Minnesota Prescription Drug Affordability Board

Title:	**Proprietary and Trade Secret Information; Confidentiality; Board Members**	Policy No.:	**02-A**

Date Issued:	(pending)
Dates Reviewed:	(none)
Amendments Approved:	(none)

I. Purpose

The Minnesota Prescription Drug Affordability Board ("Board") was established "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." Minn. Stat. § 62J.87, subd. 1 (2024). Information submitted to the Board regarding prescription drugs is generally public, but the Board is required to protect bona fide trade secret and otherwise proprietary or nonpublic information from public release under certain circumstances.

The Board recognizes that some information necessary for its work is protected by state and federal laws regarding misappropriation of trade secrets and constitutional protections against the taking of private property without just compensation. The Board has an obligation to provide for the protection of properly designated confidential material. Therefore, the Board adopts this policy to establish procedures for the protection and use of such information and to resolve disputes about data classifications. It is the intent of the Board for this policy to comply with all provisions of Minnesota and federal law. To the extent it does not, the Board shall apply applicable law.

Other state entities, including the Minnesota Department of Health (MDH), also collect information related to the issues addressed by the Board, including some information that may be shared with the Board. To minimize burdens on entities submitting information to the State of Minnesota, this policy also attempts to coordinate the Board's process with the processes of state entities.

II. Statutory Provisions

The Board's statutory authority provides as follows related to proprietary and trade secret information and confidentiality:

62J.87 PRESCRIPTION DRUG AFFORDABILITY BOARD.

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Subd. 7. Meetings. (a)

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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.

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62J.90 PRESCRIPTION DRUG PRICE INFORMATION; DECISION TO CONDUCT COST REVIEW.

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Subd. 2. Identification of certain prescription drug products.

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(c) 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.

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62J.91 PRESCRIPTION DRUG PRODUCT REVIEWS.

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Subd. 3. Public data; proprietary information. (a) Any submission made to the board related to a drug cost review must be made available to the public 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 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.

(b) 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 proprietary information for submissions for a cost review of a drug that is not yet approved by the FDA.

(c) Prior to the board establishing the standards under paragraph (b), the public shall be provided notice and the opportunity to submit comments.

(d) The establishment of standards under this subdivision is exempt from the rulemaking requirements under chapter 14, and section 14.386 does not apply.

III. Procedures for Protection of Proprietary and Trade Secret Data

Public Comments. The Board has developed this policy with public notice and the opportunity for the public to submit comments to consider the viewpoints of affected stakeholders. The Board accepts public comments at each of its public meetings and through submission on the Board website; any individual or entity that wants to submit comments on this policy or any issue may use those channels to provide comments on this policy, both before and after its adoption.

Submission of Proprietary and Trade Secret Information. A person or entity submitting information for the Board's consideration shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary, and the basis for any such designation. The submitting party shall provide this information and must cooperate with any requests from the Board or its counsel for information or clarification as to the nature or basis of its designations. If it fails to do so, the Board may take that into account in evaluating the basis of the designation.

If making such a designation, the submitting person or entity must certify and attest to its knowledge that the information so designated is not otherwise publicly available and that it has been handled and maintained to preserve its confidential, trade secret, or proprietary nature. The submitting person or entity must also designate if the information belongs to it or to a third party; if the information belongs to a third party, the third party must be identified along with the nature of the agreements for handling of the information between the submitting personal or entity and the third party.

Classification Determination by Board. The Board may elect to treat information as confidential, trade secret, or proprietary even where it was not submitted with such a designation, if the Board finds the standards for such treatment are met.

Request for Additional Information. The Board or its counsel may seek additional information regarding whether the information is confidential, trade secret, or proprietary from the person or entity submitting the information or, to the extent the Board is able to determine who created the document or information, the person or entity who created the document or information.

