House Language H2128-4

Section 1. Minnesota Statutes 2020, section 16A.151, subdivision 2, is amended to read:

Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific injured persons or entities, this section does not prohibit distribution of money to the specific injured persons or entities on whose behalf the litigation or settlement efforts were initiated. If money recovered on behalf of injured persons or entities cannot reasonably be distributed to those persons or entities because they cannot readily be located or identified or because the cost of distributing the money would outweigh the benefit to the persons or entities, the money must be paid into the general fund.

(b) Money recovered on behalf of a fund in the state treasury other than the general fund may be deposited in that fund.

(c) This section does not prohibit a state official from distributing money to a person or entity other than the state in litigation or potential litigation in which the state is a defendant or potential defendant.

(d) State agencies may accept funds as directed by a federal court for any restitution or monetary penalty under United States Code, title 18, section 3663(a)(3), or United States Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue account and are appropriated to the commissioner of the agency for the purpose as directed by the federal court.

(e) Tobacco settlement revenues as defined in section 16A.98, subdivision 1, paragraph (t), may be deposited as provided in section 16A.98, subdivision 12.

(f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, ~~against one or more opioid manufacturers or opioid wholesale drug distributors~~ related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall notify the chairs and ranking minority members of the Finance Committee in the senate and the Ways and Means Committee in the house of representatives that an account has been created. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section 151.065, subdivision 1, clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response fund under section 256.043 an amount that ensures that $20,940,000 each fiscal year is available for distribution in accordance with section 256.043, subdivisions 2 and 3.

Senate Language UEH2128-1

Section 1. Minnesota Statutes 2020, section 16A.151, subdivision 2, is amended to read:

Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific injured persons or entities, this section does not prohibit distribution of money to the specific injured persons or entities on whose behalf the litigation or settlement efforts were initiated. If money recovered on behalf of injured persons or entities cannot reasonably be distributed to those persons or entities because they cannot readily be located or identified or because the cost of distributing the money would outweigh the benefit to the persons or entities, the money must be paid into the general fund.

(b) Money recovered on behalf of a fund in the state treasury other than the general fund may be deposited in that fund.

(c) This section does not prohibit a state official from distributing money to a person or entity other than the state in litigation or potential litigation in which the state is a defendant or potential defendant.

(d) State agencies may accept funds as directed by a federal court for any restitution or monetary penalty under United States Code, title 18, section 3663(a)(3), or United States Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue account and are appropriated to the commissioner of the agency for the purpose as directed by the federal court.

(e) Tobacco settlement revenues as defined in section 16A.98, subdivision 1, paragraph (t), may be deposited as provided in section 16A.98, subdivision 12.

(f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, against one or more opioid manufacturers or opioid wholesale drug distributors or consulting firms working for an opioid manufacturer or opioid wholesale drug distributor related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall notify the chairs and ranking minority members of the Finance Committee in the senate and the Ways and Means Committee in the house of representatives that an account has been created. Notwithstanding section 11A.20, all investment income and all investment losses attributable to the investment of this account shall be credited to the account. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section 151.065, subdivision 1, clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response fund under section 256.043 an amount that ensures that $20,940,000

each fiscal year is available for distribution in accordance with section 256.043, ~~subdivisions 2 and~~ subdivision 3.

(g) Notwithstanding paragraph (f), if money is received from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state or a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency against a consulting firm working for an opioid manufacturer or opioid wholesale drug distributor and deposited into the separate account created under paragraph (f), the commissioner shall annually transfer from the separate account to the opiate epidemic response fund under section 256.043 an amount equal to the estimated amount submitted to the commissioner by the Board of Pharmacy in accordance with section 151.066, subdivision 3, paragraph (b). The amount transferred shall be included in the amount available for distribution in accordance with section 256.043, subdivision 3. This transfer shall occur each year until the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, or the money deposited in the account in accordance with this paragraph has been transferred, whichever occurs first.

