Bill Summary Comparison of Health and Human Services

House File 2128-4
Article 5: Prescription Drugs

Senate File UEH2128-1
Article 4: Prescription Drugs and Opiates

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Section	Article 5: Prescription Drugs		Article 4: Prescription Drugs and Opiates
	Article 12, section 1. Exceptions. Amends § 16A.151, subd. 2. Strikes language specifying that money received from opioid manufacturers or opioid wholesale drug distributors will go to the Opioid Stewardship fund, so that money from any source resulting from an opioid-related settlement, assurance of discontinuance, or court order on behalf of the state will be deposited into the fund.	House strikes specific references to opioid manufacturers and wholesalers, so that money from any source resulting from an opioid-related settlement will go to the opiate epidemic response fund. Senate specifies that money from a settlement against consulting firms working for an opioid manufacturer or wholesaler goes to the fund. Senate also requires MMB to make a transfer from the settlement funds in an amount equal to the loss in revenue due to the exemption from the opiate registration fee described in section 151.066, subd. 3.(senate section 7).	**Section 1 (16A.151, subd. 2)** clarifies that any money received by the state from a settlement agreement involving a consulting firm working for an opiate manufacturer or wholesaler must be deposited into the separate account required to be created under this section. It also specifies that any investment income or losses attributable to this account must be credited to the account. It also requires the commissioner of management and budget to transfer from any settlement funds received from a consulting firm and deposited into this separate account to the opiate epidemic response fund an amount that is equal to the loss of revenue to the fund due to the exemption from the opiate registration fee opiates used for medication assisted therapy for substance use disorders.
1	**Definitions.** Adds § 62J.841. Defines the following terms: Consumer Price Index, generic or off-patent drug, manufacturer, prescription drug, wholesale acquisition cost, and wholesale distributor.	Page R2: House only	
2	**Excessive price increases prohibited.** Adds § 62J.842. **Subd. 1. Prohibition.** Prohibits a manufacturer from imposing, or causing to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to consumers in the state. **Subd. 2. Excessive price increase.** Provides that a price increase is excessive when: 1) the price increase, adjusted by the CPI, exceeds: (i) 15 percent of the WAC over the immediately preceding	Page R3: House only	

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	calendar year; or (ii) 40 percent of the WAC over the three immediately preceding calendar years; and 2) the price increase, adjusted by the CPI, exceeds $30 for a 30-day supply, or course of treatment lasting less than 30 days. **Subd. 3. Exemption.** States that it is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the increase is directly attributable to additional costs imposed by the manufacturer.		
3	**Registered agent and office within the state.** Adds § 62J.843. Requires manufacturers of generic or off-patent drugs made available in the state to maintain a registered agent and office within the state.	Page R3: House only	
4	**Enforcement.** Adds § 62J.844. **Subd. 1. Notification.** Requires the commissioner of management and budget and any other state agency that provides or purchases a pharmacy benefit except the Department of Human Services, and any entity under contract with a state agency to provide a pharmacy benefit, other than an entity under contract with the Department of Human Services, to notify the manufacturer of the drug, the attorney general, and the Board of Pharmacy of any price increase of a generic or off-patent drug that violates section 62J.842. **Subd. 2. Submission of drug cost statement and other information by manufacturer; investigation by attorney general.** (a) Requires the manufacturer, within 45 days of	Page R3: House only	

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	receiving notice under subdivision 1, to submit a drug cost statement to the attorney general. Requires the statement to: 1) itemize the cost components related to drug production; 2) identify the circumstances and timing of any increase in materials or manufacturing costs that caused any price increase, in the preceding calendar year or preceding three calendar years as applicable; and 3) provide any other information the manufacturer believes to be relevant. (b) Allows the attorney general to investigate whether a violation has occurred, is occurring, or is about to occur, in accordance with section 8.31, subdivision 2 (general investigative powers of the attorney general). **Subd. 3. Petition to court.** (a) Allows a court, on petition of the attorney general, to issue an order: 1) compelling the manufacturer to provide the drug cost statement, and answer interrogatories, produce records or documents, or be examined under oath, as required by the attorney general; 2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including restoring drug prices to levels that comply with section 62J.842; 3) requiring the manufacturer to account for all revenues resulting from a violation of section 62J.842;		

