MN HOUSE RESEARCH

Bill Summary

H.F. 3228

As introduced

Subject	Prescription Drug Affordability Act
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Overview

This bill establishes the Prescription Drug Affordability Commission and a related advisory council to review the cost of prescription drugs and set maximum reimbursement levels for drugs whose cost creates an affordability challenge to the state health care system or patients. The bill requires drug manufacturers to notify the commission of certain drug and biologic price increases and new product introductions. The commission is to review the justification for these drug prices and may initiate a review of the cost of the drug. If the commission determines that spending on a drug product creates an affordability challenge, the commission is directed to establish maximum reimbursement levels 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, brand name drug, commission, generic drug, group purchaser, manufacturer, prescription drug product, and wholesale acquisition cost (WAC).
3	**Prescription drug affordability commission.** Adds § 62J.87. **Subd. 1. Establishment.** Establishes the Prescription Drug Affordability Commission to protect consumers, state and local governments, health plan

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companies, providers, pharmacies, and other stakeholders from excessive costs of certain prescription drugs.

Subd. 2. Membership. (a) Provides that the commission 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 health care economics and finance, and not be an employee or board member of, or consultant to, a manufacturer or trade association for manufacturers.

(c) Requires initial appointments to be made by January 1, 2021, with appointees serving staggered terms.

Subd. 3. Terms. Following initial appointments, specifies that members serve four-year terms and shall not serve 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. Allows the commission to hire an executive director and employ or contract with others for assistance. Requires the attorney general to provide legal services to the commission.

Subd. 6. Compensation. States that members shall not receive compensation but may be reimbursed for expenses.

Subd. 7. Meetings. Requires the commission 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.

Subd. 8. Expiration. States that the commission does not expire.

4 **Prescription drug affordability advisory council.**

Adds § 62J.88.

Subd. 1. Establishment. Requires the governor to appoint an 11-member 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.

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Subd. 3. Terms. Requires initial appointments to be made by January 1, 2021, 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 commission and advisory council members, commission 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 commission and advisory council members, commission 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 **Required manufacturer reporting requirement.**

Adds § 62J.90.

Subd. 1. Brand name drugs or biologics. Requires a drug manufacturer to notify the commission if the manufacturer: (1) increases the WAC or a brand name drug or biologic by more than 10 percent or by more than $10,000 during any 12-month period or course of treatment less than 12 months; or (2) intends to introduce or market a brand name drug or biologic at a WAC of $30,000 per calendar year of course of treatment.

Subd. 2. Biosimilar drugs. Requires a manufacturer to notify the commission if it intends to introduce or market a biosimilar at a WAC that is not at least 15 percent lower than the referenced brand biologic.

Subd. 3. Generic drugs. Requires a manufacturer to notify the commission if: (1) it increases the WAC of a generic drug by $100 or more for a 30-day supply, a supply less than 30 days based on recommended dosage, or one unit of the drug; and (2) the WAC is increased by 200 percent or more during the preceding 12-month period.

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Subd. 4. Other reporting requirements. Allows the commission, in consultation with the advisory council, to establish a manufacturer reporting threshold for other drugs that may impose costs that create significant affordability challenges.

Subd. 5. Notification; justification. (a) Requires manufacturer notices to be provided at least 30 days before the effective date of the increase or introduction. Upon notification, requires the commission to review the justification for the introductory price or price increase.

(b) Requires the commission, to the extent practicable, to access manufacturer justification information made public by other states.

(c) If justification information is not available from other states, allows the commission to require a manufacturer to submit documents and research related to the introductory price or price increase, including but not limited to life cycle management, net average price in Minnesota, market competition and context, projected revenue, and value or cost-effectiveness.

Subd. 6. Public input. Requires the commission to make public all notifications and justifications, unless the information is likely to compromise the financial or competitive position of the manufacturer or could qualify as trade secret. Provides that the public may request the commission to proceed with a cost review.

Subd. 7. Determination to proceed with review. (a) Allows the commission to initiate a review of the cost of a production drug reported to the commission.

(b) Requires the commission to review any public requests for a cost review and determine whether to proceed with a review.

(c) If there is no consensus of whether to review a drug, allows any member of the commission to request a vote on whether to review.

7 **Affordability of a prescription drug product.**

Adds § 62J.91.

Subd. 1. General. Upon a decision to proceed with a cost review, requires the commission 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 commission may consider in reviewing the cost of a prescription drug product. The specified factors include, but are not limited to: selling price of the drug; average monetary

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price concession, discount, or rebate provided to group purchasers; total amount of the concession, discount, or rebate provided to each PBM; price of therapeutic alternatives and 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; cost impact relative to baseline effect of existing alternatives; and copays and cost-sharing.

Subd. 3. Further review factors. If the commission, after considering the factors listed under subdivision 2, is unable to determine whether the drug has 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, and additional factors determined by the commission to be relevant.

Subd. 4. Public data; proprietary information. (a) Requires submissions to the commission related to a drug cost review to be made public, with the exception of information the commission determines is proprietary.

(b) Requires the commission to establish standards for proprietary information.

(c) Requires the commission 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. Maximum reimbursement level. (a) If the commissioner determines that spending on a prescription drug product creates an affordability challenge, directs the commission to establish a maximum reimbursement level after considering the cost of administering the drug, cost of delivering the drug to consumers, and other relevant administrative costs.

(b) States that the maximum reimbursement level 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.

(c) Requires the commission to determine how much each participant in the supply chain is remunerated.

Subd. 2. Noncompliance. (a) Requires noncompliance by an entity to bill or pay a reimbursement rate set by the commission 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 level established by the commission shall not be considered noncompliance. (d) Requires the attorney general to provide guidance to stakeholders on activities that could be considered noncompliant that are in addition to billing and payment where drug costs exceed the level established by the commission. **Subd. 3. Compliance with reporting.** Requires the failure of a drug company to report to the commission as required by section 62J.90 or submit information requested by the commission under sections 62J.86 to 62J.95 to be referred to the attorney general for review and possible action as permitted under chapter 8. **Subd. 4. Appeals.** Allows appeals of commission decisions and specifies procedures.
9	**Reports.** Adds § 62J.93. Requires the commission, beginning March 1, 2021, and each March 1 thereafter, to report to the governor and legislature on general price trends in prescription drug products, the number of manufacturers required to report under section 62J.90, and the number of drugs subject to 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 commission decisions. Provides that these plans are free to choose to reimburse more than the maximum level set by the commission. (b) Requires providers who dispense and administer drugs in the state to bill all payers no more than the maximum level 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 maximum level. (c) Defines an ERISA plan or group health plan.
11	**Severability.** Adds § 62J.95. Provides that sections 62J.85 to 62J.94 are severable.

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12	**Financing recommendations.** Requires the prescription drug affordability commission, by March 1, 2021, to submit recommendations to the legislature on financing options for the commission beginning fiscal year 2022, to ensure ongoing financing for the commission and implementation of the act.
13	**Appropriation.** Appropriates money in fiscal year 2021 from the general fund to the commissioner of health for the prescription drug affordability commission and implementation of the act.