procurement of prescription drugs, clinical formulary development and management services, claims processing, and rebate contracting and administration.

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

Subd. 2. **Prescription drug benefit disclosure.** (a) A health plan company that provides prescription drug benefit coverage and uses a formulary must make its formulary and related benefit information available by electronic means and, upon request, in writing, at least 30 days prior to annual renewal dates.

(b) Formularies must be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's (USP) Model Guidelines.

(c) For each item or category of items on the formulary, the specific enrollee benefit terms must be identified, including enrollee cost-sharing and expected out-of-pocket costs.

Subd. 3. **Formulary changes.** (a) Once a formulary has been established, a health plan company may, at any time during the enrollee's contract term:

(1) expand its formulary by adding drugs to the formulary;

(2) reduce co-payments or coinsurance; or

(3) move a drug to a benefit category that reduces an enrollee's cost.

(b) A health plan company may remove a brand name drug from its formulary or place a brand name drug in a benefit category that increases an enrollee's cost only upon the addition to the formulary of 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 a lower cost to the enrollee, and upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

(c) A health plan company may change utilization review requirements or move drugs to a benefit category that increases an enrollee's cost during the enrollee's contract term upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees, provided that these changes do not apply to enrollees who are currently taking the drugs affected by these changes for the duration of the enrollee's contract term.

(d) A health plan company may remove any drugs from its formulary that have been deemed unsafe by the Food and Drug Administration, that have been withdrawn by either the Food and Drug Administration or the product manufacturer, or when an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

Sec. 6. [62W.01] CITATION.

This chapter may be cited as the "Minnesota Pharmacy Benefit Manager Licensure and Regulation Act."

Sec. 7. [62W.02] DEFINITIONS.

Subdivision 1. **Scope.** For purposes of this chapter, the following terms have the meanings given.

Subd. 2. **Aggregate retained rebate.** "Aggregate retained rebate" means the percentage of all rebates received by a pharmacy benefit manager from a drug manufacturer for drug utilization that is not passed on to the pharmacy benefit manager's health carrier's clients.

Subd. 3. **Claims processing service.** "Claims processing service" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacy services that includes:

(1) receiving payments for pharmacy services;

(2) making payments to pharmacists or pharmacies for pharmacy services; or

(3) both clause (1) and clause (2).

Subd. 4. **Commissioner.** "Commissioner" means the commissioner of commerce.

Subd. 5. **Enrollee.** "Enrollee" means a natural person covered by a health plan and includes an insured, policyholder, subscriber, contract holder, member, covered person, or certificate holder.

Subd. 6. **Health carrier.** "Health carrier" has the meaning given in section 62A.011, subdivision 2.

Subd. 7. **Health plan.** "Health plan" means a policy, contract, certificate, or agreement defined in section 62A.011, subdivision 3.

Subd. 8. **Mail order pharmacy.** "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, fax, or through electronic submissions, dispense prescription drugs to enrollees through the use of the United States mail or other common carrier services, and provide consultation with patients electronically rather than face-to-face.

Subd. 9. **Maximum allowable cost price.** "Maximum allowable cost price" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for a group

of therapeutically and pharmaceutically equivalent multiple source drugs. The maximum allowable cost price does not include a dispensing or professional fee.

Subd. 10. **Multiple source drugs.** "Multiple source drugs" means a therapeutically equivalent drug that is available from at least two manufacturers.

Subd. 11. **Network pharmacy.** "Network pharmacy" means a retail or other licensed pharmacy provider that directly contracts with a pharmacy benefit manager.

Subd. 12. **Other prescription drug or device services.** "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including:

(1) negotiating rebates, discounts, or other financial incentives and arrangements with drug manufacturers;

(2) disbursing or distributing rebates;

(3) managing or participating in incentive programs or arrangements for pharmacy services;

(4) negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) developing prescription drug formularies;

(6) designing prescription benefit programs; or

(7) advertising or promoting services.

Subd. 13. **Pharmacist.** "Pharmacist" means an individual with a valid license issued by the Board of Pharmacy under chapter 151.

Subd. 14. **Pharmacy.** "Pharmacy" or "pharmacy provider" means a place of business licensed by the Board of Pharmacy under chapter 151 in which prescription drugs are prepared, compounded, or dispensed, or under the supervision of a pharmacist.

Subd. 15. **Pharmacy benefit manager.** (a) "Pharmacy benefit manager" means a person, business, or other entity that contracts with a plan sponsor to perform pharmacy benefits management, including but not limited to:

(1) contracting directly or indirectly with pharmacies to provide prescription drugs to enrollees or other covered individuals;

(2) administering a prescription drug benefit;

(3) processing or paying pharmacy claims;

(4) creating or updating prescription drug formularies;

(5) making or assisting in making prior authorization determinations on prescription drugs;

(6) administering rebates on prescription drugs; or

(7) establishing a pharmacy network.

(b) "Pharmacy benefit manager" does not include the Department of Human Services.

Subd. 16. **Plan sponsor.** "Plan sponsor" means a group purchaser as defined under section 62J.03; an employer in the case of an employee health benefit plan established or maintained by a single employer; or an employee organization in the case of a health plan established or maintained by an employee organization, an association, joint board trustees, a committee, or other similar group that establishes or maintains the health plan. This term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefits management. Plan sponsor does not include the Department of Human Services.

Subd. 17. **Specialty drug.** "Specialty drug" means a prescription drug that:

(1) cannot be routinely dispensed at a majority of retail pharmacies;

(2) is used to treat chronic and complex, or rare, medical conditions; and

(3) meets a majority of the following criteria:

(i) requires special handling or storage;

(ii) requires complex and extended patient education or counseling;

(iii) requires intensive monitoring;

(iv) requires clinical oversight; and

(v) requires product support services.

Subd. 18. **Retail pharmacy.** "Retail pharmacy" means a chain pharmacy, a supermarket pharmacy, an independent pharmacy, or a network of independent pharmacies, licensed under chapter 151, that dispenses prescription drugs to the public.

Subd. 19. **Rebates.** "Rebates" means all price concessions paid by a drug manufacturer to a pharmacy benefit manager or plan sponsor, including discounts and other price concessions that are based on the actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness of a prescription drug as in a value-based or performance-based contract.

Sec. 8. [62W.03] LICENSE TO DO BUSINESS.

Subdivision 1. **General.** (a) Beginning January 1, 2020, no person shall perform, act, or do business in this state as a pharmacy benefits manager unless the person has a valid license issued under this chapter by the commissioner of commerce.

(b) A license issued in accordance with this chapter is nontransferable.

Subd. 2. **Application.** (a) A pharmacy benefit manager seeking a license shall apply to the commissioner of commerce on a form prescribed by the commissioner. The application form must include at a minimum the following information:

(1) the name, address, and telephone number of the pharmacy benefit manager;

(2) the name and address of the pharmacy benefit manager agent for service of process in this state;

(3) the name, address, official position, and professional qualifications of each person responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, or other governing board or committee; the principal officers in the case of a corporation; or the partners or members in the case of a partnership or association; and

(4) a statement reasonably describing the geographic area or areas to be served and the type or types of enrollees to be served.

(b) Each application for licensure must be accompanied by a nonrefundable fee of $8,500 and evidence of financial responsibility in the amount of $1,000,000 to be maintained at all times by the pharmacy benefit manager during its licensure period. The fees collected under this subdivision shall be deposited in the general fund.

(c) Within 30 days of receiving an application, the commissioner may require additional information or submissions from an applicant and may obtain any document or information reasonably necessary to verify the information contained in the application. Within 90 days after receipt of a completed application, evidence of financial responsibility, the network adequacy report required under section 62W.05, and the applicable license fee, the commissioner shall review the application and issue a license if the applicant is deemed qualified under this section. If the commissioner determines the applicant is not qualified, the commissioner shall notify the applicant and shall specify the reason or reasons for the denial.

Subd. 3. **Renewal.** (a) A license issued under this chapter is valid for a period of one year. To renew a license, an applicant must submit a completed renewal application on a form prescribed by the commissioner, the network adequacy report required under section 62W.05, and a renewal fee of $8,500. The commissioner may request a renewal applicant to submit additional information to clarify any new information presented in the renewal application. The fees collected under this paragraph shall be deposited in the general fund.

(b) A renewal application submitted after the renewal deadline date must be accompanied by a nonrefundable late fee of $500. The fees collected under this paragraph shall be deposited in the general fund.

(c) The commissioner shall deny the renewal of a license for any of the following reasons:

(1) the pharmacy benefit manager is operating in a financially hazardous condition relative to its financial condition and the services it administers for health carriers;

(2) the pharmacy benefit manager has been determined by the commissioner to be in violation or noncompliance with the requirements of state law or the rules promulgated under this chapter; or

(3) the pharmacy benefit manager has failed to timely submit a renewal application and the information required under paragraph (a).

In lieu of a denial of a renewal application, the commissioner may permit the pharmacy benefit manager to submit to the commissioner a corrective action plan to cure or correct deficiencies.

Subd. 4. **Oversight.** (a) The commissioner may suspend, revoke, or place on probation a pharmacy benefit manager license issued under this chapter for any of the following circumstances:

(1) the pharmacy benefit manager has engaged in fraudulent activity that constitutes a violation of state or federal law;

(2) the commissioner has received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers;

(3) the pharmacy benefit manager fails to pay an application license or renewal fee; and

(4) the pharmacy benefit manager fails to comply with a requirement set forth in this chapter.

(b) The commissioner may issue a license subject to restrictions or limitations, including the types of services that may be supplied or the activities in which the pharmacy benefit manager may be engaged.

Subd. 5. **Penalty.** If a pharmacy benefit manager acts without a license, the pharmacy benefit manager may be subject to a fine of $5,000 per day for the period the pharmacy benefit manager is found to be in violation. Any penalties collected under this subdivision shall be deposited in the general fund.

Subd. 6. **Rulemaking.** The commissioner may adopt rules to implement this section.

Subd. 7. **Enforcement.** The commissioner shall enforce this chapter under the provisions of chapter 45.

Sec. 9. [62W.04] PHARMACY BENEFIT MANAGER GENERAL BUSINESS PRACTICES.

(a) A pharmacy benefit manager has a fiduciary duty to a health carrier and must discharge that duty in accordance with the provisions of state and federal law.

