ARTICLE 8
MISCELLANEOUS

Section 1. Minnesota Statutes 2016, section 151.01, subdivision 5, is amended to read:

Subd. 5. **Drug.** "Drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof~~, vaccines and biologicals, and~~; biological products, other than blood or blood components; all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals~~;~~; and all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals. The term drug shall also mean any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

Sec. 2. Minnesota Statutes 2016, section 151.01, is amended by adding a subdivision to read:

Subd. 40. **Biological product.** "Biological product" has the meaning given in United States Code, title 42, section 262.

Sec. 3. Minnesota Statutes 2016, section 151.01, is amended by adding a subdivision to read:

Subd. 41. **Interchangeable biological product.** "Interchangeable biological product" means a biological product that the United States Food and Drug Administration has:

(1) licensed, and determined to meet the standards for interchangeability under United States Code, title 42, section 262(k)(4); or

(2) determined to be therapeutically equivalent, as set forth in the most recent edition or supplement of the United States Food and Drug Administration publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

Sec. 4. Minnesota Statutes 2016, section 151.21, is amended to read:

151.21 SUBSTITUTION.

Subdivision 1. **Generally.** Except as provided in this section, it shall be unlawful for any pharmacist or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of ~~an order or~~ a prescription drug order without the approval of the prescriber.

Subd. 2. ~~**Brand name specified**~~ **Dispense as written prescription drug orders.** When a pharmacist receives a paper or hard copy prescription drug order on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription ~~in~~ for which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the ~~brand name legend~~ drug as prescribed.

Subd. 3. ~~**Brand name not specified**~~ **Other prescription drug orders.** When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug ~~that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug~~ or, if a biological product is prescribed, a less expensive interchangeable biological product, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the ~~generic~~ generically equivalent drug or the interchangeable biological product, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug ~~product~~ unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist may not substitute a biological product unless the United States Food and Drug Administration has determined the substituted biological product to be interchangeable with the prescribed biological product. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug or biological product other than the ~~brand name~~ specific drug or biological product prescribed.

Subd. 3a. **Prescriptions by electronic transmission.** Nothing in this section permits a prescriber to maintain "dispense as written" or "D.A.W." as a default on all prescriptions. Prescribers must add the "dispense as written" or "D.A.W." designation to electronic prescriptions individually, as appropriate.

Subd. 4. **Pricing.** A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the ~~brand name~~ drug prescribed.

If more than one safely interchangeable ~~generic~~ drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative. ~~Any difference between acquisition cost to the pharmacist of the drug dispensed and the brand name drug prescribed shall be passed on to the purchaser.~~

Subd. 4a. **Sign.** A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor, unless you object to this substitution."

Subd. 5. **Reimbursement.** Nothing in this section requires a pharmacist to substitute a ~~generic~~ drug if the substitution will make the transaction ineligible for third-party reimbursement.

Subd. 6. **Disclosure.** When a pharmacist dispenses a brand name legend drug and, at that time, a less expensive generically equivalent drug or interchangeable biological product is also available in the pharmacist's stock, the pharmacist shall disclose to the purchaser that a ~~generic~~ generically equivalent drug or interchangeable biological product is available.

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

Subd. 8. **List of excluded products.** The Drug Formulary Committee established under section 256B.0625, subdivision 13, shall establish a list of drug products that are to be excluded from this section. This list shall be updated on an annual basis and shall be provided to the board for dissemination to pharmacists licensed in the state.

Subd. 9. **Extended supply.** (a) After a patient has obtained an initial 30-day supply of a prescription drug, and the patient returns to the pharmacy to obtain a refill, a pharmacist may dispense up to a 90-day supply of that prescription drug to the patient when the following requirements are met:

(1) the total quantity of dosage units dispensed by the pharmacist does not exceed the total quantity of dosage units of the remaining refills authorized by the prescriber; and

(2) the pharmacist is exercising the pharmacist's professional judgment.

(b) The initial 30-day supply requirement in paragraph (a) is not required if the prescription has previously been filled with a 90-day supply.

(c) Notwithstanding paragraph (a), a pharmacist may not exceed the number of dosage units authorized by a prescriber for an initial prescription or subsequent refills if:

(1) the prescriber has specified on the prescription that, due to medical necessity, the pharmacist may not exceed the number of dosage units identified on the prescription; or

(2) the prescription drug is a controlled substance, as defined in section 152.01, subdivision 4.

Subd. 10. **Electronic entry.** (a) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the name and manufacturer of the biological product dispensed.

(b) The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) an interoperable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefit management system; or

(4) a pharmacy record.

(c) Entry into an electronic records system as described in paragraph (b) is presumed to provide notice to the prescriber.

(d) When electronic communication as specified in paragraph (b) is not possible, the pharmacist or the pharmacist's designee shall communicate to the prescriber the name and manufacturer of the biological product dispensed by using mail, facsimile, telephone, or other secure means of electronic transmission.