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	4) requiring the manufacturer to repay all consumers, including third-party payers, any money acquired as a result of a price increase that violates section 62J.842; 5) requiring that all revenues generated from a violation of section 62J.842 be remitted to the state and deposited into a special fund, to be used to reduce consumer drug costs, if the manufacturer is unable to determine the individual transactions necessary to make repayments under clause (4); 6) imposing a civil penalty of up to $10,000 per day for each violation of section 62J.842; 7) providing for the recovery of costs and disbursements incurred by the attorney general in bringing an action; and 8) providing any other appropriate relief, including any other equitable relief as determined by the court. (b) Provides that for purposes of paragraph (a), clause (6), requires every individual transaction in violation of section 62J.842 to be considered a separate violation. **Subd. 4. Private right of action.** States that any action brought by a person injured by a violation of this section is for the benefit of the public.		
5	**Prohibition on withdrawal of generic or off-patent drugs for sale.** Adds § 62J.845. **Subd. 1. Prohibition.** Prohibits a manufacturer of a generic or off-patent drug from withdrawing that drug from sale or	Page R5: House only	

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	distribution in the state for purposes of avoiding the prohibition on excessive price increases. **Subd. 2. Notice to board and attorney general.** Requires any manufacturer that intends to withdraw a generic or off-patent drug from sale or distribution in the state to provide 180 days' written notice of withdrawal to the Board of Pharmacy and the attorney general. **Subd. 3. Financial penalty.** Requires the attorney general to assess a $500,000 penalty on any manufacturer that it determines has failed to comply with the requirements of this section.		
6	**Severability.** Adds § 62J.846. Provides that the provisions of sections 62J.841 to 62J.845 are severable.	Page R5: House only	
		Page R5: Senate only	**Section 2 (62J.85)** creates incentives to drug manufacturers to use the importation pathway created under federal regulations for certain prescription drug products that meet the federal importation guidelines.
7	**Prescription drug benefits.** Amends § 62Q.81, by adding subd. 6. (a) Requires that 25 percent of the individual health plans offered by an insurer apply a predeductible flat-dollar amount co-pay structure for prescription drugs. (b) Requires that 25 percent of the small group health plans offered by an insurer apply a predeductible flat-dollar co-pay structure for prescription drugs.	Page R7: House only	

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	(c) Limits the highest co-pay under this subdivision to 1/12 of the plan's out-of-pocket maximum. (d) Requires the co-pay structure for prescription drugs under this subdivision to be graduated and proportionate. (e) Requires individual and small group health plans offered under this subdivision to be clearly named, marketed in the same way as other health plans, and offered for purchase to any individual or small group. (f) Clarifies that this subdivision does not apply to catastrophic plans, grandfathered plans, large group health plans, health savings accounts (HSA), qualified high deductible health benefit plans, limited health benefit plans, or short-term limited-duration health insurance policies. (g) Requires health plans to meet the requirements of this subdivision separately for plans offered through MNsure under chapter 62V and plans offered outside of MNsure. Effective date: This section is effective January 1, 2022, and applies to individual and small group health plans offered, issued, or renewed on or after that date.		
8	**Prescription drug benefit transparency and management.** Adds § 62Q.83. **Subd. 1. Definitions.** Defines the following terms: drug, enrollee contract term, formulary, health plan company, pharmacy benefits management, and prescription. "Enrollee contract term" is defined as a 12-month term for health plan company products	Page R8: House only	

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	and a calendar quarter for managed care and county-based purchasing plans under MA and MinnesotaCare. **Subd. 2. Prescription drug benefit disclosure.** (a) Requires a health plan company that provides drug coverage and uses a formulary to make its formulary and related benefit information available by electronic means, and upon request in writing, at least 30 days prior to annual renewal dates. (b) Requires formularies to be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's Model Guidelines. (c) Requires the specific enrollee benefit terms, including cost-sharing and out-of-pocket costs, to be identified for each item or category of items on the formulary. **Subd. 3. Formulary changes.** (a) Allows a health plan company, at any time during a contract term, to expand the formulary, reduce copayments or coinsurance, or move a drug to a lower cost benefit category. (b) Allows a health plan company to remove a brand name drug from the formulary or place the drug in a higher cost benefit category only if a generic or multisource drug rated as therapeutically equivalent, or a biologic drug rated as interchangeable, that is at a lower cost to the enrollee, is added, with at least 60 days' notice. (c) Allows a health plan company to change utilization review requirements or move drugs to a higher cost benefit category, that increases enrollee costs during a contract term, only with 60 days'		