(b) A pharmacy benefit manager must perform its duties with care, skill, prudence, diligence, and professionalism. A pharmacy benefit manager must exercise good faith and fair dealing in the performance of its contractual duties. A provision in a contract between a pharmacy benefit manager and a health carrier or a network pharmacy that attempts to waive or limit this obligation is void.

(c) A pharmacy benefit manager must notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the duties imposed in this section.

Sec. 10. [62W.05] PHARMACY BENEFIT MANAGER NETWORK ADEQUACY.

(a) A pharmacy benefit manager must provide an adequate and accessible pharmacy network for the provision of prescription drugs as defined under section 62K.10. Mail order pharmacies must not be included in the calculations of determining the adequacy of the pharmacy benefit manager's pharmacy network under section 62K.10.

(b) A pharmacy benefit manager must submit to the commissioner a pharmacy network adequacy report describing the pharmacy network and pharmacy accessibility in this state, with the pharmacy benefit manager's license application and renewal, in a manner prescribed by the commissioner.

(c) A pharmacy benefit manager may apply for a waiver of the requirements in paragraph (a) if it is unable to meet the statutory requirements. A waiver application must be submitted on a form provided by the commissioner and must (1) demonstrate with specific data that the requirement of paragraph (a) is not feasible in a particular service area or part of a service area, and (2) include information as to the steps that were and will be taken to address the network inadequacy. The waiver shall automatically expire after three years. If a renewal of the waiver is sought, the commissioner shall take into consideration steps that have been taken to address network adequacy.

(d) The pharmacy benefit manager must establish a pharmacy network service area consistent with the requirements under section 62K.13 for every pharmacy network subject to review under this section.

Sec. 11. [62W.06] PHARMACY BENEFIT MANAGER TRANSPARENCY.

Subdivision 1. **Transparency to plan sponsors.** (a) Beginning in the second quarter after the effective date of a contract between a pharmacy benefit manager and a plan sponsor, the pharmacy benefit manager must disclose, upon the request of the plan sponsor, the following information with respect to prescription drug benefits specific to the plan sponsor:

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs;

(2) the aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of prescription drugs. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;

(3) any other fees received from a drug manufacturer or wholesale drug distributor;

(4) whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a drug manufacturer to exclusively dispense or provide a drug to a plan sponsor's employees or enrollees, and the application of all consideration or economic benefits collected or received pursuant to the arrangement;

(5) prescription drug utilization information for the plan sponsor's employees or enrollees that is not specific to any individual employee or enrollee;

(6) de-identified claims level information in electronic format that allows the plan sponsor to sort and analyze the following information for each claim:

(i) the drug and quantity for each prescription;

(ii) whether the claim required prior authorization;

(iii) patient cost-sharing paid on each prescription;

(iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges;

(v) any spread between the net amount paid to the pharmacy in item (iv) and the amount charged to the plan sponsor;

(vi) identity of the pharmacy for each prescription;

(vii) whether the pharmacy is, or is not, under common control or ownership with the pharmacy benefit manager;

(viii) whether the pharmacy is, or is not, a preferred pharmacy under the plan;

(ix) whether the pharmacy is, or is not, a mail order pharmacy; and

(x) whether enrollees are required by the plan to use the pharmacy;

(7) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager;

(8) the aggregate amount of payments made by the pharmacy benefit manager to pharmacies not owned or controlled by the pharmacy benefit manager; and

(9) the aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, including point-of-sale fees and retroactive charges, and the application of those amounts collected pursuant to the contract with the plan sponsor.

Subd. 2. **Transparency report to the commissioner.** (a) Beginning June 1, 2020, and annually thereafter, each pharmacy benefit manager must submit to the commissioner of commerce a transparency report containing data from the prior calendar year. The report must contain the following information:

(1) the aggregate wholesale acquisition costs from a drug manufacturer or wholesale drug distributor for each therapeutic category of prescription drugs for all of the pharmacy benefit manager's health carrier clients and for each health carrier client, and these costs net of all rebates and other fees and payments, direct or indirect, from all sources;

(2) the aggregate amount of all rebates that the pharmacy benefit manager received from all drug manufacturers for all of the pharmacy benefit manager's health carrier clients and for each health carrier client. The aggregate amount of rebates must include any utilization discounts the pharmacy benefit manager receives from a drug manufacturer or wholesale drug distributor;

(3) the aggregate of all fees from all sources, direct or indirect, that the pharmacy benefit manager received for all of the pharmacy benefit manager's health carrier clients, and the amount of these fees for each health carrier client separately;

(4) the aggregate retained rebates and other fees, as listed in clause (3), that the pharmacy benefit manager received from all sources, direct or indirect, that were not passed through to the health carrier;

(5) the aggregate retained rebate and fees percentage;

(6) the highest, lowest, and mean aggregate retained rebate and fees percentage for all of the pharmacy benefit manager's health carrier clients and for each health carrier client; and

(7) de-identified claims level information in electronic format that allows the commissioner to sort and analyze the following information for each claim:

(i) the drug and quantity for each prescription;

(ii) whether the claim required prior authorization;

(iii) patient cost-sharing paid on each prescription;

(iv) the amount paid to the pharmacy for each prescription, net of the aggregate amount of fees or other assessments imposed on the pharmacy, including point-of-sale and retroactive charges;

(v) any spread between the net amount paid to the pharmacy in item (iv) and the amount charged to the plan sponsor;

(vi) identity of the pharmacy for each prescription;

(vii) whether the pharmacy is, or is not, under common control or ownership with the pharmacy benefit manager;

(viii) whether the pharmacy is, or is not, a preferred pharmacy under the plan;

(ix) whether the pharmacy is, or is not, a mail order pharmacy; and

(x) whether enrollees are required by the plan to use the pharmacy.

(b) Within 60 days upon receipt of the transparency report, the commissioner shall publish the report from each pharmacy benefit manager on the Department of Commerce's website, with the exception of data considered trade secret information under section 13.37.

(c) For purposes of this subdivision, the aggregate retained rebate and fee percentage must be calculated for each health carrier for rebates and fees in the previous calendar year as follows:

(1) the sum total dollar amount of rebates and fees from all drug manufacturers for all utilization of enrollees of a health carrier that was not passed through to the health carrier; and

(2) divided by the sum total dollar amount of all rebates and fees received from all sources, direct or indirect, for all enrollees of a health carrier.

Subd. 3. **Penalty.** The commissioner may impose civil penalties of not more than $1,000 per day per violation of this section.

Sec. 12. [62W.07] PHARMACY OWNERSHIP INTEREST; SPECIALTY PHARMACY SERVICES; NONDISCRIMINATION.

(a) A pharmacy benefit manager that has an ownership interest either directly or indirectly, or through an affiliate or subsidiary, in a pharmacy must disclose to a plan sponsor that contracts with the pharmacy benefit manager any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor.

(b) A pharmacy benefit manager or a pharmacy benefit manager's affiliates or subsidiaries must not own or have an ownership interest in a patient assistance program or a mail order specialty pharmacy, unless the pharmacy benefit manager, affiliate, or subsidiary agrees to fair competition, no self-dealing, and no interference with prospective economic advantage, and establishes a firewall between the administrative functions and the mail order pharmacy.

(c) A pharmacy benefit manager or health carrier is prohibited from penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, co-payments, or coinsurance, to an enrollee as an incentive to use a retail pharmacy, mail order pharmacy,

specialty pharmacy, or other network pharmacy provider in which a pharmacy benefit manager has an ownership interest or that has an ownership interest in a pharmacy benefit manager.

(d) A pharmacy benefit manager or health carrier is prohibited from imposing limits, including quantity limits or refill frequency limits, on a patient's access to medication that differ based solely on whether the health carrier or pharmacy benefit manager has an ownership interest in a pharmacy or the pharmacy has an ownership in the pharmacy benefit manager.

(e) A pharmacy benefit manager must not require pharmacy accreditation standards or recertification requirements to participate in a network that are inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

(f) A pharmacy benefit manager or health carrier must not prohibit an entity authorized to participate in the federal 340B Drug Pricing Program under section 340B of the Public Health Service Act (United States Code, title 42, chapter 6A), or a pharmacy under contract with such an entity to provide pharmacy services from participating in the pharmacy benefit manager's or health carrier's provider network. A pharmacy benefit manager or health carrier must not reimburse an entity or a pharmacy under contract with such an entity participating in the federal 340B Drug Pricing Program differently than other similarly situated pharmacies. A pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L must comply with this paragraph only if the entity or contracted pharmacy can identify all claims eligible for 340B drugs at the time of initial claims submission at the point-of-sale. This paragraph does not preclude a pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L, from reimbursing an entity or pharmacy identified in this paragraph at a lower rate for any prescription drug purchased by the entity or pharmacy through the federal 340B Drug Pricing Program.

Sec. 13. [62W.08] MAXIMUM ALLOWABLE COST PRICING.

(a) With respect to each contract and contract renewal between a pharmacy benefit manager and a pharmacy, the pharmacy benefits manager must:

(1) provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager;

(2) update any maximum allowable cost price list at least every seven business days, noting any price changes from the previous list, and provide a means by which network pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day at no cost to the pharmacy;

(3) maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace;

(4) ensure that the maximum allowable cost prices are not set below sources utilized by the pharmacy benefits manager; and

(5) upon request of a network pharmacy, disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the network pharmacy. A pharmacy benefit manager must make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy.

(b) A pharmacy benefit manager must not place a prescription drug on a maximum allowable cost list unless the drug is available for purchase by pharmacies in this state from a national or regional drug wholesaler and is not obsolete.

(c) Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a 15-business-day limit on the right to appeal following the initial claim;

(2) a requirement that the appeal be investigated and resolved within seven business days after the appeal is received; and

(3) a requirement that a pharmacy benefit manager provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(d) If an appeal is upheld, the pharmacy benefit manager must make an adjustment to the maximum allowable cost price no later than one business day after the date of determination. The pharmacy benefit manager must make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.

Sec. 14. [62W.09] PHARMACY AUDITS.

