

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

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

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

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

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

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

468.5 (f) Any money received by the state resulting from a settlement agreement or an assurance
 468.6 of discontinuance entered into by the attorney general of the state, or a court order in litigation
 468.7 brought by the attorney general of the state, on behalf of the state or a state agency, ~~against~~
 468.8 ~~one or more opioid manufacturers or opioid wholesale drug distributors~~ related to alleged
 468.9 violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this
 468.10 state or other alleged illegal actions that contributed to the excessive use of opioids, must
 468.11 be deposited in a separate account in the state treasury and the commissioner shall notify
 468.12 the chairs and ranking minority members of the Finance Committee in the senate and the
 468.13 Ways and Means Committee in the house of representatives that an account has been created.
 468.14 This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney
 468.15 General's Office, to contract attorneys hired by the state or Attorney General's Office, or to
 468.16 other state agency attorneys. If the licensing fees under section 151.065, subdivision 1,
 468.17 clause (16), and subdivision 3, clause (14), are reduced and the registration fee under section
 468.18 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then
 468.19 the commissioner shall transfer from the separate account created in this paragraph to the
 468.20 opiate epidemic response fund under section 256.043 an amount that ensures that \$20,940,000
 468.21 each fiscal year is available for distribution in accordance with section 256.043, subdivisions
 468.22 2 and 3.

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

131.7 Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific
 131.8 injured persons or entities, this section does not prohibit distribution of money to the specific
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 131.13 money must be paid into the general fund.

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 131.15 may be deposited in that fund.

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 131.17 entity other than the state in litigation or potential litigation in which the state is a defendant
 131.18 or potential defendant.

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 131.21 Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue
 131.22 account and are appropriated to the commissioner of the agency for the purpose as directed
 131.23 by the federal court.

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

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

132.13 each fiscal year is available for distribution in accordance with section 256.043, ~~subdivisions~~
132.14 ~~2 and subdivision~~ 3.

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

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

ARTICLE 5

PRESCRIPTION DRUGS

ARTICLE 4

PRESCRIPTION DRUGS AND OPIATES

285.15
285.16
285.17 Section 1. **[62J.841] DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

286.21 (2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds
286.22 \$30 for:

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

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

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

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

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

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

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

- 287.10 notify the manufacturer of a generic or off-patent drug, the attorney general, and the Board
287.11 of Pharmacy of any price increase that is in violation of section 62J.842.
- 287.12 **Subd. 2. Submission of drug cost statement and other information by manufacturer;**
287.13 **investigation by attorney general.** (a) Within 45 days of receiving a notice under subdivision
287.14 1, the manufacturer of the generic or off-patent drug shall submit a drug cost statement to
287.15 the attorney general. The statement must:
- 287.16 (1) itemize the cost components related to production of the drug, including any fees or
287.17 costs imposed by the state such as opioid registration fees;
- 287.18 (2) identify the circumstances and timing of any increase in materials or manufacturing
287.19 costs that caused any increase during the preceding calendar year, or preceding three calendar
287.20 years as applicable, in the price of the drug; and
- 287.21 (3) provide any other information that the manufacturer believes to be relevant to a
287.22 determination of whether a violation of section 62J.842 has occurred.
- 287.23 (b) The attorney general may investigate whether a violation of section 62J.842 has
287.24 occurred, is occurring, or is about to occur, in accordance with section 8.31, subdivision 2.
- 287.25 **Subd. 3. Petition to court.** (a) On petition of the attorney general, a court may issue an
287.26 order:
- 287.27 (1) compelling the manufacturer of a generic or off-patent drug to:
- 287.28 (i) provide the drug cost statement required under subdivision 2, paragraph (a); and
287.29 (ii) answer interrogatories, produce records or documents, or be examined under oath,
287.30 as required by the attorney general under subdivision 2, paragraph (b);
- 288.1 (2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including issuing
288.2 an order requiring that drug prices be restored to levels that comply with section 62J.842;
- 288.3 (3) requiring the manufacturer to provide an accounting to the attorney general of all
288.4 revenues resulting from a violation of section 62J.842;
- 288.5 (4) requiring the manufacturer to repay to all consumers, including any third-party payers,
288.6 any money acquired as a result of a price increase that violates section 62J.842;
- 288.7 (5) notwithstanding section 16A.151, requiring that all revenues generated from a
288.8 violation of section 62J.842 be remitted to the state and deposited into a special fund, to be
288.9 used for initiatives to reduce the cost to consumers of acquiring prescription drugs, if a
288.10 manufacturer is unable to determine the individual transactions necessary to provide the
288.11 repayments described in clause (4);
- 288.12 (6) imposing a civil penalty of up to \$10,000 per day for each violation of section 62J.842;