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	notice, and provides that the changes do not apply to enrollees taking the drugs for the duration of the contract term. (d) Allows a health plan company to remove drugs from its formulary that have been deemed unsafe by the Food and Drug Administration (FDA), been withdrawn by the FDA or manufacturer, or when an independent source of research, guidelines, or standards has issued drug-specific warnings or recommended changes in drug usage. **Subd. 4. Exclusion.** Exempts health coverage provided through the State Employees Group Insurance Plan (SEGIP) from this section.		
9	**Alternative biological products.** Adds § 62W.0751. **Subd. 1. Definitions.** Defines the following terms: biological product, biosimilar or biosimilar product, interchangeable biological product, and reference biological product. **Subd. 2. Pharmacy and provider choice related to dispensing reference biological products, interchangeable biological products, or biosimilar products.** (a) Prohibits a PBM or health carrier from requiring or demonstrating a preference for a pharmacy or health care provider to prescribe or dispense a single biological product for which there is a U.S. Food and Drug Administration (FDA) approved biosimilar or interchangeable biological product, except as provided in paragraph (b). (b) If a PBM or health carrier elects coverage of a product listed in paragraph (a), requires the PBM or health carrier to also elect equivalent coverage for at least three reference, biosimilar, or	Page R9: House only	

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	interchangeable biological products, or the total number of FDA approved products relative to the reference product if less than three, for which the wholesale acquisition cost (WAC) is less than the WAC of the product listed in paragraph (a). (c) Prohibits a PBM or health carrier from imposing limits on access to a product required to be covered in paragraph (b) that are more restrictive than the limits imposed on a product listed in paragraph (a) or that have the effect of giving preferred status to the product listed in paragraph (a). (d) Provides that the section does not apply to MA, MinnesotaCare, or SEGIP coverage. Provides a January 1, 2022, effective date.		
10	**Gag clause prohibition.** Amends § 62W.11. Provides that a PBM or health carrier must not prohibit a pharmacist or pharmacy from discussing with patients the pharmacy's acquisition cost for a prescription drug and the amount the pharmacy is being reimbursed by the PBM or health carrier for the drug. Also provides that a PBM must not prohibit a pharmacist or pharmacy from discussing with the health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the PBM or the pharmacy's acquisition cost for a drug.	Page R10: Identical	**Section 3 (62W.11)** prohibits pharmacy benefit managers and health carriers from restricting a pharmacy or pharmacist from discussing with an enrollee the pharmacy's acquisition cost for a prescription drug and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug. It also prohibits the pharmacy benefit manager from restricting a pharmacy or pharmacist from discussing with a health carrier the amount the pharmacy is being reimbursed for a drug by the pharmacy benefit manager or the pharmacy's acquisition cost for the drug.
11	**Biosimilar.** Amends § 151.01, by adding subd. 43. Defines "biosimilar" or "biosimilar product" as a biological product that the FDA has licensed and determined to be biosimilar.	Page R11: House only	

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	Provides a January 1, 2022, effective date.		
12	**Reference biological product.** Amends § 151.01, by adding subd. 44. Defines "reference biological product" as the single biological product for which the FDA has approved an initial biological product license application, against which other biological products are evaluated for licensure as biosimilar or interchangeable. Provides a January 1, 2022, effective date.	Page R11: House only	
		Page R11: Senate only	**Section 4 (151.065, subd. 1)** decreases the applications fee for medical gas manufacturers and wholesalers.
		Page R12: Senate only	**Section 5 (151.065, subd. 3)** decreases the renewal licensure fees for medic al gas manufacturers and wholesalers.
		Page R13: Senate only	**Section 6 (151.065, subd. 7)** makes a corresponding change to conform to the change in fees.
		Page R13: Senate only	**Section 7 (151.066, subd. 3)** exempts from the calculation of opiate units distributed within or into the state when determining which opiate manufacturers are going to be required to pay the annual opiate registration fee, any opiate that is used for medication assisted therapy for substance use disorders.
13	**Forms of disciplinary action.** Amends § 151.071, subd. 1. Allows the Board of Pharmacy to impose a civil penalty not exceeding $25,000 for each separate violation of section 62J.842.	Page R14: House only	