Subdivision 1. **Procedure and process for conducting and reporting an audit.** (a) Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures:

(1) a pharmacy must be given notice 14 days before an initial on-site audit is conducted;

(2) an audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist; and

(3) each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

(b) Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following items apply:

(1) the period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;

(2) if an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

(3) an on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy;

(4) auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers;

(5) any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;

(6) a pharmacy benefit manager may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(i) additional information is required in the provider manual; or

(ii) the information is required by the Food and Drug Administration (FDA); or

(iii) the information is required by the drug manufacturer's product safety program; and

(iv) the information in item (i), (ii), or (iii) is not readily available for the auditor at the time of the audit; and

(7) the auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

(c) An amendment to pharmacy audit terms in a contract between a pharmacy benefit manager and a pharmacy must be disclosed to the pharmacy at least 60 days prior to the effective date of the proposed change.

Subd. 2. **Requirement for recoupment or chargeback.** For recoupment or chargeback, the following criteria apply:

(1) audit parameters must consider consumer-oriented parameters based on manufacturer listings;

(2) a pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the pharmacy provider contract;

(3) a finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(4) the entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations;

(5) calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee;

(6) an entity may not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud, however such errors may be subject to recoupment;

(7) in the case of errors that have no actual financial harm to the patient or plan, the pharmacy benefit manager must not assess any chargebacks. Errors that are a result of the pharmacy failing to comply with a formal corrective action plan may be subject to recovery; and

(8) interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

Subd. 3. **Documentation.** (a) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including

medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

Subd. 4. **Appeals process.** The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

Subd. 5. **Audit information and reports.** (a) A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

Subd. 6. **Disclosure to plan sponsor.** Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

Subd. 7. **Applicability of other laws and regulations.** This section does not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

Subd. 8. **Definitions.** For purposes of this section, "entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

Sec. 15. [62W.10] SYNCHRONIZATION.

(a) For purposes of this section, "synchronization" means the coordination of prescription drug refills for a patient taking two or more medications for one or more chronic conditions, to allow the patient's medications to be refilled on the same schedule for a given period of time.

(b) A contract between a pharmacy benefit manager and a pharmacy must allow for synchronization of prescription drug refills for a patient on at least one occasion per year, if the following criteria are met:

(1) the prescription drugs are covered under the patient's health plan or have been approved by a formulary exceptions process;

(2) the prescription drugs are maintenance medications as defined by the health plan and have one or more refills available at the time of synchronization;

(3) the prescription drugs are not Schedule II, III, or IV controlled substances;

(4) the patient meets all utilization management criteria relevant to the prescription drug at the time of synchronization;

(5) the prescription drugs are of a formulation that can be safely split into short-fill periods to achieve synchronization; and

(6) the prescription drugs do not have special handling or sourcing needs that require a single, designated pharmacy to fill or refill the prescription.

(c) When necessary to permit synchronization, the pharmacy benefit manager must apply a prorated, daily patient cost-sharing rate to any prescription drug dispensed by a pharmacy under this section. The dispensing fee must not be prorated, and all dispensing fees shall be based on the number of prescriptions filled or refilled.

(d) Synchronization may be requested by the patient or by the patient's parent or legal guardian. For purposes of this paragraph, "legal guardian" includes but is not limited to a guardian of an incapacitated person appointed pursuant to chapter 524.

Sec. 16. [62W.11] GAG CLAUSE PROHIBITION.

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

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

(c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount, the pharmacy's own usual and customary price of the prescription, and the net amount the pharmacy will receive from all sources for dispensing the prescription drug, once the claim has been completed by the pharmacy benefit manager or the patient's health carrier.

(d) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy's usual and customary price when that

amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee's health plan.

Sec. 17. [62W.12] POINT OF SALE.

No pharmacy benefit manager or health carrier shall require an enrollee to make a payment at the point of sale for a covered prescription drug in an amount greater than the lesser of:

(1) the applicable co-payment for the prescription drug;

(2) the allowable claim amount for the prescription drug;

(3) the amount an enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using a health plan or any other source of prescription drug benefits or discounts; or

(4) the amount the pharmacy will be reimbursed for the prescription drug from the pharmacy benefit manager or health carrier.

Sec. 18. [62W.13] RETROACTIVE ADJUSTMENTS.

No pharmacy benefit manager shall retroactively adjust a claim for reimbursement submitted by a pharmacy for a prescription drug, unless the adjustment is a result of a:

(1) pharmacy audit conducted in accordance with section 62W.09; or

(2) technical billing error.

Sec. 19. Minnesota Statutes 2018, section 147.37, is amended to read:
147.37 INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.

At least annually, the board shall encourage licensees who are authorized to prescribe drugs to make available to patients information on ~~free and discounted prescription drug programs offered by pharmaceutical manufacturers when the information is provided to the licensees at no cost~~ sources of lower cost prescription drugs and shall provide these licensees with the address for the website established by the Board of Pharmacy pursuant to section 151.06, subdivision 6.

Sec. 20. [148.192] INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.

At least annually, the board shall encourage licensees who are authorized to prescribe drugs to make available to patients information on sources of lower cost prescription drugs

ARTICLE 11:

Sec. 16. [214.122] INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.

(a) The Board of Medical Practice and the Board of Nursing shall at least annually inform licensees who are authorized to prescribe prescription drugs of the availability of the Board of Pharmacy's website that contains information on resources and programs to assist patients

and shall provide these licensees with the address for the website established by the Board of Pharmacy pursuant to section 151.06, subdivision 6.

Sec. 21. Minnesota Statutes 2018, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

Sec. 22. Minnesota Statutes 2018, section 151.06, is amended by adding a subdivision to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) pharmaceutical manufacturer patient assistance programs;

(2) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(3) the emergency insulin assistance program established under section 256.937;

(4) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(5) the program established under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

with the cost of prescription drugs. The boards shall provide licensees with the website address established by the Board of Pharmacy under section 151.06, subdivision 6, and the materials described under section 151.06, subdivision 6, paragraph (b).

(b) Licensees must make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established by the Board of Pharmacy under section 151.06, subdivision 6.

Sec. 10. Minnesota Statutes 2018, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

Sec. 11. Minnesota Statutes 2018, section 151.06, is amended by adding a subdivision to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) patient assistance programs offered by drug manufacturers, including information on how to access the programs;

(2) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(3) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(4) availability of providers that are authorized to participate under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b;

(5) having a discussion with the pharmacist or the consumer's health care provider about alternatives to a prescribed drug, including a lower cost or generic drug if the drug prescribed is too costly for the consumer; and

(6) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board shall prepare educational documents and materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The documents and materials shall be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by practitioners who are licensed to prescribe. The board is not required to provide printed copies of these documents and materials.

(c) At least annually, the board shall encourage licensed pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs and shall provide these licensees with the address for the website established under paragraph (a).

Sec. 23. Minnesota Statutes 2018, section 151.071, subdivision 1, is amended to read:

Subdivision 1. **Forms of disciplinary action.** When the board finds that a licensee, registrant, or applicant has engaged in conduct prohibited under subdivision 2, it may do one or more of the following:

(1) deny the issuance of a license or registration;

(2) refuse to renew a license or registration;

(3) revoke the license or registration;

(4) suspend the license or registration;

(5) impose limitations, conditions, or both on the license or registration, including but not limited to: the limitation of practice to designated settings; the limitation of the scope of practice within designated settings; the imposition of retraining or rehabilitation requirements; the requirement of practice under supervision; the requirement of participation in a diversion program such as that established pursuant to section 214.31 or the conditioning of continued practice on demonstration of knowledge or skills by appropriate examination or other review of skill and competence;

(6) impose a civil penalty not exceeding $10,000 for each separate violation, except that a civil penalty not exceeding $25,000 may be imposed for each separate violation of section 151.462, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members; and

(7) reprimand the licensee or registrant.

(6) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board must prepare educational materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The materials must be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by health care practitioners who are licensed to prescribe. The board is not required to provide printed copies of these materials.

(c) The board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established under paragraph (a).

Sec. 24. Minnesota Statutes 2018, section 151.071, subdivision 2, is amended to read:

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

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

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

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

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

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

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

(i) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration in another state or jurisdiction, failure to report to the board that charges or allegations regarding the person's license or registration have been brought in

another state or jurisdiction, or having been refused a license or registration by any other state or jurisdiction. The board may delay the issuance of a new license or registration if an investigation or disciplinary action is pending in another state or jurisdiction until the investigation or action has been dismissed or otherwise resolved; and

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

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

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

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

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

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

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

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

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

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

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

(17) fee splitting, including without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

(25) for a manufacturer or wholesale drug distributor, a violation of section 151.462.

Sec. 25. Minnesota Statutes 2018, section 151.21, subdivision 7, is amended to read:

Subd. 7. **Drug formulary.** ~~This section~~ Subdivision 3 does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed health care plan that maintains a mandatory or closed drug formulary.

Sec. 26. Minnesota Statutes 2018, section 151.21, is amended by adding a subdivision to read:

Subd. 7a. **Coverage by substitution.** (a) When a pharmacist receives a prescription order by paper or hard copy, by electronic transmission, or by oral instruction from the prescriber, in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated and the drug prescribed is not covered under the purchaser's health plan or prescription drug plan, the pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product that is covered under the purchaser's plan, if the pharmacist has a written protocol with the prescriber that outlines the class of drugs of the same generation and designed for the same indication that can be substituted and the required communication between the pharmacist and the prescriber.

(b) The pharmacist must inform the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product prescribed and the reason for the substitution.

House Language H2414-2

(c) The pharmacist must communicate to the prescriber the name and manufacturer of the substituted drug that was dispensed and the reason for the substitution, in accordance with the written protocol.

Sec. 27. Minnesota Statutes 2018, section 151.211, subdivision 2, is amended to read:

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

Sec. 28. Minnesota Statutes 2018, section 151.211, is amended by adding a subdivision to read:

Subd. 3. **Emergency prescription refills.** (a) A pharmacist may, using sound professional judgment and in accordance with accepted standards of practice, dispense a legend drug without a current prescription drug order from a licensed practitioner if all of the following conditions are met:

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

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

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

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

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

Senate Language UEH2414-1

ARTICLE 11:

Sec. 12. Minnesota Statutes 2018, section 151.211, subdivision 2, is amended to read:

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

ARTICLE 11:

Sec. 13. Minnesota Statutes 2018, section 151.211, is amended by adding a subdivision to read:

Subd. 3. **Emergency prescription refills.** (a) A pharmacist may, using sound professional judgment and in accordance with accepted standards of practice, dispense a legend drug without a current prescription drug order from a licensed practitioner if all of the following conditions are met:

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

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

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

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

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

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

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

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

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

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

Sec. 29. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

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

(b) In addition to the license required under paragraph (a), a manufacturer of insulin must pay the applicable insulin registration fee in section 151.254, by June 1 of each year, beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new owner must pay the registration fee in section 151.254 that the original owner would have been assessed had it retained ownership. The board may assess a late fee of ten percent per month for any portion of a month that the registration fee is paid after the due date. The registration fee collected under this paragraph, including any late fees, shall be deposited in the insulin assistance account established under section 256.938.

