

Minnesota Prescription Drug Affordability Board

Title:	Conflicts of Interest; Board Members	Policy No.: 01-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). The Board seeks to ensure that it conducts its business for the benefit of the public in a manner that instills public confidence in its actions and in the absence of improper financial or personal associations.

Therefore, the Board adopts this policy to govern the conduct of its members during their terms of office. 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.

II. Statutory Provisions

Board members shall follow all statutory provisions regarding conflicts of interest and shall annually confirm such compliance.

Manufacturer or PBM Affiliation. Membership of the Board, including both voting members and nonvoting members, is governed by section 62J.87. *Id.*, subd. 2(a). “A member must not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers, or a pharmacy benefit manager or trade association for pharmacy benefit managers.” *Id.*, subd. 2(b); *see also* Minn. Stat. § 62J.86, subd. 9 (2024) (defining “manufacturer”). Although the statute regarding membership qualifications refers only to affiliations with a manufacturer, trade association, or pharmacy benefit manager, other relationships or affiliations with stakeholders in the pharmaceutical drug supply chain could cause similar concerns and should be considered by the member for the potential of conflicts of interest under this policy.

Board Conflicts of Interest Statute. Section 62J.89 provides as follows:

Subdivision 1. Definition.

For purposes of this section, "conflict of interest" means a financial or personal association that has the potential to bias or have the appearance of biasing a person's decisions in matters related to the board, the advisory council, or in the conduct of the board's or council's activities. A conflict of interest includes any instance in which a person, a person's immediate family member, including a spouse, parent, child, or other legal dependent, or an in-law of any of the preceding individuals, has received or could

receive a direct or indirect financial benefit of any amount deriving from the result or findings of a decision or determination of the board. For purposes of this section, a financial benefit includes honoraria, fees, stock, the value of the member's, immediate family member's, or in-law's stock holdings, and any direct financial benefit deriving from the finding of a review conducted under sections 62J.85 to 62J.95. Ownership of securities is not a conflict of interest if the securities are: (1) part of a diversified mutual or exchange traded fund; or (2) in a tax-deferred or tax-exempt retirement account that is administered by an independent trustee.

Subd. 2. General.

(a) Prior to the acceptance of an appointment or employment, or prior to entering into a contractual agreement, a board or advisory council member, board staff member, or third-party contractor must disclose to the appointing authority or the board any conflicts of interest. The information disclosed must include the type, nature, and magnitude of the interests involved.

(b) A board member, board staff member, or third-party contractor with a conflict of interest with regard to any prescription drug product under review must recuse themselves from any discussion, review, decision, or determination made by the board relating to the prescription drug product.

(c) Any conflict of interest must be disclosed in advance of the first meeting after the conflict is identified or within five days after the conflict is identified, whichever is earlier.

Subd. 3. Prohibitions.

Board members, board staff, or third-party contractors are prohibited 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 activities of the board.

Minn. Stat. § 62J.89 (2024).

III. Procedures for Identifying and Managing Potential Conflicts of Interest

A financial or personal association that *does not* have the potential to bias or have the appearance of biasing a person's decisions in matters related to the Board or in the conduct of the Board's activities *does not* constitute a conflict of interest.

Recognition of Need for Early Evaluation. The law requires disclosure of potential conflicts of interest prior to appointment or reappointment as a member, as well as an on-going evaluation based on the evolving subject matter of the Board's work. The Board also has responsibility for ensuring that potential employees and contractors are subjected to appropriate procedures to evaluate conflicts of interest, both before beginning work for the Board and during their on-going work. All pre-appointment, pre-employment, and pre-

contract disclosures must include the *type, nature, and magnitude* of the interests involved. *Id.*, subd. 2(a).