Use of Proprietary and Trade Secret Information. The Board will not disclose confidential, trade secret, or proprietary information publicly or in an open meeting or its public meeting materials or otherwise, unless the classification of the information is changed in accordance with the provisions of the "Procedures for Challenges to Claims of Proprietary and Trade Secret Protections" section, below.

To the extent the information submitted to the Board contains information that is confidential, trade secret, or proprietary, the Board, if needed, will consider such information in closed session and will not disclose the information publicly.

The Board will employ reasonable efforts to ensure confidential, trade secret, and proprietary information can be securely submitted and maintained for the Board's consideration and is only accessible to authorized persons.

Any information designated as confidential, trade secret, or proprietary, whether by designation by the person or entity submitting it or by determination of the Board, shall be considered to be "trade secret information" within the meaning of Minnesota Statutes section 13.37 and be treated as nonpublic data or private data, as appropriate, pursuant to the Minnesota Government Data Practices Act, unless the classification of the information is changed in accordance with the provisions of the "Procedures for Challenges to Claims of Proprietary and Trade Secret Protections" section, below.

Provisions for Drug Not Approved by FDA. A person or entity submitting information for the Board's consideration as part of a cost review of a drug shall be instructed to clearly designate if the drug has been approved by the FDA. For any information related to a drug that is not yet approved by the FDA, the Board shall apply standards for heightened consideration of proprietary information for such submissions in accordance with the provisions of Minnesota Statutes, section 62J.91, subdivision 3(b). The submitting party may be asked to provide additional information regarding the nature and status of the claims of confidential, trade secret, or proprietary designations.

IV. Procedures for Challenges to Claims of Proprietary and Trade Secret Protections

These procedures will not be used to challenge the claims of proprietary or trade secret protections for data disseminated to the Board by another government entity subject to Minnesota Statutes, Chapter 13. In compliance with Minnesota Statutes section 13.03, subdivision 4(c), and unless classification is required by law to change, such data shall generally have the same classification when received by the Board as they had at the entity providing them.

In other situations, if the Board or its counsel seek additional information regarding whether the claimed information is confidential, trade secret, or proprietary from the person or entity who submitted or created the document or information, the information provided to the Board and other available information will be considered, along with the cooperation of the submitter or the creator of the document or information, in determining if a reasonable basis exists for continuation of the claimed protection.

If the Board determines in a closed meeting to challenge any designations of confidential, trade secret, or proprietary information for any reason, the Board will give at least ninety (90) days' notice to the submitter of the information, along with any other potentially affected parties it can identify before treating the information as public. During this notice

period, the Board will maintain the treatment of all such information as confidential, trade secret, or proprietary.

The Board may consider new information obtained during the notice period and may take further action to cease its challenge of any designations in whole or in part, or it may extend the period under which it agrees to maintain the treatment of any such information as confidential, trade secret, or proprietary.

V. Board's Oversight Role as to Employees and Contractors

Although members must ensure their own compliance with this policy, they also must recognize their additional responsibility in overseeing compliance with the statutes and this policy for Board employees and contractors.

VI. Annual Review and Training

The Board shall review this policy on an annual basis and conduct periodic training for members at the discretion of the Board.

VII. No Application to Public Participation

The Board adopts this policy to ensure its own compliance with statutory provisions for protection of proprietary and trade secret data and to ensure public and industry confidence in its actions. It is *not* the intent of the Board through adoption of this policy to discourage participation by individuals or advocates with direct experience or knowledge about the issues under consideration by the Board. The Board accepts public comments at all meetings and through its website. The Board believes the public's comments on these matters are valuable and are encouraged. The Board invites members of the public to share their comments, and this policy is not intended to govern the sharing of public comments.

Minnesota Prescription Drug Affordability Board

Title:	**Proprietary and Trade Secret Information; Confidentiality; Board Staff Members**	Policy No.:	**02-B**

Date Issued:	(pending)
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Minnesota Prescription Drug Affordability Board

Title:	**Proprietary and Trade Secret Information; Confidentiality; Third-Party Contractors**	Policy No.:	**02-C**

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