

290.17

**ARTICLE 8**

290.18

**MISCELLANEOUS**

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

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

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

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

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

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

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

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

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

291.15 **151.21 SUBSTITUTION.**

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

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

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

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

292.22 Subd. 4. **Pricing.** A pharmacist dispensing a drug under the provisions of subdivision  
 292.23 3 shall not dispense a drug of a higher retail price than that of the ~~brand name~~ drug prescribed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

294.1 (1) an interoperable electronic medical records system;

294.2 (2) an electronic prescribing technology;

294.3 (3) a pharmacy benefit management system; or

294.4 (4) a pharmacy record.

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

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

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

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

294.15 (2) a prescription is being refilled and the biological product being dispensed is the same  
294.16 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**

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

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

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

298.13 (2) the individual designated as the authorized agent under section 245A.04, subdivision  
298.14 1, paragraph (b);

298.15 (3) the individual designated as the compliance officer under section 256B.04, subdivision  
298.16 21, paragraph (b); and

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

298.19 (b) Controlling individual does not include:

- 298.20 (1) a bank, savings bank, trust company, savings association, credit union, industrial  
 298.21 loan and thrift company, investment banking firm, or insurance company unless the entity  
 298.22 operates a program directly or through a subsidiary;
- 298.23 (2) an individual who is a state or federal official, or state or federal employee, or a  
 298.24 member or employee of the governing body of a political subdivision of the state or federal  
 298.25 government that operates one or more programs, unless the individual is also an officer,  
 298.26 owner, or managerial official of the program, receives remuneration from the program, or  
 298.27 owns any of the beneficial interests not excluded in this subdivision;
- 298.28 (3) an individual who owns less than five percent of the outstanding common shares of  
 298.29 a corporation:
- 298.30 (i) whose securities are exempt under section 80A.45, clause (6); or
- 298.31 (ii) whose transactions are exempt under section 80A.46, clause (2); ~~or~~
- 299.1 (4) an individual who is a member of an organization exempt from taxation under section  
 299.2 290.05, unless the individual is also an officer, owner, or managerial official of the program  
 299.3 or owns any of the beneficial interests not excluded in this subdivision. This clause does  
 299.4 not exclude from the definition of controlling individual an organization that is exempt from  
 299.5 taxation; or
- 299.6 (5) an employee stock ownership plan trust, or a participant or board member of an  
 299.7 employee stock ownership plan, unless the participant or board member is a controlling  
 299.8 individual according to paragraph (a).
- 299.9 (c) For purposes of this subdivision, "managerial official" means an individual who has  
 299.10 the decision-making authority related to the operation of the program, and the responsibility  
 299.11 for the ongoing management of or direction of the policies, services, or employees of the  
 299.12 program. A site director who has no ownership interest in the program is not considered to  
 299.13 be a managerial official for purposes of this definition.
- 299.14 Sec. 10. Minnesota Statutes 2016, section 245A.02, is amended by adding a subdivision  
 299.15 to read:
- 299.16 Subd. 10b. **Owner.** "Owner" means an individual or organization that has a direct or  
 299.17 indirect ownership interest of five percent or more in a program licensed under this chapter.  
 299.18 For purposes of this subdivision, "direct ownership interest" means the possession of equity  
 299.19 in capital, stock, or profits of an organization, and "indirect ownership interest" means a  
 299.20 direct ownership interest in an entity that has a direct or indirect ownership interest in a  
 299.21 licensed program. For purposes of this chapter, "owner of a nonprofit corporation" means

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

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

299.27 (a) Before submitting an application for a federal waiver or approval (1) under section  
 299.28 1332 of the Affordable Care Act or section 1115 of the Social Security Act, or (2) to modify  
 299.29 or add a benefit covered by medical assistance or otherwise amend the state's Medicaid  
 299.30 plan, the commissioner, governing board, or director of a state agency seeking the federal  
 299.31 waiver or approval must provide notice and a copy of the application for the federal waiver  
 299.32 or approval to the chairs and ranking minority members of the legislative committees with  
 299.33 jurisdiction over health and human services policy and finance and commerce.

