Prescription Drug Affordability Board Policy and Procedure

Policy Number: 01

Title: Delegation to Division of Insurance Staff Policy and Procedure

Date Issued: November 12, 2021

Dates Reviewed: June 3, 2022

Purpose

1. To clarify when Staff within the Colorado Division of Insurance ("Division") may perform work on behalf of the Colorado Prescription Drug Affordability Board ("Board").
2. To provide guidance to Board Members regarding their duties and responsibilities with respect to Staff.

Background

The Board is an independent unit of state government, created by a Type 1 transfer, in the Division. The Board exercises its statutory powers, duties, and functions, including the promulgation of rules, regulations, and standards, and the rendering of findings, orders, and adjudications, independently of the Division and the Commissioner of Insurance ("Commissioner"). The Division performs any powers, duties, and functions not specifically vested by statute in the Board, including but not limited to, all budgeting, purchasing, planning, and related management functions of the Board. The Commissioner is the head of the Division pursuant to section 10-1-104(1), C.R.S.

The Division is further authorized by statute to provide specific support services to the Board, including but not limited to: maintaining a public website for the Board (§ 10-16-1402(3)(d), C.R.S.); entering into contracts with qualified, independent third parties for any service necessary to carry out the powers and duties of the Board (§ 10-16-1403(3), C.R.S.); and seeking and accepting gifts, grants, and donations from private or public sources that do not create a conflict of interest or appearance of conflict of interest for the Board (§ 10-16-1403(6)(a), C.R.S.).

The Board adopts this policy regarding the scope of assistance that may be properly provided by Staff so Staff may assist in the Board's expedient and informed performance of its statutory duties and obligations.

Definitions

"Advisory Council" means the Colorado Prescription Drug Affordability Advisory

Council created in section 10-16-1409, C.R.S.

"Counsel" means any assistant attorneys general assigned by the Attorney General to provide legal counsel to the Board (§ 10-16-1402(4), C.R.S.).

"Staff" means any individual employed by the Division of Insurance providing support to and/or doing work on behalf of the Board.

Policy Statement

The Board delegates its authority to Staff to perform the following functions on the Board's behalf. The Board may also delegate its authority to Staff in other specific policies and procedures, or during meetings through oral direction or by written resolution. The Board may elect to perform any of these duties at its discretion, including to delegate any of these duties to an individual Board Member.

Board Meetings

a. Facilitate meetings of the Board and ad hoc committees, including scheduling meetings, arranging meeting platforms and/or locations, and sending calendar invitations and Board-related notices.
b. Provide public notice of Board meetings and agenda items on the Board's website.
c. Develop agendas for Board meetings in coordination with the Board Chair.
d. Serve as the recording secretary for the Board and prepare meeting minutes for consideration by the Board.
e. Prepare Board materials.
f. Distribute agenda and materials in support of the Board's agenda to each Board Member, in accordance with Board Policy No. ***-** [COI Policy].
g. Review meeting materials and agenda items with Counsel prior to the Board meeting.
h. Record all meetings.
i. Record and securely store recordings of all executive sessions entered into by the Board at Board meetings in compliance with sections 10-16-1404(3) and 24-6-402(1)(d.5)(1)(A), C.R.S.

Contracts

a. Pursuant to section 10-16-1403(3), C.R.S., and in compliance with any procurement policies developed by the Board, facilitate contracts for work deemed necessary by the Board to carry out its powers and duties and ensure contract deliverables requested by the Board, if any, are prepared and presented to the Board.
b. The Board determines that to necessarily carry out its powers and duties, the Division is authorized to contract on its behalf for work

related to the following: Data identification, collection, and analysis related to pharmaceutical markets and supply chains, prescription drug pricing, and other state and federal programs related to prescription drug pricing;

i. Data, research, analysis, and supporting materials to inform the process for and conducting of affordability reviews;
ii. Data, research, analysis, and supporting materials to inform the methodology and process for and consideration of whether to set an upper payment limit;
iii. Data, research, analysis, and initial recommendations related to the development of a formula to calculate savings pursuant to section 10-16-1410, C.R.S.;
iv. Equity and cultural responsiveness related to the Board's activities; and
v. Data, research, analysis, and supporting materials for the Board's consideration in identifying potential policy recommendations to the Governor and General Assembly and compiling the Board's recommendations.

Administration

a. Serve as the custodian of record for the Board.
b. Maintain records for the Board in accordance with the Board's retention policies and all applicable laws and regulations, including but not limited to securely storing information, documents, and records received by the Board and executing the Board's destruction policy.
c. Establish and maintain an electronic mail account for the Board for submission of public comment, public inquiries, or submissions of information for the Board's consideration.
d. Receive and respond to requests made pursuant to the Colorado Open Records Act related to the Board in accordance with any applicable Board policies and all applicable laws and regulations and seek assistance of Counsel in connection with any such request, if necessary.
e. The Program Director or any other Staff for the Board may accept service on behalf of the Board.
f. Draft and issue correspondence on behalf of the Board, including with stakeholders, to communicate the Board's positions and determinations, provide notice of Board activities, respond to administrative or ministerial requests made to the Board, and/or seek additional information on behalf of the Board.
g. Receive and maintain documents and correspondence addressed or submitted to the Board and ensure Board review of such materials, if necessary.
h. Draft reports and memoranda pertaining to work completed by or on

behalf of the Board.

i. Collect and distribute any moneys received for the Board pursuant to section 10-16-1403(6)(a), C.R.S.