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

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

~~(d)~~ (e) No license shall be issued or renewed for a drug manufacturer that is required to be registered pursuant to United States Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards

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

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

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

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

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

for licensure of drug manufacturers that are not required to be registered under United States Code, title 21, section 360.

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

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

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

Sec. 30. [151.254] INSULIN REGISTRATION FEE.

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

(b) "Manufacturer" means a manufacturer licensed under section 151.252 engaged in the manufacturing of insulin.

(c) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 and engaged in the wholesale drug distribution of insulin.

Subd. 2. **Reporting requirements.** (a) Effective March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the Board of Pharmacy every sale, delivery, or other distribution within or into the state of insulin that was made to any practitioner, pharmacy, hospital, or other person who is permitted by section 151.37 to possess insulin for administration or was dispensed to human patients during the previous calendar year. Reporting must be in a manner specified by the board. If the manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty shall not be

ARTICLE 11:

Sec. 14. [151.254] INSULIN REGISTRATION FEE.

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

(b) "Manufacturer" means a manufacturer licensed under section 151.252 engaged in the manufacturing of insulin.

(c) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 and engaged in the wholesale drug distribution of insulin.

Subd. 2. **Reporting requirements.** (a) Effective March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the Board of Pharmacy every sale, delivery, or other distribution within or into the state of insulin that was made to any practitioner, pharmacy, hospital, or other person who is permitted by section 151.37 to possess insulin for administration or was dispensed to human patients during the previous calendar year. Reporting must be in a manner specified by the board. If the manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty shall not be

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considered a form of disciplinary action. Any penalty assessed under this section shall be deposited in the insulin assistance account established under section 256.938.

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

Subd. 3. **Determination of manufacturer's registration fee.** (a) The board shall annually assess manufacturers a registration fee that in aggregate equals the total cost of the insulin assistance program established under section 256.937 for the previous fiscal year, including any administration costs incurred by the commissioner of human services or the board in collecting the fee. The board shall determine each manufacturer's annual insulin registration fee that is prorated and based on the manufacturer's percentage of the total number of units reported to the board under subdivision 2. For the first assessment, the commissioner shall estimate the cost of the program for the first fiscal year and notify the board of the estimated cost by March 1, 2020. The board shall determine each manufacturer's initial registration fee based on the estimated cost.

(b) By April 1 of each year, beginning April 1, 2020, the board shall notify each manufacturer of the annual amount of the manufacturer's insulin registration fee to be paid in accordance with section 151.252, subdivision 1, paragraph (b).

(c) A manufacturer may dispute the fee assessed under this section as determined by the board no later than 30 days after the date of notification. However, the manufacturer must still remit the registration fee required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the fee was incorrect or otherwise unwarranted. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the original fee was incorrect, the board must: (1) adjust the manufacturer's fee; (2) adjust the manufacturer's fee due the next year by the amount in excess of the correct fee that should have been paid; or (3) refund the amount paid in error.

Senate Language UEH2414-1

considered a form of disciplinary action. Any penalty assessed under this section shall be deposited in the insulin assistance account established under section 256.938.

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

Subd. 3. **Determination of manufacturer's registration fee.** (a) The board shall annually assess manufacturers a registration fee that in aggregate equals the total cost of the insulin assistance program established under section 256.937 for the previous fiscal year, not to exceed $....., including any administration costs incurred by the commissioner of human services or the board in collecting the fee. The board shall determine each manufacturer's annual insulin registration fee that is prorated and based on the manufacturer's percentage of the total number of units reported to the board under subdivision 2. For the first assessment, the commissioner shall estimate the cost of the program for the first fiscal year and notify the board of the estimated cost by March 1, 2020. The board shall determine each manufacturer's initial registration fee based on the estimated cost.

(b) By April 1 of each year, beginning April 1, 2020, the board shall notify each manufacturer of the annual amount of the manufacturer's insulin registration fee to be paid in accordance with section 151.252, subdivision 1, paragraph (b).

(c) A manufacturer may dispute the fee assessed under this section as determined by the board no later than 30 days after the date of notification. However, the manufacturer must still remit the registration fee required by section 151.252, subdivision 1, paragraph (b). The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the fee was incorrect or otherwise unwarranted. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the original fee was incorrect, the board must: (1) adjust the manufacturer's fee; (2) adjust the manufacturer's fee due the next year by the amount in excess of the correct fee that should have been paid; or (3) refund the amount paid in error.

Subd. 4. **Exclusion.** This section does not include biosimilars produced or distributed pursuant to a biologics license application, approved under United States Code, title 42, section 262(k)(3).

Sec. 31. [151.462] PROHIBITION AGAINST CHARGING UNCONSCIONABLE PRICES FOR PRESCRIPTION DRUGS.

Subdivision 1. **Purpose.** The purpose of this section is to promote public health in Minnesota by preventing unconscionable price gouging with respect to the price of essential prescription drugs sold in Minnesota. Essential prescription drugs are a necessity. These drugs, which are made available in this state by drug manufacturers and wholesale distributors, provide critically important benefits to the health and well-being of Minnesota citizens. Abuses in the pricing of various essential prescription drugs are well-documented, jeopardize the health and welfare of the public, and have caused the death of patients who could not afford to pay an unconscionable price for these drugs. For example, these price gouging practices have created a public health catastrophe in Minnesota regarding the sale of insulin, an essential prescription drug for the treatment of more than 320,000 people residing in Minnesota who are diabetic. This section is intended to address such abuses, but allow drug manufacturers and wholesale drug distributors a fair rate of return with respect to their sale of essential prescription drugs in the state of Minnesota.

Subd. 2. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "Essential prescription drug" means a patented (including an exclusivity-protected drug), off-patent, or generic drug prescribed in Minnesota by a practitioner:

(1) that either:

(i) is covered under the medical assistance program or by any Medicare Part D plan offered in the state of Minnesota; or

(ii) has been designated by the commissioner of human services under subdivision 4 as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living; and

(2) for which:

(i) a 30-day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(ii) a full course of treatment with the drug, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(iii) if the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

Essential prescription drug also includes a patented or off-patent drug-device combination product, whose wholesale acquisition cost is more than $80, and which is used at least in part for delivery of a drug described in this paragraph.

(c) "Health plan company" has the meaning provided in section 62Q.01, subdivision 4.

(d) "Unconscionable price" means a price that:

(1) is not reasonably justified by the actual cost of inventing, producing, selling, and distributing the essential prescription drug, and any actual cost of an appropriate expansion of access to the drug to promote public health; and

(2) applies to an essential prescription drug sold to:

(i) consumers in Minnesota;

(ii) the commissioner of human services for use in a Minnesota public health care program; or

(iii) a health plan company providing medical care to Minnesota consumers; and the consumer, commissioner, or health plan company has no meaningful choice about whether to purchase the drug, because there is no other comparable drug sold in Minnesota at a price that is reasonably justified by the actual cost of inventing, producing, selling, and distributing the comparable drug, and any actual cost of an appropriate expansion of access to the drug to promote public health.

(e) "Wholesale acquisition cost" has the meaning given in United States Code, title 42, section 1395w-3a.

Subd. 3. **Prohibition.** No drug manufacturer or wholesale drug distributor shall charge or cause to be charged in Minnesota an unconscionable price for an essential prescription drug sold in Minnesota. It is not a violation of this section for a wholesale drug distributor to charge a price for an essential prescription drug to be sold in Minnesota that is directly and substantially attributable to the cost of the drug charged by the manufacturer.

Subd. 4. **Commissioner of human services; list of essential prescription drugs.** The commissioner of human services, in consultation with the Formulary Committee established under section 256B.0625, subdivision 13c, may designate essential medicines in accordance with subdivision 2, paragraph (b), clause (1), item (ii), and shall maintain a list of all essential prescription drugs on the agency website. The commissioner is exempt from the rulemaking requirements of chapter 14 in making the essential medicine designation and compiling the list of all essential prescription drugs under this subdivision.

Subd. 5. **Notification of attorney general.** The Minnesota Board of Pharmacy, the commissioner of human services, and health plan companies providing health coverage to Minnesota consumers, shall notify the attorney general of any increase of 15 percent or

more during a one-year period in the price of any essential prescription drug sold in Minnesota.

Subd. 6. **Attorney general's office to confer with drug manufacturer or distributor.** In order for the attorney general to bring an action for an alleged violation of subdivision 3 against a drug manufacturer or wholesale distributor, the attorney general must have provided the manufacturer or wholesale distributor an opportunity to meet with the attorney general to present any justification for the price of the essential prescription drug. This meeting shall be in addition to any response or responses that the drug manufacturer or wholesale distributor may make to prelitigation investigation or discovery conducted by the attorney general pursuant to section 8.31.

Subd. 7. **Private right of action.** Any action brought pursuant to section 8.31, subdivision 3a, by a person injured by a violation of this section is for the benefit of the public.

Subd. 8. **Severability.** In accordance with section 645.20, it is the intent of the legislature that the provisions, or any part of a provision, of this section or its effective date are severable in the event any provision, or any part of a provision, of this section or its effective date is found by a court to be unconstitutional.

EFFECTIVE DATE. This section is effective the day following final enactment and, notwithstanding any statutory or common law to the contrary, applies retroactively to any prices charged by a drug manufacturer or drug wholesaler for essential prescription drugs sold or distributed in Minnesota on or after July 1, 2014.

Sec. 32. [151.555] PRESCRIPTION DRUG REPOSITORY PROGRAM.

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

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

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

(d) "Donor" means:

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

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

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

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

(5) a drug wholesaler licensed under section 151.47;

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

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

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

(f) "Health care facility" means:

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

(2) a hospital licensed under section 144.50;

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

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

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

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

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

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

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

Subd. 3. **Central repository requirements.** (a) The board shall publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the drug repository program. The board shall follow all applicable state procurement procedures in the selection process.