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

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

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

288.20 Subd. 4. **Private right of action.** Any action brought pursuant to section 8.31, subdivision
 288.21 3a, by a person injured by a violation of this section is for the benefit of the public.

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

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

288.27 Subd. 2. **Notice to board and attorney general.** Any manufacturer that intends to
 288.28 withdraw a generic or off-patent drug from sale or distribution within the state shall provide
 288.29 a written notice of withdrawal to the Board of Pharmacy and the attorney general, at least
 288.30 180 days prior to the withdrawal.

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

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

289.5 If any provision of sections 62J.841 to 62J.845 or the application thereof to any person
 289.6 or circumstance is held invalid for any reason in a court of competent jurisdiction, the
 289.7 invalidity does not affect other provisions or any other application of sections 62J.841 to
 289.8 62J.845 that can be given effect without the invalid provision or application.

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

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

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

- 133.4 does not include biological products that are intended for transfusions, including blood or
133.5 blood products; or allogeneic-, cellular-, or tissue-based products.
- 133.6 (c) "FD&C Act" means the federal Food, Drug, and Cosmetic Act, United States Code,
133.7 title 21, section 301, et seq.
- 133.8 (d) "Importation guidance" means the draft guidance released by the federal Food and
133.9 Drug Administration (FDA) titled "Importation of Certain FDA-Approved Human
133.10 Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal
133.11 Food, Drug, and Cosmetic Act; Draft Guidance for the Industry," which if finalized allows
133.12 for the importation of MMA products.
- 133.13 (e) "Manufacturer" means the entity that is the holder of the New Drug Application or
133.14 Biologics License Application for the drug product.
- 133.15 (f) "Multimarket-approved product" or "MMA product" means a FDA-approved drug
133.16 product that:
- 133.17 (1) was manufactured outside the United States and authorized for marketing by another
133.18 country's regulatory authority;
- 133.19 (2) is subject to a new drug application or biologics license application;
- 133.20 (3) is imported into the United States and is authorized by the manufacturer to be
133.21 marketed in the United States; and
- 133.22 (4) continues to meet the quality standards for marketing in its originally intended foreign
133.23 market.
- 133.24 Subd. 2. **Application.** This section applies to any MMA product in which the
133.25 manufacturer of the product has obtained a new National Drug Code (NDC) for the MMA
133.26 product and has imported the MMA product in compliance with the FD&C Act and any
133.27 importation guidance finalized by the FDA.
- 133.28 Subd. 3. **Incentives.** (a) In order to facilitate importation of drugs pursuant to importation
133.29 guidance finalized by the FDA, any MMA product offered for sale in Minnesota at a cost
133.30 that is at least 23 percent lower than the wholesale acquisition cost for the FDA-approved
133.31 product manufactured in the United States shall be:
- 134.1 (1) included on the uniform preferred drug list and covered under the medical assistance
134.2 and MinnesotaCare programs; and
- 134.3 (2) a covered drug under the state employee group insurance program pursuant to chapter
134.4 43A.
- 134.5 (b) A health plan company must provide coverage for each MMA product that meets
134.6 the requirements in paragraph (a) if the manufacturer's FDA-approved drug product
134.7 manufactured in the United States is covered by the health plan company and the health

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

290.20 (e) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, and
290.21 includes an entity that performs pharmacy benefits management for the health plan company.

290.22 (f) "Pharmacy benefits management" means the administration or management of
290.23 prescription drug benefits provided by the health plan company for the benefit of its enrollees
290.24 and may include but is not limited to procurement of prescription drugs, clinical formulary
290.25 development and management services, claims processing, and rebate contracting and
290.26 administration.