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

ARTICLE 5

PRESCRIPTION DRUGS

Section 1. **[62J.841] DEFINITIONS.**

Subdivision 1. **Scope.** For purposes of sections 62J.841 to 62J.845, the following definitions apply.

Subd. 2. **Consumer Price Index.** "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All Items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

Subd. 3. **Generic or off-patent drug.** "Generic or off-patent drug" means any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired, including any drug-device combination product for the delivery of a generic drug.

Subd. 4. **Manufacturer.** "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.

Subd. 5. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 6. **Wholesale acquisition cost.** "Wholesale acquisition cost" has the meaning provided in United States Code, title 42, section 1395w-3a.

Subd. 7. **Wholesale distributor.** "Wholesale distributor" has the meaning provided in section 151.441, subdivision 14.

Sec. 2. **[62J.842] EXCESSIVE PRICE INCREASES PROHIBITED.**

Subdivision 1. **Prohibition.** No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state.

Subd. 2. **Excessive price increase.** A price increase is excessive for purposes of this section when:

(1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:

(i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or

(ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and

(2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:

(i) a 30-day supply of the drug; or

(ii) a course of treatment lasting less than 30 days.

Subd. 3. **Exemption.** It is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug.

Sec. 3. **[62J.843] REGISTERED AGENT AND OFFICE WITHIN THE STATE.**

Any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state is required to maintain a registered agent and office within the state.

Sec. 4. **[62J.844] ENFORCEMENT.**

Subdivision 1. **Notification.** The commissioner of management and budget and any other state agency that provides or purchases a pharmacy benefit except the Department of Human Services, and any entity under contract with a state agency to provide a pharmacy benefit other than an entity under contract with the Department of Human Services, shall

notify the manufacturer of a generic or off-patent drug, the attorney general, and the Board of Pharmacy of any price increase that is in violation of section 62J.842.

Subd. 2. **Submission of drug cost statement and other information by manufacturer; investigation by attorney general.** (a) Within 45 days of receiving a notice under subdivision 1, the manufacturer of the generic or off-patent drug shall submit a drug cost statement to the attorney general. The statement must:

(1) itemize the cost components related to production of the drug, including any fees or costs imposed by the state such as opioid registration fees;

(2) identify the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding calendar year, or preceding three calendar years as applicable, in the price of the drug; and

(3) provide any other information that the manufacturer believes to be relevant to a determination of whether a violation of section 62J.842 has occurred.

(b) The attorney general may investigate whether a violation of section 62J.842 has occurred, is occurring, or is about to occur, in accordance with section 8.31, subdivision 2.

Subd. 3. **Petition to court.** (a) On petition of the attorney general, a court may issue an order:

(1) compelling the manufacturer of a generic or off-patent drug to:

(i) provide the drug cost statement required under subdivision 2, paragraph (a); and

(ii) answer interrogatories, produce records or documents, or be examined under oath, as required by the attorney general under subdivision 2, paragraph (b);

(2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including issuing an order requiring that drug prices be restored to levels that comply with section 62J.842;

(3) requiring the manufacturer to provide an accounting to the attorney general of all revenues resulting from a violation of section 62J.842;

(4) requiring the manufacturer to repay to all consumers, including any third-party payers, any money acquired as a result of a price increase that violates section 62J.842;

(5) notwithstanding section 16A.151, requiring that all revenues generated from a violation of section 62J.842 be remitted to the state and deposited into a special fund, to be used for initiatives to reduce the cost to consumers of acquiring prescription drugs, if a manufacturer is unable to determine the individual transactions necessary to provide the repayments described in clause (4);

(6) imposing a civil penalty of up to $10,000 per day for each violation of section 62J.842;

(7) providing for the attorney general's recovery of its costs and disbursements incurred in bringing an action against a manufacturer found in violation of section 62J.842, including the costs of investigation and reasonable attorney's fees; and

(8) providing any other appropriate relief, including any other equitable relief as determined by the court.