(b) To be eligible to act as the central repository, the participant must be a wholesale drug distributor located in Minnesota, licensed pursuant to section 151.47, and in compliance with all applicable federal and state statutes, rules, and regulations.

(c) The central repository shall be subject to inspection by the board pursuant to section 151.06, subdivision 1.

(d) The central repository shall comply with all applicable federal and state laws, rules, and regulations pertaining to the drug repository program, drug storage, and dispensing. The facility must maintain in good standing any state license or registration that applies to the facility.

Subd. 4. **Local repository requirements.** (a) To be eligible for participation in the drug repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the drug repository program, drug storage, and dispensing. The facility must also agree to maintain in good standing any required state license or registration that may apply to the facility.

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

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

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

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

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

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

(1) is a resident of Minnesota;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subd. 7. **Standards and procedures for inspecting and storing donated prescription drugs and supplies.** (a) A pharmacist or authorized practitioner who is employed by or

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

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

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

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

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

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

(1) the date of destruction;

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

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

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

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

(c) Before a drug or supply is dispensed or administered to an individual, the individual must sign a drug repository recipient form acknowledging that the individual understands the information stated on the form. The board shall develop the form and make it available on the board's website. The form must include the following information:

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

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

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

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

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

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

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

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

(1) intake application form described under subdivision 5;

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

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

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

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

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

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

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

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

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

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

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

(b) A health care facility participating in the program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner dispensing or administering a drug or

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

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

Sec. 33. [151.80] PRESCRIPTION DRUG PRICE TRANSPARENCY ACT.

Sections 151.80 to 151.83 shall be known as the "Prescription Drug Price Transparency Act."

Sec. 34. [151.81] DEFINITIONS.

Subdivision 1. **Applicability.** Only for purposes of sections 151.80 to 151.83, the terms defined in this section have the meanings given.

Subd. 2. **Commissioner.** "Commissioner" means the commissioner of health.

ARTICLE 9:

Sec. 5. [62J.84] PRESCRIPTION DRUG PRICE TRANSPARENCY.

Subdivision 1. **Short title.** This section may be cited as the "Prescription Drug Price Transparency Act."

Subd. 2. **Definitions.** (a) For purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).

(c) "Brand name drug" means a drug that is produced or distributed pursuant to:

(1) an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or

(2) a biologics license application approved under United States Code, title 45, section 262(a)(c).

(d) "Commissioner" means the commissioner of health.

(e) "Generic drug" means a drug that is marketed or distributed pursuant to:

(1) an abbreviated new drug application approved under United States Code, title 21, section 355(j);

(2) an authorized generic as defined under Code of Federal Regulations, title 45, section 447.502; or

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Subd. 3. **New prescription drug.** "New prescription drug" means a prescription drug approved for marketing by the United States Food and Drug Administration (FDA) for which no previous wholesale acquisition cost has been established for comparison.

Subd. 4. **Patient assistance program or program.** "Patient assistance program" or "program" means a program that a manufacturer offers to the general public in which a consumer may reduce the out-of-pocket costs for prescription drugs paid by the consumer by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or other reduction in out-of-pocket costs by other means.

Subd. 5. **Prescription drug.** "Prescription drug" has the meaning provided in section 151.44, paragraph (d).

Subd. 6. **Price.** "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).

Subd. 7. **Profit.** "Profit" means the total sales revenue for a prescription drug during the previous calendar year and the manufacturer's profit attributable to the same prescription drug during the previous calendar year.

Sec. 35. [151.83] REPORTING PRESCRIPTION DRUG PRICES.

Subdivision 1. **Applicability.** Beginning October 1, 2019, a manufacturer shall report the information described in subdivisions 2, 3, and 4 to the commissioner according to the requirements in subdivision 2, 3, or 4 as applicable.

Subd. 2. **Prescription drug price increases reporting.** For every prescription drug priced more than $40 for a course of therapy, whose price increases by more than ten percent in a 12-month period or more than 16 percent in a 24-month period, the manufacturer shall report to the commissioner at least 60 days in advance of the increase, in the form and manner prescribed by the commissioner, the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost of the drug for each of the last five calendar years, as applicable;

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(3) a drug that entered the market the year before 1962 and was not originally marketed under a new drug application.

(f) "Manufacturer" means a drug manufacturer licensed under section 151.252.

(g) "New prescription drug" or "new drug" means a prescription drug approved for marketing by the United States Food and Drug Administration for which no previous wholesale acquisition cost has been established for comparison.

(h) "Patient assistance program" means a program that a manufacturer offers to the public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or by other means.

(i) "Prescription drug" or "drug" has the meaning provided in section 151.44, paragraph (d).

(j) "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).

Subd. 3. **Prescription drug price increases reporting.** (a) Beginning July 1, 2020, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which:

(1) the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days; and

(2) for brand name drugs, there was a net increase of ten percent or greater in the price over the previous 12-month period, and for generic drugs, there was a net increase of 100 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 name and price of the drug and the net increase, expressed as a percentage;

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(2) the price increase as a percentage of the drug's price for each of the last five calendar years, as applicable;

(3) the price of the drug at its initial launch;

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

(5) the introductory price of the prescription drug when it was approved for marketing by the FDA;

(6) the direct costs incurred by the manufacturer that are associated with the drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

(7) the percentage of the price spent on developing, manufacturing, and distributing the drug;

(8) a description of the change or improvement in the drug, if any, that necessitates the price increase;

(9) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(10) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(11) the patent expiration date of the drug if it is under patent;

(12) the research and development costs associated with the prescription drug that were paid using public funds;

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(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 introductory price of the prescription drug when it was approved for marketing by the Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(5) the direct costs incurred 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 manufacturer's net profit attributable to the prescription drug during the previous 12-month period;

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

(8) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs, if applicable;

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

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

(13) any other information that the manufacturer deems relevant to the price increase described in this subdivision; and

(14) the documentation necessary to support the information reported under this subdivision.

Subd. 3. **New prescription drug price reporting.** For every new prescription drug that is a brand name drug that is priced over $500 for a 30-day supply or a generic name drug that is priced over $200 for a 30-day supply, 60 days or less after a manufacturer introduces a new prescription drug for sale in the United States, the manufacturer shall notify the commissioner, in the form and manner prescribed by the commissioner, of all the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost of the drug;

(2) the price of the drug at its initial launch;

(3) the factors that contributed to the price;

(4) the direct costs incurred by the manufacturer that are associated with that drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

(5) the percentage of the price spent on developing, manufacturing, and distributing the drug;

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

(12) if a brand name prescription drug, the ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.

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

Subd. 4. **New prescription drug price reporting.** (a) Beginning March 15, 2020, no later than 60 days after a manufacturer introduces a new prescription drug for sale in the United States that is a new brand name drug with a price that is greater than $500 for a 30-day supply or a new generic or biosimilar drug with a price that is greater than $500 for a 30-day supply and is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the price of the prescription drug;

(2) whether the Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(3) the direct costs incurred 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; and

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(6) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(7) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(8) the patent expiration date of the drug if it is under patent;

(9) the research and development costs associated with the prescription drug that were paid using public funds;

(10) any other information that the manufacturer deems relevant to the price described in this subdivision; and

(11) the documentation necessary to support the information reported under this subdivision.

Subd. 4. **Newly acquired prescription drug price reporting.** For every newly acquired prescription drug that is a brand name drug that is priced over $100 for a 30-day supply or a generic name drug that is priced over $50 for a 30-day supply, the acquiring manufacturer shall report to the commissioner at least 60 days in advance of the acquisition, in the form and manner prescribed by the commissioner, the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost at the time of acquisition and in the calendar year prior to acquisition;

(2) the name of the company from which the drug was acquired, the date acquired, and the purchase price;

(3) the year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction;

(4) the previous five calendar years' wholesale acquisition cost of the newly acquired brand name drug or newly acquired generic name drug;

(5) the direct costs incurred by the manufacturer that are associated with the drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

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(4) the patent expiration date of the drug if it is under patent.

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

Subd. 5. **Newly acquired prescription drug price reporting.** (a) Beginning July 1, 2020, for every newly acquired prescription drug for which the price increases by more than $100 for a 30-day supply from the price before the acquisition and the price after the acquisition, the acquiring manufacturer must submit to the commissioner at least 60 days after the acquiring manufacturer begins to sell the newly acquired prescription drug, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the price of the prescription drug at the time of acquisition and in the calendar year prior to acquisition;

(2) the name of the company from which the prescription drug was acquired, the date acquired, and the purchase price;

(3) the year the prescription drug was introduced to market and the price of the prescription drug at the time of introduction;

(4) the price of the prescription drug for the previous five years;

(6) the percentage of the price projected to be spent on developing, manufacturing, and distributing the drug;

(7) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(8) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(9) the patent expiration date of the drug if it is under patent;

(10) the research and development costs associated with the prescription drug that were paid using public funds; and

(11) if available, the price as determined reasonable through effectiveness measures.

Subd. 5. **Comparison data.** The commissioner may use any publicly available prescription drug price information the commissioner deems appropriate to verify that manufacturers have properly reported price increases as required by subdivision 2 of this section.

Subd. 6. **Additional information requested.** After receiving the report or information described in subdivision 2, 3, 4, or 5, the commissioner may make a written request to the manufacturer for supporting documentation or additional information concerning the report.

Subd. 7. **Public posting of prescription drug price information.** (a) Except as provided in paragraph (c), the commissioner shall post to the department's website 30 days before a price change is effective the information from the manufacturer, in an easy-to-read format, that includes all of the following information:

(1) a list of the prescription drugs reported under subdivisions 2, 3, and 4 and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 2 to 6.

The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow for identification of the drug.

(b) The commissioner may not post to the department's website any information described in this section if:

(5) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the manufacturer's drug; and

(6) the patent expiration date of the drug if it is under patent.

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

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 5, and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 3, 4, and 5.

(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

(1) the information is not public data under section 13.02, subdivision 8a; and

(2) the commissioner determines that public interest does not require disclosure of the information that is unrelated to the price of a prescription drug.

(c) The commissioner shall publicly announce the posting of information required under paragraph (a) and shall allow the public to comment on the posted information for a minimum of 30 calendar days.

(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.