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

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

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

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

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

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

291.8 (2) reduce co-payments or coinsurance; or

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

291.10 (b) A health plan company may remove a brand name drug from its formulary or place
291.11 a brand name drug in a benefit category that increases an enrollee's cost only upon the

291.12 addition to the formulary of a generic or multisource brand name drug rated as therapeutically
291.13 equivalent according to the Food and Drug Administration (FDA) Orange Book or a biologic
291.14 drug rated as interchangeable according to the FDA Purple Book at a lower cost to the
291.15 enrollee and upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

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

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

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

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

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

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

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

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

292.5 (e) "Reference biological product" has the meaning given in section 151.01, subdivision
292.6 44.

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

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

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

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

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

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

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

292.30 **62W.11 GAG CLAUSE PROHIBITION.**

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

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

293.11 (c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or
 293.12 pharmacy from discussing information regarding the total cost for pharmacy services for a
 293.13 prescription drug, including the patient's co-payment amount ~~and~~ the pharmacy's own usual
 293.14 and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the
 293.15 prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit
 293.16 manager or health carrier for the prescription drug.

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

293.21 ~~(c)~~ (e) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or
 293.22 pharmacy from discussing the availability of any therapeutically equivalent alternative
 293.23 prescription drugs or alternative methods for purchasing the prescription drug, including

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

134.14 **62W.11 GAG CLAUSE PROHIBITION.**

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

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

134.27 (c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or
 134.28 pharmacy from discussing information regarding the total cost for pharmacy services for a
 134.29 prescription drug, including the patient's co-payment amount ~~and~~ the pharmacy's own usual
 134.30 and customary price ~~of~~ for the prescription drug, the pharmacy's acquisition cost for the
 134.31 prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit
 134.32 manager or health carrier for the prescription drug.

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

135.5 ~~(c)~~ (e) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or
 135.6 pharmacy from discussing the availability of any therapeutically equivalent alternative
 135.7 prescription drugs or alternative methods for purchasing the prescription drug, including

293.24 but not limited to paying out-of-pocket the pharmacy's usual and customary price when that
 293.25 amount is less expensive to the enrollee than the amount the enrollee is required to pay for
 293.26 the prescription drug under the enrollee's health plan.

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

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

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

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

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

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

135.8 but not limited to paying out-of-pocket the pharmacy's usual and customary price when that
 135.9 amount is less expensive to the enrollee than the amount the enrollee is required to pay for
 135.10 the prescription drug under the enrollee's health plan.

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

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

135.14 (1) pharmacist licensed by examination, \$175;

135.15 (2) pharmacist licensed by reciprocity, \$275;

135.16 (3) pharmacy intern, \$50;

135.17 (4) pharmacy technician, \$50;

135.18 (5) pharmacy, \$260;

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

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

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

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

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

- 135.25 (11) drug manufacturer, nonopiate legend drugs only, \$5,260;
- 135.26 (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;
- 135.27 (13) drug manufacturer, nonlegend or veterinary legend drugs, \$5,260;
- 135.28 (14) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each
135.29 additional facility;
- 135.30 (15) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;
- 136.1 (16) drug manufacturer of opiate-containing controlled substances listed in section
136.2 152.02, subdivisions 3 to 5, \$55,260;
- 136.3 (17) medical gas dispenser, \$260;
- 136.4 (18) controlled substance researcher, \$75; and
- 136.5 (19) pharmacy professional corporation, \$150.
- 136.6 **EFFECTIVE DATE.** This section is effective the day following final enactment.
- 136.7 Sec. 5. Minnesota Statutes 2020, section 151.065, subdivision 3, is amended to read:
- 136.8 Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as
136.9 follows:
- 136.10 (1) pharmacist, \$175;
- 136.11 (2) pharmacy technician, \$50;
- 136.12 (3) pharmacy, \$260;
- 136.13 (4) drug wholesaler, legend drugs only, \$5,260;
- 136.14 (5) drug wholesaler, legend and nonlegend drugs, \$5,260;
- 136.15 (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$5,260;
- 136.16 (7) drug wholesaler, medical gases, \$5,260 for the first facility and \$260 for each
136.17 additional facility;
- 136.18 (8) third-party logistics provider, \$260;
- 136.19 (9) drug manufacturer, nonopiate legend drugs only, \$5,260;
- 136.20 (10) drug manufacturer, nonopiate legend and nonlegend drugs, \$5,260;
- 136.21 (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$5,260;
- 136.22 (12) drug manufacturer, medical gases, \$5,260 for the first facility and \$260 for each
136.23 additional facility;
- 136.24 (13) drug manufacturer, also licensed as a pharmacy in Minnesota, \$5,260;

