MN HOUSE RESEARCH

Bill Summary

H.F. 801

As introduced

Subject	Prescription Drug Affordability Act
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Overview

This bill 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 the drug for public and private purchases, payments, and payer reimbursements. 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.

Summary

Section	Description
1	**Citation.** Adds § 62J.85. States that sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."
2	**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).
3	**Prescription Drug Affordability Board.** Adds § 62J.87. **Subd. 1. Establishment.** Establishes the Prescription Drug Affordability Board to protect consumers, state and local governments, health plan companies,

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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, 2022.

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 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.

4 **Prescription drug affordability advisory council.**

Adds § 62J.88.

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Subd. 1. Establishment. Requires the governor to appoint an advisory council to advise the commission 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, 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. Exemption. Provides that the council does not expire.

5 **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.

6 **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:

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(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;

(2) brand name drugs or biologics that have been introduced at a WAC of $30,000 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: (i) increases by $100 or more, after adjusting for changes in the CPI for medical care, 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) is 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.

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.

7 **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:

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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 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).

8 **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 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.

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(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. 3. Appeals. Allows appeals of board decisions and specifies procedures.

9 **Reports.**

Adds § 62J.93. Requires the board, beginning March 1, 2022, 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.

10 **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.

11 **Severability.**

Adds § 62J.95. Provides that sections 62J.85 to 62J.94 are severable.

12 **Appropriation.**

Appropriates money for the biennium beginning July 1, 2021, from the general fund to the Prescription Drug Affordability Board for implementation of the act.