MN HOUSE RESEARCH

Bill Summary

H.F. 17

Third Engrossment

Subject Excessive Drug Price Increases; Prescription Drug Affordability Board

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Overview

This bill prohibits a manufacturer from imposing or causing to be imposed an excessive price increase on the sale of any generic or off-patent drug. The bill requires the commissioner of health to notify the manufacturer, attorney general, and Board of Pharmacy of any violation of the prohibition on excessive price increases. The bill requires manufacturers that receive a notice to provide specified information on drug costs to the attorney general, and allows the attorney general to investigate a possible violation and petition the court to issue orders for various remedies. The bill also prohibits a manufacturer from withdrawing a drug from sale in the state in order to avoid the prohibition on excessive price increases. The bill makes a violation by a manufacturer of the prohibition on excessive price increases, and related requirements, grounds for disciplinary action by the Board of Pharmacy. (See §§ 1-6, 18, 19.)

This bill also establishes the Prescription Drug Affordability Board and a related advisory council to review the cost of prescription drugs and set upper payment limits for drugs whose cost creates an affordability challenge to the state health care system or patients. The bill requires the board to identify drug products whose introductory prices and price increases meet specified criteria, and allows the board to conduct drug cost reviews. If the board determines that spending on a drug product creates an affordability challenge, the board is directed to set upper payment limits for purchases of, and reimbursement for, the drug. Failures of entities to comply with these reimbursement levels, and failures of drug manufacturers to comply with reporting requirements, are subject to action by the attorney general. (See §§ 7-17, 20.)

Summary

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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.
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 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.
4	**Enforcement.** Adds § 62J.844. **Subd. 1. Notification.** (a) Requires the commissioner of health to notify the manufacturer of a generic or off-patent drug, the attorney general, and the Board of Pharmacy of any price increase that the commissioner believes may violate the prohibition on excessive pricing. (b) Allows the commissioner of management and budget and any other state agency, except the Department of Human Services, 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

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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 the prohibition on excessive pricing.

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;
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, 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 Minnesota 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

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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) (civil penalties), 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 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 at least 90 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.

7 **Citation.**

Adds § 62J.85. States that sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."

8 **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).

9 **Prescription Drug Affordability Board.**

Adds § 62J.87.

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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 nine members – seven voting members appointed by the governor, one nonvoting member appointed by the majority leader of the Senate, and one nonvoting member appointed by the speaker of the House.

(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, 2024.

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.

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 qualifications for the executive director.

(b) Requires the commissioner of health to provide technical assistance to the board. Allows the board to also employ or contract for professional and technical assistance.

(c) 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.

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10 **Prescription drug affordability advisory council.**

Adds § 62J.88.

Subd. 1. Establishment. Requires the governor to appoint an advisory council to advise the board on drug cost 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, 2024, 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.

11 **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.

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.

12 **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 (current law drug transparency requirements), within 30 days of the date the information is received.

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(b) Allows 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 selected prescription drug products, based on the following criteria:

1) brand name drugs or biologics for which the WAC increases by more than $3,000 during any 12- month period or course of treatment if less than 12 months, after adjusting for changes in the CPI;
2) brand name drugs or biologics with a WAC of $60,000 or more per calendar year or course of treatment;
3) biosimilar drugs with a WAC that is not at least 20 percent lower than the referenced brand name biologic; and
4) generic drugs for which: (i) the price increase, adjusted by the CPI, exceeds 15 percent of the WAC over the immediately preceding calendar year, or 40 percent of the WAC over the three immediately preceding calendar years; and (ii) the price increase, adjusted by the CPI, exceeds $30 for a 30-day supply or course of treatment lasting less than 30 days.

States that the board is not required to identify all prescription drug products that meet the criteria in this paragraph.

(b) Allows the board, in consultation with the advisory council and the commissioner of health, 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 and information provided by the commissioner of health classified as not public data or as trade secret information.

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.

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13 **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; manufacturer monetary price concessions, discounts, or rebates, and drug-specific patient assistance; price of therapeutic alternatives; cost to group purchasers; measures of patient access; and the extent to which the attorney general or a court has determined that a price increase for a generic or off-patent drug was excessive under sections 62J.842 and 62J.844; any information a manufacturer chooses to provide; and any other factors as determined by the board.

Subd. 3. 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 and information provided by the commissioner of health classified as not public data or as trade secret information.

(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).

(d) Exempts the establishment of standards for proprietary information from rulemaking requirements.

14 **Determinations; compliance; remedies.**

Adds § 62J.92.

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 any applicable extraordinary supply costs, 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 an upper payment limit applies to all purchases of, and payer reimbursements for, a prescription drug that is dispensed or administered to

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individuals in the state in person, by mail, or by other means, for which an upper payment limit has been established.

Subd. 2. Implementation and administration of the upper payment limit. (a) Prohibits an upper payment limit from taking effect sooner than 120 days following its public release by the board.

(b) Requires the board to set the upper payment limit for a drug subject to the Medicare maximum fair price at the Medicare maximum fair price.

(c) States that pharmacy dispensing fees shall not be counted toward or be subject to any upper payment limit. Prohibits health carriers and pharmacy benefit managers from reimbursing independent pharmacies at amounts less than the upper payment limit.

(d) Requires health plan companies and pharmacy benefit managers to report annually to the board on how cost savings resulting from an upper payment limit have been used to benefit enrollees, including but not limited to reducing enrollee cost-sharing.

Subd. 3. Noncompliance. (a) Requires the board, and allows other persons, to notify the attorney general of a potential failure by an entity to comply with an upper payment limit.

(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.

(d) Allows the attorney general to provide guidance to stakeholders on activities that could be considered noncompliant.

Subd. 4. Appeals. Allows appeals of board decisions and specifies procedures.

15 **Reports.**

Adds § 62J.93. Requires the board, beginning March 1, 2024, and each March 1 thereafter, to report to the governor and legislature on general price trends for 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.

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16	**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.
17	**Severability.** Adds § 62J.95. Provides that sections 62J.85 to 62J.94 are severable.
18	**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 (prohibition on excessive drug price increases).
19	**Grounds for disciplinary action.** Amends § 151.071, subd. 2. Provides that a violation of section 62J.842 (prohibition on excessive drug price increases) or section 62J.845 (withdrawal of a drug from sale or distribution to avoid the prohibition on excessive price increases) by a manufacturer is grounds for the Board of Pharmacy to take disciplinary action.
20	**Appropriation.** Appropriates money in fiscal years 2024 and 2025 from the general fund to the Prescription Drug Affordability Board for implementation of the Prescription Drug Affordability Act.