

Prescription Drug Affordability Board Policies and Procedures

Policy Number: 03

Title: Conflict of Interest Policy and Procedure

Date Issued: December 17, 2021

Dates Reviewed: February 17, 2023

Purpose

1. To ensure that the Colorado Prescription Drug Affordability Board (“Board”) conducts business for the benefit of the public, and in the absence of personal, financial, or otherwise improper interests.
2. To provide guidance to individual Board Members on how to identify and manage Conflicts of Interest in relation to their statutory obligations as Board Members.

Background

The Board consists of five (5) members and was created by a Type I transfer to the Division of Insurance within the Department of Regulatory Agencies. The Board is directed to collect and evaluate information concerning the cost of Prescription Drugs purchased by Colorado consumers, perform Affordability Reviews of Prescription Drugs, establish Upper Payment Limits where appropriate, and make policy recommendations to the General Assembly to improve the affordability of Prescription Drugs for Colorado consumers. Board Members are appointed by the Governor with the consent of the Senate for three (3) year terms. Each Board Member holds an advanced degree and has experience or expertise in health-care economics or clinical medicine.

Definitions

Terms used in this policy have the same meaning as set forth in Part 1 the Board’s Rules and section 10-16-1401, C.R.S., unless clarified further below.

“Advisory Council” means the Colorado Prescription Drug Affordability Advisory Council that was created in section 10-16-1401, C.R.S.

“Affordability Review” means the review by the Prescription Drug Affordability Board of specific Prescription Drugs to determine whether the drug is affordable for Coloradans pursuant to section 10-16-1406(3)-(7), C.R.S., to determine whether use of the Prescription Drug consistent with the labeling approved for Prescription Drug by the FDA or with standard medical practice is unaffordable for Colorado consumers. “Board Activity” means selecting Prescription Drugs for an Affordability Review; conducting an Affordability Review; selecting Prescription Drugs for an Upper Payment Limit; and establishing an Upper Payment Limit.

“Board activity” means selecting prescription drugs for an affordability review;

determining whether a prescription drug is unaffordable; selecting prescription drugs for an upper payment limit; and establishing an upper payment limit.

“Board member” or “member” means a person appointed by the Governor to serve on the Prescription Drug Affordability Board.

“Conflict of Interest” or “Conflict” means 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. “Conflict of Interest” includes any instance in which a Board Member; an Advisory Council member; a Board staff member; a contractor of the Division, on behalf of the Board; or an Immediate Family Member of a Board Member, an Advisory Council member, a Board staff member, or a contractor of the Division, on behalf of the Board, 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.

“Division” means the Colorado Division of Insurance.

“Financial Association” means a relationship, contract, or ownership interest over which the Board Member exercises meaningful control, which elicits a Financial Benefit relating to a Prescription Drug under consideration by the Board or Pharmaceutical Company associated with a Prescription Drug under consideration by the Board including employment, consultancy, direct stock ownership, affiliation with the patent for a Prescription Drug, or publication of written work or research involving a Prescription Drug under consideration by the Board that was partially or fully paid for by a Pharmaceutical Company. A Financial Association does not include a Board Member’s participation in the 340B Program on behalf of their employer, provided that the Board Member does not individually receive a Financial Benefit in the form of increased compensation, incentives, or other benefits from their employer because of the Member’s professional participation in the 340B Program.

“Financial Benefit” means honoraria, fees, stock, personal cost savings resulting from the Member or Member’s Immediate Family Member taking a Prescription Drug for which the Board is considering an Upper Payment Limit, patent royalties, or any other form of compensation, including increase to the value of existing stock holdings.

“Immediate Family Member” means a person living in the same household as a Board Member, Advisory Council Member, a staff member, and/or a contractor of the Division working on behalf of the Board.

“Personal Association” means taking the Prescription Drug that is the subject of a Board Activity, currently participating in pharmaceutical-sponsored clinical trials for the Prescription Drug or testifying in a judicial proceeding without compensation either for or against the Prescription Drug or Pharmaceutical Company associated with the Prescription Drug that is the subject of a Board Activity.

“Pharmaceutical Company” means a company that owns or manufactures a prescription

drug, service, or item that is being or will be studied by the Board and includes manufacturers as defined by section 10-16-1401(16), C.R.S.

“Prescription Drug” means a drug intended for human consumption that: (a) is required by any applicable federal or state law or rule to be dispensed only pursuant to an order; (b) is restricted by any applicable federal or state law or rule to use by practitioners only; or (c) prior to being dispensed or delivered, is required under federal law to be labeled with “Rx only.”

