Senate Language S3656-2

ARTICLE 24

HEALTH COVERAGE

Section 1. Minnesota Statutes 2016, section 62A.30, is amended by adding a subdivision to read:

Subd. 4. **Mammograms.** (a) For purposes of subdivision 2, coverage for a preventive mammogram screening shall include digital breast tomosynthesis for enrollees at risk for breast cancer, and shall be covered as a preventive item or service, as described under section 62Q.46.

(b) For purposes of this subdivision, "digital breast tomosynthesis" means a radiologic procedure that involves the acquisition of projection images over the stationary breast to produce cross-sectional digital three-dimensional images of the breast. "At risk for breast cancer" means:

(1) having a family history with one or more first- or second-degree relatives with breast cancer;

(2) testing positive for BRCA1 or BRCA2 mutations;

House Language H3138-3

ARTICLE 4

OPIOIDS AND PRESCRIPTION DRUGS

Section 1. Minnesota Statutes 2016, section 8.31, subdivision 1, is amended to read:

Subdivision 1. **Investigate offenses against provisions of certain designated sections; assist in enforcement.** The attorney general shall investigate violations of the law of this state respecting unfair, discriminatory, and other unlawful practices in business, commerce, or trade, and specifically, but not exclusively, prohibition against price gouging for essential off-patent or generic drugs (section 151.462), the Nonprofit Corporation Act (sections 317A.001 to 317A.909), the Act Against Unfair Discrimination and Competition (sections 325D.01 to 325D.07), the Unlawful Trade Practices Act (sections 325D.09 to 325D.16), the Antitrust Act (sections 325D.49 to 325D.66), section 325F.67 and other laws against false or fraudulent advertising, the antidiscrimination acts contained in section 325D.67, the act against monopolization of food products (section 325D.68), the act regulating telephone advertising services (section 325E.39), the Prevention of Consumer Fraud Act (sections 325F.68 to 325F.70), and chapter 53A regulating currency exchanges and assist in the enforcement of those laws as in this section provided.

EFFECTIVE DATE. This section is effective July 1, 2018.

HOUSE ARTICLE 2

Sec. 2. Minnesota Statutes 2016, section 62A.30, is amended by adding a subdivision to read:

Subd. 4. **Mammograms.** (a) For purposes of subdivision 2, coverage for a preventive mammogram screening shall include digital breast tomosynthesis for enrollees at risk for breast cancer, and shall be covered as a preventive item or service, as described under section 62Q.46.

(b) For purposes of this subdivision, "digital breast tomosynthesis" means a radiologic procedure that involves the acquisition of projection images over the stationary breast to produce cross-sectional digital three-dimensional images of the breast. "At risk for breast cancer" means:

(1) having a family history with one or more first or second degree relatives with breast cancer;

(2) testing positive for BRCA1 or BRCA2 mutations;

Senate Language S3656-2

(3) having heterogeneously dense breasts or extremely dense breasts based on the Breast Imaging Reporting and Data System established by the American College of Radiology; or

(4) having a previous diagnosis of breast cancer.

(c) This subdivision does not apply to coverage provided through a public health care program under chapter 256B or 256L.

(d) Nothing in this subdivision limits the coverage of digital breast tomosynthesis in a policy, plan, certificate, or contract referred to in subdivision 1 that is in effect prior to January 1, 2018.

(e) Nothing in this subdivision prohibits a policy, plan, certificate, or contract referred to in subdivision 1 from covering digital breast tomosynthesis for an enrollee who is not at risk for breast cancer.

EFFECTIVE DATE. This section is effective January 1, 2019, and applies to health plans issued, sold, or renewed on or after that date.

House Language H3138-3

(3) having heterogeneously dense breasts or extremely dense breasts based on the Breast Imaging Reporting and Data System established by the American College of Radiology; or

(4) having a previous diagnosis of breast cancer.

(c) This subdivision does not apply to coverage provided through a public health care program under chapter 256B or 256L.

(d) Nothing in this subdivision limits the coverage of digital breast tomosynthesis in a policy, plan, certificate, or contract referred to in subdivision 1 that is in effect prior to January 1, 2019.

(e) Nothing in this subdivision prohibits a policy, plan, certificate, or contract referred to in subdivision 1 from covering digital breast tomosynthesis for an enrollee who is not at risk for breast cancer.

EFFECTIVE DATE. This section is effective January 1, 2019, and applies to health plans issued, sold, or renewed on or after that date.

Sec. 3. Minnesota Statutes 2016, section 62A.65, subdivision 7, is amended to read:

Subd. 7. **Short-term coverage.** (a) For purposes of this section, "short-term coverage" means an individual health plan that:

(1) is issued to provide coverage for a period of ~~185 days or~~ less~~, except that the health plan may permit coverage to continue until the end of a period of hospitalization for a condition for which the covered person was hospitalized on the day that coverage would otherwise have ended~~ than 12 months;

(2) ~~is nonrenewable, provided that the health carrier may provide coverage for one or more subsequent periods that satisfy clause (1), if the total of the periods of coverage do not exceed a total of 365 days out of any 555-day period, plus any additional days covered as a result of hospitalization on the day that a period of coverage would otherwise have ended~~ may be renewed for only one additional period meeting the requirements of clause (1); and

(3) does not cover any preexisting conditions for the first six months of coverage, including ones that originated during a previous identical policy or contract with the same health carrier where coverage was continuous between the previous and the current policy or contract~~; and~~.

