Bill Comparison Summary of
Senate File 4410 (second unofficial engrossment) / Senate File 4410 (third engrossment)

House Article 6: Prescription Drugs
Senate Article 14: Health-Related Licensing Boards and Scope of Practice

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Comparison Summary of S.F. 4410 – House (S.F. 4410, second unofficial engrossment) / Senate (4410, third engrossment)

Section	HOUSE Article 6: Prescription Drugs		SENATE Article 14: Health-Related Licensing Boards and Scope of Practice
1	**Filing.** Amends § 62A.02, subd. 1. Requires health carriers to include the health plan's prescription drug formulary, when filing premium rates with the commissioner of commerce. Requires proposed formulary revisions to be filed with the commissioner by August 1 of the application years.	House only	
2	**Definitions.** Amends § 62J.497, subd. 1. Adds definitions of NCPDP Real-Time Prescription Benefit Standard, pharmacy benefit manager, and real-time prescription benefit tool to the statute governing the electronic prescription drug program.	House only	
3	**Standards for electronic prescribing.** Amends § 62J.497, subd. 3. In a subdivision establishing standards for electronic prescribing, a new paragraph (f) requires group purchasers and pharmacy benefit managers to use a real-time prescription benefit tool that complies with the NCPDP Real-Time Prescription Benefit Standard and that notifies a prescriber of at least the listed information for a prescribed drug. This section is effective January 1, 2023.	House only	
4	**Prescription drug price transparency.** Amends § 62J.84.	House only	

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	The amendment to subdivision 2 adds definitions of: course of treatment, National Drug Code, rebate, and 30-day supply. The amendment to subdivision 3 modifies reporting requirements for prescription drugs for which the price was $100 or greater for a 30-day supply or course of treatment lasting less than 30 days, and for which the increase in price exceeds specified thresholds, by: ▪ requiring reporting for biosimilar drugs with a price increase of 50 percent or more; ▪ requiring the manufacturer to provide a description of the drug, and to list the following information separately: National Drug Code, product name, dosage form, strength, and package size; ▪ clarifying the meaning of introductory price and requiring reporting of the price of the drug on the last day of each of the five calendar years preceding the price increase; ▪ requiring direct costs incurred and financial assistance provided to be reported for the previous 12-month period; ▪ clarifying the reporting of the ten highest prices in other countries; and ▪ requiring specified information to be reported if the drug was acquired by the manufacturer during the previous 12-month period.		

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	The amendment to subdivision 4 modifies reporting requirements for new prescription drugs with prices that exceed specified thresholds, by: ▪ clarifying that the tier price threshold also applies to a course of treatment lasting less than 30 days; and ▪ requiring the manufacturer to provide a description of the drug, and to list the following information separately: National Drug Code, product name, dosage form, strength, and package size. Strikes subdivision 5 of current law, related to reporting requirements for newly acquired prescription drugs; similar language is found in subdivision 3, as amended.		
5	**Definitions.** Amends § 62J.84, subd. 2. Applies the definitions in this subdivision (related to prescription drug transparency reporting) to § 62J.841.	House only	
6	**Definitions.** Amends § 62J.84, subd. 2. Adds definitions for drug product family, pharmacy or pharmacy provider, pharmacy benefit manager, pricing unit, reporting entity, and wholesale drug distributor or wholesaler to a subdivision defining terms for the Prescription Drug Price Transparency Act.	House only	

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7	**Public posting of prescription drug price information.** Amends § 62J.84, subd. 6. Requires the commissioner of health to post drug pricing and related information reported under § 62J.841, subd. 2, on the agency website. Also provides that the prohibition on posting trade secret information does not apply to this drug pricing and related information, reported under § 62J.841, subd. 2, paragraph (e), if that information is classified by the manufacturer as trade secret information. (This information is classified as public data under paragraph (e) of that subdivision; paragraph (e) also prohibits a manufacturer from classifying the information reported as trade secret information.)	House only	
8	**Public posting of prescription drug price information.** Amends § 62J.84, subd. 6. Adds the following to the list of prescription drugs and information that must be posted on the Health Department's website: prescription drugs and information reported by manufacturers, pharmacies, pharmacy benefit managers (PBMs), and wholesalers for prescription drugs determined to represent a substantial public interest.	House only	
9	**Consultation.** Amends § 62J.84, subd. 7. Allows the commissioner to consult with a private entity or consortium for assistance in collecting and posting the drug pricing and related information collected under § 62J.841. (Under current law, the commissioner may consult with this entity or consortium to implement prescription drug transparency reporting.)	House only	

