Bill Summary Comparison of

Health and Human Services

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| Senate File: 3656-2 | House File: 3138-3 |
| Article 24: Health Coverage | Article 2: Health Care  Article 4: Opioids and Prescription Drugs |

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| Article 24: Health Coverage |  | Article 2: Health Care  Article 4: Opioids and Prescription Drugs |
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|  | House only section | Article 4, section 1. Investigate offenses against provisions of certain designated sections; assist in enforcement. Amends § 8.31, subd. 1. Directs the attorney general to investigate violations of the prohibition against price gouging for essential off-patent or generic drugs (§ 151.462). |
| **Section 1 (62A.30)** provides health care coverage for preventive mammogram screening that includes digital breast tomosynthesis (3D) for enrollees who are at risk for breast cancer.  At risk for breast cancer includes having a family history; testing positive for BRCA1 or BRCA2; having dense breasts; or having a previous diagnosis of breast cancer. | Identical, except for:   * differences in effective date in para. (d) * technical difference in para. (b), cl. (1) (staff recommends Senate) | Article 2, Section 2. Mammograms. Amends § 62A.30, by adding subd. 4. (a) Provides that required insurance coverage of preventive mammogram screenings includes digital breast tomosynthesis if the enrollee is at risk for breast cancer. Requires this to be covered as a preventive item or service.  (b) Digital breast tomosynthesis is a radiologic procedure that produces cross-sectional three-dimensional images of the breast. To be at risk for breast cancer means having a family history or relative with breast cancer, testing positive for BRCA1 or BRCA2 mutations, having dense breasts based on criteria established by the American College of Radiology, or having previously had breast cancer.  (c) States that the subdivision does not apply to coverage provided through MA or MinnesotaCare.  (d) States that the subdivision does not limit coverage of digital breast tomosynthesis in effect prior to January 1, 2019.  (e) States that the subdivision does prohibit coverage of digital breast tomosynthesis for an enrollee not at risk of 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 only section | Article 2, section 3. Short-term coverage. Amends § 62A.65, subd. 7. Defines short-term coverage as an individual health plan that: (1) provides coverage for a period of less than 12 months; (2) can be renewed for one additional 12 month period; (3) excludes coverage of preexisting conditions for the first six months; and (4) can be medically underwritten. |
| **Section 2 (62J.824)** **Paragraph (a)** requires a provider-based clinic that charges a facility fee to provide notice to a patient that states that the clinic is a part of a hospital and the patient might receive a separate charge or billing for the facility component which may result in a higher out-of-pocket expense.  **Paragraph (b)** requires a health care facility to prominently post a statement that the provider-based clinic is part of a hospital and the patient may receive a separate billing for the facility.  **Paragraph (c)** exempts laboratory services, imaging services, and other ancillary services that are provided by staff who are not employed by the health care facility or clinic.  **Paragraph (d)** defines facility fee and provider-based clinic. | Senate only section |  |
| **Section 3 (62Q.184)** establishes a step therapy override process for enrollees and prescribing health care providers to use if a health plan company restricts coverage of a prescription drug through the use of a step therapy protocol.  **Subdivision 1** defines the following terms: clinical practice guideline; clinical review criteria; health plan company; step therapy protocol; and step therapy override. The definition of a health plan company specifies that this does not include a managed care plan or county-based purchasing plan or an integrated health partnership participating in medical assistance or MinnesotaCare.  **Subdivision 2** requires the health plan company when establishing a step therapy protocol to consider available recognized evidence-based and peer-reviewed clinical practice guidelines.  Requires a health plan company to provide to an enrollee upon request, the clinical review criteria that is applicable to a specific prescription drug.  **Subdivision 3, paragraph (a),** requires that if a health plan company restricts coverage for a prescription drug for the treatment of a medical condition by requiring the use of a step therapy protocol, enrollees and prescribing providers must have access to a process to request a step therapy override.  The override process must be accessible through the health plan company’s Web site.  Specifies the conditions where a health plan company must grant an override.  **Paragraph (b)** states that once an override has been granted, the health plan company must authorize coverage for the prescription drug if the drug is covered under the enrollee’s health plan.  **Paragraph (c)** permits the enrollee or the enrollee’s prescribing health care provider if designated by the enrollee, to appeal a denial of a step therapy override using the complaint process established under sections 62Q.68 to 62Q.73.  **Paragraph (d)** If a health plan company denies an override request or an appeal of a denial, the health plan company’s decision must state why the override request did not meet the condition cited by the override request and must provide information on how to request an external review under section 62Q.73.  **Paragraph (e)** requires a health plan company to respond to an override request or an appeal within five days of receipt of a complete request, or within 72 hours if there are exigent circumstances.  If a health plan company does not respond within these time limits, the request is granted and is binding on the health plan company.  **Paragraph (f)** requires step therapy override requests to be accessible to health care providers and providers must be able to submit the requests electronically through secure electronic transmission.  **Paragraph (g)** states that nothing in this section prohibits a health plan company from requesting relevant documentation from an enrollee’s medical record in support of a step therapy override request or from requiring an enrollee to try a generic equivalent drug or a biosimilar prior to providing coverage for the equivalent branded prescription drug,  **Paragraph (h)** specifies that this section is not to be construed to allow the use of a drug sample for the primary purpose of meeting the requirements for a step therapy override | Technical differences only. Staff recommend Senate in article 4, subd. 1, para. (d) and House in subd. 3, cl. (1), item (i). | Article 4, section 2. [62Q.184] Step therapy override.  Subd. 1. Definitions. Provides definitions.  Subd. 2. Establishment of a step therapy protocol. Requires health plan companies to establish a step therapy protocol based on clinical practice guidelines and provide an enrollee with the applicable clinical review criteria upon request.  Subd. 3. Step therapy override process; transparency. (a) Requires that if a health plan company restricts the use of a drug, they must provide a clear and convenient process for health care providers and enrollees to request an override. The process must be available on the health plan company’s website and a health plan company that has an existing medical exceptions process can continue to use that process. An override must be granted if the drug or enrollee meets certain conditions.  (b) Provides that a health plan company cover a covered prescription after an override is granted.  (c) Clarifies that an enrollee or provider can appeal the denial of an override using the complaint procedure in sections 62Q.68 to 62Q.73.  (d) Requires a health plan company to state why a step therapy override was not granted and provide information regarding a request for an external review of the denial under section 62Q.73. Provides that a denial that is upheld on appeal is final and is then eligible for a request for external review.  (e) Requires a health plan company to respond for a request for an override or an appeal within 5 days, or within 72 hours if there are exigent circumstances. Provides that if a health plan company does not respond within these time limits the request is granted.  (f) Requires step therapy override requests be accessible to health care providers and allow them to submit the request to group purchasers electronically.  (g) Clarifies that nothing in this section prohibits a health plan company from requesting relevant medical records, requiring an enrollee to try a generic or biosimilar equivalent before covering a branded drug, or using drug samples to meet the step therapy override requirements.  (h) Clarifies that this section cannot be construed to allow a drug sample to serve the primary purpose of a step therapy override.  Effective date. This section is effective January 1, 2019, and applies to health plans after that date. |
|  | House only section | Article 2, section 4. Coverage restrictions or limitations. Amends § 62Q.55, subd. 5. Establishes additional requirements to govern the provision of emergency services by nonparticipating providers. A new paragraph (b) prohibits the nonparticipating provider from requesting payment from the enrollee in addition to the applicable cost-sharing requirements, and requires the enrollee to be held harmless and not liable for payment that is in addition to the applicable cost sharing requirements.  A new paragraph (c) requires health plan companies to attempt to negotiate the reimbursement rate with the nonparticipating provider. If there is no resolution, allows the health plan company or provider to refer the matter to binding arbitration. Specifies requirements for arbitration.  States that this section is effective January 1, 2019, and applies to emergency services provided on or after that date. |
|  | House only section | Article 4, section 3. Grounds for disciplinary action. Amends § 151.071, subd. 2. Provides that a violation of § 151.462 (prohibition against price gouging for essential off-patent or generic drugs) is grounds for disciplinary action by the Board of Pharmacy against a manufacturer or drug wholesaler. |