~~(4) is available with an immediate effective date without underwriting upon receipt of a completed application indicating eligibility under the health carrier's eligibility requirements, provided that coverage that includes optional benefits may be offered on a basis that does not meet this requirement.~~

(b) Short-term coverage is not subject to subdivisions 2 and 5. Short-term coverage may exclude as a preexisting condition any injury, illness, or condition for which the covered person had medical treatment, symptoms, or any manifestations before the effective date of the coverage, but dependent children born or placed for adoption during the policy period must not be subject to this provision.

~~(c) Notwithstanding subdivision 3, and section 62A.021, a health carrier may combine short-term coverage with its most commonly sold individual qualified plan, as defined in section 62E.02, other than short-term coverage, for purposes of complying with the loss ratio requirement.~~

~~(d) The 365-day coverage limitation provided in paragraph (a) applies to the total number of days of short-term coverage that covers a person, regardless of the number of policies, contracts, or health carriers that provide the coverage. A written application for short-term coverage must ask the applicant whether the applicant has been covered by short-term coverage by any health carrier within the 555 days immediately preceding the effective date of the coverage being applied for. Short-term coverage issued in violation of the 365-day limitation is valid until the end of its term and does not lose its status as short-term coverage, in spite of the violation. A health carrier that knowingly issues short-term coverage in violation of the 365-day limitation is subject to the administrative penalties otherwise available to the commissioner of commerce or the commissioner of health, as appropriate.~~

Sec. 2. **[62J.824] FACILITY FEE DISCLOSURE.**

(a) Prior to the delivery of nonemergency services, a provider-based clinic that charges a facility fee shall provide notice to any patient stating that the clinic is part of a hospital and the patient may receive a separate charge or billing for the facility component, which may result in a higher out-of-pocket expense.

(b) Each health care facility must post prominently in locations easily accessible to and visible by patients, including its Web site, a statement that the provider-based clinic is part of a hospital and the patient may receive a separate charge or billing for the facility, which may result in a higher out-of-pocket expense.

Senate Language S3656-2

House Language H3138-3

(c) This section does not apply to laboratory services, imaging services, or other ancillary health services that are provided by staff who are not employed by the health care facility or clinic.

(d) For purposes of this section:

(1) "facility fee" means any separate charge or billing by a provider-based clinic in addition to a professional fee for physicians' services that is intended to cover building, electronic medical records systems, billing, and other administrative and operational expenses; and

(2) "provider-based clinic" means the site of an off-campus clinic or provider office located at least 250 yards from the main hospital buildings or as determined by the Centers for Medicare and Medicaid Services, that is owned by a hospital licensed under chapter 144 or a health system that operates one or more hospitals licensed under chapter 144, and is primarily engaged in providing diagnostic and therapeutic care, including medical history, physical examinations, assessment of health status, and treatment monitoring. This definition does not include clinics that are exclusively providing laboratory, x-ray, testing, therapy, pharmacy, or educational services and does not include facilities designated as rural health clinics.

HOUSE ARTICLE 4

Sec. 3. **[62Q.184] STEP THERAPY OVERRIDE.**

Sec. 2. **[62Q.184] STEP THERAPY OVERRIDE.**

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

(b) "Clinical practice guideline" means a systematically developed statement to assist health care providers and enrollees in making decisions about appropriate health care services for specific clinical circumstances and conditions developed independently of a health plan company, pharmaceutical manufacturer, or any entity with a conflict of interest.

(c) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health plan company to determine the medical necessity and appropriateness of health care services.

(d) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, but does not include a managed care organization or county-based purchasing plan participating

Senate Language S3656-2

in a public program under chapter 256B or 256L, or an integrated health partnership under section 256B.0755.

(e) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a health plan.

(f) "Step therapy override" means that the step therapy protocol is overridden in favor of coverage of the selected prescription drug of the prescribing health care provider because at least one of the conditions of subdivision 3, paragraph (a), exists.

Subd. 2. **Establishment of a step therapy protocol.** A health plan company shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon written request of an enrollee, a health plan company shall provide any clinical review criteria applicable to a specific prescription drug covered by the health plan.

Subd. 3. **Step therapy override process; transparency.** (a) When coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health plan company through the use of a step therapy protocol, enrollees and prescribing health care providers shall have access to a clear, readily accessible, and convenient process to request a step therapy override. The process shall be made easily accessible on the health plan company's Web site. A health plan company may use its existing medical exceptions process to satisfy this requirement. A health plan company shall grant an override to the step therapy protocol if at least one of the following conditions exist:

(1) the prescription drug required under the step therapy protocol is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

(i) cause an adverse reaction in the enrollee;

(ii) decrease the ability of the enrollee to achieve or maintain reasonable functional ability in performing daily activities; or

(iii) cause physical or mental harm to the enrollee;

(2) the enrollee has had a trial of the required prescription drug covered by their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and was adherent during such trial for a period of time

House Language H3138-3

in a public program under chapters 256B or 256L, or an integrated health partnership under section 256B.0755.

