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Senate

State of Minnesota

S.F. No. 168 (as amended by the A-4 Amendment) – Prohibition of excessive price increases to generic or off-patent drugs by manufacturers

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Overview

S.F. 168 prohibits a manufacturer from imposing or causing to be imposed an excessive price increase on the sale of any generic or off-patent drug sold, dispensed, or delivered to any Minnesota consumer. The bill requires the commissioner of health to notify the manufacturer, attorney general, and Board of Pharmacy of any suspected violation of this prohibition. The attorney general is authorized to investigate possible violations and courts may issue orders enjoining manufacturers from continued violations, mandating repayment to Minnesota consumers and third-party payers, and imposing additional civil penalties. S.F. 168 further prohibits a manufacturer from withdrawing a drug from sale in the state, without providing 90 days advance notice, to avoid the prohibition on excessive price increases. This bill also establishes the Prescription Drug Affordability Board and the Prescription Drug Affordability Advisory Council to review the cost of prescription drugs, represent stakeholder views, and set upper payment limits for drugs. S.F. 168 allows the board to conduct drug cost reviews for specific drugs that meet certain pricing criteria. If the board determines, which determination shall include consideration of public requests for the board to proceed with such reviews, that spending on a drug product creates an affordability challenge, the board must set an upper payment limit for the drug. Failures of entities to comply with these payment levels and related requirements are subject to action by the attorney general seeking civil and/or criminal remedies. S.F. 168 further provides that violations of the prohibition against excessive price increases constitute grounds for disciplinary action against a manufacturer's license, which may subject the entity to civil penalties. The bill also appropriates money in fiscal years 2024 and 2025.

Summary

Section 1. [Minn. Stat. § 62J.841] Definitions. This section defines key terms for purposes of sections 62J.841 to 62J.845, including "Consumer Price Index," "generic or off-patent drug," "manufacturer," prescription drug," "wholesale acquisition cost," and "wholesale distributor."

Section 2. [Minn. Stat. § 62J.842] Excessive Price Increases Prohibited. 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. Provides that a price increase is excessive when:
1) the price increase, adjusted for inflation by utilizing the CPI, exceeds: (i) 15 percent of the WAC over the prior calendar year; or (ii) 40 percent of the WAC over the three immediately preceding calendar years; and
2) the price increase, adjusted for inflation by utilizing the CPI, exceeds $30 for a 30-day supply of the drug, or a course of treatment lasting less than 30 days.

This section further provides 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.

Section 3. [Minn. Stat. § 62J.843] Registered Agent and Office Within the State. Requires manufacturers that sell, distribute, deliver, or offer for sale any generic or off-patent drugs in the state to maintain a registered agent and office within the state.

Section 4. [Minn. Stat. § 62J.844] Enforcement.

Subd. 1. (Notification) This subdivision requires the commissioner of health to notify the 1) manufacturer, 2) attorney general, and 3) Board of Pharmacy of any price increase that may violate the prohibition against excessive price increases.

Subd. 2. (Submission of drug cost statement and other information by manufacturer; investigation by attorney general) Requires a manufacturer, notified under subdivision 1 of this section, to submit a drug cost statement to the attorney general. The statement must include specific information regarding production, materials, and manufacturing costs.

Subd. 3. (Petition to court) This subdivision authorizes various action which a court may take upon petition by the attorney general, including compelling information from a manufacturer, imposing civil penalties, enjoining potential violations of this new law, and requiring the manufacturer to repay to all Minnesota consumers, including third-party payers, any money acquired as the result of an impermissible excessive price increase.

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.

Section 5. [Minn. Stat. § 62J.845] Prohibition on Withdrawal of Generic or Off-Patent Drugs for Sale. Prohibits a manufacturer from withdrawing a drug from sale or distribution in the state to avoid the prohibition on excessive price increases. Requires a manufacturer to provide at least 90 days prior written notice of withdrawal of the sale or distribution of a generic or off-patent drug from the state to the Board of Pharmacy and the attorney general. Requires the attorney general to assess a

$500,000 penalty on any manufacturer that the attorney general has determines has failed to comply with the requirements of this section.

Section 6. [Minn. Stat. § 62J.846] Severability. Provides that the provisions of sections 62J.841 to 62J.845 are severable.

Section 7. [Minn. Stat. § 62J.85] Citation. States that sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."

Section 8. [Minn. Stat. § 62J.86] Definitions. Defines key terms for the purposes of section 62J.85 to 62J.95, including "advisory council," "biologic," "biosimilar," "board," "brand name drug," "generic drug," "group purchaser," "manufacturer," "prescription drug product," and "wholesale acquisition cost or WAC."

Section 9. [Minn. Stat. § 62J.87] Prescription Drug Affordability Board. This section requires the commissioner of commerce to establish the Prescription Drug Affordability Board to protect consumers, state and local governments, health plan companies, providers, pharmacies, and other health care system stakeholders from unaffordable costs of certain prescription drugs. The board will consist of eleven members appointed by January 1, 2024, seven of which are voting members. The seven voting members will be appointed by the governor. This section provides that the board will have an executive director, the commissioner of health will provide technical assistance, and the attorney general will provide legal services to the board. Board meetings are subject to the Open Meeting Law and the board will meet at least every three months to review prescription drug product information and provide for public comments.