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10	**Consultation.** Amends § 62J.84, subd. 7. Permits the commissioner to consult with all reporting entities, not just manufacturers, to establish a standard reporting format that minimizes administrative burden.	House only	
11	**Enforcement and penalties.** Amends § 62J.84, subd. 8. Allows the commissioner of health to impose civil penalties on manufacturers for: 1) failing to submit timely reports or notices as required by section 62J.841; 2) failing to provide information required by section 62J.841; 3) providing inaccurate or incomplete information under section 62J.841; and 4) classifying drug price and other information submitted under section 62J.841 as trade secret information or increasing the wholesale acquisition cost for drugs subject to price reporting and included in a health plan formulary, for the next calendar year. Also makes conforming changes.	House only	
12	**Enforcement and penalties.** Amends 62J.84, subd. 8. Provides that penalties apply to any reporting entity that fails to register or that fails to submit	House only	

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	timely or complete reports, and authorizes the commissioner to impose a penalty for failing to register with the commissioner.		
13	**Legislative report.** Amends § 62J.84, subd. 9. Modifies requirements for the annual report to the legislature related to drug transparency, to: 1) include reporting related to section 62J.841; and 2) to require the commissioner to assess whether reporting promotes pricing transparency for health carriers and assists health carriers in managing drug costs and limiting formulary changes due to cost increases during a coverage year.	House only	
14	**Legislative report.** Amends § 62J.84, subd. 9. In addition to existing requirements for content of an annual report to the legislature, requires the annual report on implementation of the prescription drug price transparency actions to include summary information submitted to the commissioner by manufacturers, pharmacies, PBMs, and wholesalers for prescription drugs determined to represent a substantial public interest.	House only	
15	**Notice of prescription drugs of substantial public interest.** Adds subd. 10 to § 62J.84. By January 31, 2023, and quarterly thereafter, requires the commissioner to post on the department's website a list of prescription drugs that the department determines represent a substantial public interest and for which the department intends to request data under	House only	

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	subdivisions 11 to 14. Describes drug product families that the department should consider. Requires the department to provide notice to reporting entities of drugs so designated, and limits this designation to 500 or fewer prescription drugs in any one notice.		
16	**Manufacturer prescription drug substantial public interest reporting.** Adds subd. 11 to § 62J.84. Beginning January 1, 2023, requires a manufacturer to submit the listed information, in a form and manner specified by the commissioner, for any prescription drug included in a notification to report issued by the department which the manufacturer manufactures or repackages, for which the manufacturer sets a wholesale acquisition cost, and for which the manufacturer has not submitted data under this section in the 120 days prior to the notification from the department. Allows the manufacturer to submit any documentation needed to support the information reported.	House only	
17	**Pharmacy prescription drug substantial public interest reporting.** Adds subd. 12 to § 62J.84. Beginning January 1, 2023, requires a pharmacy to submit to the commissioner the listed information for any prescription drug included in a notification to report issued by the department to the pharmacy. Allows the pharmacy to submit any documentation needed to support information reported.	House only	

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18	**Pharmacy benefit manager (PBM) prescription drug substantial public interest reporting.** Adds subd. 13 to § 62J.84. Beginning January 1, 2023, requires a PBM to submit to the commissioner the listed information for any prescription drug included in a notification to report issued by the department to the PBM. Allows the PBM to submit any documentation needed to support the information reported.	House only	
19	**Wholesaler prescription drug substantial public interest reporting.** Adds subd. 14 to § 62J.84. Beginning January 1, 2023, requires a wholesaler to submit to the commissioner the listed information for any prescription drug included in a notification to report issued by the department to the wholesaler. Allows the wholesaler to submit any documentation needed to support the information reported.	House only	
20	**Registration requirement.** Adds subd. 15 to § 62J.84. Beginning January 1, 2023, requires a reporting entity to register with the department in a form and manner specified by the commissioner.	House only	
21	**Rulemaking.** Adds subd. 16 to § 62J.84. Allows the commissioner to use the expedited rulemaking process under section 14.389.	House only	

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22	**Reporting prescription drug prices; formulary development and price stability.** Adds § 62J.841. **Subd. 1. Definitions.** Defines the following terms: average wholesale price, national drug code, wholesale acquisition cost, and unit. **Subd. 2. Price reporting.** (a) Requires drug manufacturers, beginning July 31, 2023, and each July 31 thereafter, to report the information in paragraph (b) for each drug with a wholesale acquisition cost of $100 or more (for a 30-day supply or course of treatment lasting less than 30 days), for the next calendar year. (b) Requires manufacturers to report a drug's: 1) national drug code, labeler code, and manufacturer name associated with the labeler code; 2) brand name, if applicable; 3) generic name, if applicable; 4) wholesale acquisition cost (WAC) for one unit; 5) measure that constitutes a WAC unit; 6) average wholesale price; and 7) status as brand name or generic. (c) Requires the effective date of the information in (b) to be included in the report to the commissioner.	House only	

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	(d) Requires a manufacturer to report information in the form and manner specified by the commissioner. (e) Classifies the information reported under this subdivision as public data not on individuals, and prohibits manufacturers from classifying the information as trade secret. (f) Provides that the failure of a manufacturer to report required information is grounds for disciplinary action by the Board of Pharmacy. **Subd. 3. Public posting of prescription drug price information.** Requires the commissioner, by October 1 of each year, beginning October 1, 2023, to post the information reported under subdivision 2 on the department's website. **Subd. 4. Price change.** (a) If a drug is subject to price reporting under subdivision 2 and has been included in a health plan formulary that has been approved by the commissioner of commerce, allows the manufacturer to increase the WAC of that drug for the next calendar year only after providing at least 90 days' written notice. (b) States that a manufacturer's failure to comply with paragraph (a) is grounds for disciplinary action by the Board of Pharmacy.		