- 136.25 (14) drug manufacturer of opiate-containing controlled substances listed in section
 136.26 152.02, subdivisions 3 to 5, \$55,260;
- 136.27 (15) medical gas dispenser, \$260;
- 136.28 (16) controlled substance researcher, \$75; and
- 137.1 (17) pharmacy professional corporation, \$100.
- 137.2 **EFFECTIVE DATE.** This section is effective the day following final enactment.
- 137.3 Sec. 6. Minnesota Statutes 2020, section 151.065, subdivision 7, is amended to read:
- 137.4 Subd. 7. **Deposit of fees.** (a) The license fees collected under this section, with the
 137.5 exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state
 137.6 government special revenue fund.
- 137.7 (b) \$5,000 of each fee collected under subdivision 1, clauses (6) to ~~(9)~~ (8), ~~and~~ (11) to
 137.8 (13), and (15), and subdivision 3, clauses (4) to ~~(7)~~ (6), ~~and~~ (9) to (11), and (13), and \$55,000
 137.9 of each fee collected under subdivision 1, clause (16), and subdivision 3, clause (14), shall
 137.10 be deposited in the opiate epidemic response fund established in section 256.043.
- 137.11 (c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14),
 137.12 are reduced under section 256.043, \$5,000 of the reduced fee shall be deposited in the opiate
 137.13 epidemic response fund in section 256.043.
- 137.14 Sec. 7. Minnesota Statutes 2020, section 151.066, subdivision 3, is amended to read:
- 137.15 Subd. 3. **Determination of an opiate product registration fee.** (a) The board shall
 137.16 annually assess an opiate product registration fee on any manufacturer of an opiate that
 137.17 annually sells, delivers, or distributes an opiate within or into the state 2,000,000 or more
 137.18 units as reported to the board under subdivision 2.
- 137.19 (b) For purposes of assessing the annual registration fee under this section and
 137.20 determining the number of opiate units a manufacturer sold, delivered, or distributed within
 137.21 or into the state, the board shall not consider any opiate that is used for medication-assisted
 137.22 therapy for substance use disorders. If there is money deposited into the separate account
 137.23 as described in section 16A.151, subdivision 2, paragraph (g), the board shall submit to the
 137.24 commissioner of management and budget an estimate of the difference in the annual fee
 137.25 revenue collected under this section due to this exception.
- 137.26 (c) The annual registration fee for each manufacturer meeting the requirement under
 137.27 paragraph (a) is \$250,000.
- 137.28 ~~(e)~~ (d) In conjunction with the data reported under this section, and notwithstanding
 137.29 section 152.126, subdivision 6, the board may use the data reported under section 152.126,
 137.30 subdivision 4, to determine which manufacturers meet the requirement under paragraph (a)
 137.31 and are required to pay the registration fees under this subdivision.

294.9 Sec. 13. Minnesota Statutes 2020, section 151.071, subdivision 1, is amended to read:

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

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

294.14 (2) refuse to renew a license or registration;

294.15 (3) revoke the license or registration;

294.16 (4) suspend the license or registration;

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

294.24 (6) impose a civil penalty not exceeding \$10,000 for each separate violation, except that
294.25 a civil penalty not exceeding \$25,000 may be imposed for each separate violation of section
294.26 62J.842, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant
294.27 of any economic advantage gained by reason of the violation, to discourage similar violations
294.28 by the licensee or registrant or any other licensee or registrant, or to reimburse the board

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

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

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

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

294.29 for the cost of the investigation and proceeding, including but not limited to, fees paid for
294.30 services provided by the Office of Administrative Hearings, legal and investigative services
294.31 provided by the Office of the Attorney General, court reporters, witnesses, reproduction of
295.1 records, board members' per diem compensation, board staff time, and travel costs and
295.2 expenses incurred by board staff and board members; and

295.3 (7) reprimand the licensee or registrant.