j. Maintain the Board's public webpage and ensure the webpage contains the following:
    i. Conflicts of interest disclosed to the Board pursuant to sections 10-16-1402(3) and 10-16-1409(5)(b), C.R.S.
    ii. Reports prepared for the General Assembly pursuant to section 10-16-1414, C.R.S.
    iii. Notice of Board meetings and hearings.
    iv. All agendas, non-confidential and non-privileged meeting materials, and Board-approved meeting minutes.
    v. List of Board Members.
    vi. List of Advisory Council Members.
    vii. Instructions for submitting materials for the Board's consideration.
    viii. Contact information for submitting requests pursuant to the Colorado Open Records Act.
    ix. Policies and procedures adopted by the Board.
    x. Resolutions, Orders, and any other memorialized decisions by the Board.
    xi. Findings, reports, and studies conducted by the Board, redacted for confidential information as necessary.
    xii. Notices of proposed rulemaking and rulemaking hearing information.
    xiii. Regulations and guidance adopted by the Board.
    xiv. List of all prescription drugs the Board determines to be unaffordable.
    xv. List of all upper payment limits established by the Board.
    xvi. Any material specifically requested by the Board.

<u>Support for Performance of Board Duties</u>

a. Facilitate rulemaking conducted by the Board, including but not limited to:
    i. Draft rules for consideration by the Board.
    ii. Effectuate publication and/or filing of notices of draft proposed regulations on specific topics authorized by the Board, and adopted rules in the Colorado Register, on the Colorado Secretary of State's website, and to the DORA Office of Policy, Research and Regulatory Reforms.
    iii. Submit requests for Attorney General opinions regarding adopted rules.
    iv. Compile the official rulemaking record for all rulemaking conducted by the Board, including receipt and inclusion of any public comments.

b. Collect and provide conflicts of interest to the Board:
    i. Distribute conflict of interest forms and coordinate completion of

disclosures by prospective and active Board Members, Staff, contractors of the Division, prospective and active Advisory Council members, and Counsel.

ii. Seek legal advice on behalf of the Board from Counsel concerning analysis related to conflicts of interest.

c. Draft reports required by section 10-16-1414, C.R.S., and present drafts to the Board for review, amendment, and approval.

d. Coordinate with legislative staff regarding any SMART Act or other legislative hearings or presentations.

e. Coordinate data and information collection on behalf of the Board, including by working with other state agencies, stakeholders, and the Advisory Council, and present material received to the Board, including entering into a memorandum of understanding or data use agreement as needed and approved by the Board.

f. Obtain legal advice from Counsel on behalf of the Board including but not limited to the following subjects: the Board or Staff's legal authority, rulemaking, engagement with stakeholders and regulated entities, Board processes, Board policies and procedures, contract management, Open Meetings Law, Colorado Open Records Act, confidentiality of information received by the Board, Board meetings and agenda items, executive session, and Board proceedings.

g. Recruit potential Advisory Council members for consideration by the Board.

h. Request notification and copies of any notices of withdrawal received by the Commissioner of Insurance pursuant to section 10-16-1412, C.R.S.

i. Assist in the collection and presentation of data, information, or analysis necessary for the Board to perform its duties related to affordability reviews and establishing upper payment limits generally and as may be further specifically address in Board Policy **-*** [Affordability Review Policy] and Board Policy **-*** [Upper Payment Limit Policy].

j. Facilitate the Board's annual training and review of the Board's policies and procedures pursuant to section 24-3.7-102(1), C.R.S., in coordination with Counsel.

Prescription Drug Affordability Board Policy and Procedures

Policy
Number: 02

Title: Policies and Procedures required by § 24-3.7-102, C.R.S.

Date Issued: November 12, 2021

Dates Reviewed: November 12, 2021

---

1. Statutory Authority.

The Prescription Drug Affordability Board is convened in the Division of Insurance as required by § 10-16-1402, C.R.S. Nothing in this document is intended to be contrary to these, or any, statutes, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, Constitution, and judicial decisions govern.

2. Purpose.

The Prescription Drug Affordability Board (the "Board") is established by statute to protect Colorado residents from excessive prescription drug costs. The Board is directed to collect and evaluate information concerning the cost of Prescription Drugs purchased by Colorado consumers, perform Affordability Reviews of those Prescription Drugs, establish Upper Payment Limits where appropriate, and report annually to the Governor and General Assembly which may include policy recommendations to the General Assembly to improve the affordability of Prescription Drugs for Colorado consumers. For the initial Board, the Governor appointed five members on October 1, 2021, who are subject to Senate confirmation with staggered terms. Subsequent Board Members are appointed by the Governor with the consent of the Senate for three (3) year terms. Each Board Member must hold an advanced degree and have experience or expertise in health-care economics or clinical medicine. The Governor designates one Member of the Board to serve as the Chair of the Board.

3. Board Member Selection Process

Individuals interested in serving on the Board may apply through the Colorado State Boards and Commissions website. Openings will be communicated to the public through a notice or other consumer alert. The Board application process is open to the public at all times.

4. Term Length and Vacancies

The initial Board was appointed by the Governor by October 1, 2021. To ensure initial terms were staggered, two Members were appointed to serve three year terms, two Members were appointed to serve two year terms, and one Member was appointed to serve a one year term as determined by the Governor. Subsequent Board Members will be appointed by the Governor with the consent of the Senate for three year terms.