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23	**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.	House only	
24	**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 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	House only	

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	directly attributable to additional costs imposed by the manufacturer.		
25	**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.	House only	
26	**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, 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 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;	House only	

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	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; 4) repaying 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		

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	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.		
27	**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 distribution in the state for purposes of avoiding the prohibition on excessive price increases.	House only	

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	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.** Allows 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.		
28	**Severability.** Adds § 62J.846. Provides that the provisions of sections 62J.841 to 62J.845 are severable.	House only	
29	**Citation.** Adds § 62J.85. States that sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."	House only	
30	**Definitions.** Adds § 62J.86. Defines the following terms: advisory council, biologic, biosimilar, board, brand name drug, generic drug, group purchaser, manufacturer, prescription drug product, and wholesale acquisition cost (WAC).	House only	
31	**Prescription Drug Affordability Board.** Adds § 62J.87.	House only	

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	Subd. 1. Establishment. Requires the Legislative Coordinating Commission to establish the Prescription Drug Affordability Board to protect consumers, state and local governments, health plan companies, providers, pharmacies, and other stakeholders from unaffordable costs of certain prescription drugs. **Subd. 2. Membership.** (a) Provides that the board consists of seven members – three appointed by the governor, one by the majority leader and one by the minority leader of the Senate, and one by the speaker of the House and one by the House minority leader. (b) Requires members to have knowledge and expertise in pharmaceutical economics and finance or health care economics and finance, and not be an employee or board member of, or consultant to, a manufacturer or trade association for manufacturers or a pharmacy benefit manager or trade association for pharmacy benefit managers. (c) Requires initial appointments to be made by January 1, 2023. **Subd. 3. Terms.** States that appointees serve four-year terms, except that initial appointees shall serve staggered terms. Prohibits members from serving more than two consecutive terms. Allows members to resign at any time by giving written notice.		

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	Subd. 4. Chair; other officers. Specifies the procedure to be used for designating and electing the chair, vice-chair, and other officers. **Subd. 5. Staff; technical assistance.** (a) Requires the board to hire an executive director and other staff, and specifies required qualifications for the executive director. Allows the board to employ or contract for professional and technical assistance. (b) Requires the attorney general to provide legal services to the board. **Subd. 6. Compensation.** States that members shall not receive compensation but may be reimbursed for expenses. **Subd. 7. Meetings.** Applies the open meetings law to the board. Requires the board to meet publicly at least every three months to review prescription drug product information that is submitted, and to allow for public comment. Specifies other requirements related to meetings.		
32	**Prescription Drug Affordability Advisory Council.** Adds § 62J.88. **Subd. 1. Establishment.** Requires the governor to appoint an advisory council to advise the commission on drug cost	House only	

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	issues and represent stakeholder views. Specifies criteria related to knowledge and expertise of members. **Subd. 2. Membership.** Specifies membership. **Subd. 3. Terms.** Requires initial appointments to be made by January 1, 2022, and specifies requirements for staggered and regular terms and removal and vacancies. **Subd. 4. Compensation.** Provides that members receive compensation according to the standard procedures that apply to advisory councils and committees. **Subd. 5. Meetings.** States that the council is subject to the Open Meeting Law and requires the council to meet at least every three months. **Subd. 6. Exemption.** Provides that the council does not expire.		
33	**Conflicts of interest.** Adds § 62J.89. **Subd. 1. Definition.** Defines "conflict of interest." **Subd. 2. General.** Requires board and advisory council members, board staff, and third-party contractors to disclose any conflicts of interest prior to entering into any appointment, employment, or contract. Specifies recusal and disclosure requirements.	House only	

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	Subd. 3. Prohibitions. Prohibits board and advisory council members, board staff, or third-party contractors from accepting gifts, bequeaths, or donations that raise the specter of a conflict of interest or have the appearance of injecting bias.		
34	**Prescription drug price information; decision to conduct cost review.** Adds § 62J.90. **Subd. 1. Drug price information from the commissioner of health and other sources.** (a) Requires the commissioner of health to provide the board with the information provided to the commissioner by drug manufacturers under § 62J.84, subd. 3, 4, and 5, within 30 days of the date the information is received. (b) Directs the board to subscribe to one or more prescription drug pricing files. **Subd. 2. Identification of certain prescription drug products.** (a) Requires the board, in consultation with the advisory council, to identify the following drug products: (1) brand name drugs or biologics for which the WAC increases by more than 10 percent or by more than $10,000 during any 12- month period or course of treatment if less than 12 months, after adjusting for changes in the CPI;	House only	

