ARTICLE 6

PRESCRIPTION DRUGS

Section 1. Minnesota Statutes 2020, section 62A.02, subdivision 1, is amended to read:

Subdivision 1. **Filing.** For purposes of this section, "health plan" means a health plan as defined in section 62A.011 or a policy of accident and sickness insurance as defined in section 62A.01. No health plan shall be issued or delivered to any person in this state, nor shall any application, rider, or endorsement be used in connection with the health plan, until a copy of its form and of the classification of risks and the premium rates pertaining to the form have been filed with the commissioner. The filing must include the health plan's prescription drug formulary. Proposed revisions to the health plan's prescription drug formulary must be filed with the commissioner no later than August 1 of the application year. The filing for nongroup health plan forms shall include a statement of actuarial reasons and data to support the rate. For health benefit plans as defined in section 62L.02, and for health plans to be issued to individuals, the health carrier shall file with the commissioner the information required in section 62L.08, subdivision 8. For group health plans for which approval is sought for sales only outside of the small employer market as defined in section 62L.02, this section applies only to policies or contracts of accident and sickness insurance. All forms intended for issuance in the individual or small employer market must be accompanied by a statement as to the expected loss ratio for the form. Premium rates and forms relating to specific insureds or proposed insureds, whether individuals or groups, need not be filed, unless requested by the commissioner.

Sec. 2. Minnesota Statutes 2021 Supplement, section 62J.497, subdivision 1, is amended to read:

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

(b) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(c) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription.

(d) "Electronic media" has the meaning given under Code of Federal Regulations, title 45, part 160.103.

(e) "E-prescribing" means the transmission using electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or group purchaser, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser and two-way transmissions related to eligibility, formulary, and medication history information.

(f) "Electronic prescription drug program" means a program that provides for e-prescribing.

(g) "Group purchaser" has the meaning given in section 62J.03, subdivision 6.

(h) "HL7 messages" means a standard approved by the standards development organization known as Health Level Seven.

(i) "National Provider Identifier" or "NPI" means the identifier described under Code of Federal Regulations, title 45, part 162.406.

(j) "NCPDP" means the National Council for Prescription Drug Programs, Inc.

(k) "NCPDP Formulary and Benefits Standard" means the most recent version of the National Council for Prescription Drug Programs Formulary and Benefits Standard or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance.

(l) "NCPDP Real-Time Prescription Benefit Standard" means the most recent National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(2) of the Social Security Act and regulations adopted under it.

~~(l)~~ (m) "NCPDP SCRIPT Standard" means the most recent version of the National Council for Prescription Drug Programs SCRIPT Standard, or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act, and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance.

~~(m)~~ (n) "Pharmacy" has the meaning given in section 151.01, subdivision 2.

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

~~(n)~~ (p) "Prescriber" means a licensed health care practitioner, other than a veterinarian, as defined in section 151.01, subdivision 23.

~~(o)~~ (q) "Prescription-related information" means information regarding eligibility for drug benefits, medication history, or related health or drug information.

~~(p)~~ (r) "Provider" or "health care provider" has the meaning given in section 62J.03, subdivision 8.

(s) "Real-time prescription benefit tool" means a tool that is capable of being integrated into a prescriber's e-prescribing system and that provides a prescriber with up-to-date and

patient-specific formulary and benefit information at the time the prescriber submits a prescription.

Sec. 3. Minnesota Statutes 2021 Supplement, section 62J.497, subdivision 3, is amended to read:

Subd. 3. **Standards for electronic prescribing.** (a) Prescribers and dispensers must use the NCPDP SCRIPT Standard for the communication of a prescription or prescription-related information.

(b) Providers, group purchasers, prescribers, and dispensers must use the NCPDP SCRIPT Standard for communicating and transmitting medication history information.

(c) Providers, group purchasers, prescribers, and dispensers must use the NCPDP Formulary and Benefits Standard for communicating and transmitting formulary and benefit information.

(d) Providers, group purchasers, prescribers, and dispensers must use the national provider identifier to identify a health care provider in e-prescribing or prescription-related transactions when a health care provider's identifier is required.

(e) Providers, group purchasers, prescribers, and dispensers must communicate eligibility information and conduct health care eligibility benefit inquiry and response transactions according to the requirements of section 62J.536.

(f) Group purchasers and pharmacy benefit managers must use a real-time prescription benefit tool that complies with the NCPDP Real-Time Prescription Benefit Standard and that, at a minimum, notifies a prescriber:

(1) if a prescribed drug is covered by the patient's group purchaser or pharmacy benefit manager;

(2) if a prescribed drug is included on the formulary or preferred drug list of the patient's group purchaser or pharmacy benefit manager;

(3) of any patient cost-sharing for the prescribed drug;

(4) if prior authorization is required for the prescribed drug; and

(5) of a list of any available alternative drugs that are in the same class as the drug originally prescribed and for which prior authorization is not required.

EFFECTIVE DATE. This section is effective January 1, 2023.

Sec. 4. Minnesota Statutes 2020, section 62J.84, as amended by Laws 2021, chapter 30, article 3, sections 5 to 9, is amended to read:

62J.84 PRESCRIPTION DRUG PRICE TRANSPARENCY.

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

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

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

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

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

(2) a biologics license application approved under United States Code, title ~~45~~ 42, section 262(a)(c).

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

(e) "Course of treatment" means the total dosage of a single prescription for a prescription drug recommended by the Food and Drug Administration (FDA)-approved prescribing label. If the FDA-approved prescribing label includes more than one recommended dosage for a single course of treatment, the course of treatment is the maximum recommended dosage on the FDA-approved prescribing label.

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

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

(2) an authorized generic as defined under Code of Federal Regulations, title ~~45~~ 42, section 447.502; or

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

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

(h) "National Drug Code" means the three-segment code maintained by the FDA that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been

added to the front of each segment containing less than the specified number of digits so that each segment contains the specified number of digits.

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

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

~~(i)~~ (k) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

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

(m) "Rebate" means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point of sale, as part of retrospective financial reconciliations including reconciliations that also reflect other contractual arrangements, or by any other method. Rebate does not mean a bona fide service fee, as the term is defined in Code of Federal Regulations, title 42, section 447.502.

(n) "30-day supply" means the total daily dosage units of a prescription drug recommended by the prescribing label approved by the FDA for 30 days. If the FDA-approved prescribing label includes more than one recommended daily dosage, the 30-day supply is based on the maximum recommended daily dosage on the FDA-approved prescribing label.

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

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

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

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

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

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

(4) the introductory price of the prescription drug when it was introduced for sale in the United States and the price of the drug on the last day of each of the five calendar years preceding the price increase when it was approved for marketing by the Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

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

(i) to manufacture the prescription drug;

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

(iii) to distribute the prescription drug;

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

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

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

~~(7)~~ (9) the manufacturer's net profit attributable to the prescription drug during the previous 12-month period;

~~(8)~~ (10) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the previous 12-month period, if applicable;

~~(9)~~ (11) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

~~(10)~~ (12) the patent expiration date of the prescription drug if it is under patent;

~~(11)~~ (13) the name and location of the company that manufactured the drug; ~~and~~

~~(12)~~ (14) if a brand name prescription drug, the ten highest prices paid for the prescription drug during the previous calendar year in ~~any country other than~~ the ten countries, excluding the United States~~.~~, that charged the highest single price for the prescription drug; and

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

(i) price at acquisition;

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

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

(iv) date of acquisition; and

(v) acquisition price.

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

Subd. 4. **New prescription drug price reporting.** (a) Beginning January 1, 2022, no later than 60 days after a manufacturer introduces a new prescription drug for sale in the United States that is a new brand name drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-day supply or for a course of treatment lasting less than 30 days or a new generic or biosimilar drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-day supply or for a course of treatment lasting less than 30 days and is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information, if applicable:

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

~~(1)~~ (2) the price of the prescription drug;

~~(2)~~ (3) whether the Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

~~(3)~~ (4) the direct costs incurred by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to distribute the prescription drug; and

~~(4)~~ (5) the patent expiration date of the drug if it is under patent.

