STATE OF MINNESOTA

# OFFICE OF THE ATTORNEY GENERAL


TO: BOARD MEMBERS
Prescription Drug Affordability Board

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SUBJECT: **Statutory Authority of PDAB**

The following tables summarize statutory authority for the board, taken from the Prescription Drug Affordability Act, Minn. Stat. §§ 62J.85 - .95.

The first table summarizes mandatory authority from the Act, generally denoted as items the board "shall" do, and the second table summarizes permissive authority from the Act, generally denoted as items the board "may" do.

## Mandatory authority/"shall":

| Section | Title | Provision | Notes |
|---|---|---|---|
| § 62J.87, subd. 4(b) | **Elect permanent chair** | The board shall elect a chair to replace the acting chair at the first meeting of the board by a majority of the members. The chair shall serve for one year. | Must occur at first meeting. Majority of members. |
| § 62J.87, subd. 4(c) | **Vice-chair and other officers** | The board shall elect a vice-chair and other officers from its membership as it deems necessary. | "as it deems necessary" |
| § 62J.87, subd. 5(a) | **Hiring of executive director and staff** | The board shall hire an executive director and other staff, who shall serve in the unclassified service. The executive director must have knowledge and demonstrated expertise in pharmacoeconomics, pharmacology, health policy, health services research, medicine, or a related field or discipline. | |
| § 62J.87, subd. 7 | **Meet publicly at least every three months** | Meetings of the board are subject to chapter 13D. The board shall meet publicly at least every three months to review prescription drug product information | The chair may cancel or postpone. |

| Section | Title | Provision | Notes |
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| | | submitted to the board under section 62J.90. If there are no pending submissions, the chair of the board may cancel or postpone the required meeting. The board may meet in closed session when reviewing proprietary information, as determined under the standards developed in accordance with section 62J.91, subdivision 3. | |
| § 62J.87, subd. (b) | **Meeting announcements; meeting materials** | The board shall announce each public meeting at least three weeks prior to the scheduled date of the meeting. Any materials for the meeting shall be made public at least two weeks prior to the scheduled date of the meeting. | |
| § 62J.87, subd. (c) | **Public comments** | At each public meeting, the board shall provide the opportunity for comments from the public, including the opportunity for written comments to be submitted to the board prior to a decision by the board. | |
| § 62J.90, subd. 2(a) | **Criteria for selection of drugs; consultation with advisory counsel** | The board, in consultation with the advisory council, shall identify selected prescription drug products based on the following criteria:<br><br>(1) brand name drugs or biologics for which the WAC increases by more than 15 percent or 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 consumer price index (CPI);<br>(2) brand name drugs or biologics with a WAC of $60,000 or more per calendar year or per course of treatment;<br>(3) biosimilar drugs that have a WAC that is not at least 20 percent lower than the referenced brand name biologic at the time the biosimilar is introduced; and<br>(4) generic drugs for which the WAC:<br>(i) is $100 or more, after adjusting for changes in the CPI, for:<br>(A) a 30-day supply;<br>(B) a course of treatment lasting less than 30 days; or<br>(C) one unit of the drug, if the labeling approved by the Food and | |

| Section | Title | Provision | Notes |
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| | | Drug Administration does not recommend a finite dosage; and<br>(ii) increased by 200 percent or more during the immediate preceding 12-month period, as determined by the difference between the resulting WAC and the average WAC reported over the preceding 12 months, after adjusting for changes in the CPI.<br>The board is not required to identify all prescription drug products that meet the criteria in this paragraph. | |
| § 62J.90, subd. 2(c) | **Names and price information public except as proprietary or not public or trade secret** | The board shall make available to the public the names and related price information of the prescription drug products identified under this subdivision, with the exception of information determined by the board to be proprietary under the standards developed by the board under section 62J.91, subdivision 3, and information provided by the commissioner of health classified as not public data under section 13.02, subdivision 8a, or as trade secret information under section 13.37, subdivision 1, paragraph (b), or as trade secret information under the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. | |
| § 62J.90, subd. 3(b) | **Consider public cost review requests** | The board shall consider requests by the public for the board to proceed with a cost review of any prescription drug product identified under this section. | |
| § 62J.91, subd. 1 | **Cost review process** | Once a decision by the board has been made to proceed with a cost review of a prescription drug product, the board shall conduct the review and make a determination as to whether appropriate utilization of the prescription drug under review, based on utilization that is consistent with the United States Food and Drug Administration (FDA) label or standard medical practice, has led or will lead to affordability challenges for the state health care system or for patients. | |
| § 62J.91, subd. 3 | **Proprietary information standards** | The board shall establish the standards for the information to be considered proprietary under paragraph (a) and section 62J.90, subdivision 2, including standards for heightened consideration of | |