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	(2) brand name drugs or biologics that have been introduced at a WAC of $30,000 or more per calendar year or course of treatment; (3) biosimilar drugs that have been introduced at a WAC that is not at least 15 percent lower than the referenced brand name biologic; and (4) generic drugs for which the WAC is: (i) $100 or more, after adjusting for changes in the CPI, for: (A) a 30-day supply; (B) a supply lasting less than 30 days; or (C) one unit of the drug if FDA labeling does not recommend a finite dosage; and (ii) increased by 200 percent or more during the preceding 12-month period, after adjusting for changes in the CPI. (b) Requires the board, in consultation with the advisory council, to identify prescription drug products not described in paragraph (a), that may impose costs that create significant affordability challenges for the state health care system or patients, including but not limited to drugs to address public health emergencies. (c) Requires the board to make available to the public the names and price information of the prescription drug products identified under this subdivision, with the exception of information determined by the board to be proprietary.		

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	Subd. 3. Determination to proceed with review. (a) Allows the board to initiate a review of the cost of a prescription drug product identified by the board under this section. (b) Requires the board to consider public requests for a cost review of any prescription drug product identified under this section. (c) If there is no consensus on whether to review a drug, allows any member of the board to request a vote on whether to review.		
35	**Prescription drug product reviews.** Adds § 62J.91. **Subd. 1. General.** Upon a decision to proceed with a cost review, requires the board to conduct the review and determine whether appropriate utilization of the drug, based on the FDA label and standard medical practice, has led or will lead to affordability challenges for the state health care system or for patients. **Subd. 2. Review considerations.** Specifies the factors the board may consider in reviewing the cost of a prescription drug product. The specified factors are: selling price of the drug; average monetary price concession, discount, or rebate provided to group purchasers; price of therapeutic alternatives; the average concession, discount, or rebate provided for these alternatives; cost to group purchasers; impact on patient access relative to cost and insurance design; the value of patient access programs; financial	House only	

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	impact relative to baseline effects of existing alternatives; co-pays and cost-sharing; any information provided by the manufacturer; and any other factors determined by the board. **Subd. 3. Further review factors.** If the commission, after considering the factors listed under subdivision 2, is unable to determine whether the drug has produced or will produce an affordability challenge, allows the commission to consider the following additional factors: research and development costs; direct-to-consumer marketing costs; gross and net manufacturer revenues; specified factors related to the selection of the introductory price or price increase; and additional factors determined by the board to be relevant. **Subd. 4. Public data; proprietary information.** (a) Requires submissions to the board related to a drug cost review to be made public, with the exception of information the board determines is proprietary. (b) Requires the board to establish standards for proprietary information. (c) Requires the board to provide public notice and an opportunity for public comment prior to establishing standards under paragraph (b).		
36	**Determinations; compliance; remedies.** Adds § 62J.92.	House only	

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	Subd. 1. Upper payment limit. (a) If the board determines that spending on a prescription drug product creates an affordability challenge, directs the board to establish an upper payment limit after considering the cost of administering the drug, cost of delivering the drug to consumers, the range of prices at which the drug is sold in the U.S. and the range of pharmacy reimbursement in Canada, and other relevant pricing and administrative cost information. (b) States that the upper payment limit applies to all public and private purchases, payments, and payer reimbursements for the drug product intended for individuals in the state in person, by mail, or other means. **Subd. 2. Noncompliance.** (a) Requires noncompliance by an entity to comply with an upper payment limit set by the board to be referred to the attorney general. (b) If the attorney general finds that an entity was noncompliant, allows the attorney general to pursue remedies under chapter 8 or appropriate criminal charges if there is evidence of intentional profiteering. (c) Provides that an entity that obtains price concessions from a manufacturer that result in a lower net cost to the stakeholder than the limit established by the board shall not be considered noncompliance.		

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	(d) Allows the attorney general to provide guidance to stakeholders on activities that could be considered noncompliant. **Subd. 3. Appeals.** Allows appeals of board decisions and specifies procedures.		
37	**Reports.** Adds § 62J.93. Requires the board, beginning March 1, 2023, and each March 1 thereafter, to report to the governor and legislature on general price trends in prescription drug products and the number of drugs subject to the board's cost review and analysis, including the result of any analysis and the number and disposition of appeals and judicial reviews.	House only	
38	**ERISA plans and Medicare drug plans.** Adds § 62J.94. (a) States that nothing in sections 62J.85 to 62J.95 shall be construed to require ERISA plans or Medicare Part D plans to comply with board decisions. Provides that these plans are free to exceed the upper payment limit set by the board. (b) Requires providers who dispense and administer drugs in the state to bill all payers no more than the upper payment limit without regard to whether or not an ERISA plan or Medicare Part D plan chooses to reimburse the provider in an amount greater than the upper payment limit. (c) Defines an ERISA plan or group health plan.	House only	