(e) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a health plan.

(f) "Step therapy override" means that the step therapy protocol is overridden in favor of coverage of the selected prescription drug of the prescribing health care provider because at least one of the conditions of subdivision 3, paragraph (a), exists.

Subd. 2. **Establishment of a step therapy protocol.** A health plan company shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon written request of an enrollee, a health plan company shall provide any clinical review criteria applicable to a specific prescription drug covered by the health plan.

Subd. 3. **Step therapy override process; transparency.** (a) When coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health plan company through the use of a step therapy protocol, enrollees and prescribing health care providers shall have access to a clear, readily accessible, and convenient process to request a step therapy override. The process shall be made easily accessible on the health plan company's Web site. A health plan company may use its existing medical exceptions process to satisfy this requirement. A health plan company shall grant an override to the step therapy protocol if at least one of the following conditions exist:

(1) the prescription drug required under the step therapy protocol is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:

(i) cause an adverse reaction to the enrollee;

(ii) decrease the ability of the enrollee to achieve or maintain reasonable functional ability in performing daily activities; or

(iii) cause physical or mental harm to the enrollee;

(2) the enrollee has had a trial of the required prescription drug covered by their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and was adherent during such trial for a period of time

Senate Language S3656-2

House Language H3138-3

sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the enrollee's health care provider due to lack of effectiveness, or an adverse event. This clause does not prohibit a health plan company from requiring an enrollee to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice guideline, Food and Drug Administration label, or pharmaceutical manufacturer's prescribing information; or

(3) the enrollee is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on their current health plan or the immediately preceding health plan, the enrollee received coverage for the prescription drug and the enrollee's prescribing health care provider gives documentation to the health plan company that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the enrollee based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

(b) Upon granting a step therapy override, a health plan company shall authorize coverage for the prescription drug if the prescription drug is a covered prescription drug under the enrollee's health plan.

(c) The enrollee, or the prescribing health care provider if designated by the enrollee, may appeal the denial of a step therapy override by a health plan company using the complaint procedure under sections 62Q.68 to 62Q.73.

(d) In a denial of an override request and any subsequent appeal, a health plan company's decision must specifically state why the step therapy override request did not meet the condition under paragraph (a) cited by the prescribing health care provider in requesting the step therapy override and information regarding the procedure to request external review of the denial pursuant to section 62Q.73. A denial of a request for a step therapy override that is upheld on appeal is a final adverse determination for purposes of section 62Q.73 and is eligible for a request for external review by an enrollee pursuant to section 62Q.73.

(e) A health plan company shall respond to a step therapy override request or an appeal within five days of receipt of a complete request. In cases where exigent circumstances exist, a health plan company shall respond within 72 hours of receipt of a complete request. If a health plan company does not send a response to the enrollee or prescribing health care provider if designated by the enrollee within the time allotted, the override request or appeal is granted and binding on the health plan company.

sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the enrollee's health care provider due to lack of effectiveness, or an adverse event. This clause does not prohibit a health plan company from requiring an enrollee to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice guideline, Food and Drug Administration label, or pharmaceutical manufacturer's prescribing information; or

(3) the enrollee is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on their current health plan or the immediately preceding health plan, the enrollee received coverage for the prescription drug and the enrollee's prescribing health care provider gives documentation to the health plan company that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the enrollee based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

(b) Upon granting a step therapy override, a health plan company shall authorize coverage for the prescription drug if the prescription drug is a covered prescription drug under the enrollee's health plan.

(c) The enrollee, or the prescribing health care provider if designated by the enrollee, may appeal the denial of a step therapy override by a health plan company using the complaint procedure under sections 62Q.68 to 62Q.73.

(d) In a denial of an override request and any subsequent appeal, a health plan company's decision must specifically state why the step therapy override request did not meet the condition under paragraph (a) cited by the prescribing health care provider in requesting the step therapy override and information regarding the procedure to request external review of the denial pursuant to section 62Q.73. A denial of a request for a step therapy override that is upheld on appeal is a final adverse determination for purposes of section 62Q.73 and is eligible for a request for external review by an enrollee pursuant to section 62Q.73.

(e) A health plan company shall respond to a step therapy override request or an appeal within five days of receipt of a complete request. In cases where exigent circumstances exist, a health plan company shall respond within 72 hours of receipt of a complete request. If a health plan company does not send a response to the enrollee or prescribing health care provider if designated by the enrollee within the time allotted, the override request or appeal is granted and binding on the health plan company.

Senate Language S3656-2

(f) Step therapy override requests must be accessible to and submitted by health care providers, and accepted by group purchasers electronically through secure electronic transmission, as described under section 62J.497, subdivision 5.

(g) Nothing in this section prohibits a health plan company from:

(1) requesting relevant documentation from an enrollee's medical record in support of a step therapy override request; or

(2) requiring an enrollee to try a generic equivalent drug pursuant to section 151.21, or a biosimilar, as defined under United States Code, title 42, section 262(i)(2), prior to providing coverage for the equivalent branded prescription drug.