“Upper Payment Limit” means the maximum amount that may be paid or billed for a Prescription Drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the Prescription Drug.

Policy Statement

Board Members must disclose any Conflict of Interest for which the Board Member is required to recuse from a Board Activity. An association or Financial Benefit that does not have the potential to bias or appear to bias a Board Member’s participation in a Board activity does not constitute a Conflict of Interest. All Board Member applicants must disclose conflicts of interest when being considered for appointment or re-appointment to the Board.

A Financial Benefit received more than five years prior to the Board Member’s appointment to the Board presumptively does not have the potential to bias or appear to bias a Board Member’s decision. Board Members may also choose to disclose to the Board a Financial Benefit received more than five years prior to the appointment to the Board, even if the member has determined it does not constitute a conflict. However, if a Board member determines that a financial benefit received more than five years prior to the appointment to the Board does constitute a Conflict, Board Members shall disclose and recuse from the Board activity with which that conflict applies.

The Board will strive to ensure that it acts impartially. To ensure impartiality, each Board Member is required to limit participation or recuse themselves from any Board Activity that involves a Prescription Drug or Pharmaceutical Company to which the member has a Conflict. To further ensure impartiality, staff and contractors of the Division engaged in a Board Activity may be required to recuse themselves from any Board Activity in which the individual has a Conflict. The Board and Division will ensure Board Members, staff, and contractors disclose Conflicts in accordance with this policy and its requirements.

The Board appoints the members of the Advisory Council and will ensure that all potential Advisory Council members disclose their Conflicts of Interest on a form provided by the Board. The Board will consider such disclosures prior to appointment of the applicant to the Advisory Council. The Board will also consider any Council member conflicts disclosed to the Board pursuant to section 10-16- 1409(5)(b), C.R.S., the Board will disclose Conflicts of Interest for the Board, Council, staff, and contractors working on behalf of the Board on its page of the Division’s website and in the annual report to the Governor and respective committees in the General Assembly.

Conflict of Interest

Board Members may have an actual Conflict of Interest or the appearance of a Conflict of Interest. An actual Conflict of Interest occurs when a Board Member or a Board Member's Immediate Family Member has a Financial or Personal Association that could influence the Board Member's opinion on a matter before the Board.

Appearance of Impropriety

Board Members should be aware of the appearance of impropriety and should take care to avoid any conduct that may appear improper and erode public confidence in the decisions of the Board. Pursuant to section 10-16-1402(3)(e), C.R.S., Board Members shall not accept a financial benefit, gift, bequest, or donations of services or property that suggests a Conflict of Interest or appears to create bias in the work of the Board.

Procedures for Identifying and Managing Conflicts of Interest

When the Board is selecting prescription drugs for affordability review, Board members will disclose conflicts of interest prior to deliberation concerning selection in the open meeting. The Board member will not participate in any deliberations concerning a specific prescription drug or pharmaceutical company with which they have a conflict of interest. The Board member may otherwise participate in deliberations related to selection of prescription drugs for which they do not have a conflict. A Board member with a conflict of interest will recuse themselves from any vote that involves only the prescription drug or pharmaceutical company with which they have a conflict when selecting prescription drugs for affordability review.

For all other Board activities, Board members will not participate in any Board activity in which a Board member has a Conflict of Interest. Prior to each Board meeting where the Board will engage in a Board activity, Board members will review the draft agenda and identify any potential Conflicts of Interest with a prescription drug or pharmaceutical company that is the subject of the Board activity. When a Board member determines they have a Conflict of Interest, the Board Member must disclose the conflict in an open meeting and recuse themselves. The Board Member will also notify Board staff to help ensure that the Member does not have access to confidential, proprietary, or trade secret information on matters for which the Member must recuse themselves.

For questions regarding conflicts of interest, the Board Members may seek the advice of the assistant attorney(s) general assigned to the Board.

As required by sections 10-16-1402(3)(d) and 10-16-1414(1)(f), C.R.S., the Board will disclose Conflicts of Interest for the Board, Advisory Council, Board staff, and contractors working on behalf of the Board on its page of the Division's website and in the annual report to the Governor and respective committees in the General Assembly. The Board will identify Conflicts of Interest on its website by identifying the person with the Conflict and the Prescription Drug or Pharmaceutical Company for which they have a Conflict and have recused. The Board will not identify the nature of the Conflict of Interest on the website.