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39	**Severability.** Adds § 62J.95. Provides that sections 62J.85 to 62J.94 are severable.	House only	
40	**Prohibition on use of step therapy for antiretroviral drugs.** Adds § 62Q.1842. **Subd. 1. Definitions.** Defines "health plan" and "step therapy protocol." Health plan is defined to include managed care and county-based purchasing plans, and integrated health partnerships, under MA and MinnesotaCare, as well as private sector plans. **Subd. 2. Prohibition on use of step therapy protocols.** Prohibits a health plan that covers antiretroviral drugs for the prevention of HIV/AIDS, from limiting or excluding coverage by requiring prior authorization for the drugs or by requiring an enrollee to follow a step therapy protocol.	House only	
41	**Cost-sharing for prescription drugs and related medical supplies to treat chronic disease.** Adds § 62Q.481. **Subd. 1. Cost-sharing limits.** Requires a health plan to limit any enrollee cost-sharing for prescription drugs prescribed to treat a chronic disease to no more than $25 per one-month supply for each prescription drug and to no more than $50 per month in total for all related medical supplies. States that this coverage is not subject to any deductible.	House only	

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	(b) Provides that if application of this section before an enrollee has met their deductible would result in health savings account ineligibility, then this section shall apply to the drug or related medical supply only after the deductible has been met. **Subd. 2. Definitions.** Defines the following terms: chronic disease, cost-sharing, and related medical supplies. "Chronic disease" is defined as diabetes, asthma, and allergies requiring the use of epinephrine auto-injectors. States that the section is effective January 1, 2023, and applies to health plans offered, issued, and renewed on or after that date.		
42	**Coverage for drugs to prevent the acquisition of human immunodeficiency virus.** Adds § 62Q.54. (a) Requires a health plan that provides prescription drug coverage to also cover, in accordance with this section: 1) any antiretroviral drug approved by the FDA for preventing HIV that is prescribed, dispensed, or administered by a pharmacist meeting the requirements of section 151.37, subd. 17; and 2) any laboratory testing necessary for therapy that uses the drugs, that is ordered, performed, and interpreted by a pharmacist who meets the requirements of section 151.37, subd. 17.	House only	

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	(b) Requires a health plan to provide the same terms of coverage for drugs to prevent HIV that are prescribed or administered by a pharmacist who meets the requirements of section 151.37, subd. 17, as would apply had the drug been prescribed or administered by a physician, physician assistant, or advanced practice registered nurse. Allows plans to require pharmacists or pharmacies to meet reasonable medical management requirements, if other providers must meet the same requirements. (c) Requires a health plan to reimburse an in-network pharmacy or pharmacist for the drugs and testing described in paragraph (a) at a rate equal to that provided to a physician, physician assistant, or advanced practice registered nurse providing similar services. (d) Provides that a health plan is not required to cover the drugs and testing described in paragraph (a) if provided by a pharmacist or pharmacy that is out-of-network, unless the plan covers similar services provided by out-of-network providers. Requires plans to ensure that their provider network includes in-network pharmacies that provide the services described in paragraph (a).		
43	**Prescription drug benefit transparency and management.** Adds § 62Q.83. **Subd. 1. Definitions.** Defines the following terms for this section: drug, enrollee contract term, formulary, health plan company, and prescription.	House only	

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	Subd. 2. Prescription drug benefit disclosure. Paragraph (a) requires a health plan company that provides prescription drug coverage and uses a formulary to make the plan's formulary and related benefit information available at least 30 days before annual renewal dates. Paragraph (b) requires formularies to be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's Model Guidelines. Paragraph (c) requires the specific enrollee benefit terms, including cost-sharing and expected out-of-pocket costs, to be identified for each item or category of items on the formulary. **Subd. 3. Formulary changes.** Paragraph (a) allows a health plan company, at any time during a contract term, to expand its formulary, reduce copayments or coinsurance, or move a drug to a benefit category that reduces an enrollee's cost. Paragraph (b) allows a health plan company to remove a brand name drug from the formulary or place a brand name drug in a benefit category that increases the enrollee's cost if the health plan company also adds a generic or multisource brand name drug rated as therapeutically equivalent, or a biologic drug rated as interchangeable, that is at a lower cost to the enrollee. The health plan company must also provide at least 60 days' notice before making this change.		

