

Minnesota Prescription Drug Affordability Advisory Council

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

I. Purpose

The State of Minnesota established the Minnesota Prescription Drug Affordability Advisory Council (“PDAAC”) “to provide advice to the [Minnesota Prescription Drug Affordability B]oard (“Board”) on drug cost issues and to represent stakeholders' views.” Minn. Stat. § 62J.88, subd. 1 (2024). With this policy, the PDAAC seeks to ensure that it conducts its business for the benefit of the public in a manner that instills public confidence in its actions while honoring the expertise and stakeholder-advocate roles of PDAAC Members.

The PDAAC adopts this policy to govern the conduct of its Members during their terms of office. It is the intent of the PDAAC for this policy to comply with all provisions of Minnesota and federal law. To the extent it does not, the PDAAC shall apply applicable law.

II. Statutory Provisions

PDAAC Members must follow all statutory provisions regarding conflicts of interest and must annually confirm that compliance.

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 Disclosing Potential Conflicts of Interest

PDAAC Members' statutory role differs significantly from Board members. First, each PDAAC Member is charged with representing a specific stakeholder perspective. In this role, it is appropriate for Members to hold financial or personal associations that have the potential to bias their work at the PDAAC. Indeed, the statutory role of PDAAC Members makes these conflicts of interest likely and sometimes unavoidable.

Second, because the PDAAC has no statutory decision-making authority outside its own membership and its advisory role to the Board, there is little potential for these biases to *unduly* affect state decision-making.

In this framework, it is important that the public and other Members know the contours of Members' conflicts of interest so that they can evaluate the potential for the conflict to bias that Member's decisions in matters related to the PDAAC or in the conduct of the PDAAC's activities. But unlike Board members, Board staff, and third-party contractors, PDAAC Members need not recuse themselves

from PDAAC discussions or decisions because of the existence of a potential or actual conflict of interest.

Recognition of Need for Early Evaluation. The law requires disclosure of potential conflicts of interest before appointment or reappointment as a Member, and an on-going evaluation based on the evolving subject matter of the PDAAC's work and the character of a PDAAC Member's conflicts. All pre-appointment 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. This policy recognizes that because the PDAAC lacks assigned legal staff, Members cannot seek legal advice from the State concerning whether a particular situation presents a conflict of interest. Members should use their best efforts to comply with this policy in the absence of that support.

Members are advised to identify potential financial and personal associations for themselves and their family (as described in the statute) 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 their immediate family's 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.

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

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 family'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 specified structures. Minn. Stat. § 62J.89, 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 or use of and payment for a prescription drug as a potential source for conflicts of interest, Members should consider both in addressing potential conflicts of interest. Further, although the statute does not specifically prohibit use of the Member's role on the PDAAC to inure to themselves or their family a private benefit, Members should not accept remuneration or compensation for their role on the PDAAC except as allowed by statute. *See* Minn. Stat. § 62J.88, subd. 4.

Special Considerations for Private Medical Information. The statutory definition of conflict of interest to include "any instance in which" a Member or their family "has received or *could receive* a direct or indirect financial benefit" from a decision of the Board necessarily includes a Member or their family's use of or payment for prescription drug products (a "medical conflict"). Members and their families, though, are entitled to protection of their medical privacy in their disclosures. Minn. Stat. § 13.384, subd. 3. To ensure compliance with the conflict-of-interest statute and the Minnesota Government Data Practices Act, Members may disclose all medical conflicts of interest for themselves and all their family members in a single aggregate disclosure.

Expertise Requirements. As to evaluation of financial issues and associations, Members may also consider that Minnesota law requires they have "knowledge and demonstrated expertise in" various areas related to the business of pharmaceuticals and the health care marketplace. Minn. Stat. § 62J.88, subd. 1, and, therefore, are likely to be in roles and be affiliated with various stakeholders in the prescription-drug supply chain and connected fields. Members may attend or speak at industry, patient, and advocacy 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 . . . advisory council[.]" Minn. Stat. § 62J.89, subd. 1.

Requirement of Disclosure. Any situation meeting the statutory definition of a conflict of interest must be disclosed. Minn. Stat. § 62J.89, subd. 2(c). Members should disclose their conflicts of interest in writing (including electronic writing) to the PDAAC Chair.