(e) Communication of the name and manufacturer of the biological product dispensed shall not be required if:

(1) there is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed; or

(2) a prescription is being refilled and the biological product being dispensed is the same product dispensed on the prior filling of the prescription.

HOUSE ART. 8, SEC. 5 - SEE SENATE ART. 8, SEC. 3

HOUSE ART. 8, SEC. 6 - SEE SENATE ART. 8, SEC. 4

HOUSE ART. 8, SEC. 7 - SEE SENATE ART. 8

HOUSE ART. 8, SEC. 8 - SEE SENATE ART. 8, SEC. 5

Sec. 9. Minnesota Statutes 2016, section 245A.02, subdivision 5a, is amended to read:

Subd. 5a. **Controlling individual.** (a) "Controlling individual" means ~~a public body, governmental agency, business entity, officer, owner, or managerial official whose responsibilities include the direction of the management or policies of a program. For purposes of this subdivision, owner means an individual who has direct or indirect ownership interest in a corporation, partnership, or other business association issued a license under this chapter. For purposes of this subdivision, managerial official means those individuals who have the decision-making authority related to the operation of the program, and the responsibility for the ongoing management of or direction of the policies, services, or employees of the program. A site director who has no ownership interest in the program is not considered to be a managerial official for purposes of this definition. Controlling individual does not include~~ an owner of a program or service provider licensed under this chapter and the following individuals, if applicable:

(1) each officer of the organization, including the chief executive officer and chief financial officer;

(2) the individual designated as the authorized agent under section 245A.04, subdivision 1, paragraph (b);

(3) the individual designated as the compliance officer under section 256B.04, subdivision 21, paragraph (b); and

(4) each managerial official whose responsibilities include the direction of the management or policies of a program.

(b) Controlling individual does not include:

(1) a bank, savings bank, trust company, savings association, credit union, industrial loan and thrift company, investment banking firm, or insurance company unless the entity operates a program directly or through a subsidiary;

(2) an individual who is a state or federal official, or state or federal employee, or a member or employee of the governing body of a political subdivision of the state or federal government that operates one or more programs, unless the individual is also an officer, owner, or managerial official of the program, receives remuneration from the program, or owns any of the beneficial interests not excluded in this subdivision;

(3) an individual who owns less than five percent of the outstanding common shares of a corporation:

(i) whose securities are exempt under section 80A.45, clause (6); or

(ii) whose transactions are exempt under section 80A.46, clause (2); ~~or~~

(4) an individual who is a member of an organization exempt from taxation under section 290.05, unless the individual is also an officer, owner, or managerial official of the program or owns any of the beneficial interests not excluded in this subdivision. This clause does not exclude from the definition of controlling individual an organization that is exempt from taxation~~.~~; or

(5) an employee stock ownership plan trust, or a participant or board member of an employee stock ownership plan, unless the participant or board member is a controlling individual according to paragraph (a).

(c) For purposes of this subdivision, "managerial official" means an individual who has the decision-making authority related to the operation of the program, and the responsibility for the ongoing management of or direction of the policies, services, or employees of the program. A site director who has no ownership interest in the program is not considered to be a managerial official for purposes of this definition.

Sec. 10. Minnesota Statutes 2016, section 245A.02, is amended by adding a subdivision to read:

Subd. 10b. **Owner.** "Owner" means an individual or organization that has a direct or indirect ownership interest of five percent or more in a program licensed under this chapter. For purposes of this subdivision, "direct ownership interest" means the possession of equity in capital, stock, or profits of an organization, and "indirect ownership interest" means a direct ownership interest in an entity that has a direct or indirect ownership interest in a licensed program. For purposes of this chapter, "owner of a nonprofit corporation" means

the president and treasurer of the board of directors or, for an entity owned by an employee stock ownership plan, means the president and treasurer of the entity. A government entity that is issued a license under this chapter shall be designated the owner.

Sec. 11. **[256.999] LEGISLATIVE NOTICE AND APPROVAL REQUIRED FOR CERTAIN FEDERAL WAIVERS OR APPROVALS.**

(a) Before submitting an application for a federal waiver or approval (1) under section 1332 of the Affordable Care Act or section 1115 of the Social Security Act, or (2) to modify or add a benefit covered by medical assistance or otherwise amend the state's Medicaid plan, the commissioner, governing board, or director of a state agency seeking the federal waiver or approval must provide notice and a copy of the application for the federal waiver or approval to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and commerce.

(b) If a federal waiver or approval (1) under section 1332 of the Affordable Care Act or section 1115 of the Social Security Act, or (2) to modify or add a benefit covered by medical assistance or otherwise amend the state's Medicaid plan, is received or granted during a legislative session, a commissioner, governing board, or director of a state agency is prohibited from implementing or otherwise acting on the federal waiver or approval received or granted, unless the federal waiver or approval is specifically authorized by law on a date after receipt of the federal waiver or approval.