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	Paragraph (c) allows a health plan company to change utilization review requirements or move drugs to a benefit category that increases an enrollee's cost during the contract term with at least 60 days' notice. Specifies that these changes do not apply to enrollees currently taking these drugs for the duration of the enrollees' contract terms. Paragraph (d) allows a health plan company to remove a drug from the plan's formulary if the drug has been deemed unsafe by the Food and Drug Administration or withdrawn by the FDA or the product manufacturer, or when an independent source of research, clinical guidelines, or evidence-based standards issues drug-specific warnings or recommends changes in drug use. **Subd. 4. Not severable.** States that this section is not severable from specified amendments and enactments in this act. If any of these provisions is found to be void for any reason, this section is also void. This section is effective January 1, 2024, and applies to health plans offered, sold, issued, or renewed on or after that date.		
44	**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.	House only	

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	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 reference biological product administered to a patient by a physician or health care provider or any product that is biosimilar or interchangeable to the reference biological product. (b) If a PBM or health carrier elects coverage of a product listed in paragraph (a), and there are two or less biosimilar or interchangeable products available relative to the reference product, requires the PBM or health carrier to elect equivalent coverage for all of the products that are biosimilar or interchangeable to the reference biological product. (c) If a PBM or health carrier elects coverage of a product listed in paragraph (a), and there are greater than two biosimilar or interchangeable products available relative to the reference product, requires the PBM or health carrier to elect preferential coverage for all of the products that are biosimilar or interchangeable to the reference biological product. (d) 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		

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	giving preferred status to the product listed in paragraph (a). (d) States that this section applies only to new administrations of a reference biological product, and that nothing in the section requires a patient on an active course of treatment to switch from a prescribed reference biological product. Provides a January 1, 2023, effective date.		
45	**Clinician-administered drugs.** Adds § 62W.15. **Subd. 1. Definitions.** Defines "affiliated pharmacy" and "clinician-administered drug." **Subd. 2. Prohibition on requiring coverage as a pharmacy benefit.** Prohibits a PBM or health carrier from requiring that a clinician-administered drug, or the administration of a clinician-administered drug, be covered as a pharmacy benefit. **Subd. 3. Enrollee choice.** Provides that a PBM or health carrier: 1) shall permit an enrollee to obtain a clinician-administered drug from a health care provider authorized to administer the drug, or a pharmacy; 2) shall not interfere with the enrollee's right to obtain the clinician-administered drug from their	House only	

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	provider or pharmacy of choice, and shall not offer financial or other incentives to influence the enrollee's choice; 3) shall not require the clinician-administered drug to be dispensed by a pharmacy selected by the PBM or health carrier; and 4) shall not limit or exclude coverage for a clinician-administered drug when it is not dispensed by a pharmacy selected by the PBM or health carrier, if the drug would otherwise be covered. **Subd. 4. Cost-sharing and reimbursement.** Provides that a PBM or health carrier: 1) may impose coverage or benefit limitations on an enrollee who obtains a clinician-administered drug from a health care provider or pharmacy, only if these limitations would also be imposed if the drug was obtained from an affiliated pharmacy or a pharmacy selected by the PBM or health carrier; and 2) may impose cost-sharing requirements on an enrollee who obtains a clinician-administered drug from a health care provider or pharmacy, only if this cost-sharing would also be imposed if the drug was obtained from an affiliated pharmacy or a pharmacy selected by the PBM or health carrier. **Subd. 5. Other requirements.** Provides that a PBM or health carrier:		

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	1) shall not require or encourage the dispensing of a clinician-administered drug in a manner inconsistent with supply chain security controls and chain of distribution set by the Drug Supply Chain Security Act; 2) shall not require a specialty pharmacy to dispense a clinician-administered medication directly to a patient with the intent that the patient transport the medication to a health care provider for administration; and 3) may offer, but shall not require, the use of a home infusion pharmacy to dispense or administer clinician-administered drugs to enrollees, and the use of an infusion site external to the provider's office or clinic. States that this section is effective January 1, 2023.		
46	**Practitioner.** Amends § 151.01, subd. 23. Includes in the definition of "practitioner" a pharmacist authorized to prescribe drugs to prevent HIV under section 151.37, subd. 17.	House only	
47	**Practice of pharmacy.** Amends § 151.01, subd. 27. Includes the following in the definition of the practice of pharmacy: ▪ prescribing, dispensing, and administering drugs to prevent HIV, if the pharmacist meets the requirements of section 151.37, subd. 17; and	House only	

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	▪ ordering, conducting, and interpreting laboratory tests necessary for therapies that use drugs to prevent HIV, if the pharmacist meets the requirements of section 151.37, subd. 17.		
48	**Biosimilar product.** Amends § 151.01, by adding subd. 43. Defines "biosimilar" or "interchangeable biological product" as a biological product that the FDA has licensed and determined to be biosimilar. Provides a January 1, 2023, effective date.	House only	
49	**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, 2023, effective date.	House only	
50	**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.	House only	
51	**Grounds for disciplinary action.** Amends § 151.071, subd. 2. Classifies the failure of a drug manufacturer to comply with the requirements of § 62J.841 (drug price reporting and prohibition on certain drug price	House only	