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. If, between meetings, a circumstance occurs that creates a new conflict of interest or resolves a Member's already-disclosed conflict of interest (for example, a change of employment or a relevant stock acquisition), the Member must promptly notify the Chair of the PDAAC and update their disclosures.

Contents of Disclosure. A Member's disclosure of a conflict of interest must address the type, nature, and magnitude of the interests involved. The law does not further specify the required contents of the disclosure. A Member's completion of the Conflicts of Interest; Disclosure Worksheet, Policy No. 01-0B presumptively meets this disclosure requirement.

Effect of Disclosure. The primary purpose of disclosure of PDAAC Members' conflicts of interest is to inform the public and PDAAC Members about associations and interests that may bias Members' work for and decisions at the PDAAC. To fulfil this purpose:

- (1) the Chair of the PDAAC or their designee must maintain a list of Members' disclosed conflicts of interest, which includes the type, nature, and magnitude of the conflict; and
- (2) if a Member with a conflict of interest concerning any pharmaceutical drug, class of pharmaceutical drugs, or segment of the pharmaceutical drug manufacture and distribution chain participates in PDAAC discussion, review, decision, or determination of any measure that concerns that conflict of interest, the Member must disclose the conflict at that meeting.

Members with a conflict of interest do not need to recuse themselves from any discussion, review, decision, or determination made by the PDAAC relating to the prescription drug product.

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 PDAAC. Nonetheless, if a Member identifies an unreported conflict of interest, or a previously unknown or undisclosed conflict of interest related to past action, that Member should report the conflict to Chair of the PDAAC immediately. Members appointed before the enactment of this policy must disclose all of their conflicts of interest within 30 days of the enactment of this policy.

IV. Annual Review and Training

The PDAAC will review this policy annually and may conduct periodic training for Members at the discretion of the PDAAC.

V. No Application to Public Participation

The PDAAC 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 PDAAC through adoption of this policy to discourage participation by individuals or advocates with direct experience or knowledge about the issues under consideration by the PDAAC. The PDAAC accepts public comments at all meetings and through its website. The PDAAC encourages the public's comments on these matters and believes that all such comments are valuable. The PDAAC invites members of the public to identify themselves and any affiliated organizations they represent so that their perspective is presented with transparency.

Title:	Conflicts of Interest; Disclosure Worksheet	Policy No.: 01-B
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I. Purpose

The Minnesota Prescription Drug Affordability Advisory Council (“PDAAC”) seeks to aid Members’ compliance with the disclosure obligations of Minn. Stat. § 62J.89 while also protecting the medical privacy of Members and their families.

II. Statutory Provisions

The Conflicts of Interest statute states that where a Member identifies a conflict of interest, that Member must disclose “the type, nature, and magnitude of the interests involved.” Minn. Stat. § 62J.89 Subd. 2(a) (2024) (emphasis added). The law does not further specify the required contents of the disclosure.

III. Disclosure Worksheet

Complete a disclosure worksheet for each conflict of interest or potential conflict of interest that you are aware of that you, your spouse, your parent, your spouse’s parent, your child or other legal dependent, or an in-law of your child or other legal dependent. You do not need to state who holds the interest so long as it is known to you to be a person who fits one of these categories.

PDAAC Member Conflict-of-Interest Disclosure Worksheet

For every conflict of interest that you identify under Conflicts of Interest; PDAAC Members, Policy No. 01-0A, complete the following. Each conflict should follow just one row of the table.

Member Name: _____ Date: _____

Stakeholder Represented: _____

Type of Conflict	Nature of Conflict	Identification of Conflict	Magnitude of direct or indirect financial benefit
☐ Financial Interest ☐ Personal Association	☐ Employment	Company: _____ _____ _____	☐ Full time ☐ Part time
	☐ Stock or Security (other than part of a diversified mutual or exchange traded fund; or held in a tax-deferred or tax-exempt retirement account that is administered by an independent trustee)	Company: _____ _____ _____	Amount: \$ _____
	☐ Fees ☐ Honoraria	Payor: _____ _____ _____	Amount: \$ _____
	☐ Medical	☐ Consumption of prescription drug	☐ Purchases a prescription drug ☐ Uses a prescription drug