Member Analysis of Conflicts. Members must be mindful of the use of the phrase “conflict of interest” in section 62J.89 referring broadly to: (1) either *financial* associations or *personal* associations; (2) either something having the *potential* of biasing a member’s decisions or something having the *appearance* of biasing the member’s decisions; (3) either residing with the *member himself or herself* or residing with the *member’s immediate family* (as defined, including in-laws); (4) either related to a financial benefit *actually received* or a financial benefit that *could be received*; and (5) either a *direct* financial benefit or an *indirect* financial benefit, of any amount.

Members are responsible for identifying their own conflicts. Members are advised to identify potential financial and personal associations for themselves and immediate family members that may meet the statutory definition of “conflict of interest” sufficiently in advance to aid in timely recognition and notification of conflicts. Members must determine themselves what, if any, investigation is prudent of immediate family members’ potential conflicts if they do not already have personal knowledge of the issue, depending on all surrounding circumstances. Members are entitled to recognize that an unknown potential conflict is either incapable of or unlikely to influence their actions.

Special Considerations for Financial Issues. The statutory definition of conflict of interest *includes* specific categories of financial benefits (i.e., honoraria, fees, stock, the value of the member’s or immediate family member’s or in-law’s stock holdings, or any other direct financial benefit deriving from a cost review of a prescription drug product), but *excludes* certain securities owned in particular structures. *Id.*, subd. 1. Members should review financial issues carefully with these definitions in mind to identify potential conflicts of interest. Although the statute does not specifically address employment as a potential source for conflicts of interest, members should consider employment in addressing potential financial conflicts of interest.

Special Considerations for Gifts. The law provides specific prohibitions related to gifts, providing that members are “prohibited 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 activities of the board.” *Id.*, subd. 3. Members should be mindful of gifts creating “the specter” or “appearance” of a conflict, which could erode public confidence in the decisions of the Board or otherwise appear improper.

Expertise Requirements. As to evaluation of financial issues and gifts, members may also consider that Minnesota law requires they have “knowledge and demonstrated expertise in pharmaceutical economics and finance or health care economics and finance,” Minn. Stat. § 62J.87, subd. 2(b), and, therefore, are likely to work in roles and be affiliated with various stakeholders in the prescription drug supply chain and connected fields. Members may attend or speak at industry conferences, as do many other members of the public and as is common in many industries. Although Minnesota law does not recognize a *de minimis* exception to allow for travel reimbursement or honoraria of certain amounts,

the statute only applies to interests that have “the potential to bias” or “the appearance of biasing a person’s decisions in matter related to the board.” *Id.*, subd. 1. See “Effect of Disclosure,” below, for additional information.

Requirement for Disclosure. Any situation meeting the statutory definition of a conflict of interest must be disclosed. Minn. Stat. § 62J.89, subd. 2(c).

Time of Disclosure. Disclosure must occur in advance of the first meeting after the conflict is identified or within five days after the conflict is identified, whichever is earlier. *Id.*

Prior to each meeting, members should review the draft agenda to identify any conflicts of interest. Likewise, for any work occurring between meetings (e.g., committee work), members should review any relevant materials to identify any conflicts of interest. Members may consult with the Board’s legal counsel at any time regarding analysis of any potential conflicts of interest. (If a member identifies a potential conflict during a meeting, the member should move for a brief recess to speak with the Board’s legal counsel or otherwise immediately address the issue as appropriate.)

If a member determines a conflict of interest exists outside of a board meeting, the member should notify the Executive Director of the conflict.

Contents of Disclosure. Post-appointment, post-employment, and post-contract disclosures of a conflict of interest must identify the specific prescription drug product or other matter on which a member has a conflict of interest. For proper application of the recusal process, Board staff must be able to identify to which matters a recusal applies. The law does not further specify the required contents of the disclosure. Board members may disclose potential conflicts they identify and may also identify circumstances they do not believe to create a conflict but where they request further consideration by the Board so that they may determine if a conflict exists.

Effect of Disclosure. In determining whether to disclose potential conflicts of interest, members should consider the benefit to the public and likelihood of increased confidence in the Board’s actions by disclosing potential conflicts of interest.