(b) For purposes of paragraph (a), clause (6), every individual transaction in violation of section 62J.842 shall be considered a separate violation.

Subd. 4. **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.

Sec. 5. **[62J.845] PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE.**

Subdivision 1. **Prohibition.** A manufacturer of a generic or off-patent drug is prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the prohibition on excessive price increases under section 62J.842.

Subd. 2. **Notice to board and attorney general.** Any manufacturer that intends to withdraw a generic or off-patent drug from sale or distribution within the state shall provide a written notice of withdrawal to the Board of Pharmacy and the attorney general, at least 180 days prior to the withdrawal.

Subd. 3. **Financial penalty.** The attorney general shall assess a penalty of $500,000 on any manufacturer of a generic or off-patent drug that it determines has failed to comply with the requirements of this section.

Sec. 6. **[62J.846] SEVERABILITY.**

If any provision of sections 62J.841 to 62J.845 or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of sections 62J.841 to 62J.845 that can be given effect without the invalid provision or application.

Sec. 2. **[62J.85] PRESCRIPTION DRUG MANUFACTURER IMPORTATION PATHWAY PLAN.**

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

(b) "Drug product" or "drug" means a prescription drug or biological product that is intended for human use and regulated as a drug except where specific reference is made to a drug approved under section 505 of the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 355, or biological product approved under section 351 of the federal Public Health Act, United States Code, title 42, section 262. Drug product or drug

does not include biological products that are intended for transfusions, including blood or blood products; or allogeneic-, cellular-, or tissue-based products.

(c) "FD&C Act" means the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 301, et seq.

(d) "Importation guidance" means the draft guidance released by the federal Food and Drug Administration (FDA) titled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for the Industry," which if finalized allows for the importation of MMA products.

(e) "Manufacturer" means the entity that is the holder of the New Drug Application or Biologics License Application for the drug product.

(f) "Multimarket-approved product" or "MMA product" means a FDA-approved drug product that:

(1) was manufactured outside the United States and authorized for marketing by another country's regulatory authority;

(2) is subject to a new drug application or biologics license application;

(3) is imported into the United States and is authorized by the manufacturer to be marketed in the United States; and

(4) continues to meet the quality standards for marketing in its originally intended foreign market.

Subd. 2. **Application.** This section applies to any MMA product in which the manufacturer of the product has obtained a new National Drug Code (NDC) for the MMA product and has imported the MMA product in compliance with the FD&C Act and any importation guidance finalized by the FDA.

Subd. 3. **Incentives.** (a) In order to facilitate importation of drugs pursuant to importation guidance finalized by the FDA, any MMA product offered for sale in Minnesota at a cost that is at least 23 percent lower than the wholesale acquisition cost for the FDA-approved product manufactured in the United States shall be:

(1) included on the uniform preferred drug list and covered under the medical assistance and MinnesotaCare programs; and

(2) a covered drug under the state employee group insurance program pursuant to chapter 43A.

(b) A health plan company must provide coverage for each MMA product that meets the requirements in paragraph (a) if the manufacturer's FDA-approved drug product manufactured in the United States is covered by the health plan company and the health

Sec. 7. Minnesota Statutes 2020, section 62Q.81, is amended by adding a subdivision to read:

Subd. 6. **Prescription drug benefits.** (a) A health plan company that offers individual health plans must ensure that no fewer than 25 percent of the individual health plans the company offers in each geographic area that the health plan company services at each level of coverage described in subdivision 1, paragraph (b), clause (3), applies a predeductible, flat-dollar amount co-payment structure to the entire drug benefit, including all tiers.

(b) A health plan company that offers small group health plans must ensure that no fewer than 25 percent of small group health plans the company offers in each geographic area that the health plan company services at each level of coverage described in subdivision 1, paragraph (b), clause (3), applies a predeductible, flat-dollar amount co-payment structure to the entire drug benefit, including all tiers.

(c) The highest allowable co-payment for the highest cost drug tier for health plans offered pursuant to this subdivision must be no greater than 1/12 of the plan's out-of-pocket maximum for an individual.