(h) This section shall not be construed to allow the use of a pharmaceutical sample for the primary purpose of meeting the requirements for a step therapy override.

EFFECTIVE DATE. This section is effective January 1, 2019, and applies to health plans offered, issued, or sold on or after that date.

House Language H3138-3

(f) Step therapy override requests must be accessible to and submitted by health care providers, and accepted by group purchasers electronically through secure electronic transmission, as described under section 62J.497, subdivision 5.

(g) Nothing in this section prohibits a health plan company from:

(1) requesting relevant documentation from an enrollee's medical record in support of a step therapy override request; or

(2) requiring an enrollee to try a generic equivalent drug pursuant to section 151.21, or a biosimilar, as defined under United States Code, title 42, section 262(i)(2), prior to providing coverage for the equivalent branded prescription drug.

(h) This section shall not be construed to allow the use of a pharmaceutical sample for the primary purpose of meeting the requirements for a step therapy override.

EFFECTIVE DATE. This section is effective January 1, 2019, and applies to health plans offered, issued, or sold on or after that date.

HOUSE ARTICLE 2

Sec. 4. Minnesota Statutes 2016, section 62Q.55, subdivision 5, is amended to read:

Subd. 5. **Coverage restrictions or limitations.** (a) If emergency services are provided by a nonparticipating provider, with or without prior authorization, the health plan company shall not impose coverage restrictions or limitations that are more restrictive than apply to emergency services received from a participating provider. Cost-sharing requirements that apply to emergency services received out-of-network must be the same as the cost-sharing requirements that apply to services received in-network.

(b) If emergency services are provided by a nonparticipating provider:

(1) the nonparticipating provider shall not request payment from the enrollee in addition to the applicable cost-sharing requirements authorized under paragraph (a); and

(2) the enrollee shall be held harmless and not liable for payment to the nonparticipating provider that are in addition to the applicable cost-sharing requirements under paragraph (a).

(c) A health plan company must attempt to negotiate the reimbursement, less any applicable cost sharing requirements under paragraph (a), for the emergency services from the nonparticipating provider. If a health plan company's and nonparticipating provider's

attempts to negotiate reimbursement for the emergency services do not result in a resolution, the health plan company or provider may elect to refer the matter for binding arbitration. The arbitrator must be chosen from the list created under section 62Q.556, subdivision 2, paragraph (c). The arbitrator must consider the information described in section 62Q.556, subdivision 2, paragraph (d), when reaching a decision. A nondisclosure agreement must be executed by both parties prior to engaging an arbitrator in accordance with this subdivision. The cost of arbitration must be shared equally between the parties.

EFFECTIVE DATE. This section is effective January 1, 2019, and applies to emergency services provided on or after that date.

HOUSE ARTICLE 4

Sec. 3. Minnesota Statutes 2016, 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, drunkenness, use of 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, drunkenness, use of 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 distributor, 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; and

(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;

(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

Senate Language S3656-2

House Language H3138-3

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall 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 or wholesale drug distributor, a violation of section 151.462.

EFFECTIVE DATE. This section is effective July 1, 2018.

Sec. 4. Minnesota Statutes 2016, section 151.214, is amended to read:

151.214 PAYMENT DISCLOSURE.

Subdivision 1. **Explanation of pharmacy benefits.** A pharmacist licensed under this chapter must provide to a patient, for each prescription dispensed where part or all of the cost of the prescription is being paid or reimbursed by an employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager, the patient's co-payment amount ~~and~~, the pharmacy's own usual and customary price of the prescription ~~or~~, and the net amount the pharmacy will ~~be paid for the prescription drug~~ receive from all sources for dispensing the prescription drug, once the claim has been completed by the patient's employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager.

Sec. 4. Minnesota Statutes 2016, section 151.214, subdivision 2, is amended to read:

Subd. 2. **No prohibition on disclosure.** No contracting agreement between an employer-sponsored health plan or health plan company, or its contracted pharmacy benefit manager, and a resident or nonresident pharmacy ~~registered~~ licensed under this chapter, may prohibit ~~the~~:

(1) a pharmacy from disclosing to patients information a pharmacy is required or given the option to provide under subdivision 1; or

(2) a pharmacist from informing a patient when the amount the patient is required to pay under the patient's health plan for a particular drug is greater than the amount the patient would be required to pay for the same drug if purchased out-of-pocket at the pharmacy's usual and customary price.

Sec. 5. **[151.462] PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL OFF-PATENT OR GENERIC DRUGS.**

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

(b) "Essential off-patent or generic drug" means any prescription drug:

(1) for which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act, United States Code, title 21, chapter 9; section 351 of the federal Public Health Service Act, United States Code, title 42, section 262; and federal patent law have expired;

(2) that has been designated by the board or commissioner of human services as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living;

(3) that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and

(4) that is made available for sale in the state of Minnesota.

Essential off-patent or generic drug includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired.

(c) "Health plan company" has the meaning provided in section 62Q.01, subdivision 4.

(d) "Price gouging" means an unconscionable increase in the price of a prescription drug.