| **Section 4 (151.214)** states that no contract between a health plan company or a pharmacy benefits manager and a pharmacy may prohibit a pharmacist from informing a patient when the amount the patient may be 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 if purchased out-of-pocket at the pharmacy’s usual and customary price. | Senate amends subd. 1 to clarify that a pharmacy must provide patients with information on the net amount the pharmacy will receive; House does not.  Changes to subd. 2. are identical. | Article 4, section 4. No prohibition on disclosure. Amends § 151.214, subd. 2. Provides that a contract between an employer-sponsored health plan or health plan company, or its pharmacy benefit manager, and a licensed pharmacy, may not prohibit a pharmacist from informing a patient when the amount the patient would pay for a particular drug under the patient’s health plan is greater than the amount the patient would pay out-of-pocket at the pharmacy’s usual and customary price. |
|  | House only section | Article 4, section 5. Prohibition against price gouging for essential off-patent or generic drugs. Adds § 151.462.  Subd. 1. Definitions. Defines the following: essential off-patent or generic drug, health plan company, price gouging, unconscionable increase, and wholesale acquisition cost. Defines “price gouging” as an “unconscionable increase” in the price of a prescription drug. Defines “unconscionable increase” as an increase 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, DHS, and health plan companies having no meaningful choice to purchase the drug because of the importance of the drug to the health of the consumer and insufficient market competition for the drug.  Subd. 2. Prohibition. Prohibits a manufacturer or wholesale drug distributor from price gouging in the sale of an essential off-patent or generic drug. Allows price increases by a wholesale drug distributor that are directly attributable to additional costs for the drug imposed by the manufacturer.  Subd. 3. Notification of attorney general. (a) Allows the board of pharmacy, the commissioner of human services, or a health plan company to notify the attorney general of any increase when:  (1) the price increase by itself or in combination with other increases would result in an increase of 50 percent or more, compared to the preceding one year period, in: (i) the wholesale acquisition cost of the drug or other relevant measure; or (ii) the price paid by MA or MinnesotaCare, or the health plan company; and  (2) the cost of the drug, at the drug’s wholesale acquisition cost, would be more than $80 for a 30-day supply, full course of treatment, or a single dose of the drug.  Requires the commissioner and health plan company to notify the board of any notification provided to the attorney general.  (b) Requires a manufacturer of a drug identified in a notice to provide to the attorney general, within 45 days of the request, specified information related to drug production costs, increases in materials or manufacturing costs, expenditures made to expand access and any improvement in public health, and other information the manufacturer believes to be relevant to whether a violation has occurred.  (c) States that the attorney general may require a manufacturer or wholesale drug distributor to produce relevant records and documents, and allows the attorney general to use the powers and procedures provided in this section and section 8.31 (which provides general enforcement authority to the attorney general).  (d) Prohibits the attorney general from bringing an action for a remedy under paragraph (c) unless the manufacturer or wholesaler has been provided an opportunity to meet with the attorney general to offer a justification for the price increase.  (e) Directs the attorney general to make any information provided by a health plan company, manufacturer, or distributor under paragraphs (a), (b), and (c) available to the board upon request. Classifies the information provided to the attorney general as nonpublic data, unless this classification is waived by the health plan company, manufacturer, or distributor.  (f) States that a person 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. Allows any person injured by a violation of this section to bring a civil action and recover damages and other costs, and receive other equitable relief. Allows the court to enter into a consent judgment or decree without the finding of illegality. States that any civil action is for the benefit of the public.  Subd. 5. Personal financial liability. Provides that 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. States that this section is effective contingent upon the attorney general certifying under section 12 that implementation of this section would be constitutional, but no earlier than July 1, 2018. |