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	changes) as grounds for disciplinary action by the Board of Pharmacy.		
52	**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.	House only	
53	**Delivery through common carrier; compliance with temperature requirements.** Amends § 151.335. Requires a mail order or specialty pharmacy, when complying with manufacturer temperature requirements for drugs, to include with each delivered prescription a device recognized by the United States Pharmacopeia by which the patient can easily detect improper storage or temperature variations.	House only	
54	**Drugs for preventing the acquisition of HIV.** Amends § 151.37, by adding subd. 17. (a) States that a pharmacist is authorized to prescribe and administer drugs to prevent HIV in accordance with this subdivision. (b) Requires the Board of Pharmacy, by January 1, 2023, to develop a standardized protocol for a pharmacist to follow in prescribing drugs under paragraph (a). Allows the board to consult with specified groups in developing the protocol. (c) Before a pharmacist is authorized to prescribe a drug under paragraph (a), requires the pharmacist to successfully complete	House only	

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	a training program specifically developed for prescribing drugs to prevent HIV, offered by a college of pharmacy, an accredited continuing education provider, or a program approved by the board. Requires the pharmacist to complete continuing education requirements as specified by the board, in order to maintain authorization to prescribe. (d) Before prescribing a drug under paragraph (a), requires the pharmacist to follow the appropriate standardized protocol. (e) Before dispensing a drug under paragraph (a), requires the pharmacist to provide counseling and specified information to the patient. (f) Prohibits a pharmacist from delegating prescribing authority under this subdivision. Allows a pharmacist intern to prepare the prescription, but requires a pharmacist authorized to prescribe under this subdivision to review, approve, and sign the prescription, before the prescription is processed or dispensed. (g) States that nothing in the subdivision prohibits a pharmacist from participating in the initiation, management, modification, and discontinuation of drug therapy according to a protocol authorized in this section and section 151.01, subd. 27 (authorization for participation in drug therapy under the definition of the practice of pharmacy).		

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55	**Medication repository program.** Amends § 151.555, as amended by Laws 2021, chapter 30, article 5, sections 2 to 5. The amendment to subd. 2 specifies criteria for the contract between the board of pharmacy and the central repository. These criteria include requirements that: 1) the board transfer to the central repository any money appropriated for operating the medication repository program, and the central repository spend this money only for purposes specified in the contract; 2) the central repository report on specified performance measures to the board; and 3) the board annually audit expenditures by the central repository of funds appropriated by the legislature and transferred by the board to the repository. Amendments throughout the section change the name of the program from the prescription drug repository program to the medication repository program, change references to “drug” to “medication,” and remove references to “prescription” drugs. A new subdivision 15 allows the central repository to seek grants or other funds from nonprofit charitable organizations, the federal government, and other sources, to fund the operation of the medication repository program.	House only	

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56	**Intractable pain.** Amends § 152.125. **Subd. 1. Definitions.** Provides new definitions of: drug diversion, palliative care, and rare disease. Also modifies the definition of intractable pain to list associated conditions. Makes various clarifying changes. **Subd. 1a. Criteria for the evaluation and treatment of intractable pain.** Provides that the evaluation and treatment of intractable pain is governed by the following criteria: 1) a diagnosis of intractable pain by a treating physician and by a physician specializing in pain medicine or a physician treating the part of the body that is the source of pain, is sufficient to meet the definition of intractable pain; and 2) the cause of the diagnosis of intractable pain must not interfere with medically necessary treatment, including but not limited to prescribing or administering a controlled substance. **Subd. 2. Prescription and administration of controlled substances for intractable pain.** (a) Adds references to advanced practice registered nurses and physician assistants prescribing or administering a controlled substance in the course of treatment of intractable pain. Provides that these individuals shall not be subject to disciplinary action by the Board of Nursing for appropriately prescribing or administering a controlled	Subd. 1: Differences in definition of intractable pain – House states that examples "sometimes but do not always include" specified conditions; Senate language reads "include but are not limited to" specified conditions. Senate adds references to advance practice registered nurses and physician assistants; House does not. Subd. 1a: Senate adds references to advance practice registered nurses and physician assistants; House does not. Otherwise identical. Subd. 2: House in (b) exempts prescribers of dosages above MME recommendations from "any civil or criminal action or investigation"; Senate does not. Technical difference in (c) – staff recommend Senate.	**Article 14, Section 27 (152.125)** makes modifications to the prescribing criteria for controlled substances when treating intractable pain. **Subdivision 1** adds definitions for drug diversion, palliative care, and rare disease. **Subd. 1a** establishes criteria for the evaluation and treatment of intractable pain when treating a nonterminally ill patient. **Subd. 2, paragraph (a)** authorizes advanced practice registered nurses and physician assistants to prescribe or administer a controlled substance to a patient as part of the patient's treatment of a diagnosed condition causing intractable pain. Requires the provider to enter into a patient-provider agreement. **Paragraph (b)** states that a prescriber shall not be subject to any investigation, termination, or disenrollment by either the commissioner of health or human services solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent dosage recommendations or thresholds specified in state or federal opioid prescribing guidelines or policies. **Paragraph (c)** prohibits a prescriber who is treating intractable pain with a controlled substance from tapering a patient's medication dosage solely to meet a predetermined dosage recommendation or threshold if the patient is stable and compliant with the treatment plan;