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

~~Subd. 5. **Newly acquired prescription drug price reporting.** (a) Beginning January 1, 2022, the acquiring drug manufacturer must submit to the commissioner the information described in paragraph (b) for each newly acquired prescription drug for which the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:~~

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

~~(2) for a newly acquired generic drug where there is an increase of 50 percent or greater in the price over the previous 12-month period.~~

~~(b) For each of the drugs described in paragraph (a), the acquiring manufacturer shall submit to the commissioner no later than 60 days after the acquiring manufacturer begins to sell the newly acquired drug, in the form and manner prescribed by the commissioner, the following information, if applicable:~~

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

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

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

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

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

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

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

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

(1) a list of the prescription drugs reported under subdivisions 3, 4, and 5, and the manufacturers of those prescription drugs; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subd. 9. **Legislative report.** (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, including but not limited to the effectiveness in addressing the following goals:

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

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

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

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

Sec. 5. Minnesota Statutes 2020, section 62J.84, subdivision 2, is amended to read:

Subd. 2. **Definitions.** (a) For purposes of this section and section 62J.841, the terms defined in this subdivision have the meanings given.

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

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

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

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

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

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

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

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

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

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

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

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

(i) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

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

Sec. 6. Minnesota Statutes 2020, section 62J.84, subdivision 2, is amended to read:

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

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

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

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

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

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

(e) "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description or nontrade name and dosage form.

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

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

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

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

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

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

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

(j) "Pharmacy" or "pharmacy provider" means a place of business licensed by the Board of Pharmacy under section 151.19 in which prescription drugs are prepared, compounded, or dispensed under the supervision of a pharmacist.

(k) "Pharmacy benefits manager (PBM)" means an entity licensed to act as a pharmacy benefits manager under section 62W.03.

~~(i)~~ (l) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

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

(n) "Pricing Unit" means the smallest dispensable amount of a prescription drug product that could be dispensed.

(o) "Reporting entity" means any manufacturer, pharmacy, pharmacy benefits manager, wholesale drug distributor, or any other entity required to submit data under this section.

(p) "Wholesale drug distributor" or "wholesaler" means an entity that:

(1) is licensed to act as a wholesale drug distributor under section 151.47; and

(2) distributes prescription drugs, of which it is not the manufacturer, to persons or entities other than a consumer or patient in the state.

Sec. 7. Minnesota Statutes 2021 Supplement, section 62J.84, subdivision 6, is amended to read:

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

(1) a list of the prescription drugs reported under subdivisions 3, 4, and 5, and the manufacturers of those prescription drugs; ~~and~~

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

(3) information reported to the commissioner under section 62J.841, subdivision 2.

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

(c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or is trade secret information under section 13.37, subdivision 1, paragraph (b), subject to section 62J.841, subdivision 2, paragraph (e); or is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended, subject to section 62J.841, subdivision 2, paragraph (e). If a manufacturer believes information should be withheld from public disclosure pursuant to this paragraph, the manufacturer must clearly and specifically identify that information and describe the legal basis in writing when the manufacturer submits the information under this section. If the commissioner disagrees with the manufacturer's request to withhold information from public disclosure, the commissioner shall provide the manufacturer written notice that the information will be publicly posted 30 days after the date of the notice.

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

(e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the

availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.

Sec. 8. Minnesota Statutes 2021 Supplement, section 62J.84, subdivision 6, is amended to read:

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

(1) a list of the prescription drugs reported under subdivisions 3, 4, ~~and~~ 5, 11, 12, 13, and 14 and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 3, 4, ~~and~~ 5, 11, 12, 13, and 14.

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

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

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

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

Sec. 9. Minnesota Statutes 2020, section 62J.84, subdivision 7, is amended to read:

Subd. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section and section 62J.841; in posting information pursuant to subdivision 6; and in taking any other action for the purpose of implementing this section and section 62J.841.

(b) The commissioner may consult with representatives of the manufacturers to establish a standard format for reporting information under this section and section 62J.841 and may use existing reporting methodologies to establish a standard format to minimize administrative burdens to the state and manufacturers.

Sec. 10. Minnesota Statutes 2020, section 62J.84, subdivision 7, is amended to read:

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

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

Sec. 11. Minnesota Statutes 2020, section 62J.84, subdivision 8, is amended to read:

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

(1) failing to submit timely reports or notices as required by this section and section 62J.841;

(2) failing to provide information required under this section and section 62J.841; ~~or~~

(3) providing inaccurate or incomplete information under this section and section 62J.841; or

(4) failing to comply with section 62J.841, subdivisions 2, paragraph (e), and 4.

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

(c) The commissioner shall impose civil penalties under this section and section 62J.841 as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section and section 62J.481 upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section and section 62J.841 shall be deposited in the health care access fund.

Sec. 12. Minnesota Statutes 2020, section 62J.84, subdivision 8, is amended to read:

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

(1) failing to register under subdivision 15;

~~(1)~~ (2) failing to submit timely reports or notices as required by this section;

~~(2)~~ (3) failing to provide information required under this section; or

~~(3)~~ (4) providing inaccurate or incomplete information under this section.

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

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

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

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

Sec. 13. Minnesota Statutes 2021 Supplement, section 62J.84, subdivision 9, is amended to read:

Subd. 9. **Legislative report.** (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section and section 62J.841, including but not limited to the effectiveness in addressing the following goals:

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

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

(3) assisting the state, health carriers, and other payers in the management of pharmaceutical costs and limiting formulary changes due to prescription drug cost increases during a coverage year.

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and 5, and section 62J.841.

Sec. 14. Minnesota Statutes 2021 Supplement, section 62J.84, subdivision 9, is amended to read:

Subd. 9. **Legislative report.** (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, including but not limited to the effectiveness in addressing the following goals:

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

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

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

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, ~~and~~ 5, 11, 12, 13, and 14.

Sec. 15. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 10. **Notice of prescription drugs of substantial public interest.** (a) No later than January 31, 2023, and quarterly thereafter, the commissioner shall produce and post on the department's website a list of prescription drugs that the department determines to represent a substantial public interest and for which the department intends to request data under subdivisions 11, 12, 13, and 14, subject to paragraph (c). The department shall base its inclusion of prescription drugs on any information the department determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state, and the department shall consider drug product families that include prescription drugs:

(1) that triggered reporting under subdivisions 3, 4, or 5 during the previous calendar quarter;

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

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

(b) No sooner than 30 days after publicly posting the list of prescription drugs under paragraph (a), the department shall notify, via e-mail, reporting entities registered with the department of the requirement to report under subdivisions 11, 12, 13, and 14.

(c) No more than 500 prescription drugs may be designated as having a substantial public interest in any one notice.

Sec. 16. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 11. **Manufacturer prescription drug substantial public interest reporting.** (a) Beginning January 1, 2023, a manufacturer must submit to the commissioner the information described in paragraph (b) for any prescription drug:

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

(2) which the manufacturer manufactures or repackages;

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

(4) for which the manufacturer has not submitted data under subdivisions 3 or 5 during the 120-day period prior to the date of the notification to report.

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

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

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

(ii) the introduced to market date; or

(iii) the acquisition date;

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

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

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

(i) to manufacture the prescription drug;

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

(iii) to distribute the prescription drug;

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

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

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

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

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

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

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

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

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

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

(i) price at acquisition;

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

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

(iv) date of acquisition; and

(v) acquisition price.

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

Sec. 17. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 12. **Pharmacy prescription drug substantial public interest reporting.** (a) Beginning January 1, 2023, a pharmacy must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the pharmacy by the department under subdivision 10.

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

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

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

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

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

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

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

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

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

Sec. 18. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 13. **Pharmacy benefit manager (PBM) prescription drug substantial public interest reporting.** (a) Beginning January 1, 2023, a PBM as defined in section 62W.02, subdivision 14, must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the PBM by the department under subdivision 10.

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

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

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

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

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

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

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

Sec. 19. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 14. **Wholesaler prescription drug substantial public interest reporting.** (a) Beginning January 1, 2023, a wholesaler must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the wholesaler by the department under subdivision 10.