Subd. 8. **Consultation.** The commissioner may consult with a nonprofit dedicated to collecting and reporting health care data and the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section in posting information on the department's website pursuant to subdivision 7, and in taking any other action for the purpose of implementing this section.

Subd. 9. **Legislative report.** (a) No later than January 15, 2021, and annually on January 15 every year thereafter, the commissioner shall report to the chairs and ranking members of the committees with jurisdiction over commerce, health and human services, and state finance and operations on the implementation of the Prescription Drug Price Transparency Act, including but not limited to the effectiveness in addressing the following goals:

(1) promoting transparency in pharmaceutical pricing for the state and other payers;

(2) enhancing understanding about pharmaceutical spending trends; and

(3) assisting the state and other payers in management of pharmaceutical costs.

(b) The report shall include a summary of the information reported to the commissioner under subdivisions 2 to 7 as well as a summary of any public comments received.

(c) The report shall include recommendations for legislative changes, if any, to reduce the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the State Employee Group Insurance Program, the Department of Human Services, and health insurance premiums in the fully insured markets.

Sec. 36. [151.84] ENFORCEMENT AND PENALTIES.

Subdivision 1. **Civil monetary penalties.** A manufacturer may be subject to a civil penalty, as provided in subdivision 2, for:

information under section 13.37, subdivision 1, paragraph (b); or is information that is not already available in the public domain.

(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.

Subd. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section, in posting information pursuant to subdivision 6, and in taking any other action for the purpose of implementing this section.

(b) The commissioner may consult with representatives of manufacturers to establish a standard format for reporting information under this section to minimize administrative burdens to the state and manufacturers.

Subd. 9. **Legislative report.** (a) No later than January 15 of each year, beginning January 15, 2021, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, including, but not limited to, the effectiveness in addressing the following goals:

(1) promoting transparency in pharmaceutical pricing for the state and other payers;

(2) enhancing the understanding on pharmaceutical spending trends; and

(3) assisting the state and other payers in the management of pharmaceutical costs.

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and 5.

Subd. 8. **Enforcement and penalties.** (a) A manufacturer may be subject to a civil penalty, as provided in paragraph (b), for:

(1) failing to submit timely reports or notices as required by section 151.83;

(2) failing to provide information required under section 151.83;

(3) failing to respond in a timely manner to a written request by the commissioner for additional information under section 151.83, subdivision 6; or

(4) providing inaccurate or incomplete information under section 151.83.

Subd. 2. **Enforcement.** (a) A manufacturer that fails to report or provide information as required by section 151.83 may be subject to a civil penalty as provided in this section.

(b) The commissioner shall adopt a schedule of penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(c) The commissioner shall impose civil penalties under this section as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section shall be paid to the commissioner of management and budget and deposited in the health care access fund to be made available for people served by state public health care programs.

Sec. 37. Minnesota Statutes 2018, section 152.01, subdivision 23, is amended to read:

Subd. 23. **Analog.** (a) Except as provided in paragraph (b), "analog" means a substance, the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II:

(1) that has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II; or

(2) with respect to a particular person, if the person represents or intends that the substance have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.

(b) "Analog" does not include:

(1) a controlled substance;

(2) any substance for which there is an approved new drug application under the Federal Food, Drug, and Cosmetic Act; ~~or~~

(3) with respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, as provided by United States Code, title 21, section 355,

(1) failing to submit timely reports or notices as required by this section;

(2) failing to provide information required under this section; or

(3) providing inaccurate or incomplete information under this section.

(b) The commissioner shall adopt a schedule of civil penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(c) The commissioner shall impose civil penalties under this section as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section shall be deposited in the health care access fund.

and the person is registered as a controlled substance researcher as required under section 152.12, subdivision 3, to the extent conduct with respect to the substance is pursuant to the exemption and registration; or

(4) marijuana or tetrahydrocannabinols naturally contained in a plant of the genus cannabis or in the resinous extractives of the plant.

EFFECTIVE DATE. This section is effective August 1, 2019, and applies to crimes committed on or after that date.

Sec. 38. Minnesota Statutes 2018, section 152.02, subdivision 2, is amended to read:

Subd. 2. **Schedule I.** (a) Schedule I consists of the substances listed in this subdivision.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following substances, including their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the analogs, isomers, esters, ethers, and salts is possible:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate);

(4) alphameprodine;

(5) alphamethadol;

(6) alpha-methylfentanyl benzethidine;

(7) betacetylmethadol;

(8) betameprodine;

(9) betamethadol;

(10) betaprodine;

(11) clonitazene;

(12) dextromoramide;

(13) diampromide;

(14) diethyliambutene;

(15) difenoxin;

(16) dimenoxadol;

(17) dimepheptanol;

(18) dimethyliambutene;

(19) dioxaphetyl butyrate;

(20) dipipanone;

(21) ethylmethylthiambutene;

(22) etonitazene;

(23) etoxeridine;

(24) furethidine;

(25) hydroxypethidine;

(26) ketobemidone;

(27) levomoramide;

(28) levophenacylmorphan;

(29) 3-methylfentanyl;

(30) acetyl-alpha-methylfentanyl;

(31) alpha-methylthiofentanyl;

(32) benzylfentanyl beta-hydroxyfentanyl;

(33) beta-hydroxy-3-methylfentanyl;

(34) 3-methylthiofentanyl;

(35) thenylfentanyl;

(36) thiofentanyl;

(37) para-fluorofentanyl;

(38) morpheridine;

(39) 1-methyl-4-phenyl-4-propionoxypiperidine;

(40) noracymethadol;

(41) norlevorphanol;

(42) normethadone;

(43) norpipanone;

(44) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);

(45) phenadoxone;

(46) phenampromide;

(47) phenomorphan;

(48) phenoperidine;

(49) piritramide;

(50) proheptazine;

(51) properidine;

(52) propiram;

(53) racemoramide;

(54) tilidine;

(55) trimeperidine;

(56) N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl);

(57) 3,4-dichloro-N-[(1R,2R)-2-(dimethylamino)cyclohexyl]-N-methylbenzamide(U47700);

(58) N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide(furanylfentanyl); and

(59) 4-(4-bromophenyl)-4-dimethylamino-1-phenethylcyclohexanol (bromadol).

(c) Opium derivatives. Any of the following substances, their analogs, salts, isomers, and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) acetorphine;

(2) acetyldihydrocodeine;

(3) benzylmorphine;

(4) codeine methylbromide;

(5) codeine-n-oxide;

(6) cyprenorphine;

(7) desomorphine;

(8) dihydromorphine;

(9) drotebanol;

(10) etorphine;

(11) heroin;

(12) hydromorphinol;

(13) methyldesorphine;

(14) methyldihydromorphine;

(15) morphine methylbromide;

(16) morphine methylsulfonate;

(17) morphine-n-oxide;

(18) myrophine;

(19) nicocodeine;

(20) nicomorphine;

(21) normorphine;

(22) pholcodine; and

(23) thebacon.

(d) Hallucinogens. Any material, compound, mixture or preparation which contains any quantity of the following substances, their analogs, salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) methylenedioxy amphetamine;

(2) methylenedioxymethamphetamine;

(3) methylenedioxy-N-ethylamphetamine (MDEA);

(4) n-hydroxy-methylenedioxyamphetamine;

(5) 4-bromo-2,5-dimethoxyamphetamine (DOB);

(6) 2,5-dimethoxyamphetamine (2,5-DMA);

(7) 4-methoxyamphetamine;

(8) 5-methoxy-3, 4-methylenedioxyamphetamine;

(9) alpha-ethyltryptamine;

(10) bufotenine;

(11) diethyltryptamine;

(12) dimethyltryptamine;

(13) 3,4,5-trimethoxyamphetamine;

(14) 4-methyl-2, 5-dimethoxyamphetamine (DOM);

(15) ibogaine;

(16) lysergic acid diethylamide (LSD);

(17) mescaline;

(18) parahexyl;

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) psilocybin;

(22) psilocyn;

(23) tenocyclidine (TPCP or TCP);

(24) N-ethyl-1-phenyl-cyclohexylamine (PCE);

(25) 1-(1-phenylcyclohexyl) pyrrolidine (PCPy);

(26) 1-[1-(2-thienyl)cyclohexyl]-pyrrolidine (TCPy);

(27) 4-chloro-2,5-dimethoxyamphetamine (DOC);

(28) 4-ethyl-2,5-dimethoxyamphetamine (DOET);

(29) 4-iodo-2,5-dimethoxyamphetamine (DOI);

(30) 4-bromo-2,5-dimethoxyphenethylamine (2C-B);

(31) 4-chloro-2,5-dimethoxyphenethylamine (2C-C);

(32) 4-methyl-2,5-dimethoxyphenethylamine (2C-D);

(33) 4-ethyl-2,5-dimethoxyphenethylamine (2C-E);

(34) 4-iodo-2,5-dimethoxyphenethylamine (2C-I);

(35) 4-propyl-2,5-dimethoxyphenethylamine (2C-P);

(36) 4-isopropylthio-2,5-dimethoxyphenethylamine (2C-T-4);

(37) 4-propylthio-2,5-dimethoxyphenethylamine (2C-T-7);

(38) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2-CB-FLY);

(39) bromo-benzodifuranyl-isopropylamine (Bromo-DragonFLY);

(40) alpha-methyltryptamine (AMT);

(41) N,N-diisopropyltryptamine (DiPT);

(42) 4-acetoxy-N,N-dimethyltryptamine (4-AcO-DMT);

(43) 4-acetoxy-N,N-diethyltryptamine (4-AcO-DET);

(44) 4-hydroxy-N-methyl-N-propyltryptamine (4-HO-MPT);

(45) 4-hydroxy-N,N-dipropyltryptamine (4-HO-DPT);

(46) 4-hydroxy-N,N-diallyltryptamine (4-HO-DALT);

(47) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);

(48) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DiPT);

(49) 5-methoxy-α-methyltryptamine (5-MeO-AMT);

(50) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(51) 5-methylthio-N,N-dimethyltryptamine (5-MeS-DMT);

(52) 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT);

(53) 5-methoxy-α-ethyltryptamine (5-MeO-AET);

(54) 5-methoxy-N,N-dipropyltryptamine (5-MeO-DPT);

(55) 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);

(56) 5-methoxy-N,N-diallyltryptamine (5-MeO-DALT);

(57) methoxetamine (MXE);

(58) 5-iodo-2-aminoindane (5-IAI);

(59) 5,6-methylenedioxy-2-aminoindane (MDAI);

(60) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe);

(61) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe);

(62) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe);

(63) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);

(64) 2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C-T-2);

(65) N,N-Dipropyltryptamine (DPT);

(66) 3-[1-(Piperidin-1-yl)cyclohexyl]phenol (3-HO-PCP);

(67) N-ethyl-1-(3-methoxyphenyl)cyclohexanamine (3-MeO-PCE);

(68) 4-[1-(3-methoxyphenyl)cyclohexyl]morpholine (3-MeO-PCMo);

(69) 1-[1-(4-methoxyphenyl)cyclohexyl]-piperidine (methoxydine, 4-MeO-PCP);

(70) 2-(2-Chlorophenyl)-2-(ethylamino)cyclohexan-1-one (N-Ethylnorketamine, ethketamine, NENK);

(71) methylenedioxy-N,N-dimethylamphetamine (MDDMA);

(72) 3-(2-Ethyl(methyl)aminoethyl)-1H-indol-4-yl (4-AcO-MET); and

(73) 2-Phenyl-2-(methylamino)cyclohexanone (deschloroketamine).