| Section | Title | Provision | Notes |
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| | | proprietary information for submissions for a cost review of a drug that is not yet approved by the FDA. | |
| § 62J.92, subd. 1 | **UPL** | In the event the board finds that the spending on a prescription drug product reviewed under section 62J.91 creates an affordability challenge for the state health care system or for patients, the board shall establish an upper payment limit after considering:<br>(1) extraordinary supply costs, if applicable;<br>(2) the range of prices at which the drug is sold in the United States according to one or more pricing files accessed under section 62J.90, subdivision 1, and the range at which pharmacies are reimbursed in Canada; and<br>(3) any other relevant pricing and administrative cost information for the drug. | |
| § 62J.92, subd. 2(b) | **UPL for Medicare MFP** | When setting an upper payment limit for a drug subject to the Medicare maximum fair price under United States Code, title 42, section 1191(c), the board shall set the upper payment limit at the Medicare maximum fair price. | |
| § 62J.92, subd. 3(a) | **Noncompliance** | The board shall, and other persons may, notify the Office of the Attorney General of a potential failure by an entity subject to an upper payment limit to comply with that limit. | |
| § 62J.92, subd. 4(a) | **Appeals** | Persons affected by a decision of the board may request an appeal of the board's decision within 30 days of the date of the decision. The board shall hear the appeal and render a decision within 60 days of the hearing. | |
| 62J.93 | **Reports** | Beginning March 1, 2024, and each March 1 thereafter, the board shall submit a report to the governor and legislature on general price trends for prescription drug products and the number of prescription drug products that were subject to the board's cost review and analysis, including the result of any analysis as well as the number and disposition of appeals and judicial reviews. | |

**Permissive authority/"may":**

| Section | Title | Provision | Notes |
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| § 62J.87, subd. 5(b) | **Employment or P&T authority** | The commissioner of health shall provide technical assistance to the board. The board may also employ or contract for professional and technical assistance as the board deems necessary to perform the board's duties. | |
| § 62J.87, subd. 7 | **Meetings: postpone or cancel where no pending submissions; closed session** | Meetings of the board are subject to chapter 13D. The board shall meet publicly at least every three months to review prescription drug product information submitted to the board under section 62J.90. If there are no pending submissions, the chair of the board may cancel or postpone the required meeting. The board may meet in closed session when reviewing proprietary information, as determined under the standards developed in accordance with section 62J.91, subdivision 3. | In order to meet in closed session, must establish standards re proprietary information. |
| § 62J.90, subd. 1(b) | **Drug pricing files subscription** | The board may subscribe to one or more prescription drug pricing files, such as Medispan or FirstDatabank, or as otherwise determined by the board. | |
| § 62J.90, subd. 3(a) | **Cost review permitted if identified in criteria** | The board may initiate a cost review of a prescription drug product identified by the board under this section. | |
| § 62J.90, subd. 3(c) | **Vote on cost review** | If there is no consensus among the members of the board on whether to initiate a cost review of a prescription drug product, any member of the board may request a vote to determine whether to review the cost of the prescription drug product. | |
| § 62J.91, subd. 2 | **Cost review considerations** | In reviewing the cost of a prescription drug product, the board may consider the following factors:<br><br>(1) the price at which the prescription drug product has been and will be sold in the state;<br>(2) manufacturer monetary price concessions, discounts, or rebates, and drug-specific patient assistance;<br>(3) the price of therapeutic alternatives; | |

| Section | Title | Provision | Notes |
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| | | (4) the cost to group purchasers based on patient access consistent with the FDA-labeled indications and standard medical practice;<br>(5) measures of patient access, including cost-sharing and other metrics;<br>(6) the extent to which the attorney general or a court has determined that a price increase for a generic or off-patent prescription drug product was excessive under sections 62J.842 and 62J.844;<br>(7) any information a manufacturer chooses to provide; and<br>(8) any other factors as determined by the board. | |
| § 62J.92, subd. 1(c) | **May not use cost-per-quality adjusted life year** | In determining whether a drug creates an affordability challenge or determining an upper payment limit amount, the board may not use cost-effectiveness analyses that include the cost-per-quality adjusted life year or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability. For any treatment that extends life, if the board uses cost-effectiveness results, it must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability. | |