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

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

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

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

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

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

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

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

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

Sec. 20. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 15. **Registration requirement.** Beginning January 1, 2023, a reporting entity subject to this chapter shall register with the department in a form and manner prescribed by the commissioner.

Sec. 21. Minnesota Statutes 2020, section 62J.84, is amended by adding a subdivision to read:

Subd. 16. **Rulemaking.** For the purposes of this section, the commissioner may use the expedited rulemaking process under section 14.389.

Sec. 22. **[62J.841] REPORTING PRESCRIPTION DRUG PRICES; FORMULARY DEVELOPMENT AND PRICE STABILITY.**

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

(b) "Average wholesale price" means the customary reference price for sales by a drug wholesaler to a retail pharmacy, as established and published by the manufacturer.

(c) "National drug code" means the numerical code maintained by the United States Food and Drug Administration and includes the label code, product code, and package code.

(d) "Unit" has the meaning given in United States Code, title 42, section 1395w-3a(b)(2).

(e) "Wholesale acquisition cost" has the meaning given in United States Code, title 42, section 1395w-3a(c)(6)(B).

Subd. 2. **Price reporting.** (a) Beginning July 31, 2023, and by July 31 each year thereafter, a manufacturer must report to the commissioner the information in paragraph (b) for every drug with a wholesale acquisition cost of $100 or more for a 30-day supply or for a course of treatment lasting less than 30 days, as applicable to the next calendar year.

(b) A manufacturer shall report a drug's:

(1) national drug code, labeler code, and the manufacturer name associated with the labeler code;

(2) brand name, if applicable;

(3) generic name, if applicable;

(4) wholesale acquisition cost for one unit;

(5) measure that constitutes a wholesale acquisition cost unit;

(6) average wholesale price; and

(7) status as brand name or generic.

(c) The effective date of the information described in paragraph (b) must be included in the report to the commissioner.

(d) A manufacturer must report the information described in this subdivision in the form and manner specified by the commissioner.

(e) Information reported under this subdivision is classified as public data not on individuals, as defined in section 13.02, subdivision 14, and must not be classified by the manufacturer as trade secret information, as defined in section 13.37, subdivision 1, paragraph (b).

(f) A manufacturer's failure to report the information required by this subdivision is grounds for disciplinary action under section 151.071, subdivision 2.

Subd. 3. **Public posting of prescription drug price information.** By October 1 of each year, beginning October 1, 2023, the commissioner must post the information reported under subdivision 2 on the department website, as required by section 62J.84, subdivision 6.

Subd. 4. **Price change.** (a) If a drug subject to price reporting under subdivision 2 is included in the formulary of a health plan submitted to and approved by the commissioner of commerce for the next calendar year under section 62A.02, subdivision 1, the manufacturer may increase the wholesale acquisition cost of the drug for the next calendar year only after providing the commissioner with at least 90 days' written notice.

(b) A manufacturer's failure to meet the requirements of paragraph (a) is grounds for disciplinary action under section 151.071, subdivision 2.

Sec. 23. **[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. 24. **[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. 25. **[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. 26. **[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 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;

(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, if a manufacturer is unable to determine the individual transactions necessary to provide the repayments described in clause (4), 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;

(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 must 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. 27. **[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. 28. **[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. 29. **[62J.85] CITATION.**

Sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."

Sec. 30. **[62J.86] DEFINITIONS.**

Subdivision 1. **Definitions.** For the purposes of sections 62J.85 to 62J.95, the following terms have the meanings given.

Subd. 2. **Advisory council.** "Advisory council" means the Prescription Drug Affordability Advisory Council established under section 62J.88.

Subd. 3. **Biologic.** "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under Code of Federal Regulations, title 42, section 447.502.

Subd. 4. **Biosimilar.** "Biosimilar" has the meaning provided in section 62J.84, subdivision 2, paragraph (b).

Subd. 5. **Board.** "Board" means the Prescription Drug Affordability Board established under section 62J.87.

Subd. 6. **Brand name drug.** "Brand name drug" has the meaning provided in section 62J.84, subdivision 2, paragraph (c).

Subd. 7. **Generic drug.** "Generic drug" has the meaning provided in section 62J.84, subdivision 2, paragraph (e).

Subd. 8. **Group purchaser.** "Group purchaser" has the meaning given in section 62J.03, subdivision 6, and includes pharmacy benefit managers as defined in section 62W.02, subdivision 15.

Subd. 9. **Manufacturer.** "Manufacturer" means an entity that:

(1) engages in the manufacture of a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(2) sets or changes the wholesale acquisition cost of the prescription drug product it manufacturers or markets.

Subd. 10. **Prescription drug product.** "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

Subd. 11. **Wholesale acquisition cost or WAC.** "Wholesale acquisition cost" or "WAC" has the meaning given in United States Code, title 42, section 1395W-3a(c)(6)(B).

Sec. 31. **[62J.87] PRESCRIPTION DRUG AFFORDABILITY BOARD.**

Subdivision 1. **Establishment.** The commissioner of commerce shall establish the Prescription Drug Affordability Board, which shall be governed as a board under section 15.012, paragraph (a), to protect consumers, state and local governments, health plan companies, providers, pharmacies, and other health care system stakeholders from unaffordable costs of certain prescription drugs.

Subd. 2. **Membership.** (a) The Prescription Drug Affordability Board consists of nine members appointed as follows:

(1) seven voting members appointed by the governor;

(2) one nonvoting member appointed by the majority leader of the senate; and

(3) one nonvoting member appointed by the speaker of the house.

(b) All members appointed must have knowledge and demonstrated expertise in pharmaceutical economics and finance or health care economics and finance. A member must not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers or a pharmacy benefit manager or trade association for pharmacy benefit managers.

(c) Initial appointments must be made by January 1, 2023.

Subd. 3. **Terms.** (a) Board appointees shall serve four-year terms, except that initial appointees shall serve staggered terms of two, three, or four years as determined by lot by the secretary of state. A board member shall serve no more than two consecutive terms.

(b) A board member may resign at any time by giving written notice to the board.

Subd. 4. **Chair; other officers.** (a) The governor shall designate an acting chair from the members appointed by the governor. The acting chair shall convene the first meeting of the board.

(b) The board shall elect a chair to replace the acting chair at the first meeting of the board by a majority of the members. The chair shall serve for one year.

(c) The board shall elect a vice-chair and other officers from its membership as it deems necessary.

Subd. 5. **Staff; technical assistance.** (a) The board shall hire an executive director and other staff, who shall serve in the unclassified service. The executive director must have knowledge and demonstrated expertise in pharmacoeconomics, pharmacology, health policy, health services research, medicine, or a related field or discipline. The board may employ or contract for professional and technical assistance as the board deems necessary to perform the board's duties.

(b) The attorney general shall provide legal services to the board.

Subd. 6. **Compensation.** The board members shall not receive compensation but may receive reimbursement for expenses as authorized under section 15.059, subdivision 3.

Subd. 7. **Meetings.** (a) Meetings of the board are subject to chapter 13D. The board shall meet publicly at least every three months to review prescription drug product information submitted to the board under section 62J.90. If there are no pending submissions, the chair of the board may cancel or postpone the required meeting. The board may meet in closed session when reviewing proprietary information as determined under the standards developed in accordance with section 62J.91, subdivision 4.

(b) The board shall announce each public meeting at least two weeks prior to the scheduled date of the meeting. Any materials for the meeting must be made public at least one week prior to the scheduled date of the meeting.

(c) At each public meeting, the board shall provide the opportunity for comments from the public, including the opportunity for written comments to be submitted to the board prior to a decision by the board.

Sec. 32. **[62J.88] PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL.**

Subdivision 1. **Establishment.** The governor shall appoint a 12-member stakeholder advisory council to provide advice to the board on drug cost issues and to represent stakeholders' views. The members of the advisory council shall be appointed based on their knowledge and demonstrated expertise in one or more of the following areas: the pharmaceutical business; practice of medicine; patient perspectives; health care cost trends and drivers; clinical and health services research; and the health care marketplace.