(e) Peyote. All parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church, and members of the American Indian Church are exempt from registration. Any person who manufactures peyote for or distributes peyote to the American Indian Church, however, is required to obtain federal registration annually and to comply with all other requirements of law.

(f) Central nervous system depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) mecloqualone;

(2) methaqualone;

(3) gamma-hydroxybutyric acid (GHB), including its esters and ethers;

(4) flunitrazepam; and

(5) 2-(2-Methoxyphenyl)-2-(methylamino)cyclohexanone (2-MeO-2-deschloroketamine, methoxyketamine).

(g) Stimulants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) aminorex;

(2) cathinone;

(3) fenethylline;

(4) methcathinone;

(5) methylaminorex;

(6) N,N-dimethylamphetamine;

(7) N-benzylpiperazine (BZP);

(8) methylmethcathinone (mephedrone);

(9) 3,4-methylenedioxy-N-methylcathinone (methylone);

(10) methoxymethcathinone (methedrone);

(11) methylenedioxypyrovalerone (MDPV);

(12) 3-fluoro-N-methylcathinone (3-FMC);

(13) methylethcathinone (MEC);

(14) 1-benzofuran-6-ylpropan-2-amine (6-APB);

(15) dimethylmethcathinone (DMMC);

(16) fluoroamphetamine;

(17) fluoromethamphetamine;

(18) α-methylaminobutyrophenone (MABP or buphedrone);

(19) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone);

(20) 2-(methylamino)-1-(4-methylphenyl)butan-1-one (4-MEMABP or BZ-6378);

(21) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl) pentan-1-one (naphthylpyrovalerone or naphyrone);

(22) (alpha-pyrrolidinopentiophenone (alpha-PVP);

(23) (RS)-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-hexanone (4-Me-PHP or MPHP);

(24) 2-(1-pyrrolidinyl)-hexanophenone (Alpha-PHP);

(25) 4-methyl-N-ethylcathinone (4-MEC);

(26) 4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP);

(27) 2-(methylamino)-1-phenylpentan-1-one (pentedrone);

(28) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone);

(29) 4-fluoro-N-methylcathinone (4-FMC);

(30) 3,4-methylenedioxy-N-ethylcathinone (ethylone);

(31) alpha-pyrrolidinobutiophenone (α-PBP);

(32) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (5-APDB);

(33) 1-phenyl-2-(1-pyrrolidinyl)-1-heptanone (PV8);

(34) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (6-APDB);

(35) 4-methyl-alpha-ethylaminopentiophenone (4-MEAPP);

(36) 4'-chloro-alpha-pyrrolidinopropiophenone (4'-chloro-PPP);

(37) 1-(1,3-Benzodioxol-5-yl)-2-(dimethylamino)butan-1-one (dibutylone, bk-DMBDB);

(38) 1-(3-chlorophenyl) piperazine (meta-chlorophenylpiperazine or mCPP); and

(39) any other substance, except bupropion or compounds listed under a different schedule, that is structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

(i) by substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;

(ii) by substitution at the 3-position with an acyclic alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or

(iv) by inclusion of the 2-amino nitrogen atom in a cyclic structure.

(h) ~~Marijuana,~~ Synthetic tetrahydrocannabinols~~,~~ and Synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any ~~natural or~~ synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(1) ~~marijuana;~~

~~(2)~~ synthetic tetrahydrocannabinols ~~naturally contained in a plant of the genus Cannabis~~, that are the synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant, or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including, but not limited to, 1 cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol;

~~(3)~~ (2) synthetic cannabinoids, including the following substances:

(i) Naphthoylindoles, which are any compounds containing a 3-(1-napthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl,

alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM-678);

(B) 1-Butyl-3-(1-naphthoyl)indole (JWH-073);

(C) 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081);

(D) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(E) 1-Propyl-2-methyl-3-(1-naphthoyl)indole (JWH-015);

(F) 1-Hexyl-3-(1-naphthoyl)indole (JWH-019);

(G) 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(H) 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210);

(I) 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(J) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201).

(ii) Napthylmethylindoles, which are any compounds containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindoles include, but are not limited to:

(A) 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane (JWH-175);

(B) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl)methane (JWH-184).

(iii) Naphthoylpyrroles, which are any compounds containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylpyrroles include, but are not limited to, (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone (JWH-307).

(iv) Naphthylmethylindenes, which are any compounds containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of

naphthylemethylindenes include, but are not limited to, E-1-[1-(1-naphthalenylmethylene)-1H-inden-3-yl]pentane (JWH-176).

(v) Phenylacetylindoles, which are any compounds containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of phenylacetylindoles include, but are not limited to:

(A) 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (RCS-8);

(B) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(C) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251);

(D) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

(vi) Cyclohexylphenols, which are compounds containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of cyclohexylphenols include, but are not limited to:

(A) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47,497);

(B) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (Cannabicyclohexanol or CP 47,497 C8 homologue);

(C) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl] -phenol (CP 55,940).

(vii) Benzoylindoles, which are any compounds containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of benzoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(4-methoxybenzoyl)indole (RCS-4);

(B) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694);

(C) (4-methoxyphenyl-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (WIN 48,098 or Pravadoline).

(viii) Others specifically named:

(A) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210);

(B) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (Dexanabinol or HU-211);

(C) 2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl-1-naphthalenylmethanone (WIN 55,212-2);

(D) (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

(E) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);

(F) 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide (AKB-48(APINACA));

(G) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5-Fluoro-AKB-48);

(H) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);

(I) 8-quinolinyl ester-1-(5-fluoropentyl)-1H-indole-3-carboxylic acid (5-Fluoro PB-22);

(J) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-pentyl-1H-indazole- 3-carboxamide (AB-PINACA);

(K) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (AB-FUBINACA);

(L) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide(AB-CHMINACA);

(M) (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3- methylbutanoate (5-fluoro-AMB);

(N) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl) methanone (THJ-2201);

(O) (1-(5-fluoropentyl)-1H-benzo[d]imidazol-2-yl)(naphthalen-1-yl)methanone) (FUBIMINA);

(P) (7-methoxy-1-(2-morpholinoethyl)-N-((1S,2S,4R)-1,3,3-trimethylbicyclo[2.2.1]heptan-2-yl)-1H-indole-3-carboxamide (MN-25 or UR-12);

(Q) (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-fluoro-ABICA);

(R) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide;

(S) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl) -1H-indazole-3-carboxamide;

(T) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido) -3,3-dimethylbutanoate;

(U) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)-1 H-indazole-3-carboxamide (MAB-CHMINACA);

(V) N-(1-Amino-3,3-dimethyl-1-oxo-2-butanyl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA);

(W) methyl (1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate (FUB-AMB);

(X) N-[(1S)-2-amino-2-oxo-1-(phenylmethyl)ethyl]-1-(cyclohexylmethyl)-1H-Indazole-3-carboxamide. (APP-CHMINACA);

(Y) quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (FUB-PB-22); and

(Z) methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA).

(i) A controlled substance analog, to the extent that it is implicitly or explicitly intended for human consumption.

EFFECTIVE DATE. This section is effective August 1, 2019, and applies to crimes committed on or after that date.

Sec. 39. Minnesota Statutes 2018, section 152.02, subdivision 3, is amended to read:

Subd. 3. **Schedule II.** (a) Schedule II consists of the substances listed in this subdivision.

(b) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(i) Excluding:

(A) apomorphine;

(B) thebaine-derived butorphanol;

(C) dextrophan;

(D) nalbuphine;

(E) nalmefene;

(F) naloxegol;

(G) naloxone;

(H) naltrexone; and

(I) their respective salts;

(ii) but including the following:

(A) opium, in all forms and extracts;

(B) codeine;

(C) dihydroetorphine;

(D) ethylmorphine;

(E) etorphine hydrochloride;

(F) hydrocodone;

(G) hydromorphone;

(H) metopon;

(I) morphine;

(J) oxycodone;

(K) oxymorphone;

(L) thebaine;

(M) oripavine;

(2) any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, cocaine compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, or unless listed in another schedule,

whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) alfentanil;

(2) alphaprodine;

(3) anileridine;

(4) bezitramide;

(5) bulk dextropropoxyphene (nondosage forms);

(6) carfentanil;

(7) dihydrocodeine;

(8) dihydromorphinone;

(9) diphenoxylate;

(10) fentanyl;

(11) isomethadone;

(12) levo-alpha-acetylmethadol (LAAM);

(13) levomethorphan;

(14) levorphanol;

(15) metazocine;

(16) methadone;

(17) methadone - intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;

(18) moramide - intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

(19) pethidine;

(20) pethidine - intermediate - a, 4-cyano-1-methyl-4-phenylpiperidine;

(21) pethidine - intermediate - b, ethyl-4-phenylpiperidine-4-carboxylate;

(22) pethidine - intermediate - c, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(23) phenazocine;

(24) piminodine;

(25) racemethorphan;

(26) racemorphan;

(27) remifentanil;

(28) sufentanil;

(29) tapentadol;

(30) 4-Anilino-N-phenethyl-4-piperidine (ANPP).