(d) The flat-dollar amount co-payment tier structure for prescription drugs under this subdivision must be graduated and proportionate.

(e) All individual and small group health plans offered pursuant to this subdivision must be:

(1) clearly and appropriately named to aid the purchaser in the selection process;

(2) marketed in the same manner as other health plans offered by the health plan company; and

(3) offered for purchase to any individual or small group.

(f) This subdivision does not apply to catastrophic plans, grandfathered plans, large group health plans, health savings accounts (HSAs), qualified high deductible health benefit plans, limited health benefit plans, or short-term limited-duration health insurance policies.

(g) Health plan companies must meet the requirements in this subdivision separately for plans offered through MNsure under chapter 62V and plans offered outside of MNsure.

EFFECTIVE DATE. This section is effective January 1, 2022, and applies to individual and small group health plans offered, issued, or renewed on or after that date.

plan company must not impose any enrollee cost-sharing requirements for the covered MMA product.

(c) This subdivision shall not become effective for MMA products that are offered for sale in Minnesota in accordance with paragraph (a) unless affirmative action is taken by the legislature.

Sec. 8. **[62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.**

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

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

(c) "Enrollee 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, enrollee contract term 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.

(f) "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.

(g) "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 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 Food and Drug Administration (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 FDA; that have been withdrawn by either the FDA 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.

Subd. 4. **Exclusion.** This section does not apply to health coverage provided through the State Employee Group Insurance Plan (SEGIP) under chapter 43A.

Sec. 9. **[62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.**

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

(b) "Biological product" has the meaning given in section 151.01, subdivision 40.

(c) "Biosimilar" or "biosimilar product" has the meaning given in section 151.01, subdivision 43.

(d) "Interchangeable biological product" has the meaning given in section 151.01, subdivision 41.

(e) "Reference biological product" has the meaning given in section 151.01, subdivision 44.

Subd. 2. **Pharmacy and provider choice related to dispensing reference biological products, interchangeable biological products, or biosimilar products.** (a) A pharmacy benefit manager or health carrier must not require or demonstrate a preference for a pharmacy or health care provider to prescribe or dispense a single biological product for which there is a United States Food and Drug Administration-approved biosimilar or interchangeable biological product relative to a reference biological product, except as provided in paragraph (b).

(b) If a pharmacy benefit manager or health carrier elects coverage of a product listed in paragraph (a), it must also elect equivalent coverage for at least three reference, biosimilar, or interchangeable biological products, or the total number of products that have been approved by the United States Food and Drug Administration relative to the reference

product if less than three, for which the wholesale acquisition cost is less than the wholesale acquisition cost of the product listed in paragraph (a).

(c) A pharmacy benefit manager or health carrier must not impose limits on access to a product required to be covered under paragraph (b) that are more restrictive than limits imposed on access to a product listed in paragraph (a), or that otherwise have the same effect as giving preferred status to a product listed in paragraph (a) over the product required to be covered under paragraph (b).

(d) This section does not apply to coverage provided through a public health care program under chapter 256B or 256L, or health plan coverage through the State Employee Group Insurance Plan (SEGIP) under chapter 43A.

EFFECTIVE DATE. This section is effective January 1, 2022.

Sec. 10. Minnesota Statutes 2020, section 62W.11, is amended to read:

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 ~~and~~, the pharmacy's own usual and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug.

(d) A pharmacy benefit manager must not prohibit a pharmacist or pharmacy from discussing with a health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the pharmacy benefit manager or the pharmacy's acquisition cost for a prescription drug.

~~(d)~~ (e) 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

Sec. 3. Minnesota Statutes 2020, section 62W.11, is amended to read:

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 ~~and~~, the pharmacy's own usual and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug.

(d) A pharmacy benefit manager must not prohibit a pharmacist or pharmacy from discussing with a health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the pharmacy benefit manager or the pharmacy's acquisition cost for a prescription drug.