Subd. 2. **Membership.** The council's membership shall consist of the following:

(1) two members representing patients and health care consumers;

(2) two members representing health care providers;

(3) one member representing health plan companies;

(4) two members representing employers, with one member representing large employers and one member representing small employers;

(5) one member representing government employee benefit plans;

(6) one member representing pharmaceutical manufacturers;

(7) one member who is a health services clinical researcher;

(8) one member who is a pharmacologist; and

(9) one member representing the commissioner of health with expertise in health economics.

Subd. 3. **Terms.** (a) The initial appointments to the advisory council must be made by January 1, 2023. The initial appointed advisory council members shall serve staggered terms of two, three, or four years determined by lot by the secretary of state. Following the initial appointments, the advisory council members shall serve four-year terms.

(b) Removal and vacancies of advisory council members are governed by section 15.059.

Subd. 4. **Compensation.** Advisory council members may be compensated according to section 15.059.

Subd. 5. **Meetings.** Meetings of the advisory council are subject to chapter 13D. The advisory council shall meet publicly at least every three months to advise the board on drug cost issues related to the prescription drug product information submitted to the board under section 62J.90.

Subd. 6. **Exemption.** Notwithstanding section 15.059, the advisory council shall not expire.

Sec. 33. **[62J.89] CONFLICTS OF INTEREST.**

Subdivision 1. **Definition.** (a) For purposes of this section, "conflict of interest" means a financial or personal association that has the potential to bias or have the appearance of biasing a person's decisions in matters related to the board or the advisory council, or in the conduct of the board's or council's activities.

(b) A conflict of interest includes any instance in which a person or a person's immediate family member has received or could receive a direct or indirect financial benefit of any amount deriving from the result or findings of a decision or determination of the board.

(c) For purposes of this section, a person's immediate family member includes a spouse, parent, child, or other legal dependent, or an in-law of any of the preceding individuals.

(d) For purposes of this section, a financial benefit includes honoraria, fees, stock, the value of stock holdings, and any direct financial benefit deriving from the finding of a review conducted under sections 62J.85 to 62J.95.

(e) Ownership of securities is not a conflict of interest if the securities are: (1) part of a diversified mutual or exchange traded fund; or (2) in a tax-deferred or tax-exempt retirement account that is administered by an independent trustee.

Subd. 2. **General.** (a) A board or advisory council member, board staff member, or third-party contractor must disclose any conflicts of interest to the appointing authority or the board prior to the acceptance of an appointment, an offer of employment, or a contractual agreement. The information disclosed must include the type, nature, and magnitude of the interests involved.

(b) A board member, board staff member, or third-party contractor with a conflict of interest relating to any prescription drug product under review must recuse themselves from any discussion, review, decision, or determination made by the board relating to the prescription drug product.

(c) Any conflict of interest must be disclosed in advance of the first meeting after the conflict is identified or within five days after the conflict is identified, whichever is earlier.

Subd. 3. **Prohibitions.** Board members, board staff, or third-party contractors are prohibited from accepting gifts, bequeaths, or donations of services or property that raise

the specter of a conflict of interest or have the appearance of injecting bias into the activities of the board.

Sec. 34. **[62J.90] PRESCRIPTION DRUG PRICE INFORMATION; DECISION TO CONDUCT COST REVIEW.**

Subdivision 1. **Drug price information from the commissioner of health and other sources.** (a) The commissioner of health shall provide to the board the information reported to the commissioner by drug manufacturers under section 62J.84, subdivisions 3, 4, and 5. The commissioner shall provide this information to the board within 30 days of the date the information is received from drug manufacturers.

(b) The board shall subscribe to one or more prescription drug pricing files, such as Medispan or FirstDatabank, or as otherwise determined by the board.

Subd. 2. **Identification of certain prescription drug products.** (a) The board, in consultation with the advisory council, shall identify the following prescription drug products:

(1) brand name drugs or biologics for which the WAC increases by more than ten percent or by more than $10,000 during any 12-month period or course of treatment if less than 12 months, after adjusting for changes in the consumer price index (CPI);

(2) brand name drugs or biologics introduced at a WAC of $30,000 or more per calendar year or per course of treatment;

(3) biosimilar drugs introduced at a WAC that is not at least 15 percent lower than the referenced brand name biologic at the time the biosimilar is introduced; and

(4) generic drugs for which the WAC:

(i) is $100 or more, after adjusting for changes in the CPI, for:

(A) a 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration (FDA);

(B) a supply lasting a patient for fewer than 30 days based on recommended dosage approved for labeling by the FDA; or

(C) one unit of the drug if the labeling approved by the FDA does not recommend a finite dosage; and

(ii) has increased by 200 percent or more during the immediate preceding 12-month period, as determined by the difference between the resulting WAC and the average of the WAC reported over the preceding 12 months, after adjusting for changes in the CPI.

(b) The board, in consultation with the advisory council, shall identify prescription drug products not described in paragraph (a) that may impose costs that create significant

affordability challenges for the state health care system or for patients, including but not limited to drugs to address public health emergencies.

(c) The board shall make available to the public the names and related price information of the prescription drug products identified under this subdivision, with the exception of information determined by the board to be proprietary under the standards developed by the board under section 62J.91, subdivision 4.

Subd. 3. **Determination to proceed with review.** (a) The board may initiate a cost review of a prescription drug product identified by the board under this section.

(b) The board shall consider requests by the public for the board to proceed with a cost review of any prescription drug product identified under this section.

(c) If there is no consensus among the members of the board on whether or not to initiate a cost review of a prescription drug product, any member of the board may request a vote to determine whether or not to review the cost of the prescription drug product.

Sec. 35. **[62J.91] PRESCRIPTION DRUG PRODUCT REVIEWS.**

Subdivision 1. **General.** Once the board decides to proceed with a cost review of a prescription drug product, the board shall conduct the review and make a determination as to whether appropriate utilization of the prescription drug under review, based on utilization that is consistent with the United States Food and Drug Administration (FDA) label or standard medical practice, has led or will lead to affordability challenges for the state health care system or for patients.

Subd. 2. **Review considerations.** In reviewing the cost of a prescription drug product, the board may consider the following factors:

(1) the price at which the prescription drug product has been and will be sold in the state;

(2) the average monetary price concession, discount, or rebate the manufacturer provides to a group purchaser in this state as reported by the manufacturer and the group purchaser, expressed as a percent of the WAC for the prescription drug product under review;

(3) the price at which therapeutic alternatives have been or will be sold in the state;

(4) the average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to a group purchaser or group purchasers in the state for therapeutic alternatives;

(5) the cost to group purchasers based on patient access consistent with the FDA-labeled indications;

(6) the impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(7) the current or expected dollar value of drug-specific patient access programs supported by manufacturers;

(8) the relative financial impacts to health, medical, or other social services costs that can be quantified and compared to baseline effects of existing therapeutic alternatives;

(9) the average patient co-pay or other cost-sharing for the prescription drug product in the state;

(10) any information a manufacturer chooses to provide; and

(11) any other factors as determined by the board.

Subd. 3. **Further review factors.** If, after considering the factors described in subdivision 2, the board is unable to determine whether a prescription drug product will produce or has produced an affordability challenge, the board may consider:

(1) manufacturer research and development costs, as indicated on the manufacturer's federal tax filing for the most recent tax year, in proportion to the manufacturer's sales in the state;

(2) the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that is specific to the prescription drug product under review, multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the product under review;

(3) gross and net manufacturer revenues for the most recent tax year;

(4) any information and research related to the manufacturer's selection of the introductory price or price increase, including but not limited to:

(i) life cycle management;

(ii) market competition and context; and

(iii) projected revenue; and

(5) any additional factors determined by the board to be relevant.

Subd. 4. **Public data; proprietary information.** (a) Any submission made to the board related to a drug cost review must be made available to the public with the exception of information determined by the board to be proprietary.

(b) The board shall establish the standards for the information to be considered proprietary under paragraph (a) and section 62J.90, subdivision 2, including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the FDA.

(c) Prior to the board establishing the standards under paragraph (b), the public must be provided notice and the opportunity to submit comments.