(e) "Unconscionable increase" means an increase in the price of a prescription drug that:

(1) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and

(2) results in consumers for whom the drug has been prescribed, the commissioner of human services, and health plan companies having no meaningful choice about whether to purchase the drug at an excessive price because of:

(i) the importance of the drug to the health of the consumer; and

(ii) insufficient competition in the market for the drug.

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

Subd. 2. **Prohibition.** A manufacturer or wholesale drug distributor may not engage in price gouging in the sale of an essential off-patent or generic drug. It is not a violation of this subdivision for a wholesale drug distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale drug distributor by the manufacturer of the drug.

Subd. 3. **Notification of attorney general.** (a) The board, the commissioner of human services, or a health plan company may notify the attorney general of any increase in the price of an essential off-patent or generic drug when:

(1) the price increase, by itself or in combination with other price increases:

(i) would result in an increase of 50 percent or more, compared to the preceding one-year period, in the wholesale acquisition cost of the drug or other relevant measure of drug cost; or

(ii) would result in an increase of 50 percent or more in the price paid by the medical assistance or MinnesotaCare programs, or the health plan company, for the drug compared to the preceding one-year period; and

(2)(i) a 30-day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(ii) a full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(iii) if the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

The commissioner of human services and the health plan company shall notify the board of any notification to the attorney general provided under this paragraph.

(b) On request of the attorney general, the manufacturer of an essential off-patent or generic drug identified in a notice under paragraph (a) shall, within 45 days after the request, submit a statement to the attorney general:

(1) itemizing the components of the cost of producing the drug;

(2) identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the one-year period preceding the date of the price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug and explaining any improvement in public health associated with those expenditures; and

(4) providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this section has occurred.

(c) The attorney general may require a manufacturer or a wholesale drug distributor to produce any records or other documents that may be relevant to a determination of whether a violation of this section has occurred. The attorney general or a person may use the powers and procedures provided in this section or section 8.31.

(d) The attorney general may not bring an action for a remedy under paragraph (c) unless the attorney general has provided the manufacturer or wholesale drug distributor an opportunity to meet with the attorney general to offer a justification for the increase in the price of the essential off-patent or generic drug.

(e) The attorney general shall make any information provided by a health plan company, manufacturer, or wholesale drug distributor under paragraphs (a), (b), and (c) available to the board upon request. Any information provided by a health plan company, manufacturer, or wholesale drug distributor to the attorney general under paragraphs (a), (b), and (c) shall be treated as nonpublic data under section 13.02, subdivision 9, unless the nonpublic classification of the information is waived by the health plan company, manufacturer, or wholesale drug distributor.

(f) In any action brought by the attorney general under paragraph (c), a person who is alleged to have violated a requirement of this section may not assert as a defense that the person did not deal directly with a consumer residing in the state.

Subd. 4. **Private right of action.** In addition to remedies otherwise provided by law, any person injured by a violation of this section may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable

attorney fees, and receive other equitable relief as determined by the court. The court may, as appropriate, enter a consent judgment or decree without the finding of illegality. Any civil action brought under this subdivision is for the benefit of the public.

Subd. 5. **Personal financial liability.** Notwithstanding section 3.736, the attorney general shall be personally financially liable for all legal costs to the state resulting from any legal proceeding that results in a state or federal court ruling that this section is not constitutional.

EFFECTIVE DATE. This section is effective contingent upon certification by the attorney general under section 12, that the criteria in clause (1) of that section are satisfied, but no earlier than July 1, 2018.

Sec. 6. **[151.555] PRESCRIPTION DRUG 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 registered under chapter 144D where there is centralized storage of drugs and 24-hour on-site licensed nursing coverage provided seven days a week;

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

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

(6) a drug manufacturer licensed under section 151.252.

(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. 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 nonprescription medical supply 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.** By January 1, 2019, the Board of Pharmacy shall establish a drug 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. The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the prescription drug repository program.

Subd. 3. **Central repository requirements.** (a) The board shall 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 repository program. The board shall follow all applicable state procurement procedures in the selection process.

(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.

Subd. 4. **Local repository requirements.** (a) To be eligible for participation in the drug repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the drug 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 Web site:

(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 repository program is voluntary. A local repository may withdraw from participation in the drug 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 Web site. 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 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, 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 Web site 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 repository program if the following requirements are met:

(1) the donation is accompanied by a drug 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 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 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 repository donor form and make it available on the board's Web site. The form must state that to the best of the donor's knowledge the donated drug or supply has been properly stored 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 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, and meets the requirements for donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an inspection record stating that the requirements for donation have been met. If a local repository receives drugs and supplies from the central repository, the local repository does not need to reinspect the drugs and supplies.

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory. If donated drugs or supplies are not inspected immediately upon receipt, a repository must quarantine the donated drugs or supplies separately from all dispensing stock until the donated drugs or supplies have been inspected and approved for dispensing under the program.

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

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

(e) Each repository must develop drug and medical supply recall policies and procedures. If a repository receives a recall notification, the repository shall destroy all of the drug or medical supply in its inventory that is the subject of the recall and complete a record of destruction form in accordance with paragraph (f). If a drug or medical supply that is the subject of a Class I or Class II recall has been dispensed, the repository shall immediately notify the recipient of the recalled drug or medical supply. A drug that potentially is subject

to a recall need not be destroyed if its packaging bears a lot number and that lot of the drug is not subject to the recall. If no lot number is on the drug's packaging, it must be destroyed.