295.4 Sec. 14. Minnesota Statutes 2020, section 151.071, subdivision 2, is amended to read:

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

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

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

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

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

296.1 (5) for a controlled substance researcher, conviction of a felony reasonably related to
296.2 controlled substances or to the practice of the researcher's profession. The board may delay

296.3 the issuance of a registration if the applicant has been charged with a felony until the matter
296.4 has been adjudicated;

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

296.7 (i) revocation, suspension, restriction, limitation, or other disciplinary action against a
296.8 license or registration in another state or jurisdiction, failure to report to the board that
296.9 charges or allegations regarding the person's license or registration have been brought in
296.10 another state or jurisdiction, or having been refused a license or registration by any other
296.11 state or jurisdiction. The board may delay the issuance of a new license or registration if an
296.12 investigation or disciplinary action is pending in another state or jurisdiction until the
296.13 investigation or action has been dismissed or otherwise resolved; and

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

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

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

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

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

297.5 (11) for an individual licensed or registered by the board, adjudication as mentally ill
297.6 or developmentally disabled, or as a chemically dependent person, a person dangerous to
297.7 the public, a sexually dangerous person, or a person who has a sexual psychopathic
297.8 personality, by a court of competent jurisdiction, within or without this state. Such

- 297.9 adjudication shall automatically suspend a license for the duration thereof unless the board
297.10 orders otherwise;
- 297.11 (12) for a pharmacist or pharmacy intern, engaging in unprofessional conduct as specified
297.12 in the board's rules. In the case of a pharmacy technician, engaging in conduct specified in
297.13 board rules that would be unprofessional if it were engaged in by a pharmacist or pharmacist
297.14 intern or performing duties specifically reserved for pharmacists under this chapter or the
297.15 rules of the board;
- 297.16 (13) for a pharmacy, operation of the pharmacy without a pharmacist present and on
297.17 duty except as allowed by a variance approved by the board;
- 297.18 (14) for a pharmacist, the inability to practice pharmacy with reasonable skill and safety
297.19 to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type
297.20 of material or as a result of any mental or physical condition, including deterioration through
297.21 the aging process or loss of motor skills. In the case of registered pharmacy technicians,
297.22 pharmacist interns, or controlled substance researchers, the inability to carry out duties
297.23 allowed under this chapter or the rules of the board with reasonable skill and safety to
297.24 patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type
297.25 of material or as a result of any mental or physical condition, including deterioration through
297.26 the aging process or loss of motor skills;
- 297.27 (15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas
297.28 dispenser, or controlled substance researcher, revealing a privileged communication from
297.29 or relating to a patient except when otherwise required or permitted by law;
- 297.30 (16) for a pharmacist or pharmacy, improper management of patient records, including
297.31 failure to maintain adequate patient records, to comply with a patient's request made pursuant
297.32 to sections 144.291 to 144.298, or to furnish a patient record or report required by law;
- 297.33 (17) fee splitting, including without limitation:
- 298.1 (i) paying, offering to pay, receiving, or agreeing to receive, a commission, rebate,
298.2 kickback, or other form of remuneration, directly or indirectly, for the referral of patients;
- 298.3 (ii) referring a patient to any health care provider as defined in sections 144.291 to
298.4 144.298 in which the licensee or registrant has a financial or economic interest as defined
298.5 in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the
298.6 licensee's or registrant's financial or economic interest in accordance with section 144.6521;
298.7 and
- 298.8 (iii) any arrangement through which a pharmacy, in which the prescribing practitioner
298.9 does not have a significant ownership interest, fills a prescription drug order and the
298.10 prescribing practitioner is involved in any manner, directly or indirectly, in setting the price
298.11 for the filled prescription that is charged to the patient, the patient's insurer or pharmacy
298.12 benefit manager, or other person paying for the prescription or, in the case of veterinary
298.13 patients, the price for the filled prescription that is charged to the client or other person

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

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

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

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

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

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

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

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

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

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

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

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

299.16 (25) for a manufacturer, a violation of section 62J.842 or section 62J.845.