Sec. 36. **[62J.92] DETERMINATIONS; COMPLIANCE; REMEDIES.**

Subdivision 1. **Upper payment limit.** (a) In the event the board finds that the spending on a prescription drug product reviewed under section 62J.91 creates an affordability challenge for the state health care system or for patients, the board shall establish an upper payment limit after considering:

(1) the cost of administering the drug;

(2) the cost of delivering the drug to consumers;

(3) the range of prices at which the drug is sold in the United States according to one or more pricing files accessed under section 62J.90, subdivision 1, and the range at which pharmacies are reimbursed in Canada; and

(4) any other relevant pricing and administrative cost information for the drug.

(b) The upper payment limit must apply to all public and private purchases, payments, and payer reimbursements for the prescription drug products received by an individual in the state in person, by mail, or by other means.

Subd. 2. **Noncompliance.** (a) The failure of an entity to comply with an upper payment limit established by the board under this section shall be referred to the Office of the Attorney General.

(b) If the Office of the Attorney General finds that an entity was noncompliant with the upper payment limit requirements, the attorney general may pursue remedies consistent with chapter 8 or appropriate criminal charges if there is evidence of intentional profiteering.

(c) An entity that obtains price concessions from a drug manufacturer that result in a lower net cost to the stakeholder than the upper payment limit established by the board must not be considered to be in noncompliance.

(d) The Office of the Attorney General may provide guidance to stakeholders concerning activities that could be considered noncompliant.

Subd. 3. **Appeals.** (a) Persons affected by a decision of the board may request an appeal of the board's decision within 30 days of the date of the decision. The board shall hear the appeal and render a decision within 60 days of the hearing.

(b) All appeal decisions are subject to judicial review in accordance with chapter 14.

Sec. 37. **[62J.93] REPORTS.**

Beginning March 1, 2023, and each March 1 thereafter, the board shall submit a report to the governor and legislature on general price trends for prescription drug products and the number of prescription drug products that were subject to the board's cost review and

analysis, including the result of any analysis and the number and disposition of appeals and judicial reviews.

Sec. 38. **[62J.94] ERISA PLANS AND MEDICARE DRUG PLANS.**

(a) Nothing in sections 62J.85 to 62J.95 shall be construed to require ERISA plans or Medicare Part D plans to comply with decisions of the board. ERISA plans or Medicare Part D plans may choose to exceed the upper payment limit established by the board under section 62J.92.

(b) Providers who dispense and administer drugs in the state must bill all payers no more than the upper payment limit without regard to whether or not an ERISA plan or Medicare Part D plan chooses to reimburse the provider in an amount greater than the upper payment limit established by the board.

(c) For purposes of this section, an ERISA plan or group health plan is an employee welfare benefit plan established or maintained by an employer or an employee organization, or both, that provides employer sponsored health coverage to employees and the employee's dependents and is subject to the Employee Retirement Income Security Act of 1974 (ERISA).

Sec. 39. **[62J.95] SEVERABILITY.**

If any provision of sections 62J.85 to 62J.94 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.85 to 62J.94 that can be given effect without the invalid provision or application.

Sec. 40. **[62Q.1842] PROHIBITION ON USE OF STEP THERAPY FOR ANTIRETROVIRAL DRUGS.**

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

(b) "Health plan" has the meaning given in section 62Q.01, subdivision 3, and includes health coverage provided by a managed care plan or a county-based purchasing plan participating in a public program under chapter 256B or 256L or an integrated health partnership under section 256B.0755.

(c) "Step therapy protocol" has the meaning given in section 62Q.184.

Subd. 2. **Prohibition on use of step therapy protocols.** A health plan that covers antiretroviral drugs that are medically necessary for the prevention of HIV/AIDS, including preexposure prophylaxis and postexposure prophylaxis, must not limit or exclude coverage for the antiretroviral drugs by requiring prior authorization or by requiring an enrollee to follow a step therapy protocol.

Sec. 41. **[62Q.481] COST-SHARING FOR PRESCRIPTION DRUGS AND RELATED MEDICAL SUPPLIES TO TREAT CHRONIC DISEASE.**

Subdivision 1. **Cost-sharing limits.** (a) A health plan must limit the amount of any enrollee cost-sharing for prescription drugs prescribed to treat a chronic disease to no more than $25 per one-month supply for each prescription drug and to no more than $50 per month in total for all related medical supplies. Coverage under this section must not be subject to any deductible.

(b) If application of this section before an enrollee has met their plan's deductible would result in health savings account ineligibility under United States Code, title 26, section 223, then this section must apply to that specific prescription drug or related medical supply only after the enrollee has met their plan's deductible.

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

(b) "Chronic disease" means diabetes, asthma, and allergies requiring the use of epinephrine auto-injectors.

(c) "Cost-sharing" means co-payments and coinsurance.

(d) "Related medical supplies" means syringes, insulin pens, insulin pumps, epinephrine auto-injectors, test strips, glucometers, continuous glucose monitors, and other medical supply items necessary to effectively and appropriately administer a prescription drug prescribed to treat a chronic disease.

EFFECTIVE DATE. This section is effective January 1, 2023, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 42. **[62Q.524] COVERAGE FOR DRUGS TO PREVENT THE ACQUISITION OF HUMAN IMMUNODEFICIENCY VIRUS.**

(a) A health plan that provides prescription drug coverage must provide coverage in accordance with this section for:

(1) any antiretroviral drug approved by the United States Food and Drug Administration (FDA) for preventing the acquisition of human immunodeficiency virus (HIV) that is prescribed, dispensed, or administered by a pharmacist who meets the requirements described in section 151.37, subdivision 17; and

(2) any laboratory testing necessary for therapy that uses the drugs described in clause (1) that is ordered, performed, and interpreted by a pharmacist who meets the requirements described in section 151.37, subdivision 17.

(b) A health plan must provide the same terms of prescription drug coverage for drugs to prevent the acquisition of HIV that are prescribed or administered by a pharmacist if the pharmacist meets the requirements described in section 151.37, subdivision 17, as would

apply had the drug been prescribed or administered by a physician, physician assistant, or advanced practice registered nurse. The health plan may require pharmacists or pharmacies to meet reasonable medical management requirements when providing the services described in paragraph (a) if other providers are required to meet the same requirements.

(c) A health plan must reimburse an in-network pharmacist or pharmacy for the drugs and testing described in paragraph (a) at a rate equal to the rate of reimbursement provided to a physician, physician assistant, or advanced practice registered nurse if providing similar services.

(d) A health plan is not required to cover the drugs and testing described in paragraph (a) if provided by a pharmacist or pharmacy that is out-of-network unless the health plan covers similar services provided by out-of-network providers. A health plan must ensure that the health plan's provider network includes in-network pharmacies that provide the services described in paragraph (a).

Sec. 43. **[62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.**

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

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

(c) "Enrollee 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 developed by clinical and pharmacy experts that represents the health plan company's medically appropriate and cost-effective prescription drugs approved for use.

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

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

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

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

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

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

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

(2) reduce co-payments or coinsurance; or

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

(b) A health plan company may remove a brand name drug from the plan's formulary or place a brand name drug in a benefit category that increases an enrollee's cost only upon the addition to the formulary of a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book or a biologic drug rated as interchangeable according to the FDA Purple Book at a lower cost to the enrollee, and upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

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

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

(e) The state employee group insurance program and coverage offered through that program are exempt from the requirements of this subdivision.

Subd. 4. **Not severable.** (a) The provisions of this section are not severable from the amendments and enactments in this act to sections 62A.02, subdivision 1; 62J.84, subdivisions 2, 6, 7, 8, and 9; 62J.841; and 151.071, subdivision 2.

(b) If any amendment or enactment listed in paragraph (a) or its application to any individual, entity, or circumstance is found to be void for any reason, this section is also void.

EFFECTIVE DATE. This section is effective January 1, 2024, and applies to health plans offered, sold, issued, or renewed on or after that date.

Sec. 44. **[62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following terms 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) Except as provided in paragraphs (b) and (c), a pharmacy benefit manager or health carrier must not require or demonstrate a preference for a reference biological product administered to a patient by a physician or health care provider or any product that is biosimilar or interchangeable to the reference biological product administered to a patient by a physician or health care provider.