|  | House only section | Article 4, section 6. Prescription drug repository program. Adds § 151.555.  Subd. 1. Definitions. Defines the following terms: central repository, distribute, donor, drug, health care facility, local repository, medical supplies, and practitioner.  “Central repository” means a wholesale distributor that meets certain requirements and enters into a contract with the Board of Pharmacy.  “Donor” means a health care facility, skilled nursing facility, assisted living facility meeting certain requirements, pharmacy, drug wholesaler, or drug manufacturer.  “Health care facility” means a physician’s office or health care clinic, hospital, pharmacy, or nonprofit community clinic.  “Local repository” means a health care facility that elects to accept donated drugs and meets certain requirements.  Subd. 2. Establishment. Requires the Board of Pharmacy to establish, by January 1, 2019, a drug repository program through which donors may donate a drug or medical supply, to be used by eligible individuals. Requires the board to contract with a central repository to implement and administer the program.  Subd. 3. Central repository requirements. Requires the board to select a wholesale drug distributor to act as central repository using a request for proposal process. Specifies related requirements.  Subd. 4. Local repository requirements. In order to serve as a local repository, requires a health care facility to agree to comply with all federal and state requirements related to the drug repository program, drug storage, and dispensing, and maintain any required state license or registration. Specifies application requirements. Provides that participation as a drug repository is voluntary and specifies the process to be used to withdraw from participation.  Subd. 5. Individual eligibility and application requirements. (a) In order to participate in the program, requires an individual to submit an application form to the local repository that attests that the individual: (1) is a state resident; (2) is uninsured, has no prescription drug coverage, or is underinsured; (3) acknowledges that the drugs or medical supplies received may have been donated; and (4) consents to a waiver of child resistant packaging requirements. Requires the local repository to issue eligible individuals with an identification card that is valid for one year, can be used at any local repository, and may be reissued upon expiration. Requires the local repository to send a copy of the application form to the central repository. Requires the board to make available on its 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) Allows a donor to donate to the central repository or a local repository prescription drugs and medical supplies that meet specified requirements.  (b) Specifies requirements for prescriptions drugs to be eligible for donation.  (c) Specifies requirements for medical supplies to be eligible for donation.  (d) Requires the board to develop a drug repository donor form, which must accompany each donation. Specifies requirements for the form and requires the form to be available on the board’s Web site.  (e) Allows donated drugs and supplies to be shipped or delivered to the central repository or a local repository. Requires the drugs and supplies to be inspected by the pharmacist or other practitioner designated by the repository to accept donations. Prohibits the use of a drop box to deliver or accept donations.  (f) Requires the central repository and local repository to inventory all drugs and supplies that are donated, and specifies related requirements.  Subd. 7. Standards and procedures for inspecting and storing donated prescription drugs and supplies. (a) Specifies requirements for the pharmacist or authorized practitioner to follow when inspecting all donated drugs and supplies.  (b) Specifies storage requirements for donated drugs and supplies.  (c) Requires the central repository and local repositories to dispose of all drugs and supplies not suitable for donation in compliance with applicable federal and state requirements related to hazardous waste.  (d) Requires shipments or deliveries of controlled substances or drugs that can only be dispensed to a patient registered with the drug’s manufacturer to be documented by the central or local repository, and returned immediately to the donor or donor’s representative that provided the drugs.  (e) Requires each repository to develop drug and medical supply recall policies and procedures, and specifies related requirements.  (f) Specifies record keeping requirements related to donated drugs and supplies that are destroyed.  Subd. 8. Dispensing requirements. (a) Allows donated drugs and supplies to be dispensed if they are prescribed by a practitioner for the eligible individual. Specifies a priority order for dispensing and other requirements.  (b) Requires the visual inspection of a drug or supply for adulteration, misbranding, tampering, and expiration, and prohibits dispensing or administering of drugs meeting these criteria.  (c) Requires individuals to sign a drug repository recipient form and specifies form requirements.  Subd. 9. Handling fees. (a) Allows a repository to charge an individual receiving a drug or supply a handling fee of no more than 250 percent of the MA dispensing fee.  (b) Prohibits a repository from receiving MA or MinnesotaCare reimbursement for a drug or supply provided through the program.  Subd. 10. Distribution of donated drugs and supplies. (a) Allows the central repository and local repositories to distribute donated drugs and supplies to other repositories.  (b) Requires a local repository that elects not to participate to transfer all donated drugs and supplies to the central repository, and provide copies of the donor forms at the time of the transfer.  