Board staff will notify all members and the Board’s counsel of any conflict report and take appropriate action to make sure any member with a conflict of interest does not have access to information on matters where the member must recuse himself or herself. Such action may include Board action to further evaluate whether a conflict of interest exists based on review of all relevant circumstances. Members with a conflict of interest should be careful to ensure they do not obtain, review, or retain confidential, proprietary, or trade secret information about a matter on which they have recused. For any prescription drug product under review or other matter on which a member has a conflict of interest, the law requires that the member “must recuse themselves from any discussion, review, decision, or determination made by the board relating to the prescription drug product.” *Id.*, subd. 2(b).

Members may participate in other matters and votes for which they do not have a conflict of interest.

Recusal of any member affects the calculation of a quorum for consideration of an issue and other board operations, so members are encouraged to provide as much advance notice of recusal as possible in all circumstances.

Retroactive Identification of Conflict. The law does not provide a specific mechanism to report a conflict of interest not disclosed prior to appointment or related to a matter for which the member already participated in discussion, review, decision, or any determination made by the board. Nonetheless, if a member identifies an unreported conflict of interest, or a previously unknown or undisclosed conflict of interest related to past action, it should be reported to the Board's counsel immediately.

A financial or personal association that is not on-going and was received more than two years prior to the Board's action on a related topic presumptively does not have the potential to bias or appear to bias a Board Member's decision. If a Board Member determines that a financial or personal association that is not on-going and was received more than two years prior to the Board's action on a related topic does constitute a conflict or may appear to bias their decision, the Member shall disclose the conflict and recuse from the Board activity with which that conflict applies.

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

Although members must ensure their own compliance with this policy, they should also recognize their additional responsibility in overseeing compliance with the statute and corresponding additional policies for Board employees and contractors. The provisions of the statute regarding recusal, disclosure, and gift prohibitions apply equally to board employees and third-party contractors.

V. 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. The Board's annual review shall include related policies regarding oversight of employees and third-party contractors.

VI. No Application to Public Participation

The Board adopts this policy to ensure its own compliance with statutory provisions for conflict of interest 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 identify

themselves and any affiliated organizations they represent so that their perspective is presented with transparency.

Minnesota Prescription Drug Affordability Board

Title:	Conflicts of Interest; Board Staff Members	Policy No.: 01-B
Date Issued:	(pending)	
Dates Reviewed:	(none)	
Amendments Approved:	(none)	

[This policy will be finalized based on the final form of the “Board Members” version, using the same headings:

- I. Purpose
- II. Statutory Provisions
- III. Procedures for Identifying and Managing Potential Conflicts of Interest
- IV. Board’s Oversight Role as to Employees and Contractors
- V. Annual Review and Training

In addition, this policy regarding Board Employees will also address the following issues:

1. Pre-employment requirements will be emphasized
2. Will include section 16C.04 (State Procurement: Ethical Practices and Conflict of Interest) and section 43A.38 (State Personnel Management: Code of Ethics for Employees in the Executive Branch) and any other applicable provisions.]

Minnesota Prescription Drug Affordability Board

Title:	Conflicts of Interest; Third-Party Contractors	Policy No.: 01-C
Date Issued:	(pending)	
Dates Reviewed:	(none)	
Amendments Approved:	(none)	

[This policy will be finalized based on the final form of the “Board Members” version, using the same headings:

- I. Purpose
- II. Statutory Provisions
- III. Procedures for Identifying and Managing Potential Conflicts of Interest
- IV. Board’s Oversight Role as to Employees and Contractors
- V. Annual Review and Training

In addition, this policy regarding Third-Party Contractors will also address the following issues:

1. Pre-contracting requirements will be emphasized
2. Will include section 16C.08 (State Procurement: Professional or Technical Services) and section 16C.29 (State Procurement: Contract Management and Review) and other applicable provisions.]