(b) If a pharmacy benefit manager or health carrier elects coverage of a product listed in paragraph (a), and there are two or less biosimilar or interchangeable biological products available relative to the reference product, the pharmacy benefit manager or health carrier must elect equivalent coverage for all of the products that are biosimilar or interchangeable to the reference biological product.

(c) If a pharmacy benefit manager or health carrier elects coverage of a product listed in paragraph (a), and there are greater than two biosimilar or interchangeable biological products available relative to the reference product, the pharmacy benefit manager or health carrier must elect preferential coverage for all of the products that are biosimilar or interchangeable to the reference biological product.

(d) 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).

(e) This section only applies to new administrations of a reference biological product. Nothing in this section requires switching from a prescribed reference biological product for a patient on an active course of treatment.

Subd. 3. **Exemption.** The state employee group insurance program, and coverage offered through that program, are exempt from the requirements of this section.

EFFECTIVE DATE. This section is effective January 1, 2023.

Sec. 45. **[62W.15] CLINICIAN-ADMINISTERED DRUGS.**

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

(b) "Affiliated pharmacy" means a pharmacy in which a pharmacy benefit manager or health carrier has an ownership interest either directly or indirectly, or through an affiliate or subsidiary.

(c) "Clinician-administered drug" means an outpatient prescription drug other than a vaccine that:

(1) cannot reasonably be self-administered by the patient to whom the drug is prescribed or by an individual assisting the patient with self-administration; and

(2) is typically administered:

(i) by a health care provider authorized to administer the drug, including when acting under a physician's delegation and supervision; and

(ii) in a physician's office, hospital outpatient infusion center, or other clinical setting.

Subd. 2. **Prohibition on requiring coverage as a pharmacy benefit.** A pharmacy benefit manager or health carrier shall not require that a clinician-administered drug or the administration of a clinician-administered drug be covered as a pharmacy benefit.

Subd. 3. **Enrollee choice.** A pharmacy benefit manager or health carrier:

(1) shall permit an enrollee to obtain a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy;

(2) shall not interfere with the enrollee's right to obtain a clinician-administered drug from their provider or pharmacy of choice, and shall not offer financial or other incentives to influence the enrollee's choice of a provider or pharmacy;

(3) shall not require clinician-administered drugs to be dispensed by a pharmacy selected by the pharmacy benefit manager or health carrier; and

(4) shall not limit or exclude coverage for a clinician-administered drug when it is not dispensed by a pharmacy selected by the pharmacy benefit manager or health carrier, if the drug would otherwise be covered.

Subd. 4. **Cost-sharing and reimbursement.** A pharmacy benefit manager or health carrier:

(1) may impose coverage or benefit limitations on an enrollee who obtains a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy, only if these limitations would also be imposed were the drug to be obtained from an affiliated pharmacy or a pharmacy selected by the pharmacy benefit manager or health carrier; and

(2) may impose cost-sharing requirements on an enrollee who obtains a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy, only if these requirements would also be imposed were the drug to be obtained from an affiliated pharmacy or a pharmacy selected by the pharmacy benefit manager or health carrier.

Subd. 5. **Other requirements.** A pharmacy benefit manager or health carrier:

(1) shall not require or encourage the dispensing of a clinician-administered drug to an enrollee in a manner that is inconsistent with the supply chain security controls and chain of distribution set by the federal Drug Supply Chain Security Act, United States Code, title 21, section 360eee, et seq.;

(2) shall not require a specialty pharmacy to dispense a clinician-administered medication directly to a patient with the intention that the patient will transport the medication to a health care provider for administration; and

(3) may offer, but shall not require:

(i) the use of a home infusion pharmacy to dispense or administer clinician-administered drugs to enrollees; and

(ii) the use of an infusion site external to the enrollee's provider office or clinic.

EFFECTIVE DATE. This section is effective January 1, 2023.

Sec. 46. Minnesota Statutes 2020, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, licensed advanced practice registered nurse, or licensed physician assistant. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A. For purposes of sections 151.252, subdivision 3, and 151.461, "practitioner" also means a pharmacist authorized to prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists under section 151.37, subdivision 14, 15, or 16, or authorized to prescribe drugs to prevent the acquisition of human immunodeficiency virus (HIV) under section 151.37, subdivision 17.

MINNESOTA STATUTES, SECTION 151.01, SUBDIVISION 27, IS ALSO AMENDED IN UES4401-2, ARTICLE 5, SECTION 18.

Sec. 47. Minnesota Statutes 2020, section 151.01, subdivision 27, is amended to read:

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

(1) interpretation and evaluation of prescription drug orders;

(2) compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);

(3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs, including the performance of laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq., provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement;

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; intramuscular and subcutaneous administration used for the treatment of alcohol or opioid dependence; drug regimen reviews; and drug or drug-related research;

(5) drug administration, through intramuscular and subcutaneous administration used to treat mental illnesses as permitted under the following conditions:

(i) upon the order of a prescriber and the prescriber is notified after administration is complete; or

(ii) pursuant to a protocol or collaborative practice agreement as defined by section 151.01, subdivisions 27b and 27c, and participation in the initiation, management, modification, administration, and discontinuation of drug therapy is according to the protocol or collaborative practice agreement between the pharmacist and a dentist, optometrist, physician, podiatrist, or veterinarian, or an advanced practice registered nurse authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy or medication administration made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

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

(i) the protocol includes, at a minimum:

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

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

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

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

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

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

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

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

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

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

(7) participation in the initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between: (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice registered nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

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

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

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

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

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

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

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

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

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

Sec. 48. Minnesota Statutes 2020, section 151.01, is amended by adding a subdivision to read:

Subd. 43. **Biosimilar product.** "Biosimilar product" or "interchangeable biologic 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, 2023.

Sec. 49. 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, 2023.

Sec. 50. 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 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. 51. 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; and

(25) for a drug manufacturer, failure to comply with section 62J.841.

Sec. 52. 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~~.~~; and

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

Sec. 53. Minnesota Statutes 2021 Supplement, section 151.335, is amended to read:

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 methods used to ensure compliance must include but are not limited to enclosing in each medication's packaging a device recognized by the United States Pharmacopeia by which the patient can easily detect improper storage or temperature variations. 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. 54. Minnesota Statutes 2020, section 151.37, is amended by adding a subdivision to read:

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

(b) By January 1, 2023, the board of pharmacy shall develop a standardized protocol for a pharmacist to follow in prescribing the drugs described in paragraph (a). In developing the protocol, the board may consult with community health advocacy groups, the board of medical practice, the board of nursing, the commissioner of health, professional pharmacy associations, and professional associations for physicians, physician assistants, and advanced practice registered nurses.

(c) Before a pharmacist is authorized to prescribe a drug described in paragraph (a), the pharmacist must successfully complete a training program specifically developed for prescribing drugs for preventing the acquisition of HIV that is offered by a college of pharmacy, a continuing education provider that is accredited by the Accreditation Council

for Pharmacy Education, or a program approved by the board. To maintain authorization to prescribe, the pharmacist shall complete continuing education requirements as specified by the board.

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

(e) Before dispensing a drug described under paragraph (a) that is prescribed by the pharmacist, the pharmacist must provide counseling to the patient on the use of the drugs and must provide the patient with a fact sheet that includes the indications and contraindications for the use of these drugs, the appropriate method for using these drugs, the need for medical follow up, and any other additional information listed in Minnesota Rules, part 6800.0910, subpart 2, that is required to be provided to a patient during the counseling process.

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

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

Sec. 55. Minnesota Statutes 2020, section 151.555, as amended by Laws 2021, chapter 30, article 5, sections 2 to 5, is amended to read:

151.555 ~~PRESCRIPTION DRUG~~ MEDICATION REPOSITORY PROGRAM.

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

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

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

(d) "Donor" means:

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

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

(3) an assisted living facility licensed under chapter 144G;

(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 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~~ or 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.

Subd. 2. **Establishment; contract and oversight.** (a) By January 1, 2020, the Board of Pharmacy shall establish a ~~drug~~ medication repository program, through which donors may

donate a drug or medical supply for use by an individual who meets the eligibility criteria specified under subdivision 5.