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14	**Grounds for disciplinary action.** Amends § 151.071, subd. 2. Provides that a violation of section 62J.842 or section 62J.845 by a manufacturer is grounds for the Board of Pharmacy to take disciplinary action.	Page R15: House only	
15	**Delivery through common carrier; compliance with temperature requirements.** Adds § 151.335. Requires mail order or specialty pharmacies that use the U.S. Postal Service or other common carrier to deliver a drug to a patient to ensure that the drug is delivered in compliance with manufacturer temperature requirements. Requires the pharmacy to develop policies and procedures consistent with the U.S. Pharmacopeia and with nationally recognized standards issued by entities recognized by the board through guidance. Requires the policies and procedures to be provided to the board upon request.	Page R19: House only	
16	**Definitions.** Amends § 151.555, subd. 1. Includes over-the-counter medications in the definition of drugs that may be donated to the drug repository program. Provides an immediate effective date.	Page R19: Identical	**Section 8 (151.555, subd. 1)** includes over the counter drugs to the drug repository program.
17	**Standards and procedures for inspecting and storing donated prescription drugs and supplies.** Amends § 151.555, subd. 7. The amendment to paragraph (b) eliminates the requirement that donated drugs and supplies that are not inspected immediately upon receipt be quarantined separately from dispensing stock until inspection. The amendment to paragraph (f) reduces from five to two years the time period during which a repository must maintain records of drugs and supplies that are destroyed because they are not	Page R20: Identical	**Section 9 (151.555, subd. 7)** removes the requirement that donated drugs be immediately inspected upon receipt and kept separately until inspected and reduces the numbers of years that the repository must keep a record of the donated drugs destroyed from five years to two years.

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	dispensed, subject to recall, or not suitable for donation. Provides an immediate effective date.		
18	**Forms and record-keeping requirements.** Amends § 151.555, subd. 11. Reduces from five to two years the time period during which a repository must maintain all records. Provides an immediate effective date.	Page R21: Identical	**Section 10 (151.555, subd. 11)** reduces the number of years the repository must keep all records that are required to be maintained from five years to two years.
19	**Cooperation.** Amends § 151.555, by adding subd. 14. Allows the central repository, with the approval of the Board of Pharmacy, to enter into an agreement with another state that has a drug repository or drug donation program that meets specified standards, to permit the central repository to offer inventory to another state program, and to accept inventory from another state program. Provides an immediate effective date.	Page R22: Identical	**Section 11 (151.555, subd. 14)** authorizes the central repository to enter into an agreement with another state that has established a drug repository or donation program to offer to the other state inventory that is not needed by a Minnesota resident and to accept inventory from the other state that could be distributed to a Minnesota resident.
	Article 12, section 19. Appropriations from fund. Amends § 256.043, subd. 3. Specifies that grant funds and funds for county and tribal social services agencies from the opiate epidemic response fund will be distributed on a calendar year basis beginning in fiscal year 2022.	Page R22: House requires funds for social service agencies and certain grants to be distributed on a calendar year basis; Senate extends appropriations for results first evaluations and ECHO projects.	**Section 12 (256.043, subd.3)** extends the appropriations from the opiate epidemic response fund for the results first evaluations and for the ECHO projects.
		Page R23: Senate only	**Article 1, section 11 (256.04, subd. 4)** specifies that any funds received by the state as a result of a settlement agreement against a consulting firm working of a n opioid manufacturer or wholesaler shall be counted towards the $250,000,000 amount that triggers the sunset of the opiate licensing fees and the opiate registration fee.

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20	**Service delivery.** Amends § 256B.69, subd. 6. Requires managed care plans and county-based purchasing plans under Medical Assistance to comply with § 62Q.83.	Page R24: House only	
21	**Study of pharmacy and provider choice of biological products.** Requires the commissioner of health, within the limits of existing resources, to analyze the effect of section 62W.0751 on the net price for different payors of biological products, interchangeable biological products, and biosimilar products. Requires the commissioner to report to the legislature by December 15, 2023.	Page R24: House only	
22	**Study of temperature monitoring.** Requires the Board of Pharmacy to study the appropriateness and feasibility of requiring mail order and specialty pharmacies to enclose in each medication's packaging a method for the patient to detect improper storage and temperature violations. Requires the board to report to the legislature by January 15, 2022.	Page R25: House only	
		Page R25: Senate only	**Section 13 [Opiate registration fee reduction]** exempts from the calculation of opiate units distributed within or into the state when determining which opiate manufacturers are going to be required to pay the opiate registration fee due on June 1, 2021, any injectable opiate product distributed to a hospital or hospital pharmacy. It also requires the commissioner of management and budget to transfer an amount into the opiate epidemic response fund that equals the estimated revenue loss due to this exemption.