Except for the initial term for certain members, Board members will serve three year terms and may serve no more than two three year terms. Members seeking re-appointment for a second term should notify the Division and the Governor's Office sixty (60) days before the end of their term and will be required to complete a new application if more than two years have passed since they submitted an application for Board membership. Reappointments are not automatic and must be confirmed by the Colorado Senate. Members who are appointed to fill vacancies that occur mid-term shall serve the remainder of the unexpired term of the member whose vacancy is being filled. If more than half the term is remaining when a vacancy is filled, the partial term counts as a full term for purposes of reappointment.

5. Conflict of Interest

The Board's Conflict of Interest Policy is set forth in Prescription Drug Affordability Board, Policy No. ***-**.

6. Responsibilities of the Chair of the Board

The Governor delegates one Member to serve as the Chair of the Board. The Chair provides

leadership for the Board, presides over all Board meetings, and provides strategic planning to help the Board comply with its statutory duties and responsibilities. The Chair shall designate a Member to preside over a Board meeting in their absence. The Chair works with Board staff to develop Board meeting agendas as set forth in Section 8. The Chair also ensures Member compliance with the Conflict of Interest Policy, Policy No. ***-**.

7. Open Records and Open Meetings

The Board's activities are subject to the Colorado Open Records Act, § 24-72-201 *et seq.*, C.R.S., and the Open Meetings Law, § 24-6-402, C.R.S. Consistent with those laws, the

Board's activities generally will be conducted in public pursuant to public notice, unless the Open Meetings Law permits particular matters to be discussed in executive session or as expressly required by § 10-16-1404(3), C.R.S. to consider trade secret, confidential, or proprietary data that is not otherwise available to the public. The Board's records are generally subject to the Colorado Open Records Act, subject to any exclusions from disclosure contained in that Act or exclusions provided under § 10-16-1401 *et seq.*, C.R.S. The Board adopts as its Colorado Open Records Act policy the Division's Colorado Open Records Act policy contained in Division of Insurance Bulletin 1.06. Under some circumstances, the Board may meet in Executive Session. See Section 11 below.

8. Meetings

The Board will hold meetings at least every six weeks. The Chair of the Board may decide to cancel or postpone a meeting when there are no prescription drugs to review whether as a result of incomplete data or the need for further analysis and no other Board business to conduct. The meetings may be referred to as meetings or hearings depending on what types of business the Board plans to conduct. The Board has discretion to set the time for its meetings. The Board may decide to adjourn a meeting or hearing to the next available day because a meeting or hearing is running long or for any other reason. A Member can participate in person, by phone, or virtually. Board meetings are broadcast live over the internet, other than executive sessions.

The Board will provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally during the designated time and when speaking should introduce themselves with their name and affiliation, if any. The Board is not obligated to respond to comments.

9. Meeting Agendas, Materials, and Notes

Division staff will post Board meeting minutes, agendas, and notices of upcoming meetings on the Prescription Drug Affordability Board website. The meeting agenda will be designed,

among other things, to ensure the Board meets its statutory obligations. The Board Chair in collaboration with the Staff will prepare a draft agenda and provide it to the Members prior to the Board meeting or hearing. Each Member will review the draft agenda and notify the assigned Assistant Attorney(s) General at the Colorado Department of Law of any potential conflict of interest. Counsel will notify the Staff of whether Members have recused themselves from certain agenda items. Prior to the meeting or hearing, the Staff will provide each Member with a Board packet of items, excluding materials related to any agenda item from which a Member has recused themselves. The Board packet may include materials, information, and/or analysis from the Advisory Council, Staff, and any third-party contractors necessary for the Board to make informed decisions. The Agenda will be posted on the Board's website two days prior to the Board meeting or hearing.

Staff will coordinate Board meeting times, location (virtual and/or in-person), materials, and other logistics including providing accommodations as requested.

10. Quorum, Decisions, and Voting

A majority of the five (5) person Board constitutes a quorum. Voting will be conducted by a Member roll call. Motions to conduct Board business should follow the processes set forth in Robert's Rules of Order (e.g. motion, second, discussion, vote).

11. Executive Session

The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Colorado Department of Law or as permitted by section 24-6-402, C.R.S. The Board must retire into executive session to discuss proprietary, trade secret, or confidential information pursuant to section 10-16-1404(3), C.R.S.

To enter executive session, a Member will state the topic for discussion in the executive session and the statutory provision which authorizes the Board to meet in executive session. Upon a majority vote, the open meeting will be adjourned and the executive session will begin. No official Board business may be conducted during the executive session and the Board may only discuss the topic(s) announced during the open meeting. The Board will not deliberate concerning whether to subject a prescription drug to an affordability review, vote concerning whether to establish an upper payment limit on a prescription drug, or otherwise make any final decision of the Board in executive session.

Upon reconvening the open meeting at the conclusion of the executive session, all Members will maintain the confidentiality of the information discussed and/or legal advice provided in executive session. The Board will ensure that electronic recordings of executive sessions are securely stored and will not result in the disclosure of any material or information containing trade-secret, confidential, or proprietary data. The Board will also ensure that

no minutes from executive session disclose or include materials or information containing trade-secret, confidential, or proprietary data.

12. Meeting Attendance, Absences, and Participation

Board Members are expected to make every effort to attend Board meetings. Members may participate in a meeting in person, by telephone, or any other means of electronic communication by which all persons participating in the meeting can hear each other at the same time. If a Member is unable to attend a meeting, the Member must notify the Chair prior to the meeting. If a Member misses more than three consecutive meetings without

informing the Chair, the Board may vote to recommend to the Governor that Member be removed.