(b) The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the ~~prescription drug~~ medication repository program. The contract must:

(1) require the board to transfer to the central repository any money appropriated by the legislature for the purpose of operating the medication repository program and require the central repository to spend any money transferred only for purposes specified in the contract;

(2) require the central repository to report the following performance measures to the board:

(i) the number of individuals served and the types of medications these individuals received;

(ii) the number of clinics, pharmacies, and long-term care facilities with which the central repository partnered;

(iii) the number and cost of medications accepted for inventory, disposed of, and dispensed to individuals in need; and

(iv) locations within the state to which medications are shipped or delivered; and

(3) require the board to annually audit the expenditure by the central repository of any funds appropriated by the legislature and transferred by the board to ensure that this funding is used only for purposes specified in the contract.

Subd. 3. **Central repository requirements.** (a) The board may publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the ~~drug~~ medication repository program. If the board publishes a request for proposal, it shall follow all applicable state procurement procedures in the selection process. The board may also work directly with the University of Minnesota to establish a central repository.

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

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

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

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

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

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

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

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

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

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

(1) is a resident of Minnesota;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory.

(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 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.

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

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

(c) Before a drug or supply is dispensed or administered to an individual, the individual must sign a drug repository recipient form acknowledging that the individual understands

the information stated on the form. The board shall develop the form and make it available on the board's website. The form must include the following information:

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

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

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

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

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

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

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

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

(1) intake application form described under subdivision 5;

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

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

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

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

(6) ~~drug~~ medication 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 two years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

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

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

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

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

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

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

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

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.

Subd. 15. **Funding.** The central repository may seek grants and other funds from nonprofit charitable organizations, the federal government, and other sources to fund the ongoing operations of the medication repository program.

Sec. 56. Minnesota Statutes 2020, section 152.125, is amended to read:

152.125 INTRACTABLE PAIN.

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

(b) "Drug diversion" means the unlawful transfer of prescription drugs from their licit medical purpose to the illicit marketplace.

(c) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Examples of conditions associated with intractable pain sometimes but do not always include cancer and the recovery period, sickle cell disease, noncancer pain, rare diseases, orphan diseases, severe injuries, and health conditions requiring the provision of palliative care or hospice care. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:

(1) when treating a nonterminally ill patient for intractable pain, an evaluation conducted by the attending physician and one or more physicians specializing in pain medicine or the treatment of the area, system, or organ of the body confirmed or perceived as the source of the intractable pain; or

(2) when treating a terminally ill patient, an evaluation conducted by the attending physician who does so in accordance with the standard of care and the level of care, skill, and treatment that would be recognized by a reasonably prudent physician under similar conditions and circumstances.

(d) "Palliative care" has the meaning provided in section 144A.75, subdivision 12.

(e) "Rare disease" means a disease, disorder, or condition that affects fewer than 200,000 individuals in the United States and is chronic, serious, life altering, or life threatening.

Subd. 1a. **Criteria for the evaluation and treatment of intractable pain.** The evaluation and treatment of intractable pain when treating a nonterminally ill patient is governed by the following criteria:

(1) a diagnosis of intractable pain by the treating physician and either by a physician specializing in pain medicine or a physician treating the area, system, or organ of the body that is the source of the pain is sufficient to meet the definition of intractable pain; and

SEC. 27. MINNESOTA STATUTES 2020, SECTION 152.125, AMENDMENT MOVED FROM S4410-3, ARTICLE 14, SECTION 27, TO MATCH UES4410-2, ARTICLE 6, SECTION 56.

Sec. 27. Minnesota Statutes 2020, section 152.125, is amended to read:

152.125 INTRACTABLE PAIN.

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

(b) "Drug diversion" means the unlawful transfer of prescription drugs from their licit medical purpose to the illicit marketplace.

(c) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Conditions associated with intractable pain include but are not limited to cancer and the recovery period, sickle cell disease, noncancer pain, rare diseases, orphan diseases, severe injuries, and health conditions requiring the provision of palliative care or hospice care. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:

(1) when treating a nonterminally ill patient for intractable pain, an evaluation conducted by the attending physician, advanced practice registered nurse, or physician assistant and one or more physicians, advanced practice registered nurses, or physician assistants specializing in pain medicine or the treatment of the area, system, or organ of the body confirmed or perceived as the source of the intractable pain; or

(2) when treating a terminally ill patient, an evaluation conducted by the attending physician, advanced practice registered nurse, or physician assistant who does so in accordance with the standard of care and the level of care, skill, and treatment that would be recognized by a reasonably prudent physician, advanced practice registered nurse, or physician assistant under similar conditions and circumstances.

(d) "Palliative care" has the meaning provided in section 144A.75, subdivision 12.

(e) "Rare disease" means a disease, disorder, or condition that affects fewer than 200,000 individuals in the United States and is chronic, serious, life altering, or life threatening.

Subd. 1a. **Criteria for the evaluation and treatment of intractable pain.** The evaluation and treatment of intractable pain when treating a nonterminally ill patient is governed by the following criteria:

(2) the cause of the diagnosis of intractable pain must not interfere with medically necessary treatment including but not limited to prescribing or administering a controlled substance in Schedules II to V of section 152.02.

Subd. 2. **Prescription and administration of controlled substances for intractable pain.** (a) Notwithstanding any other provision of this chapter, a physician, advanced practice registered nurse, or physician assistant may prescribe or administer a controlled substance in Schedules II to V of section 152.02 to ~~an individual~~ a patient in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of the ~~individual~~ patient for a diagnosed condition causing intractable pain. No physician, advanced practice registered nurse, or physician assistant shall be subject to disciplinary action by the Board of Medical Practice or Board of Nursing for appropriately prescribing or administering a controlled substance in Schedules II to V of section 152.02 in the course of treatment of ~~an individual~~ a patient for intractable pain, provided the physician, advanced practice registered nurse, or physician assistant:

(1) keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147~~,~~ or 148 or in accordance with the current standard of care; and

(2) enters into a patient-provider agreement that meets the criteria in subdivision 5.

(b) No physician, advanced practice registered nurse, or physician assistant, acting in good faith and based on the needs of the patient, shall be subject to any civil or criminal action or investigation, disenrollment, or termination by the commissioner of health or human services solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent dosage recommendations or thresholds specified in state or federal opioid prescribing guidelines or policies, including but not limited to the Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention, Minnesota opioid prescribing guidelines, the Minnesota opioid prescribing improvement program, and the Minnesota quality improvement program established under section 256B.0638.

(c) A physician, advanced practice registered nurse, or physician assistant treating intractable pain by prescribing, dispensing, or administering a controlled substance in Schedules II to V of section 152.02 that includes but is not opioid analgesics must not taper a patient's medication dosage solely to meet a predetermined morphine milligram equivalent dosage recommendation or threshold if the patient is stable and compliant with the treatment plan, is experiencing no serious harm from the level of medication currently being prescribed or previously prescribed, and is in compliance with the patient-provider agreement as described in subdivision 5.

(d) A physician's, advanced practice registered nurse's, or physician assistant's decision to taper a patient's medication dosage must be based on factors other than a morphine milligram equivalent recommendation or threshold.

(1) a diagnosis of intractable pain by the treating physician, advanced practice registered nurse, or physician assistant and either by a physician, advanced practice registered nurse, or physician assistant specializing in pain medicine or a physician, advanced practice registered nurse, or physician assistant treating the area, system, or organ of the body that is the source of the pain is sufficient to meet the definition of intractable pain; and

(2) the cause of the diagnosis of intractable pain must not interfere with medically necessary treatment including but not limited to prescribing or administering a controlled substance in Schedules II to V of section 152.02.