~~(d)~~ (e) 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

House Language H2128-4

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. 11. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 43. **Biosimilar.** "Biosimilar" or "biosimilar product" means a biological product that the United States Food and Drug Administration has licensed, and determined to be "biosimilar" under United States Code, title 42, section 262(i)(2).

EFFECTIVE DATE. This section is effective January 1, 2022.

Sec. 12. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 44. **Reference biological product.** "Reference biological product" means the single biological product for which the United States Food and Drug Administration has approved an initial biological product license application, against which other biological products are evaluated for licensure as biosimilar products or interchangeable biological products.

EFFECTIVE DATE. This section is effective January 1, 2022.

Senate Language UEH2128-1

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. 4. Minnesota Statutes 2020, section 151.065, subdivision 1, is amended to read:

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

(1) pharmacist licensed by examination, $175;

(2) pharmacist licensed by reciprocity, $275;

(3) pharmacy intern, $50;

(4) pharmacy technician, $50;

(5) pharmacy, $260;

(6) drug wholesaler, legend drugs only, $5,260;

(7) drug wholesaler, legend and nonlegend drugs, $5,260;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,260;

(9) drug wholesaler, medical gases, ~~$5,260 for the first facility and~~ $260 ~~for each additional facility~~;

(10) third-party logistics provider, $260;

(11) drug manufacturer, nonopiate legend drugs only, $5,260;

(12) drug manufacturer, nonopiate legend and nonlegend drugs, $5,260;

(13) drug manufacturer, nonlegend or veterinary legend drugs, $5,260;

(14) drug manufacturer, medical gases, ~~$5,260 for the first facility and~~ $260 ~~for each additional facility~~;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,260;

(16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260;

(17) medical gas dispenser, $260;

(18) controlled substance researcher, $75; and

(19) pharmacy professional corporation, $150.

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

Sec. 5. Minnesota Statutes 2020, section 151.065, subdivision 3, is amended to read:

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

(1) pharmacist, $175;

(2) pharmacy technician, $50;

(3) pharmacy, $260;

(4) drug wholesaler, legend drugs only, $5,260;

(5) drug wholesaler, legend and nonlegend drugs, $5,260;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $5,260;

(7) drug wholesaler, medical gases, ~~$5,260 for the first facility and~~ $260 ~~for each additional facility~~;

(8) third-party logistics provider, $260;

(9) drug manufacturer, nonopiate legend drugs only, $5,260;

(10) drug manufacturer, nonopiate legend and nonlegend drugs, $5,260;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, $5,260;

(12) drug manufacturer, medical gases, ~~$5,260 for the first facility and~~ $260 ~~for each additional facility~~;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, $5,260;

(14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, $55,260;

(15) medical gas dispenser, $260;

(16) controlled substance researcher, $75; and

(17) pharmacy professional corporation, $100.

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

Sec. 6. Minnesota Statutes 2020, section 151.065, subdivision 7, is amended to read:

Subd. 7. **Deposit of fees.** (a) The license fees collected under this section, with the exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state government special revenue fund.

(b) $5,000 of each fee collected under subdivision 1, clauses (6) to ~~(9)~~ (8), ~~and~~ (11) to (13), and (15), and subdivision 3, clauses (4) to ~~(7)~~ (6), ~~and~~ (9) to (11), and (13), and $55,000 of each fee collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response fund established in section 256.043.

(c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14), are reduced under section 256.043, $5,000 of the reduced fee shall be deposited in the opiate epidemic response fund in section 256.043.

Sec. 7. Minnesota Statutes 2020, section 151.066, subdivision 3, is amended to read:

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

(b) For purposes of assessing the annual registration fee under this section and determining the number of opiate units a manufacturer sold, delivered, or distributed within or into the state, the board shall not consider any opiate that is used for medication-assisted therapy for substance use disorders. If there is money deposited into the separate account as described in section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner of management and budget an estimate of the difference in the annual fee revenue collected under this section due to this exception.