13. Member Resignation and Replacement

Any Board Member who can no longer perform the responsibilities of the Board must notify the Chair (unless that Member is the Chair), Board Staff, and the Governor's Office in writing to resign from their position. Any such resignation shall take effect at the date of receipt of such notice or at any later date specified therein if the later date is acceptable to the Governor. The Governor, with the consent of the Senate, will appoint a replacement Member. The new Member will serve for the remainder of the resigning Member's term.

When a Member's term expires, the Member, at the Governor's discretion, may remain on the Board until a replacement is appointed by the Governor.

Please see "Member Selection Process" at Section 3 above.

14. Board Members are Public Representatives

Members of the Board are Public Representatives, appointed by the Governor, with the purpose of protecting Colorado consumers from excessive prescription drug costs. Members accept appointment to the Board with the understanding that they will represent the public interest in their actions and decisions on the Board. As such, it is imperative Members do not engage in any activity of the Board where there is a Conflict of Interest.

15. Coordinating with other Entities

The Board may, from time to time, coordinate with other boards, commissions, industry, educational institutions, and state agencies where the responsibilities and interests overlap in creating transparency for the cost of prescription drugs and determining the affordability

of prescription drugs for Colorado consumers.

16. Interaction with the Media and Lobbyists

Unless otherwise delegated to them by a majority vote of the Board, individual Board Members do not have the authority to speak on behalf of the Board. The Board operates as a single entity when communicating with external parties. If Board Members receive media requests related to their Board work and participation, they should notify Assistant Commissioner Vince Plymell at vincent.plymell@state.co.us.

17. Division of Insurance Staff

Staff from the Division of Insurance ("Staff") shall provide support to the Board including serving as the Recording Secretary for the Board; coordinating Board meeting times, location (virtual or otherwise), materials, and other logistics; compiling information necessary for the Board to conduct Affordability Reviews and setting Upper Payment Limits; tracking health benefit plan savings; and additional tasks as delegated by the Board. The Staff may also provide support to the Board in preparing policy recommendations to the General Assembly and preparation of annual reports to the General Assembly (pursuant to § 10-16-1407(10)(b) and § 10-16-1414, C.R.S.). The Division, on behalf of the Board, may enter into contracts with qualified, independent third parties for services necessary to carry out the powers and duties of the Board. All third-party contractors are required to enter into a nondisclosure agreement to protect trade-secret, confidential, or proprietary information. In retaining third-party contractors on behalf of the Board, the staff is exempt from the state "Procurement Code", articles 101 to 112 of title 24 (pursuant to section 10-16-1403(4), C.R.S.). The Staff may be reached at ***-***-**** and *****@state.co.us. The Board's standing authorization to the Division of Insurance may also be found at [location of adopted Staff delegation policy]. The Board may also delegate particular tasks to the Division of Insurance on a case-by-case basis to perform its duties. These particular delegations may be found at ["Resolutions" tab of PDAB website].

18. Advisory Council

The Board shall appoint an Advisory Council pursuant to § 10-16-1409, C.R.S., comprised of fifteen (15) members. The executive director of the Department of Health Care Policy and Financing or their designee shall serve as a member of the Council. The Board will appoint the members of the initial Advisory Council no later than January 1, 2022. The Advisory Council will provide stakeholder input to the Board regarding the affordability of prescription drugs for Colorado consumers.

19. Annual Review

The Board will review this Policy and the Conflict of Interest Policy at least annually. The Board will also receive annual training as required by section 24-3.7-102, C.R.S.

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.

Prescription Drug Affordability Board Policy and Procedures

Policy Number: **04**

Title: **Affordability Review Policy and Procedure**

Date Issued: **April 11, 2025**

Dates Reviewed: August 30, 2024, November 20, 2024, January 10, 2025

Authority

The statutory authority for this policy is section 10-16-1406, C.R.S. Nothing in this document is intended to be contrary to any statutes, rules, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, rules, Constitution, and judicial decisions govern.

Scope and Purpose

The purpose of this policy is to further establish methodologies and processes for the Board to identify and select drugs eligible for affordability review, and conduct affordability reviews of prescription drugs to determine whether use of the prescription drug consistent with the labeling approved for the prescription drug by the U.S. Food and Drug Administration (FDA) or with standard medical practice is unaffordable for Colorado consumers in compliance with section 10-16-1406(3), C.R.S.

As directed by PDAB Policy 01, Delegation to Division of Insurance Staff Policy and Procedure, this policy outlines specific delegations to Board Staff (or "Staff") associated with the affordability review process. In connection with the delegations and processes set forth below, Staff is authorized to perform these functions through whatever means Staff deems appropriate, whether by doing this work themselves, working with other state entities, other states, or stakeholders, or using a qualified third-party contractor pursuant to section 10-16-1403(3), C.R.S.

Further, this policy sets forth the interpretations employed by the Board in performing its work related to the affordability review, provides additional information regarding what types of data and information the Board will consider and how it will get or determine that information, and sets forth the Board's processes and procedures for performing an affordability review. Terms used in this policy have the same meaning as set forth in Parts 1 and 3 of the Board's Rules.

Identifying Prescription Drugs for Affordability Reviews

Staff will prepare a list of prescription drugs that meet the criteria set forth in section 10-16-1406(1), C.R.S., Part 3 of the Board's Rules, 3 C.C.R. 702-9.