Subd. 2. **Prescription and administration of controlled substances for intractable pain.** (a) Notwithstanding any other provision of this chapter, a physician, advanced practice registered nurse, or physician assistant may prescribe or administer a controlled substance in Schedules II to V of section 152.02 to ~~an individual~~ a patient in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of the ~~individual~~ patient for a diagnosed condition causing intractable pain. No physician, advanced practice registered nurse, or physician assistant shall be subject to disciplinary action by the Board of Medical Practice or Board of Nursing for appropriately prescribing or administering a controlled substance in Schedules II to V of section 152.02 in the course of treatment of ~~an individual~~ a patient for intractable pain, provided the physician, advanced practice registered nurse, or physician assistant:

(1) keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147~~,~~ or 148 or in accordance with the current standard of care; and

(2) enters into a patient-provider agreement that meets the criteria in subdivision 5.

(b) No physician, advanced practice registered nurse, or physician assistant, acting in good faith and based on the needs of the patient, shall be subject to disenrollment or termination by the commissioner of health or human services solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent dosage recommendations or thresholds specified in state or federal opioid prescribing guidelines or policies, including but not limited to the Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention, Minnesota opioid prescribing guidelines, the Minnesota opioid prescribing improvement program, and the Minnesota quality improvement program established under section 256B.0638.

(c) A physician, advanced practice registered nurse, or physician assistant treating intractable pain by prescribing, dispensing, or administering a controlled substance in Schedules II to V of section 152.02 that includes but is not limited to opioid analgesics must not taper a patient's medication dosage solely to meet a predetermined morphine milligram equivalent dosage recommendation or threshold if the patient is stable and compliant with the treatment plan, is experiencing no serious harm from the level of medication currently

(e) No pharmacist, health plan company, or pharmacy benefit manager shall refuse to fill a prescription for an opiate issued by a licensed practitioner with the authority to prescribe opiates solely based on the prescription exceeding a predetermined morphine milligram equivalent dosage recommendation or threshold. Health plan companies that participate in Minnesota health care programs under chapters 256B and 256L, and pharmacy benefit managers under contract with these health plan companies, must comply with section 1004 of the federal SUPPORT Act, Public Law 115-271, when providing services to medical assistance and MinnesotaCare enrollees.

Subd. 3. **Limits on applicability.** This section does not apply to:

(1) a physician's, advanced practice registered nurse's, or physician assistant's treatment of ~~an individual~~ a patient for chemical dependency resulting from the use of controlled substances in Schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in Schedules II to V of section 152.02 to ~~an individual~~ a patient whom the physician, advanced practice registered nurse, or physician assistant knows to be using the controlled substances for nontherapeutic or drug diversion purposes;

(3) the prescription or administration of controlled substances in Schedules II to V of section 152.02 for the purpose of terminating the life of ~~an individual~~ a patient having intractable pain; or

(4) the prescription or administration of a controlled substance in Schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

Subd. 4. **Notice of risks.** Prior to treating ~~an individual~~ a patient for intractable pain in accordance with subdivision 2, a physician, advanced practice registered nurse, or physician assistant shall discuss with the ~~individual~~ patient or the patient's legal guardian, if applicable, the risks associated with the controlled substances in Schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of ~~an individual~~ a patient, and document the discussion in the ~~individual's~~ patient's record as required in the patient-provider agreement described in subdivision 5.

Subd. 5. **Patient-provider agreement.** (a) Before treating a patient for intractable pain, a physician, advanced practice registered nurse, or physician assistant and the patient or the patient's legal guardian, if applicable, must mutually agree to the treatment and enter into a provider-patient agreement. The agreement must include a description of the prescriber's and the patient's expectations, responsibilities, and rights according to best practices and current standards of care.

being prescribed or previously prescribed, and is in compliance with the patient-provider agreement as described in subdivision 5.

(d) A physician's, advanced practice registered nurse's, or physician assistant's decision to taper a patient's medication dosage must be based on factors other than a morphine milligram equivalent recommendation or threshold.

(e) No pharmacist, health plan company, or pharmacy benefit manager shall refuse to fill a prescription for an opiate issued by a licensed practitioner with the authority to prescribe opiates solely based on the prescription exceeding a predetermined morphine milligram equivalent dosage recommendation or threshold.

Subd. 3. **Limits on applicability.** This section does not apply to:

(1) a physician's, advanced practice registered nurse's, or physician assistant's treatment of ~~an individual~~ a patient for chemical dependency resulting from the use of controlled substances in Schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in Schedules II to V of section 152.02 to ~~an individual~~ a patient whom the physician, advanced practice registered nurse, or physician assistant knows to be using the controlled substances for nontherapeutic or drug diversion purposes;

(3) the prescription or administration of controlled substances in Schedules II to V of section 152.02 for the purpose of terminating the life of ~~an individual~~ a patient having intractable pain; or

(4) the prescription or administration of a controlled substance in Schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

Subd. 4. **Notice of risks.** Prior to treating ~~an individual~~ a patient for intractable pain in accordance with subdivision 2, a physician, advanced practice registered nurse, or physician assistant shall discuss with the ~~individual~~ patient or the patient's legal guardian, if applicable, the risks associated with the controlled substances in Schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of ~~an individual~~ a patient, and document the discussion in the ~~individual's~~ patient's record as required in the patient-provider agreement described in subdivision 5.

Subd. 5. **Patient-provider agreement.** (a) Before treating a patient for intractable pain, a physician, advanced practice registered nurse, or physician assistant and the patient or the patient's legal guardian, if applicable, must mutually agree to the treatment and enter into a provider-patient agreement. The agreement must include a description of the prescriber's and the patient's expectations, responsibilities, and rights according to best practices and current standards of care.

House Language UES4410-2

(b) The agreement must be signed by the patient or the patient's legal guardian, if applicable, and the physician, advanced practice registered nurse, or physician assistant and included in the patient's medical records. A copy of the signed agreement must be provided to the patient.

(c) The agreement must be reviewed by the patient and the physician, advanced practice registered nurse, or physician assistant annually. If there is a change in the patient's treatment plan, the agreement must be updated and a revised agreement must be signed by the patient or the patient's legal guardian. A copy of the revised agreement must be included in the patient's medical record and a copy must be provided to the patient.

(d) A patient-provider agreement is not required in an emergency or inpatient hospital setting.

Sec. 57. Minnesota Statutes 2021 Supplement, section 256B.0625, subdivision 13, is amended to read:

Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs when specifically used to enhance fertility, if prescribed by a licensed practitioner and dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance program as a dispensing physician, or by a physician, a physician assistant, or an advanced practice registered nurse employed by or under contract with a community health board as defined in section 145A.02, subdivision 5, for the purposes of communicable disease control.

(b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, unless authorized by the commissioner or the drug appears on the 90-day supply list published by the commissioner. The 90-day supply list shall be published by the commissioner on the department's website. The commissioner may add to, delete from, and otherwise modify the 90-day supply list after providing public notice and the opportunity for a 15-day public comment period. The 90-day supply list may include cost-effective generic drugs and shall not include controlled substances.

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

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

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

Senate Language S4410-3

(b) The agreement must be signed by the patient or the patient's legal guardian, if applicable, and the physician, advanced practice registered nurse, or physician assistant and included in the patient's medical records. A copy of the signed agreement must be provided to the patient.

(c) The agreement must be reviewed by the patient and the physician, advanced practice registered nurse, or physician assistant annually. If there is a change in the patient's treatment plan, the agreement must be updated and a revised agreement must be signed by the patient or the patient's legal guardian. A copy of the revised agreement must be included in the patient's medical record and a copy must be provided to the patient.

(d) A patient-provider agreement is not required in an emergency or inpatient hospital setting.

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

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

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

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

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

(h) Medical assistance coverage of, and reimbursement for, antiretroviral drugs to prevent the acquisition of human immunodeficiency virus (HIV) and any laboratory testing necessary for therapy that uses these drugs must meet the requirements that would otherwise apply to a health plan under section 62Q.524.

Sec. 58. Minnesota Statutes 2020, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

(d) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates

"dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

(e) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

(f) Prior authorization under this subdivision shall comply with ~~section~~ sections 62Q.184 and 62Q.1842.

(g) Any step therapy protocol requirements established by the commissioner must comply with ~~section~~ sections 62Q.1841 and 62Q.1842.

Sec. 59. **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 commissioner of health shall report findings to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services finance and policy and insurance by December 15, 2024.