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

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

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

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

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

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

300.2 (d) "Donor" means:

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

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

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

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

300.9 (5) a drug wholesaler licensed under section 151.47;

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

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

300.13 (e) "Drug" means any prescription drug that has been approved for medical use in the
 300.14 United States, is listed in the United States Pharmacopoeia or National Formulary, and
 300.15 meets the criteria established under this section for donation; or any over-the-counter
 300.16 medication that meets the criteria established under this section for donation. This definition
 300.17 includes cancer drugs and antirejection drugs, but does not include controlled substances,
 300.18 as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed

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

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

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

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

138.25 (d) "Donor" means:

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

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

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

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

139.1 (5) a drug wholesaler licensed under section 151.47;

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

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

139.5 (e) "Drug" means any prescription drug that has been approved for medical use in the
 139.6 United States, is listed in the United States Pharmacopoeia or National Formulary, and
 139.7 meets the criteria established under this section for donation; or any over-the-counter
 139.8 medication that meets the criteria established under this section for donation. This definition
 139.9 includes cancer drugs and antirejection drugs, but does not include controlled substances,
 139.10 as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed

300.19 to a patient registered with the drug's manufacturer in accordance with federal Food and
300.20 Drug Administration requirements.

300.21 (f) "Health care facility" means:

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

300.24 (2) a hospital licensed under section 144.50;

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

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

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

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

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

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

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

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

301.12 Subd. 7. **Standards and procedures for inspecting and storing donated prescription**
301.13 **drugs and supplies.** (a) A pharmacist or authorized practitioner who is employed by or
301.14 under contract with the central repository or a local repository shall inspect all donated
301.15 prescription drugs and supplies before the drug or supply is dispensed to determine, to the
301.16 extent reasonably possible in the professional judgment of the pharmacist or practitioner,
301.17 that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe
301.18 and suitable for dispensing, has not been subject to a recall, and meets the requirements for
301.19 donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an
301.20 inspection record stating that the requirements for donation have been met. If a local
301.21 repository receives drugs and supplies from the central repository, the local repository does
301.22 not need to reinspect the drugs and supplies.

301.23 (b) The central repository and local repositories shall store donated drugs and supplies
301.24 in a secure storage area under environmental conditions appropriate for the drug or supply

139.11 to a patient registered with the drug's manufacturer in accordance with federal Food and
139.12 Drug Administration requirements.

139.13 (f) "Health care facility" means:

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

139.16 (2) a hospital licensed under section 144.50;

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

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

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

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

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

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

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

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

140.2 Subd. 7. **Standards and procedures for inspecting and storing donated prescription**
140.3 **drugs and supplies.** (a) A pharmacist or authorized practitioner who is employed by or
140.4 under contract with the central repository or a local repository shall inspect all donated
140.5 prescription drugs and supplies before the drug or supply is dispensed to determine, to the
140.6 extent reasonably possible in the professional judgment of the pharmacist or practitioner,
140.7 that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe
140.8 and suitable for dispensing, has not been subject to a recall, and meets the requirements for
140.9 donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an
140.10 inspection record stating that the requirements for donation have been met. If a local
140.11 repository receives drugs and supplies from the central repository, the local repository does
140.12 not need to reinspect the drugs and supplies.

140.13 (b) The central repository and local repositories shall store donated drugs and supplies
140.14 in a secure storage area under environmental conditions appropriate for the drug or supply

301.25 being stored. Donated drugs and supplies may not be stored with nondonated inventory. If
301.26 ~~donated drugs or supplies are not inspected immediately upon receipt, a repository must~~
301.27 ~~quarantine the donated drugs or supplies separately from all dispensing stock until the~~
301.28 ~~donated drugs or supplies have been inspected and (1) approved for dispensing under the~~
301.29 ~~program; (2) disposed of pursuant to paragraph (e); or (3) returned to the donor pursuant to~~
301.30 ~~paragraph (d).~~

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

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

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

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

302.17 (1) the date of destruction;

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

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

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

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

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

302.25 (1) intake application form described under subdivision 5;

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

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

140.15 being stored. Donated drugs and supplies may not be stored with nondonated inventory. If
140.16 ~~donated drugs or supplies are not inspected immediately upon receipt, a repository must~~
140.17 ~~quarantine the donated drugs or supplies separately from all dispensing stock until the~~
140.18 ~~donated drugs or supplies have been inspected and (1) approved for dispensing under the~~
140.19 ~~program; (2) disposed of pursuant to paragraph (e); or (3) returned to the donor pursuant to~~
140.20 ~~paragraph (d).~~

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

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

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

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

141.7 (1) the date of destruction;

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

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

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

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

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

141.15 (1) intake application form described under subdivision 5;

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

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

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

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

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

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

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

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

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

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

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

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

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

490.13 Subd. 3. Appropriations from fund. (a) After the appropriations in Laws 2019, chapter
490.14 63, article 3, section 1, paragraphs (e), (f), (g), and (h) are made, \$249,000 is appropriated
490.15 to the commissioner of human services for the provision of administrative services to the
490.16 Opiate Epidemic Response Advisory Council and for the administration of the grants awarded
490.17 under paragraph (e).