(f) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 8, are subject to a recall under paragraph (e), or are not suitable for donation shall be maintained by the repository for at least five 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 Web site. 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 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 Web site:

(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 repository donor form described under subdivision 6;

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

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

Senate Language S3656-2

House Language H3138-3

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

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

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

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.

Sec. 5. Minnesota Statutes 2016, section 151.71, is amended by adding a subdivision to read:

Subd. 3. **Synchronization of refills.** (a) For purposes of this subdivision, "synchronization" means the coordination of prescription drug refills for a patient taking two or more medications for one or more chronic conditions, to allow the patient's medications to be refilled on the same schedule for a given period of time.

Senate Language S3656-2

(b) A contract between a pharmacy benefit manager and a pharmacy must allow for synchronization of prescription drug refills for a patient on at least one occasion per year, if the following criteria are met:

(1) the prescription drugs are covered under the patient's health plan or have been approved by a formulary exceptions process;

(2) the prescription drugs are maintenance medications as defined by the health plan and have one or more refills available at the time of synchronization;

(3) the prescription drugs are not Schedule II, III, or IV controlled substances;

(4) the patient meets all utilization management criteria relevant to the prescription drug at the time of synchronization;

(5) the prescription drugs are of a formulation that can be safely split into short-fill periods to achieve synchronization; and

(6) the prescription drugs do not have special handling or sourcing needs that require a single, designated pharmacy to fill or refill the prescription.

(c) When necessary to permit synchronization, the pharmacy benefit manager shall apply a prorated, daily patient cost-sharing rate to any prescription drug dispensed by a pharmacy under this subdivision. The dispensing fee shall not be prorated, and all dispensing fees shall be based on the number of prescriptions filled or refilled.

House Language H3138-3

Sec. 7. Minnesota Statutes 2016, section 151.71, is amended by adding a subdivision to read:

Subd. 3. **Lowest cost to consumers.** (a) A health plan company or pharmacy benefits manager shall not require an individual to make a payment at the point of sale for a covered prescription medication in an amount greater than the allowable cost to consumers, as defined in paragraph (b).

(b) For purposes of paragraph (a), "allowable cost to consumers" means the lowest of: (1) the applicable co-payment for the prescription medication; or (2) the amount an individual would pay for the prescription medication if the individual purchased the prescription medication without using a health plan benefit.

Senate Language S3656-2

Sec. 6. Minnesota Statutes 2017 Supplement, section 152.105, subdivision 2, is amended to read:

Subd. 2. **Sheriff to maintain collection receptacle or medicine disposal program.** (a) The sheriff of each county shall maintain or contract for the maintenance of at least one collection receptacle or implement a medicine disposal program for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs, as permitted by federal law. For purposes of this section, "legend drug" has the meaning given in section 151.01, subdivision 17. The collection receptacle and medicine disposal program must comply with federal law. In maintaining and operating the collection receptacle or medicine disposal program, the sheriff shall follow all applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017.

(b) For purposes of this subdivision:

(1) a medicine disposal program means providing to the public educational information, and making materials available for safely destroying unwanted legend drugs, including, but not limited to, drug destruction bags or drops; and

(2) a collection receptacle means the operation and maintenance of at least one drop-off receptacle.

House Language H3138-3

Sec. 8. Minnesota Statutes 2017 Supplement, section 152.105, subdivision 2, is amended to read:

Subd. 2. **Sheriff to maintain collection receptacle.** The sheriff of each county shall maintain or contract for the maintenance of at least one collection receptacle for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs, as permitted by federal law. For purposes of this section, "legend drug" has the meaning given in section 151.01, subdivision 17. The collection receptacle must comply with federal law. In maintaining and operating the collection receptacle, the sheriff shall follow all applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017. The sheriff of each county may meet the requirements of this subdivision though the use of an alternative method for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs that has been approved by the Board of Pharmacy. This may include making available to the public, without charge, at-home prescription drug deactivation and disposal products that render drugs and medications inert and irretrievable.

Sec. 9. Minnesota Statutes 2016, section 152.11, is amended by adding a subdivision to read:

Subd. 5. **Limitations on the dispensing of opioid prescription drug orders.** (a) No prescription drug order for an opioid drug listed in Schedule II may be dispensed by a pharmacist or other dispenser more than 30 days after the date on which the prescription drug order was issued.

(b) No prescription drug order for an opioid drug listed in Schedules III through V may be initially dispensed by a pharmacist or other dispenser more than 30 days after the date on which the prescription drug order was issued. No prescription drug order for an opioid drug listed in Schedules III through V may be refilled by a pharmacist or other dispenser more than 45 days after the previous date on which it was dispensed.

(c) For purposes of this section, "dispenser" has the meaning given in section 152.126, subdivision 1.