Section 10. [Minn. Stat. § 62J.88] Prescription Drug Affordability Advisory Council. This section requires the governor to appoint a seventeen-member advisory council to advise the board on drug cost issues and represent stakeholder views. Specifies criteria related to knowledge, experience, professional affiliation, and expertise of the members. Requires initial appointments to be made by January 1, 2024, and specifies that meetings of the council are subject to the Open Meeting Law. The advisory council must meet publicly at least every three months.

Section 11. [Minn. Stat. § 62J.89] Conflicts of Interest.

Subd. 1. (Definition) Defines "conflict of interest" for the purposes of this section.

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 of services or property that raise the specter of a conflict of interest or have the appearance of injecting bias into the board's activities.

Section 12. [Minn. Stat. § 62J.90] Prescription Drug Price Information; Decision to Conduct Cost Review. This section requires the commissioner of health to provide the Prescription Drug Affordability Board with the information reported to the commissioner by drug manufacturers under section 62J.84. The board must identity specific prescription drugs to become subject to a cost review based on certain enumerated factors and in consultation with the advisory council. The board may also identify prescription drug products independently of information provided by the commissioner

of health if the drugs may impose costs that create significant affordability challenges for the state health care system or for patients.

Section 13. [Minn. Stat. § 62J.91]. Prescription Drug Product Reviews.

Subd. 1. (General) Requires the board, through its conducting of a drug review, to determine whether appropriate utilization of the drug, based on the FDA label or 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 in the state; manufacturer monetary price concessions, discounts, or rebates, and drug-specific patient assistance; price of therapeutic alternatives; cost to group purchasers; measures of patient access; 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) This section clarifies that submissions to the board related to a drug cost review must be made available to the public, subject to certain exceptions. Exceptions from this general rule include information determined by the board to be proprietary and information provided by the commissioner of health classified as not public data under state law, trade secret information under state law, or trade secret information under federal law. The board is authorized to use exempt rulemaking to establish standards for information to be considered proprietary.

Section 14. [Minn. Stat. § 62J.92] Determinations; Compliance; Remedies.

Subd. 1. (Upper payment limit) (a) Requires the board to establish an upper payment limit if the board finds that prescription drug product spending for a reviewed drug creates an affordability challenge for the state health care system or for patients. The limit applies to all purchases of, and payer reimbursements for, a prescription drug that is dispensed or administered to individuals in the state.

Subd. 2. (Implementation and administration of the upper payment limit) This subdivision sets a 120 day waiting period, commencing on the public release of an upper payment limit by the board, before the limit can take effect. It further 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, and requires health plan companies and pharmacy benefit managers to report annually on the cost effects of upper payment limits.

Subd. 3. (Noncompliance) This subdivision requires the board to notify the attorney general of potential noncompliance by an entity required to comply with an upper payment limit. Authorizes the attorney general to pursue remedies under chapter 8 or appropriate criminal charges, as applicable. Provides that an entity may obtain price concessions from a manufacturer that result in a lower net cost to the stakeholder than the limit established by the board without violating the upper payment limit prohibitions. This subdivision further permits the attorney general to provide guidance to stakeholders on activities that could be considered noncompliant.

Subd. 4. (Appeals) Provides that persons affected by a decision of the board may request an appeal of the board's decision within 30 days of the decision's date. The board must hear the appeal and then must decide on the appeal with 60 days of the hearing.

Section 15. [Minn. Stat. § 62J.93] Reports. 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.

Section 16. [Minn. Stat. § 62J.94] ERISA Plans and Medicare Drug Plans. This section exempts ERISA plans or Medicare Part D from the new law's requirements to comply with board decisions. The section expressly provides that ERISA plans or Medicare Part D plans are free to choose to exceed the upper payment limit established by the board under section 62J.92. Mandates that providers who dispense and administer drugs in the state must bill all payers no more than the upper payment limit without regard to whether an ERISA plan or Medicare Part D plan chooses to reimburse the provider in an amount greater than the upper payment limit. Finally, this section defines an ERISA plan or group health plan as "an employee welfare benefit plan established by or maintained by an employer or an employee organization, or both, that provides employer sponsored health coverage to employees and the employee's dependents and is subject to the Employee Retirement Income Security Act of 1974."

Section 17. [Minn. Stat. § 62J.95] Severability. Provides that sections 62J.85 to 62J.94 are severable.

Section 18. Amends Minn. Stat. § 151.071, subd. 1, a subdivision within the state's Pharmacy Practice Act regarding "Forms of disciplinary action." This modification proposes to add a provision that each separate violation of the new section 62J.842 regarding the prohibition against excessive price increases by manufacturers subjects the licensee to a civil penalty of up to $25,000.

Section 19. Amends Minn. Stat. § 151.071, subd. 2, a subdivision within the state's Pharmacy Practice Act regarding "Grounds for disciplinary action." It expressly provides that a violation by a manufacturer of the new section 62J.842 or 62J.845 is prohibited and grounds for disciplinary action.

Section 20. Appropriation. This section makes appropriations from the general fund in fiscal years 2024 and 2025 to the Prescription Drug Affordability Board for implementation of the Prescription Drug Affordability Act.