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	substance for intractable pain if specified conditions are met. Adds as a new condition that physicians, advanced practice registered nurses, and physician assistants enter into a patient-provider agreement. (b) Provides that a physician, advanced practice registered nurse, or physician assistant, acting in good faith and based on the needs of the patient, shall not be subject to civil or criminal action or investigation, disenrollment, or termination by the commissioners of health or human services, solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent (MME) dosage recommendations or thresholds specified in state or federal opioid prescribing guidelines or policies. Specifies that these guidelines or policies include, but are not limited to: the Guideline for Prescribing Opioids for Chronic Pain issued by the Center for Disease Control and Prevention, Minnesota opioid prescribing guidelines, the Minnesota opioid prescribing improvement program, and the Minnesota quality improvement program. (c) Prohibits a physician, advanced practice registered nurse, or physician assistant treating intractable pain from tapering a patient's controlled substance medication solely to meet a predetermined MME dosage recommendation or threshold, if the patient is stable and compliant with the treatment plan, is not experiencing serious harm from the level of medication, and is in compliance with the patient-provider agreement.	House in (e) requires health plan companies and PBMs under contract to comply with federal SUPPORT act requirements; Senate does not. Otherwise identical.	is experiencing no serious harm from the level of medication prescribed and is in compliance with the patient-provider agreement. **Paragraph (d)** specifies that a prescriber's decision to taper a patient's medication dosage must be based on factors other than a morphine milligram equivalent recommendation or threshold. **Paragraph (e)** specifies that no pharmacist, health plan company, or pharmacy benefit manager shall refuse to fill a prescription for an opiate issued by a licensed practitioner authorized to prescribe opiates solely on the prescription exceeding a predetermined morphine milligram equivalent dosage recommendation or threshold. **Subd. 3 and 4** add advanced practice registered nurse and physician assistant to these subdivisions. Make other technical changes. **Subd. 5, paragraph (a)** requires the prescriber and patient to enter into an agreement that includes the patient's and prescriber's expectations, responsibilities, and rights according to the best practices and current standard of care. **Paragraph (b)** requires that the agreement be signed by the patient and the prescriber, and a copy of the agreement included with the patient's medical record and be provided to the

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	(d) Provides that a decision to taper a patient's medication dosage must be based on factors other than an MME recommendation or threshold. (e) Prohibits a pharmacist, health plan company, or pharmacy benefit manager from refusing to fill a prescription for an opiate based solely on the prescription exceeding a predetermined MME dosage recommendation or threshold. Requires health plan companies that participate in MA and MinnesotaCare, and related PBMs, to comply with federal SUPPORT Act requirements related to safety edits and claims review. **Subd. 3. Limits on applicability.** Provides that the section does not apply to patients known to be using controlled substances for drug diversion. Also makes clarifying and conforming changes. **Subd. 4. Notice of risks.** Makes conforming changes, adding references to advanced practice registered nurses and physician assistants and the patient-provider agreement. Also requires discussions of treatment for intractable pain using controlled substances to be held with the patient's legal guardian, if applicable. **Subd. 5. Patient-provider agreement.** (a) Before treating a patient for intractable pain, requires a physician, advanced practice registered nurse, or physician assistant, and the patient or legal guardian if applicable, to mutually agree to the treatment and enter into a patient-provider agreement. Requires the agreement to include a description of the	Subd. 3: Identical Subd. 4: Identical Subd. 5: Identical	patient. **Paragraph (c)** requires the agreement to be reviewed at least annually and if there is a change to the patient's treatment plan, the agreement must be revised and updated and signed by the patient with a copy provided to the patient and included in the patient's medical record. **Paragraph (d)** specifies that a patient provider agreement is not required in an emergency or inpatient hospital setting.

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	prescriber's and patient's expectations, responsibilities, and rights according to best practices and current standards of care. (b) Requires the agreement to be signed by the parties, and included in the patient's medical records. Requires a copy of the signed agreement to be provided to the patient. (c) Requires the agreement to be reviewed by the patient and the provider annually. Specifies requirements related to updated and revised agreements. (d) States that a patient-provider agreement is not required in an emergency or inpatient hospital setting.		
57	**Drugs.** Amends § 256B.0625, subd. 13. Requires MA coverage of, and reimbursement for, antiretroviral drugs to prevent HIV, and any laboratory testing necessary for therapy using these drugs, to meet the requirements that would otherwise apply to a health plan under section 62Q.524. This requirement also applies to MinnesotaCare by cross-reference in other law.	House only	
58	**Prior authorization.** Amends § 256B.0625, subd. 13f. Prohibits MA, and MinnesotaCare by cross-reference in other law, from applying prior authorization and step therapy protocol requirements to antiretroviral drugs used to prevent HIV.	House only	

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59	**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, 2024.	House only	