Once Staff has compiled the list of eligible prescription drugs as delegated by the Board, Staff will present the list to the Board. The Board will review the list and vote on whether to approve the list.

To the extent that Staff develops methodologies or draws from existing data sources to identify the drugs, the methodologies and sources will be publicly presented to the Board, or presented in executive session pursuant to section 10-16-1404(3), C.R.S., as applicable.

In accordance with the above parameters, Staff will identify drugs according to the criteria as outlined in 10-16-1406(1), C.R.S. Staff will utilize methodologies, including the following where practicable, to identify prescription drugs eligible for affordability reviews:

1. For all prescription drugs:

    a. Wholesale Acquisition Costs (WAC), where the initial WAC means the earliest listed WAC for a prescription drug, and the current WAC means the most recently available WAC for a prescription drug in the relevant database.

    b. Brand name drugs and biological products will be identified utilizing National Drug Code (NDC) identifications. Brand name drugs and biological products will be identified for eligibility by identifying, consolidating, and listing NDCs with the same brand name and active ingredient.

    c. Twelve-month supply and course of treatment will be determined by multiplying the initial WAC/unit for a prescription drug by a measure of central tendency (e.g., mean, median, mode) as calculated from utilization data in Colorado's APCD. Staff may provide additional utilization statistics to provide more context regarding how actual utilization compares to common understandings of a twelve-month supply or course of treatment.

2. For a biosimilar product:

    a. Biosimilar products will be identified utilizing National Drug Code (NDC) identifications. Biosimilar products will be identified for eligibility by identifying, consolidating, and listing NDCs for FDA-approved biosimilar drugs by manufacturer, brand name, and active ingredient.
    b. Initial WAC amounts for biosimilars will be compared to the corresponding biological product's most recent WAC listed before the date when the initial biosimilar WAC was listed.

Selection of Eligible Prescription Drugs for Affordability Review

After approving the list of eligible prescription drugs, the Board will select which drug(s), if any, for which to conduct an affordability review. The affordability review will include consideration of statutory factors, as further described in Part 3, 3 C.C.R. 702-9.

Staff will prepare the following information, to the extent it is available, for the Board's consideration and deliberation as part of the selection process. After identifying prescription drugs as described in Section C above, the Board will determine whether to conduct an affordability review for an identified prescription drug by considering the following criteria.

The Board must examine all criteria for a prescription drug before deciding whether to conduct an affordability review for that drug.

1. Identifying the initial date of FDA approval of the eligible prescription drug, including whether the prescription drug was approved through an expedited pathway, and evaluating the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale by gathering:

    a. Information on the class of the prescription drug, as identified in the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) Classification, US Pharmacopeia (USP) Drug Classification System, or other similar classification system.

    b. Information on whether there are any therapeutically equivalent prescription drugs:

        i. Are approved: therapeutic equivalent prescription drugs will be identified by examination of the FDA Orange Book, FDA Purple Book, or other therapeutic equivalence databases.

        ii. Are for sale: information on the availability of therapeutic equivalents for sale, as opposed to therapeutic equivalents that are FDA approved but not currently marketed, will be gathered by examining information regarding utilization of the therapeutic equivalent prescription drug within the previous 12 months, in aggregate and by payer, as well as additional information gathered from experts regarding whether the therapeutically equivalent drug is for sale.

1. The following aggregated data sources may be utilized:

    a. Pricing Information: Including WAC pricing trends over time, Average Sales Price trends over time, and National Average Drug Acquisition Cost trends over time.

    b. Expenditures: APCD data showing spending amounts by line of business and payers, by consumers, and by total amounts, including data collected pursuant to section 10-16-1405, C.R.S.. Board staff will summarize required data submitted by carriers.

    c. Utilization: APCD data showing claim counts, unit counts, and per person utilization.

    d. Combined expenditure and utilization aggregated data: APCD data that incorporates both expenditure and utilization (e.g., cost per person, per member per month expenditure, etc.).

    e. Health equity impact: information showing whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations, as such conditions are identified from sources like the Colorado Department of Public Health & Environment's Health Equity office, the Centers for Disease

Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion, and other sources.

f. Information estimating manufacturer net-cost and net-sales amounts of an eligible drug.

g. Aggregated data analyses will examine up to five years of data for all categories and all prescription drugs.

2. Input from the Prescription Drug Affordability Advisory Council:

a. After presenting the list of identified prescription drugs to the Board, Staff will email the list to the Advisory Council and convey Board requests.

b. Before the next Board meeting, Staff will assist in convening an Advisory Council meeting to gather Advisory Council input.

c. Staff will present the Advisory Council input to the Board.

d. Nothing in this policy precludes the Advisory Council from identifying additional methods for delivering input to the Board (e.g., Advisory Council written or verbal reports directly to the Board).

3. Average patient's out-of-pocket cost for the prescription drug for up to five years for each prescription drug based on:

a. APCD data, in aggregate and by payer type, for out-of-pocket costs, and

b. Other data sources that approximate out-of-pocket costs not captured in APCD data.

4. Input regarding orphan drug designation: consideration of whether the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications. If the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications then the Board will consider input from consumers and the rare disease advisory council created in section 25-1-1503, C.R.S. Input sought may include:

a. Whether consumers and the Rare Disease Advisory Council have observed affordability concerns with the prescription drug,

b. Consumer and the Rare Disease Advisory Council observations regarding other selection criteria outlined in selection criteria outlined in Part 3, 3 C.C.R. 702-9 D.1-4.