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

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

House Language H2128-4

Sec. 13. Minnesota Statutes 2020, 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 62J.842, 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

Senate Language UEH2128-1

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

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

~~(f)~~ (g) For purposes of this subdivision, a unit means the individual dosage form of the particular drug product that is prescribed to the patient. One unit equals one tablet, capsule, patch, syringe, milliliter, or gram.

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

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.

Sec. 14. Minnesota Statutes 2020, 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, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills. In the case of registered pharmacy technicians, pharmacist interns, or controlled substance researchers, the inability to carry out duties allowed under this chapter or the rules of the board with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills;

(15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas dispenser, 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;

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

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person

paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, in writing and with each prescription dispensed, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required;

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

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

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

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

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

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

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

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

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board must 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~~.~~<u>; and</u>

<u>(25) for a manufacturer, a violation of section 62J.842 or section 62J.845.</u>

Sec. 15. **[151.335] DELIVERY THROUGH COMMON CARRIER; COMPLIANCE WITH TEMPERATURE REQUIREMENTS.**

In addition to complying with the requirements of Minnesota Rules, part 6800.3000, a mail order or specialty pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must ensure that the drug is delivered in compliance with temperature requirements established by the manufacturer of the drug. The pharmacy must develop written policies and procedures that are consistent with United States Pharmacopeia, chapters 1079 and 1118, and with nationally recognized standards issued by standard-setting or accreditation organizations recognized by the board through guidance. The policies and procedures must be provided to the board upon request.

Sec. 16. Minnesota Statutes 2020, section 151.555, subdivision 1, is amended to read:

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

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

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

(d) "Donor" means:

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

(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; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed

Sec. 8. Minnesota Statutes 2020, section 151.555, subdivision 1, is amended to read:

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

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

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

(d) "Donor" means:

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

(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; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed

House Language H2128-4

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 supplies 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.

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

Sec. 17. Minnesota Statutes 2020, section 151.555, subdivision 7, is amended to read:

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

Senate Language UEH2128-1

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 supplies 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.

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

Sec. 9. Minnesota Statutes 2020, section 151.555, subdivision 7, is amended to read:

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~~ two years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

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

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

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

Sec. 18. Minnesota Statutes 2020, section 151.555, subdivision 11, is amended to read:

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

(1) intake application form described under subdivision 5;

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

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

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~~ two years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

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

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

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

Sec. 10. Minnesota Statutes 2020, section 151.555, subdivision 11, is amended to read:

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

(1) intake application form described under subdivision 5;

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

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

House Language H2128-4

(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~~ two 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.

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

Sec. 19. Minnesota Statutes 2020, section 151.555, is amended by adding a subdivision to read:

Subd. 14. **Cooperation.** The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

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

Sec. 19. Minnesota Statutes 2020, section 256.043, subdivision 3, is amended to read:

Subd. 3. **Appropriations from fund.** (a) After the appropriations in Laws 2019, chapter 63, article 3, section 1, paragraphs (e), (f), (g), and (h) are made, $249,000 is appropriated to the commissioner of human services for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the administration of the grants awarded under paragraph (e).

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

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

Senate Language UEH2128-1

(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~~ two 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.

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

Sec. 11. Minnesota Statutes 2020, section 151.555, is amended by adding a subdivision to read:

Subd. 14. **Cooperation.** The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

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

Sec. 12. Minnesota Statutes 2020, section 256.043, subdivision 3, is amended to read:

Subd. 3. **Appropriations from fund.** (a) After the appropriations in Laws 2019, chapter 63, article 3, section 1, paragraphs (e)~~;~~ and (f), ~~(g), and (h)~~ are made, $249,000 is appropriated to the commissioner of human services for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the administration of the grants awarded under paragraph (e).

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

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

House Language H2128-4

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

(e) After making the appropriations in paragraphs (a) to (d), the remaining amount in the fund is appropriated to the commissioner to award grants as specified by the Opiate Epidemic Response Advisory Council in accordance with section 256.042, unless otherwise appropriated by the legislature.