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) methamphetamine, its salts, isomers, and salts of its isomers;

(3) phenmetrazine and its salts;

(4) methylphenidate;

(5) lisdexamfetamine.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) amobarbital;

(2) glutethimide;

(3) secobarbital;

(4) pentobarbital;

(5) phencyclidine;

(6) phencyclidine immediate precursors:

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile;

(7) phenylacetone.

(f) ~~Hallucinogenic substances~~ Cannabis and cannabinoids:

(1) nabilone;

(2) unless specifically excepted or unless listed in another schedule, any natural material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(i) marijuana; and

(ii) tetrahydrocannabinols naturally contained in a plant of the genus cannabis or in the resinous extractives of the plant.

EFFECTIVE DATE. This section is effective August 1, 2019, and applies to crimes committed on or after that date.

Sec. 40. Minnesota Statutes 2018, section 152.11, is amended by adding a subdivision to read:

Subd. 5. **Exception.** References in this section to Schedule II controlled substances do not extend to marijuana or tetrahydrocannabinols.

Sec. 41. Minnesota Statutes 2018, section 152.12, is amended by adding a subdivision to read:

Subd. 6. **Exception.** References in this section to Schedule II controlled substances do not extend to marijuana or tetrahydrocannabinols.

Sec. 42. Minnesota Statutes 2018, section 152.125, subdivision 3, is amended to read:

Subd. 3. **Limits on applicability.** This section does not apply to:

(1) a physician's treatment of an individual for chemical dependency resulting from the use of controlled substances in Schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in Schedules II to V of section 152.02 to an individual whom the physician knows to be using the controlled substances for nontherapeutic purposes;

(3) the prescription or administration of controlled substances in Schedules II to V of section 152.02 for the purpose of terminating the life of an individual having intractable pain; ~~or~~

(4) the prescription or administration of a controlled substance in Schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief; or

(5) the administration of medical cannabis under sections 152.21 to 152.37.

Sec. 43. Minnesota Statutes 2018, section 152.126, subdivision 1, is amended to read:

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

(b) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

(c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12. For the purposes of this section, controlled substances includes butalbital and gabapentin but does not include medical cannabis under sections 152.21 to 152.37.

(d) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(e) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

(f) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1 or 2.

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

Sec. 44. [256.937] INSULIN ASSISTANCE PROGRAM.

Subdivision 1. **Establishment.** (a) The commissioner of human services shall implement an insulin assistance program by July 1, 2020. Under the program, the commissioner shall:

(1) pay participating pharmacies for insulin that is dispensed by a participating pharmacy to an eligible individual subject to a valid prescription; and

(2) ensure pharmacy participation in the program in all areas of the state and maintain an up-to-date list of participating pharmacies on the department's website.

(b) The commissioner may contract with a private entity or enter into an interagency agreement with another state agency to implement this program.

Subd. 2. **Eligible individual.** (a) To be eligible for the insulin assistance program, an individual must submit to the commissioner an application form that is signed by the individual. To be eligible, an individual must:

(1) be a resident of Minnesota;

ARTICLE 8:

Sec. 4. [256.937] INSULIN ASSISTANCE PROGRAM.

Subdivision 1. **Establishment.** (a) The commissioner of human services shall implement an insulin assistance program by July 1, 2020. Under the program, the commissioner shall:

(1) pay participating pharmacies for insulin that is dispensed by a participating pharmacy to an eligible individual subject to a valid prescription;

(2) maintain an up-to-date list of eligible individuals and make the list available to participating pharmacies; and

(3) ensure pharmacy participation in the program in all areas of the state and maintain an up-to-date list of participating pharmacies on the department's website.

(b) The commissioner may contract with a private entity or enter into an interagency agreement with another state agency to implement this program.

Subd. 2. **Eligible individual.** (a) To be eligible for the insulin assistance program, an individual must submit to the commissioner an application form that is signed by the individual. Eligibility for the insulin assistance program is subject to the limits of available funding. To be eligible, an individual must:

(1) be a resident of Minnesota;

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(2) not be eligible for Medicare, medical assistance, or MinnesotaCare;

(3) have a family income that is equal to or less than 400 percent of the federal poverty guidelines; and

(4) be uninsured, have no prescription drug coverage, or be covered by an individual or group health plan with an out-of-pocket limit of $5,000 or greater.

Eligibility for the insulin assistance program is subject to the limits of available funding.

(b) The commissioner shall develop an application form and make the form available to pharmacies, health care providers, and to individuals on the department's website. An applicant must include their income and insurance status information with the application. The commissioner may require the applicant to submit additional information to verify eligibility if deemed necessary by the commissioner.

(c) Upon receipt of a completed application and any additional information requested by the commissioner, the commissioner shall determine eligibility to the program. Once the individual has been determined eligible, the individual shall be issued an identification card. The card shall be valid for 90 days from the date of issuance and may be used at any participating pharmacy. An individual is not eligible for renewal until 12 months from the card's expiration date, at which time the individual must submit a new application form and meet the qualifications in paragraph (a).

Subd. 3. **Pharmacy participation.** (a) Pharmacy participation in the program is voluntary. In order to participate, a pharmacy must register with the commissioner and agree to reimbursement and other contract terms. A pharmacy may withdraw from participation at any time by providing written notice to the commissioner.

(b) A pharmacy shall dispense insulin to eligible individuals who present a valid prescription and an identification card.

(c) Eligible individuals are responsible for paying an insulin co-payment to the participating pharmacy that is equal to the prescription co-payment required under section 256L.03, subdivision 5.

(d) Notwithstanding paragraph (c), if an eligible individual has coverage through an individual or group health plan, the pharmacy must process the insulin in accordance with the individual's health plan.

(e) When dispensing insulin to an eligible individual, a pharmacy must provide the individual with the address for the website established under section 151.06, subdivision 6, paragraph (a).

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(2) not be eligible for Medicare, medical assistance, or MinnesotaCare;

(3) have a family income that is equal to or less than 400 percent of the federal poverty guidelines; and

(4) be uninsured or have no prescription drug coverage.

(b) The commissioner shall develop an application form and make the form available to pharmacies, health care providers, and to individuals on the department's website. An applicant must include their income and insurance status information with the application. The commissioner shall require the applicant to submit additional information to verify eligibility if deemed necessary by the commissioner.

(c) Upon receipt of a completed application and any additional information requested by the commissioner, the commissioner shall determine eligibility to the program. Once the individual has been determined eligible, the individual shall be issued an identification card. The card shall be valid for 30 days from the date of issuance and may be used at any participating pharmacy. An individual is not eligible for renewal until 12 months from the card's expiration date, at which time the individual must submit a new application form and meet the qualifications in paragraph (a).

Subd. 3. **Pharmacy participation.** (a) Pharmacy participation in the program is voluntary. In order to participate, a pharmacy must register with the commissioner and agree to reimbursement and other contract terms. A pharmacy may withdraw from participation at any time by providing written notice to the commissioner.

(b) A pharmacy shall dispense insulin to eligible individuals who present a valid prescription and an identification card.

(c) Eligible individuals are responsible for paying an insulin co-payment to the participating pharmacy that is equal to the prescription co-payment required under section 256L.03, subdivision 5.

(d) Notwithstanding paragraph (c), if an eligible individual has coverage through an individual or group health plan, the pharmacy must process the insulin in accordance with the individual's health plan.

Sec. 5. [256.938] INSULIN ASSISTANCE ACCOUNT.

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Subdivision 1. **Establishment.** The insulin assistance account is established in the special revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section 151.252, subdivision 1, paragraph (b), shall be deposited into the account.

Subd. 2. **Use of account funds.** For fiscal year 2021 and subsequent fiscal years, money in the insulin assistance account is appropriated to the commissioner of human services to fund the insulin assistance program established under section 256.937.

Sec. 46. Minnesota Statutes 2018, section 256B.69, subdivision 6, is amended to read:

Subd. 6. **Service delivery.** (a) Each demonstration provider shall be responsible for the health care coordination for eligible individuals. Demonstration providers:

(1) shall authorize and arrange for the provision of all needed health services including but not limited to the full range of services listed in sections 256B.02, subdivision 8, and 256B.0625 in order to ensure appropriate health care is delivered to enrollees. Notwithstanding section 256B.0621, demonstration providers that provide nursing home and community-based services under this section shall provide relocation service coordination to enrolled persons age 65 and over;

(2) shall accept the prospective, per capita payment from the commissioner in return for the provision of comprehensive and coordinated health care services for eligible individuals enrolled in the program;

(3) may contract with other health care and social service practitioners to provide services to enrollees; and

(4) shall institute recipient grievance procedures according to the method established by the project, utilizing applicable requirements of chapter 62D. Disputes not resolved through this process shall be appealable to the commissioner as provided in subdivision 11.

(b) Demonstration providers must comply with the standards for claims settlement under section 72A.201, subdivisions 4, 5, 7, and 8, when contracting with other health care and social service practitioners to provide services to enrollees. A demonstration provider must pay a clean claim, as defined in Code of Federal Regulations, title 42, section 447.45(b), within 30 business days of the date of acceptance of the claim.

(c) Managed care plans and county-based purchasing plans must comply with section 62Q.83.

Sec. 47. **SEVERABILITY.**

If any provision of the amendments to Minnesota Statutes, sections 62Q.83, 62W.01 to 62W.13, and 151.21, subdivisions 7 and 7a, are held invalid or unenforceable, the remainder of the sections are not affected and the provisions of the sections are severable.

Sec. 48. **CITATION.**

Senate Language UEH2414-1

Subdivision 1. **Establishment.** The insulin assistance account is established in the special revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section 151.252, subdivision 1, paragraph (b), shall be deposited into the account.

Subd. 2. **Use of account funds.** For fiscal year 2021 and subsequent fiscal years, money in the insulin assistance account is appropriated to the commissioner of human services to fund the insulin assistance program established under section 256.937.

The amendments to Minnesota Statutes, sections 147.37, 148.192, 151.06, subdivision 6, 151.252, subdivision 1, 151.254, 256.937, and 256.938, may be cited as "The Alec Smith Emergency Insulin Act."

Sec. 49. **REPEALER.**

Minnesota Statutes 2018, sections 151.214, subdivision 2; 151.60; 151.61; 151.62; 151.63; 151.64; 151.65; 151.66; 151.67; 151.68; 151.69; 151.70; and 151.71, are repealed.