Sec. 10. **STUDENT HEALTH INITIATIVE TO LIMIT OPIOID HARM.**

Subdivision 1. **Grant awards.** The commissioner of human services, in consultation with the commissioner of education, the Board of Trustees of the Minnesota State Colleges and Universities, the Board of Directors of the Minnesota Private College Council, and the regents of the University of Minnesota, shall develop and administer a program to award grants to secondary school students in grades 7 through 12 and undergraduate students attending a Minnesota postsecondary educational institution, and their community partner or partners, to conduct opioid awareness and opioid abuse prevention activities. If a grant proposal includes more than one community partner, the proposal must designate a primary community partner. Grant applications must be submitted by the primary community partner and any grant award must be managed by the primary community partner on behalf of secondary school and undergraduate student applicants and grantees. Grants shall be awarded for a fiscal year and are onetime.

Subd. 2. **Grant criteria.** (a) Grant dollars may be used for opioid awareness campaigns and events, education related to opioid addiction and abuse prevention, initiatives to limit inappropriate opioid prescriptions, peer education programs targeted to students at high risk of opioid addiction and abuse, and other related initiatives as approved by the commissioner. Grant projects must include one or more of the following components as they relate to opioid abuse and prevention and the role of the community partner: high-risk populations, law enforcement, education, clinical services, or social services.

(b) The commissioner of human services shall seek to provide grant funding for at least one proposal that addresses opioid abuse in the American Indian community.

Subd. 3. **Community partners.** For purposes of the grant program, community partners may include but are not limited to public health agencies; local law enforcement; community health centers; medical clinics; emergency medical service professionals; schools and postsecondary educational institutions; opioid addiction, advocacy, and recovery organizations; tribal governments; local chambers of commerce; and city councils and county boards.

Subd. 4. **Report.** The commissioner of human services shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, K-12 education policy and finance, and higher education policy and finance by September 1, 2019, on the implementation of the grant program and the grants awarded under this section.

Subd. 5. **Federal grants.** (a) The commissioner of human services shall apply for any federal grant funding that aligns with the purposes of this section. The commissioner shall submit to the legislature any changes to the program established under this section that are necessary to comply with the terms of the federal grant.

(b) The commissioner shall notify the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, K-12 education policy and finance, and higher education policy and finance of any grant applications submitted and any federal actions taken related to the grant applications.

HOUSE ARTICLE 4, SECTION 11 IS MATCHED WITH SENATE ARTICLE 23, SECTION 17.

Sec. 12. **CERTIFICATION BY THE ATTORNEY GENERAL.**

The attorney general shall analyze whether implementation of Minnesota Statutes, section 151.462, would be constitutional under the United States Constitution and the Minnesota Constitution. Upon completion of this analysis, the attorney general shall certify that either:

(1) implementation of the section would be constitutional; or

(2) implementation of the section would not be constitutional.

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

HOUSE ARTICLE 2

Sec. 17. **STUDY AND REPORT ON DISPARITIES BETWEEN GEOGRAPHIC RATING AREAS IN INDIVIDUAL AND SMALL GROUP MARKET HEALTH INSURANCE RATES.**

Subdivision 1. **Study and recommendations.** (a) As permitted by the availability of resources, the legislative auditor is requested to study disparities between Minnesota's nine geographic rating areas in individual and small group market health insurance rates and recommend ways to reduce or eliminate rate disparities between the geographic rating areas and provide for stability of the individual and small group health insurance markets in the state. In the study, if conducted, the legislative auditor shall:

(1) identify the factors that cause higher individual and small group market health insurance rates in certain geographic rating areas, and determine the extent to which each identified factor contributes to the higher rates;

(2) identify the impact of referral centers on individual and small group market health insurance rates in southeastern Minnesota, and identify ways to reduce the rate disparity between southeastern Minnesota and the metropolitan area, taking into consideration the patterns of referral center usage by patients in those regions;

(3) determine the extent to which individuals and small employers located in a geographic rating area with higher health insurance rates than surrounding geographic rating areas have obtained health insurance in a lower-cost geographic rating area, identify the strategies that individuals and small employers use to obtain health insurance in a lower-cost geographic rating area, and measure the effects of this practice on the rates of the individuals and small employers remaining in the geographic rating area with higher health insurance rates; and

(4) develop proposals to redraw the boundaries of Minnesota's geographic rating areas, and calculate the effect each proposal would have on rates in each of the proposed rating areas. The legislative auditor shall examine at least three options for redrawing the boundaries of Minnesota's geographic rating areas, at least one of which must reduce the number of geographic rating areas. All options for redrawing Minnesota's geographic rating areas considered by the legislative auditor must be designed:

(i) with the purposes of reducing or eliminating rate disparities between geographic rating areas and providing for stability of the individual and small group health insurance markets in the state;

(ii) with consideration of the composition of existing provider networks and referral patterns in regions of the state; and

(iii) in compliance with the requirements for geographic rating areas in Code of Federal Regulations, title 45, section 147.102(b), and other applicable federal law and guidance.

(b) The legislative auditor may secure de-identified data necessary to complete the study and recommendations according to this subdivision directly from health carriers. For purposes of this paragraph "de-identified" means a process to remove all identifiable information regarding an individual or group from data. Data classified as nonpublic data or private data on individuals, as defined in section 13.02, subdivisions 9 and 12, remains classified as such.