5. The Board may use information from selection criteria to prioritize affordability goals in the selection of prescription drugs for an affordability review. Examples of affordability goals the Board may want to consider prioritizing in selecting prescription drugs for an affordability review include:

a. Price increases that exceed reasonable levels, as such levels are identified by the Board,

b. Consumer costs that threaten Coloradans' economic well-being,

c. Costs that contribute significantly to rises in health-care costs and health insurance premiums that threaten financial and physical health of Coloradans,

d. Costs for prescription drugs for conditions and disease that disproportionately impact priority populations, and/or

e. Excessive costs that contribute significantly to rising state budget costs.

To the extent permissible pursuant to section 10-16-1404(3), C.R.S, the Board will publicly deliberate over the selection criteria. The Board will deliberate over any information relating to the selection criteria containing trade-secret, confidential, or proprietary data that is not otherwise available to the public in executive session. The Board will take and consider public comment regarding its selection of eligible drugs for affordability review.

If the Board chooses to conduct an affordability review for a prescription drug, the Board will adopt a resolution, by majority vote, selecting the prescription drug and setting forth the selection criteria relied upon for its action. The Board will not deliberate concerning whether to subject a prescription drug to an affordability review in executive session, as required by section 10-16-1404(3)(a), C.R.S. All drugs for which the Board has determined to conduct an affordability review will be posted on the Board's website.

Conducting an Affordability Review

A. Assembling and Presenting Required Information to the Board

Staff shall compile information to support each of the factors identified in sections 10-16-1406(4) and (6), C.R.S., and Part 3, 3 C.C.R. 702-9. Staff may compile the information through internal analysis, engaging contractors, referencing the transparency reporting information pursuant to section 10-16-1405, C.R.S., accessing data sources, soliciting feedback from stakeholders, procuring pricing information from other states, the APCD and state entities, or other countries as appropriate.

Staff will draft a report for the Board's consideration detailing the information compiled to support each factor in the affordability review. Staff's draft report shall not contain a recommendation as to unaffordability. To the degree the Board has identified whether certain criteria should be weighted for consideration more strongly than other criteria, Staff will reflect this weighting in the draft report. Staff will identify in the draft report whether any information or data could not be obtained because it was not practicable. When all the information has been compiled, Staff shall present the draft report to the Board. The Board will consider the factual information presented by Staff in support of each factor in the affordability review. Staff may engage third party consultants to assist in compiling and/or analyzing the data. All third party contractors will be required to execute a nondisclosure agreement as required by section 10-16-1406(5), C.R.S. The Board will take and consider public comment regarding the factual information presented by Staff. The Board may request additional information from Staff.

Once the Board has established it has sufficient information, it will deliberate over the information to make a determination as to whether a prescription drug is unaffordable for

Colorado consumers. The Board will weigh the factors and information according to its expertise and discretion. All Board members will comply with the Board's Conflict of Interest Policy and recuse themselves from deliberations if required by the Policy.

The Board will take and consider public comment regarding its deliberations concerning whether a prescription drug is unaffordable for Colorado consumers. When the Board determines it has sufficiently considered the information, the Board will:

1. Vote to adopt the affordability review report, and

2. Vote to determine whether a prescription drug is unaffordable.

Staff will finalize the report, incorporating a summary of the Board's deliberations and identifying the Board's determination as to unaffordability. The final report will be made available to the public on the Board's website.

B. Compiling Supporting Evidence and Information for Required Factors

1. Wholesale Acquisition Cost: Information regarding the initial WAC, the current WAC, and changes to WAC over time.

2. Therapeutic Alternatives: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research.

   Information prepared for the Board's consideration includes:

   a. The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;

   b. The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and

   c. Rebate, discount, and price concessions data for the therapeutic alternative(s) by examining external databases.

3. Price Effect on Colorado Consumer Access: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information will also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:

   a. When therapeutic alternative(s) were available;

   b. Changes to patents;

   c. Changes in rebate amounts for the prescription drug or therapeutic alternative; and

d. Utilization rate of the drug per approved indication.

e. The Board may consider the impact of the drug's price on insurance consumer premiums and out-of-pocket costs, the impacts of formulary placement on access, and the extent to which and manner in which rebates are shared with patients purchasing the drug.

4. Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services cost, or impacts on premiums, state expenditures on the drug or disease, and other broader system financial impacts. This will be done by reviewing research that is:

   a. Publicly available;

   b. To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or

   c. Is voluntarily provided by manufacturers, PBMs, or carriers.

5. Patient Copayment or Other Cost Sharing: Information from:

   a. APCD data, in aggregate and by line of business, payer, and insurance plan type, for out-of-pocket costs;

   b. Other data sources that approximate out-of-pocket costs not captured in APCD data; and

   c. Out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs.

6. Impact on Safety Net Providers: As part of the Board's obligation to consider the impact of an affordability review of the cost of a prescription drug on safety net providers, Staff will request all safety net providers to voluntarily provide information to the Board. To facilitate gathering the information from safety net providers, Staff may request a list of 340B approved safety net providers from HCPF.

7. Orphan Drug Status: Information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414), including:

   a. Reviewing the Orphan Drug List for the quarter during which the affordability review begins.

   b. Designation date of the prescription drug on the orphan drug list.

   c. Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.

   d. Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses and unmet need or treats a rare or serious disease for which limited therapeutic

alternatives are available.