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

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

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

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

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

- 300.25 Minnesota Statutes, chapter 62V. In working with the secretary of the United States  
300.26 Department of Health and Human Services to implement the federally facilitated marketplace  
300.27 in Minnesota, the commissioner of commerce shall:
- 300.28 (1) seek to incorporate, where appropriate and cost-effective, elements of the Minnesota  
300.29 eligibility system as defined in Minnesota Statutes, section 62V.055, subdivision 1;
- 300.30 (2) regularly consult with stakeholder groups, including but not limited to representatives  
300.31 of state agencies, health care providers, health plan companies, brokers, and consumers;  
300.32 and
- 300.33 (3) seek all available federal grants and funds for state planning and development costs.
- 301.1 (b) All health plans that are offered to Minnesota residents through the federally facilitated  
301.2 marketplace, when implemented, and that are offered by a health carrier that meets the  
301.3 applicability criteria in Minnesota Statutes, section 62K.10, subdivision 1, must satisfy  
301.4 requirements for:
- 301.5 (1) geographic accessibility to providers that at least satisfy the maximum distance or  
301.6 travel times specified in Minnesota Statutes, section 62K.10, subdivisions 2 and 3; and
- 301.7 (2) provider network adequacy that guarantees at least the level of network adequacy  
301.8 required by Minnesota Statutes, section 62K.10, subdivision 4.
- 301.9 For purposes of this paragraph, "health plan" has the meaning given in Minnesota Statutes,  
301.10 section 62A.011, subdivision 3, and "health carrier" has the meaning given in Minnesota  
301.11 Statutes, section 62A.011, subdivision 2.
- 301.12 **Subd. 2. Implementation plan; draft legislation.** The commissioner of commerce, in  
301.13 consultation with the commissioner of human services, the chief information officer of  
301.14 MN.IT, and the MNsure board, shall develop and present to the 2018 legislature an  
301.15 implementation plan for conversion to a federally facilitated marketplace. The plan must:
- 301.16 (1) address and provide recommendations on the following issues:
- 301.17 (i) the state agency or other entity responsible for state oversight and administration  
301.18 related to the state's use of the federally facilitated marketplace;
- 301.19 (ii) plan management functions, including certification of qualified health plans;



- 301.20 (iii) the operation of navigator and in-person assister programs, and the operation of a  
301.21 call center and Web site; and
- 301.22 (iv) funding for federally facilitated marketplace activities, including a user fee rate that  
301.23 shall not exceed the federal platform user fee rate of two percent of premiums charged for  
301.24 a coverage year; and
- 301.25 (2) include draft legislation for any changes in state law necessary to implement a  
301.26 federally facilitated marketplace, including but not limited to necessary changes to Laws  
301.27 2013, chapter 84, and technical and conforming changes related to the repeal of Minnesota  
301.28 Statutes, chapter 62V.
- 301.29 Subd. 3. **Vendor contract.** The commissioner of commerce, in consultation with the  
301.30 commissioner of human services, the chief information officer of MN.IT, and the MNSure  
301.31 board, shall contract with a vendor to provide technical assistance in developing and  
301.32 implementing the plan for conversion to a federally facilitated marketplace.
- 302.1 **Sec. 13. MNSURE; SPECIAL ENROLLMENT PERIOD.**
- 302.2 (a) The board of MNSure has determined that exceptional circumstances exist under  
302.3 Code of Federal Regulations, title 45, section 155.420(d)(9) which trigger the need for a  
302.4 special enrollment period for individuals to purchase individual health plans through MNSure,  
302.5 if the individual may be reimbursed for medical care from a qualified small employer health  
302.6 reimbursement arrangement in compliance with the 21st Century Cures Act, Public Law  
302.7 114-255, section 18001.
- 302.8 (b) The special enrollment period shall occur from the effective date of this section until  
302.9 October 31, 2017.
- 302.10 **EFFECTIVE DATE.** This section is effective seven days following final enactment  
302.11 and applies to individual health plans sold inside of MNSure or outside of MNSure on or  
302.12 after that date.
- 302.13 **Sec. 14. REPEALER.**
- 302.14 Minnesota Statutes 2016, sections 62V.01; 62V.02; 62V.03; 62V.04; 62V.05; 62V.051;  
302.15 62V.055; 62V.06; 62V.07; 62V.08; 62V.09; 62V.10; and 62V.11, are repealed effective  
302.16 January 1, 2019.