Subd. 11. Forms and record-keeping requirements. (a) Specifies forms that must be available on the board’s Web site.  (b) Requires all records to be maintained by a repository for at least five years, and maintained pursuant to all applicable practice acts.  (c) Requires data collected by the program from local repositories to be submitted quarterly or upon request of the central repository.  (d) Requires the central repository to submit reports to the board as required by contract or upon request.  Subd. 12. Liability. (a) Provides that manufacturers are not subject to criminal or civil liability for causes of action related to: (1) alteration of a drug or supply by a party not under the control of the manufacturer; or (2) failure of a party not under the control of the manufacturer to communicate product or consumer information or the expiration date of a donated drug or supply.  (b) Provides civil immunity for a health care facility, pharmacist, practitioner, or donor related to participation in the program and also prohibits a health-related licensing board from taking disciplinary action. States that 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 supply. |
| **Section 5 (151.71)** requires a contract between a pharmacy benefits manager and a pharmacy to permit for the synchronization of prescription drug refills for a patient on at least one occasion per year if the following conditions are met:   1. The drugs are covered under the patient’s health plan or have been approved by a formulary exceptions process; 2. The drugs are maintenance medications and have one or more refills available at time of synchronization; 3. The drugs are not Schedule II, III or IV controlled substances; 4. The patient meets all utilization management criteria ; 5. The drugs are of a formation that can be safely split into short fill periods; and 6. The drugs do not have special handling or sourcing needs that require a single designated pharmacy to fill or refill the prescription. | Senate only section |  |
|  | House only section | Article 4, section 7. Lowest cost to consumers. Amends § 151.71, by adding subd. 3. (a) Prohibits a health plan company or a pharmacy benefits manager from requiring an individual to pay, for a covered prescription medication at the point of sale, an amount greater than the allowable cost to consumers as defined in paragraph (b).  (b) Defines “allowable cost to consumers” as the lowest of: (1) the applicable copayment; or (2) the cost of the medication if purchased without using a health plan benefit. |
| **Section 6 (152.105, subdivision 2)** permits the sheriff of each county to implement a medicine disposal program as an alternative to the requirement that each sheriff maintains at least one collection receptacle for the disposal of prescription drugs.  Defines a medicine disposal program as providing educational information and making materials available for safely destroying unwanted prescription drugs. | Similar intent. Senate refers to a medicine disposal program and includes the provision of educational information. House refers to alternative methods of disposal approved by the Board of Pharmacy. | Article 4, section 8. Sheriff to maintain collection receptacle. Amends § 152.105, subd. 2. Allows county sheriffs satisfy the requirement to maintain a collection receptacle for the disposal of controlled substances and other drugs, by using an alternate method for disposal 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. |
|  | House only section | Article 4, section 9. Limitations on the dispensing of opioid prescription drug orders. Amends § 152.11 by adding subd. 5.  (a) Prohibits a pharmacist or dispenser from filling a prescription drug order for an opioid drug listed in Schedule II more than 30 days after the date on which the prescription drug order was issued.  (b) Prohibits a pharmacist or dispenser from filling a prescription drug order for an opioid drug listed in Schedule III through V more than 30 days after the date on which the prescription drug order was issued and prohibits a pharmacist or dispenser from refilling the drug more than 45 days after the previous date on which it was dispensed.  (c) Provides a definition of “dispenser.” |
|  | House only section | Article 4, section 10. Student health initiative to limit opioid harm.  Subd. 1. Grant awards. Directs the commissioner of human services, in consultation with the commissioner of education, the Board of Trustees of Minnesota State Colleges and Universities, the Board of Directors of the Minnesota Private College Council, and the regents of the University of Minnesota, to develop and administer a grant program for secondary school students in grades 7 to 12 and undergraduate students, to conduct opioid awareness and opioid abuse prevention activities. Requires grant proposals with more than one community partner to designate a primary community partner. Requires grant applications to be submitted by, and any grant awards managed by, the primary community partner. Provides that grants are for a fiscal year and are one-time.  Subd. 2. Grant criteria. (a) Allows grant dollars to be used for opioid awareness, education on addiction and abuse, initiatives to limit inappropriate prescriptions, peer education, and other initiatives as approved by the commissioner. Requires grant projects to include one or more of the following components: high-risk populations, law enforcement, education, clinical services, or social services.  (b) Directs the commissioner to seek to provide grant funding for at least one proposal that addresses opioid abuse in the American Indian community.  Subd. 3. Community partners. Provides a partial listing of the entities that may serve as community partners.  Subd. 4. Report. Requires the commissioner to report to the chairs and ranking minority members of specified legislative committees, by September 1, 2019, on implementation of the grant program and the grants awarded.  Subd. 5. Federal grants. (a) Requires the commissioner of human services to apply for any federal grant funding that aligns with the purposes of this section. Requires the commissioner to submit to the legislature any changes to the program established under this section necessary to comply with the terms of the federal grant.  (b) Requires the commissioner to notify the chairs and ranking minority members of specified legislative committees of any grant applications submitted, and federal actions taken related to the applications. |

| Article 24: Health Coverage |  | Article 2: Health Care  Article 4: Opioids and Prescription Drugs |
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|  | House only section | Article 4, section 12. Certification by the attorney general. Requires the attorney general to analyze whether implementation of § 151.462 (prohibition against price gouging for certain drugs) would be constitutional under the U.S. and Minnesota Constitutions. Requires the attorney general to certify that either: (1) implementation of the section would be constitutional; or (2) implementation of the section would not be constitutional. Provides that this section is effective the day following final enactment. |
|  | House only section | **Article 2, section 17. Study and report on disparities between geographic rating areas in individual and small group market health insurance rates.**  Subd. 1. Study and recommendations. (a) Requests a study from the OLA to examine the differences between the geographic rating areas for individual and small group health insurance rates. The report should examine the factors that cause higher rates in certain geographic areas, the impact referral centers have on rates in southeastern Minnesota, and the extent that those located in a geographic area with higher rates have obtained health insurance from a lower-cost area. The report should also develop at least three options to redraw the geographic boundaries, at least one of which must reduce the number of rating areas. Specifies other requirements for these options.  (b) Allows the OLA to secure de-identified data necessary to complete the study directly from health carriers. Defines “de-identified” and provides that data classified as nonpublic data or private data on individuals retains these classifications.  (c) Permits the OLA to recommend one or more proposals for redrawing the geographic boundaries, if the proposals will eliminate differences in rating areas and provide stability to the market.  Subd. 2. Contract. Allows the OLA to contract with another entity for technical assistance in conducting the study and developing recommendations.  Subd. 3. Report. Requests that the OLA complete the study and recommendations by January 1, 2019, and submit the report to the chairs and ranking minority members of the legislative committees with jurisdiction over health care and health insurance. |
|  | House only section | Article 2, Section 18. Testimony on use of digital breast tomosynthesis by members of state employee group insurance program. Directs the director of the state employee group insurance program to prepare and submit written testimony to legislative committees by December 31, 2019, on the impact of coverage of digital breast tomosynthesis, and specifies requirements for the testimony. |
|  | House only section | Article 2, section 19. Mental health and substance use disorder parity work group.  Subd. 1. Establishment; membership. Establishes a mental health and substance use disorder parity work group and specifies membership and related requirements.  Subd. 2. First appointments; first meeting; chair. Requires appointments to be made by July 1, 2018. Requires the commissioner of commerce or a designee to convene the first meeting by August 1, 2018, and to act as chair.  Subd. 3. Duties. Requires the work group to 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 plans, and report recommendations to the legislature.  Subd. 4. Report. Requires the work group to submit recommendations to the legislative committees with jurisdiction over health care policy and finance by February 15, 2019. Specifies requirements for the report.  Subd. 5. Expiration. States that the work group expires February 16, 2019, or the day after submitting the required report, whichever is earlier. |
|  | House only section | Article 2, section 20. Repealer. Repeals section 62A.65, subdivision 7a, which excluded short-term coverage from the loss ratio requirements of section 62A.021. |
|  | House only section | Article 4, section 13. Repealer. Repeals § 151.55 (cancer drug repository program). |