8. Input from Specified Stakeholders

   a. Staff will gather input from patients and caregivers affected by a condition or disease that is treated by the prescription drug. To gather information from patients and caregivers, Board staff may:

      i. Facilitate a public meeting(s) with patients, caregivers, and Board members.

      ii. Facilitate individual or small group meetings with patients and caregivers.

      iii. Conduct focus groups with patients and caregivers.

      iv. Distribute a survey to gather information from patients and caregivers who were unable to attend public or small group meetings.

      v. Patients and caregivers may continue to provide input via verbal public comment and written public comment.

      vi. During the following Board meeting(s), Staff will present input provided by patients and caregivers and will report such information in their final report.

   b. Staff will gather input from individuals who possess scientific or medical training in regards to a prescription drug under review. To gather information from individuals with scientific and medical training, Board staff may:

      i. Facilitate a public meeting(s) with individuals with scientific or medical training and Board members.

      ii. Facilitate individual or small group meetings with individuals with scientific or medical training.

      iii. Conduct focus groups.

      iv. Distribute a survey to gather information from individuals with scientific or medical training who were not able to attend public or small group meetings.

      v. Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.

      vi. Individuals who possess scientific or medical training with respect to the condition or disease will be asked to voluntarily disclose any conflicts of interest with the drug under review. At the request of the Board, Staff may further investigate the CMS Open Payments database for potential conflicts of interest.

vii. During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report.

c. Staff will gather input from the Rare Disease Advisory Council (RDAC). To gather information from the RDAC, Board staff will work with the RDAC Chair or RDAC staff, and may:

i. Facilitate a public meeting(s) with the RDAC.

ii. The RDAC may continue to provide input via verbal public comment and written public comment.

iii. During the following Board meeting(s), Staff will present input provided by the RDAC and will report such information in their final report.

d. Prior to or while gathering input from specified stakeholders, the Board may direct Board staff to facilitate a public meeting or workgroup with members of PDAAC, RDAC, or other stakeholders, including organizations representing or advocating for patients affected by a condition or disease treated by the prescription drug, to identify best practices regarding: gathering sensitive patient experience information, requesting voluntary disclosures of conflicts of interest; and determining preferred methods to gather information.

9. Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration. This may include requests from manufacturers or PBMs to provide information on patient assistance programs, negotiated rebates, and 340B discounts.

   After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the PDAAC, using its listserv and by posting on its website, of the ability to submit information pursuant to section 10-16-1406(4)(i), C.R.S., if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities.

10. Additional Factors:

    a. Rebates, Discounts, and Price Concessions: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Board staff will include estimates that separate 340B discounts from negotiated rebates if data or estimates that separate 340B discounts from negotiated rebates if data or estimates become available.

    b. Health Equity Factors: Staff will prepare information regarding utilization and expenditures as identified in APCD data, attempting to understand utilization

by:

i. People experiencing homelessness;

ii. People involved in the criminal justice system;

iii. Black people, indigenous people, and people of color;

iv. American Indians and Alaska natives;

v. Veterans;

vi. People who are lesbian, gay, bisexual, transgender, queer, or questioning;

vii. People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth;

viii. People who have AIDs or HIV;

ix. Older adults;

x. Children and families;

xi. People with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities;

xii. Other populations as deemed appropriate by the Prescription Drug Affordability Board.

c. Information from the Department of Health Care Policy and Financing: Staff will review any additional analyses conducted by HCPF relevant to the prescription drug or therapeutic alternative under review for presentation to the Board.

d. Non-adherence and Utilization Management Information: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions and prior authorization requirements placed on the prescription drug.

e. Patient Assistance Program Information: Staff will gather information regarding patient assistance programs available to patients in Colorado, potentially including utilization, eligibility criteria, financial impacts, and ease of accessing assistance programs. Staff will accept information from:

i. Manufacturers providing voluntarily submitted information regarding manufacturer assistance programs and other assistance programs affiliated with the manufacturer; and

ii. Other entities that provide financial assistance programs. Other entities may be identified by patients, caregivers, individuals with scientific and medical training, and the RDAC.

C. Compiling Supporting Evidence and Information for Permissive Factors

1. The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

    a. Life-cycle management;

    b. Average cost of the prescription drug in Colorado;

    c. Market competition;

    d. Projected revenue;

    e. Estimated cost-effectiveness of the prescription drug; and

    f. Off-label usage of the prescription drug.

2. The Board may access pricing information for prescription drugs by:

    a. Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.

    b. Accessing available pricing information from the APCD and from state entities.

    c. Staff will review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.

    d. Staff will review pricing information available from state entities and provide such information to the Board.

    e. Accessing information that is available from other countries. Staff will review pricing information from other countries and provide such information to the extent it is available.

D. Notice and Submissions of Information

On an annual basis, Staff will conduct outreach to trade associations for manufacturers, carriers, pharmacy benefit management firms, providers, pharmacies, wholesalers, patients, consumers, and caregivers requesting the trade organizations notify members of the activities of the Board, including that the Board may conduct affordability reviews and potentially set upper payment limits pursuant to sections 10-16-1406 and 1407, C.R.S. All interested parties will be encouraged to provide information for the Board's listserv in order to ensure they receive notice of the Board's upcoming actions including specific affordability reviews and consideration of specific upper payment limits.