(c) The legislative auditor may recommend one or more proposals for redrawing Minnesota's geographic rating areas if the legislative auditor determines that the proposal would reduce or eliminate individual and small group market health insurance rate disparities between the geographic rating areas and provide for stability of the individual and small group health insurance markets in the state.

Subd. 2. **Contract.** The legislative auditor may contract with another entity for technical assistance in conducting the study and developing recommendations according to subdivision 1.

Subd. 3. **Report.** The legislative auditor is requested to complete the study and recommendations by January 1, 2019, and to submit a report on the study and recommendations by that date to the chairs and ranking minority members of the legislative committees with jurisdiction over health care and health insurance.

Sec. 18. **TESTIMONY ON USE OF DIGITAL BREAST TOMOSYNTHESIS BY MEMBERS OF THE STATE EMPLOYEE GROUP INSURANCE PROGRAM.**

The director of the state employee group insurance program must prepare and submit written testimony to the house of representatives and senate committees with jurisdiction over health and human services and state government finance regarding the impact of Minnesota Statutes, section 62A.30, subdivision 4. The director must provide data on actual utilization of the coverage under Minnesota Statutes, section 62A.30, subdivision 4 by members of the state employee group insurance program from January 1, 2019, to June 30, 2019. The director may make recommendations for legislation addressing any issues relating to the coverage required by Minnesota Statutes, section 62A.30, subdivision 4. The testimony required under this section is due by December 31, 2019.

Sec. 19. **MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY WORK GROUP.**

Subdivision 1. **Establishment; membership.** (a) A mental health and substance use disorder parity work group is established and shall include the following members:

(1) two members representing health plan companies that offer health plans in the individual market, appointed by the commissioner of commerce;

(2) two members representing health plan companies that offer health plans in the group markets, appointed by the commissioner of commerce;

(3) the commissioner of health or a designee;

(4) the commissioner of commerce or a designee;

(5) the commissioner of management and budget or a designee;

(6) two members representing employers, appointed by the commissioner of commerce;

(7) two members who are providers representing the mental health and substance use disorder community, appointed by the commissioner of commerce; and

(8) two members who are advocates representing the mental health and substance use disorder community, appointed by the commissioner of commerce.

(b) Members of the work group must have expertise in standards for evidence-based care, benefit design, or knowledge relating to the analysis of mental health and substance use disorder parity under federal and state law, including nonquantitative treatment limitations.

Subd. 2. **First appointments; first meeting; chair.** Appointing authorities shall appoint members to the work group by July 1, 2018. The commissioner of commerce or a designee shall convene the first meeting of the work group on or before August 1, 2018. The commissioner of commerce or the commissioner's designee shall act as chair.

Subd. 3. **Duties.** The mental health and substance use disorder parity work group shall:

(1) develop recommendations on the most effective approach to determine and demonstrate mental health and substance use disorder parity, in accordance with state and federal law for individual and group health plans offered in Minnesota; and

(2) report recommendations to the legislature.

Subd. 4. **Report.** (a) By February 15, 2019, the work group shall submit a report with recommendations to the chairs and ranking minority members of the legislative committees with jurisdiction over health care policy and finance.

(b) The report must include the following:

(1) a summary of completed state enforcement actions relating to individual and group health plans offered in Minnesota during the preceding 12-month period regarding compliance with parity in mental health and substance use disorders benefits in accordance with state and federal law and a summary of the results of completed state enforcement actions. Data that is protected under state or federal law as nonpublic, private, or confidential shall remain nonpublic, private, or confidential. This summary must include:

(i) the number of formal enforcement actions taken;

(ii) the benefit classifications examined in each enforcement action; and

(iii) the subject matter of each enforcement action, including quantitative and nonquantitative treatment limitations;

(2) detailed information about any regulatory actions the commissioner of health or commissioner of commerce has taken as a result of a completed state enforcement action pertaining to health plan compliance with Minnesota Statutes, sections 62Q.47 and 62Q.53, and United States Code, title 42, section 18031(j);

(3) a description of the work group's recommendations on educating the public about alcoholism, mental health, or chemical dependency parity protections under state and federal law; and

(4) recommendations on the most effective approach to determine and demonstrate mental health and substance use disorder parity, in accordance with state and federal law for individual and group health plans offered in Minnesota.

(c) In developing the report and recommendations, the work group may consult with the Substance Abuse and Mental Health Services Agency and the National Association of Insurance Commissioners for the latest developments on evaluation of mental health and substance use disorder parity.

(d) The report must be written in plain language and must be made available to the public by being posted on the Web sites of the Department of Health and Department of Commerce. The work group may make the report publicly available in additional ways, at its discretion.

(e) The report must include any draft legislation necessary to implement the recommendations of the work group.

Subd. 5. **Expiration.** The mental health and substance use disorder parity work group expires February 16, 2019, or the day after submitting the report required in this section, whichever is earlier.

Sec. 20. **REPEALER.**

Minnesota Statutes 2016, section 62A.65, subdivision 7a, is repealed.

HOUSE ARTICLE 4

Sec. 13. **REPEALER.**

Minnesota Statutes 2016, section 151.55, is repealed.