(f) Beginning in fiscal year 2022 and each year thereafter, funds for county social service and tribal social service agencies under paragraph (d) and grant funds specified by the Opiate Epidemic Response Advisory Council under paragraph (e) shall be distributed on a calendar year basis.

Senate Language UEH2128-1

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

(e) After making the appropriations in paragraphs (a) to (d), the remaining amount in the fund is appropriated to the commissioner to award grants as specified by the Opiate Epidemic Response Advisory Council in accordance with section 256.042, unless otherwise appropriated by the legislature.

EFFECTIVE DATE. This section is effective July 1, 2024.

Sec. 11. Minnesota Statutes 2020, section 256.043, subdivision 4, is amended to read:

Subd. 4. **Settlement; sunset.** (a) If the state receives a total sum of $250,000,000 either as a result of a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or resulting from a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency, against one or more opioid manufacturers or opioid wholesale drug distributors or consulting firms working for an opioid manufacturer or opioid wholesale drug distributor related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state, or other alleged illegal actions that contributed to the excessive use of opioids, or from the fees collected under sections 151.065, subdivisions 1 and 3, and 151.066, that are deposited into the opiate epidemic response fund established in this section, or from a combination of both, the fees specified in section 151.065, subdivisions 1, clause (16), and 3, clause (14), shall be reduced to $5,260, and the opiate registration fee in section 151.066, subdivision 3, shall be repealed.

House Language H2128-4

Sec. 20. Minnesota Statutes 2020, 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. 21. **STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL PRODUCTS.**

The commissioner of health, within the limits of existing resources, shall analyze the effect of Minnesota Statutes, section 62W.0751, on the net price for different payors of biological products, interchangeable biological products, and biosimilar products. The

Senate Language UEH2128-1

(b) The commissioner of management and budget shall inform the Board of Pharmacy, the governor, and the legislature when the amount specified in paragraph (a) has been reached. The board shall apply the reduced license fee for the next licensure period.

(c) Notwithstanding paragraph (a), the reduction of the license fee in section 151.065, subdivisions 1 and 3, and the repeal of the registration fee in section 151.066 shall not occur before July 1, 2024.

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

House Language H2128-4

commissioner of health shall report findings to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, and insurance, by December 15, 2023.

Sec. 22. **STUDY OF TEMPERATURE MONITORING.**

The Board of Pharmacy shall conduct a study to determine the appropriateness and feasibility of requiring mail order and specialty pharmacies to enclose in each medication's packaging a method by which the patient can easily detect improper storage or temperature variations that may have occurred during the delivery of a medication. The board shall report the results of the study by January 15, 2022, to the chairs and ranking minority members of the legislative committees with jurisdiction over health finance and policy.

Senate Language UEH2128-1

Sec. 13. **OPIATE REGISTRATION FEE REDUCTION.**

(a) For purposes of assessing the opiate registration fee under Minnesota Statutes, section 151.066, subdivision 3, that is required to be paid on June 1, 2021, in accordance with Minnesota Statutes, section 151.252, subdivision 1, paragraph (b), the Board of Pharmacy shall not consider any injectable opiate product distributed to a hospital or hospital pharmacy. If there is money deposited into the separate account as described in Minnesota Statutes, section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner of management and budget an estimate of the difference in the annual opiate registration fee revenue collected under Minnesota Statutes, section 151.066, due to the exception described in this paragraph.

(b) Any estimated loss to the opiate registration fee revenue attributable to paragraph (a) must be included in any transfer that occurs under Minnesota Statutes, section 16A.151, subdivision 2, paragraph (g), in calendar year 2021.

(c) If a manufacturer has already paid the opiate registration fee due on June 1, 2021, the Board of Pharmacy shall return the amount of the fee to the manufacturer if the manufacturer would not have been required to pay the fee after the calculations described in paragraph (a) were made.

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