

## **Prescription Drug Affordability Advisory Council Policies and Procedures**

**Policy Number:** 01

**Title:** Conflict of Interest Policy and Procedure

**Date Issued:** March \*\*, 2023

**Date(s) Reviewed:**

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### **Purpose**

1. To set forth the applicable conflict of interest standards and disclosure requirements applicable to the members of the Colorado Prescription Drug Affordability Advisory Council (“Advisory Council”).
2. To inform the public and provide guidance to councilmembers regarding councilmembers’ statutory disclosure requirements and the circumstances under which a councilmember should recuse from voting.

### **Applicable Law**

The Advisory Council was created as an advisory body to the Prescription Drug Affordability Board (“Board”) pursuant to statute. § 10-16-1401 *et seq.*, C.R.S. Council members are appointed based, in large part, on their affiliations. For example, the Advisory Council is required to have members representing various manufacturers, consumer advocacy organizations, health care professionals, pharmacies, and consumers. § 10-16-1409(1)(a), C.R.S.

Prior to appointment, the statute requires would-be council members to “disclose any conflict of interest to the board in a form and manner prescribed by the board.” § 10-16-1409(5)(a), C.R.S. The chair of the Advisory Council has an ongoing duty to “report to the board any conflict of interest that is disclosed to the advisory council.” § 10-16-1409(5)(b), C.R.S. The Board is required to publish such disclosures on its public website. *Id.*

“Conflict of interest” is defined as: an association, including a financial or personal association, that has the potential to bias or appear to bias an individual's decisions in matters related to the board or the advisory council or the conduct of the activities of the board or the advisory council. § 10-16-1401(10), C.R.S. “Conflict of interest” includes any instance in which an Advisory Council member or an immediate family member has received or could receive:

- (a) A financial benefit of any amount derived from the results or findings of a study or determination that is reached by or for the Board; or
- (b) A financial benefit from an individual or company that owns or manufactures a prescription drug, service, or item that is being or will be studied by the Board.

“Financial benefit” means honoraria, fees, stock, or any other form of compensation, including increases to the value of existing stock holdings. § 10-16-1401(11), C.R.S. An “immediate family member” is someone who is related to an Advisory Council member by blood, marriage, civil union, or adoption. § 2-4-401(3.7), C.R.S.

A conflict that “appear[s] to bias” an Advisory Council member’s decisions is one which has not yet ripened into an actual conflict, but creates an appearance of impropriety that would damage public confidence. Because an appearance of bias is included within the definition of “conflict of interest” in § 10-16-1401(10), C.R.S., Advisory Council members should err on the side of disclosure even if the financial or personal association at issue would not impact the Advisory Council member’s impartiality.

Colorado law also provides that unpaid members of boards, commissions and councils “shall not perform an official act which may have a direct economic benefit on a business or other undertaking in which such member has a direct or substantial financial interest.” § 24-18-108.5(2), C.R.S. “Official act” is defined broadly, and includes recommendations. § 24-18-102(7), C.R.S. “Financial interest” is defined as an ownership interest, creditor interest, loan or debtor interest, employment or potential employment, or a directorship or officership in a business. § 24-18-102(4), C.R.S.

## **Policy**

Disclosure: All Advisory Council members shall disclose known conflicts of interest to the Board, through Division of Insurance (“DOI”) staff, prior to appointment. Advisory Council members’ duty of disclosure continues throughout their tenure on the Council. When the Advisory Council is making recommendations to the Board regarding whether to conduct an affordability review for a specific prescription drug pursuant to §10-16-1406(2)(c), council members should disclose conflicts of interest to DOI staff as soon as practicable. Preferably, council members will disclose conflicts of interest to DOI staff upon reviewing the

list of prescription drugs that qualify for an affordability review, or such other specific information, on a meeting agenda or otherwise, as may identify a conflict.

While Advisory Council members are expected to disclose all known conflicts of interest, the possibility exists that certain conflicts may not be known. For example, an Advisory Council member—or an immediate family member—may unknowingly have investments in an index fund that includes stock in drug manufacturers. Advisory Council members are not expected to rule out or disclose such conflicts if there is no other reason to investigate. However, if Advisory Council members directly own shares of a drug manufacturer and are aware of their ownership interest, disclosure is required.

If a council member's role as representative of a stakeholder group creates a conflict that is common to all or a large class of prescription drugs—e.g., the representative of manufacturers of generic drugs perceives a conflict with placing an upper payment limit on any generic drug—the council member shall disclose the conflict generally but is not required to specify the conflict on a drug-by-drug basis.

DOI staff will provide a summary of Advisory Council members' conflicts to the Advisory Council chair in compliance with §10-16-1409(5)(b), C.R.S. The Advisory Council chair shall report Advisory Council members' disclosures to the Board. The nature of the conflicts—i.e., whether the council member's association is personal or financial, or the basis of the conflict—shall not be disclosed to the chair or to the Board. The only information that shall be publicly disclosed is the Advisory Council member's name and the manufacturer/drug at issue.

Notably, the statutory scheme does not require council members to recuse from voting on or participating in recommendations to the Board based on conflicts of interest. The statutory scheme that establishes the Advisory Council expressly provides that council members hold stakeholder roles. Therefore, recusal from official action is not necessary unless otherwise required by law. An Advisory Council member always has the option to abstain from discussion or from voting.

Recusal: An Advisory Council member's conflict of interest requires a recusal when their official action, including participating in a recommendation to the Board, may have a direct economic benefit on a business in which the Advisory Council member has a direct or substantial financial interest. § 24-18-108.5, C.R.S. If an Advisory Council member is unsure whether their interest in a business, or employment by that business, constitutes a "direct or substantial financial interest," the councilmember should consult with DOI staff and the Council's general counsel prior to taking official action.

In the event that an Advisory Council member is recused from taking official action on a matter pending before the Council, the Advisory Council member will announce their recusal in open session, physically leave the meeting room or remote meeting platform, refrain from participating in any discussion regarding the matter, and refrain from attempting to influence their fellow council members in voting on the matter.