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

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

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

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

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

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

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

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

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

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

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

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

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

142.12 Subd. 3. Appropriations from fund. (a) After the appropriations in Laws 2019, chapter
142.13 63, article 3, section 1, paragraphs (e); and (f), ~~(g), and (h)~~ are made, \$249,000 is appropriated
142.14 to the commissioner of human services for the provision of administrative services to the
142.15 Opiate Epidemic Response Advisory Council and for the administration of the grants awarded
142.16 under paragraph (e).

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

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

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

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

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

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

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

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

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

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

303.21 Sec. 20. Minnesota Statutes 2020, section 256B.69, subdivision 6, is amended to read:

303.22 Subd. 6. **Service delivery.** (a) Each demonstration provider shall be responsible for the

303.23 health care coordination for eligible individuals. Demonstration providers:

303.24 (1) shall authorize and arrange for the provision of all needed health services including

303.25 but not limited to the full range of services listed in sections 256B.02, subdivision 8, and

303.26 256B.0625 in order to ensure appropriate health care is delivered to enrollees.

303.27 Notwithstanding section 256B.0621, demonstration providers that provide nursing home

303.28 and community-based services under this section shall provide relocation service coordination

303.29 to enrolled persons age 65 and over;

303.30 (2) shall accept the prospective, per capita payment from the commissioner in return for

303.31 the provision of comprehensive and coordinated health care services for eligible individuals

303.32 enrolled in the program;

304.1 (3) may contract with other health care and social service practitioners to provide services

304.2 to enrollees; and

304.3 (4) shall institute recipient grievance procedures according to the method established

304.4 by the project, utilizing applicable requirements of chapter 62D. Disputes not resolved

304.5 through this process shall be appealable to the commissioner as provided in subdivision 11.

304.6 (b) Demonstration providers must comply with the standards for claims settlement under

304.7 section 72A.201, subdivisions 4, 5, 7, and 8, when contracting with other health care and

304.8 social service practitioners to provide services to enrollees. A demonstration provider must

304.9 pay a clean claim, as defined in Code of Federal Regulations, title 42, section 447.45(b),

304.10 within 30 business days of the date of acceptance of the claim.

304.11 (c) Managed care plans and county-based purchasing plans must comply with section

304.12 62Q.83.

304.13 Sec. 21. **STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL**

304.14 **PRODUCTS.**

304.15 The commissioner of health, within the limits of existing resources, shall analyze the

304.16 effect of Minnesota Statutes, section 62W.0751, on the net price for different payors of

304.17 biological products, interchangeable biological products, and biosimilar products. The

14.19 (b) The commissioner of management and budget shall inform the Board of Pharmacy,

14.20 the governor, and the legislature when the amount specified in paragraph (a) has been

14.21 reached. The board shall apply the reduced license fee for the next licensure period.

14.22 (c) Notwithstanding paragraph (a), the reduction of the license fee in section 151.065,

14.23 subdivisions 1 and 3, and the repeal of the registration fee in section 151.066 shall not occur

14.24 before July 1, 2024.

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

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

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

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

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

143.9 (a) For purposes of assessing the opiate registration fee under Minnesota Statutes, section
 143.10 151.066, subdivision 3, that is required to be paid on June 1, 2021, in accordance with
 143.11 Minnesota Statutes, section 151.252, subdivision 1, paragraph (b), the Board of Pharmacy
 143.12 shall not consider any injectable opiate product distributed to a hospital or hospital pharmacy.
 143.13 If there is money deposited into the separate account as described in Minnesota Statutes,
 143.14 section 16A.151, subdivision 2, paragraph (g), the board shall submit to the commissioner
 143.15 of management and budget an estimate of the difference in the annual opiate registration
 143.16 fee revenue collected under Minnesota Statutes, section 151.066, due to the exception
 143.17 described in this paragraph.

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

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

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