(c) If a federal waiver or approval (1) under section 1332 of the Affordable Care Act or section 1115 of the Social Security Act, or (2) to modify or add a benefit covered by medical assistance or otherwise amend the state's Medicaid plan, is received or granted while the legislature is not in session, a commissioner, governing board, or director of a state agency is prohibited from implementing or otherwise acting on the federal waiver or approval received or granted, unless the federal waiver or approval is submitted to the Legislative Advisory Commission and the commission makes a positive recommendation. If the commission makes no recommendation, a negative recommendation, or a recommendation for further review, the commissioner, governing board, or director shall not implement or otherwise act on the federal waiver or approval received or granted.

EFFECTIVE DATE. This section is effective the day following final enactment and applies to initial requests for federal waivers or approvals sought on or after that date.

Sec. 12. **ESTABLISHMENT OF FEDERALLY FACILITATED MARKETPLACE.**

Subdivision 1. **Establishment.** (a) The commissioner of commerce, in cooperation with the secretary of the United States Department of Health and Human Services, shall establish a federally facilitated marketplace for Minnesota for coverage beginning January 1, 2019. The federally facilitated marketplace shall take the place of MNsure, established under

Minnesota Statutes, chapter 62V. In working with the secretary of the United States Department of Health and Human Services to implement the federally facilitated marketplace in Minnesota, the commissioner of commerce shall:

(1) seek to incorporate, where appropriate and cost-effective, elements of the Minnesota eligibility system as defined in Minnesota Statutes, section 62V.055, subdivision 1;

(2) regularly consult with stakeholder groups, including but not limited to representatives of state agencies, health care providers, health plan companies, brokers, and consumers; and

(3) seek all available federal grants and funds for state planning and development costs.

(b) All health plans that are offered to Minnesota residents through the federally facilitated marketplace, when implemented, and that are offered by a health carrier that meets the applicability criteria in Minnesota Statutes, section 62K.10, subdivision 1, must satisfy requirements for:

(1) geographic accessibility to providers that at least satisfy the maximum distance or travel times specified in Minnesota Statutes, section 62K.10, subdivisions 2 and 3; and

(2) provider network adequacy that guarantees at least the level of network adequacy required by Minnesota Statutes, section 62K.10, subdivision 4.

For purposes of this paragraph, "health plan" has the meaning given in Minnesota Statutes, section 62A.011, subdivision 3, and "health carrier" has the meaning given in Minnesota Statutes, section 62A.011, subdivision 2.

Subd. 2. **Implementation plan; draft legislation.** The commissioner of commerce, in consultation with the commissioner of human services, the chief information officer of MN.IT, and the MNsure board, shall develop and present to the 2018 legislature an implementation plan for conversion to a federally facilitated marketplace. The plan must:

(1) address and provide recommendations on the following issues:

(i) the state agency or other entity responsible for state oversight and administration related to the state's use of the federally facilitated marketplace;

(ii) plan management functions, including certification of qualified health plans;

(iii) the operation of navigator and in-person assister programs, and the operation of a call center and Web site; and

(iv) funding for federally facilitated marketplace activities, including a user fee rate that shall not exceed the federal platform user fee rate of two percent of premiums charged for a coverage year; and

(2) include draft legislation for any changes in state law necessary to implement a federally facilitated marketplace, including but not limited to necessary changes to Laws 2013, chapter 84, and technical and conforming changes related to the repeal of Minnesota Statutes, chapter 62V.

Subd. 3. **Vendor contract.** The commissioner of commerce, in consultation with the commissioner of human services, the chief information officer of MN.IT, and the MNsure board, shall contract with a vendor to provide technical assistance in developing and implementing the plan for conversion to a federally facilitated marketplace.

Sec. 13. **MNSURE; SPECIAL ENROLLMENT PERIOD.**

(a) The board of MNsure has determined that exceptional circumstances exist under Code of Federal Regulations, title 45, section 155.420(d)(9) which trigger the need for a special enrollment period for individuals to purchase individual health plans through MNsure, if the individual may be reimbursed for medical care from a qualified small employer health reimbursement arrangement in compliance with the 21st Century Cures Act, Public Law 114-255, section 18001.

(b) The special enrollment period shall occur from the effective date of this section until October 31, 2017.

EFFECTIVE DATE. This section is effective seven days following final enactment and applies to individual health plans sold inside of MNsure or outside of MNsure on or after that date.

Sec. 14. **REPEALER.**

Minnesota Statutes 2016, sections 62V.01; 62V.02; 62V.03; 62V.04; 62V.05; 62V.051; 62V.055; 62V.06; 62V.07; 62V.08; 62V.09; 62V.10; and 62V.11, are repealed effective January 1, 2019.