Staff will notify the public of the selection of the drug by posting the same to the Board's website and distributing an email on the listserv. Staff will provide guidance on how the public and interested persons may participate in the Board's affordability review and provide information on public meetings where the Board will be gathering input, and how to submit information for the Board's consideration. Staff will specifically provide information related

to how appropriate persons may submit information for the Board's consideration pursuant to subsections 10-16-1406(4)(f), (h), and (i), C.R.S.

Persons submitting information for the Board's consideration shall have 90 days from the commencement of an affordability review of the prescription drug to provide such information to the Board. Stakeholders are encouraged to disclose to the Board which type of specified stakeholder they are (e.g. patient, caregiver, or individual with scientific or medical training, etc.) and/or whether they are affiliated with an entity or organization that may have experience with or an interest in a specific position related to the prescription drug.

After determining there is no publicly available pricing information, Staff may seek pricing information from manufacturers, carriers, and PBMs pursuant to section 10-16-1406(7)(b), C.R.S. Staff will request information provided under section 10-16-1406(7)(b), C.R.S., in writing (by mail or electronic mail). Staff will inform the Board in the event a manufacturer, carrier, and/or PBM fails to voluntarily provide the requested pricing information. The Board will consider information provided within 30 days of the request from Staff. The Board will then conduct the affordability review without the requested information.

E. Maintaining Confidential Information

Staff will employ reasonable efforts to ensure confidential information can be securely submitted and maintained for the Board's consideration and is only accessible to authorized persons pursuant to sections 10-16-1404(3) and 10-16-1406(5), C.R.S. A person submitting information for the Board's consideration pursuant to Part 3 of the Board's rule shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary as "confidential". Staff will not disclose information marked as "confidential" in public Board materials, including public meeting packets. Staff will not share confidential information except with Board members, legal counsel, and qualified third-party contractors subject to a nondisclosure agreement pursuant to section 10-16-1406(5), C.R.S.

If information marked as confidential has been submitted for the Board's consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential, trade secret, or proprietary information. Staff may also determine that information submitted to the Board is confidential, trade secret, or proprietary. To the extent the Board deliberates such confidential information, the deliberations will take place in executive session pursuant to sections 10-16-1404(3). The Board will not disclose confidential, trade secret, or proprietary information in an open meeting, its public meeting materials, or its summary report. To the extent practicable, Staff will identify the need for an executive session for the Board's discussion and/or deliberation of trade-secret, proprietary, and confidential materials in advance of a public Board meeting as required by section 10-16-1404(3), C.R.S.

The Board will comply with the Colorado Open Records Act and all applicable state and federal laws in determining whether information is confidential. The Board, through Staff, will independently determine whether information otherwise identified as "confidential" by a party submitting the information is confidential pursuant to state and federal law for purposes of responding to requests for information or documents.

In responding to any requests for information or documents, Staff may request additional information from the person asserting confidentiality regarding the nature of the

confidentiality or, to the extent Staff is able to determine who created the document or information, the person who created the document or information. Staff may seek legal advice on behalf of the Board related to confidentiality of documents.

Prescription Drug Affordability Board Policy and Procedures

Policy Number: **05**

Title: **Upper Payment Limit Policy and Procedure**

Date Issued: January 13, 2023

Dates Reviewed: July 19, 2024

Authority

The statutory authority for this policy is section 10-16-1407, C.R.S. Nothing in this document is intended to be contrary to any statutes, rules, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, rules, Constitution, and judicial decisions govern.

Scope and Purpose

The purpose of this policy is to further establish the methodology and processes for the Board to establish upper payment limits for prescription drugs it has determined to be unaffordable pursuant to section 10-16-1407, C.R.S.

As directed by PDAB Policy 01, Delegation to Division of Insurance Staff Policy and Procedure, this policy outlines specific delegations to Board Staff (or "Staff") associated with the upper payment limit process. In connection with the delegations and processes set forth below, Staff is authorized to perform these functions through whatever means Staff deems appropriate, whether by doing this work themselves, working with other state entities, other states, or stakeholders, or using a qualified third-party contractor pursuant to section 10-16-1403(3), C.R.S.

Further, this policy sets forth the interpretations employed by the Board in performing its work related to establishing an upper payment limit, provides additional information regarding what types of data and information the Board will consider and how it will get or determine that information, and sets forth the Board's processes and procedures for establishing an upper payment limit. Terms used in this policy have the same meaning as set forth in Parts 1 and 4 of the Board's Rules.

Upper Payment Limits Applicability

As set forth in 3 CCR 702-9, Part 4.2.C.1, an upper payment limit, plus any reasonable fees charged by the pharmacy (as defined by section 12-280-103(43), C.R.S.) or pharmacist for dispensing or delivering a prescription drug, applies to all purchases by a Colorado consumer from a pharmacy or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means. If the Colorado consumer is insured, the consumer's portion of the payment together with the reimbursement to the pharmacy (as defined by section 12-280-103(43), C.R.S.) and provider by the carrier, state entity, or optional participating plan should not exceed the upper payment limit plus any reasonable fees charged by the pharmacy or pharmacist for dispensing or delivering a prescription drug. As set forth in 3 CCR 702-9, Part 4.2.C.2, an upper payment limit also

applies to all purchases by a pharmacy (as defined by section 12-280-103(43), C.R.S.) or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means.

An upper payment limit does not apply to the purchase or reimbursement by any federal agency, federal program, Indian Tribe, or non-participating self-funded health benefit plans, including but not limited to, purchases or reimbursements made by Medicare, TRICARE, or the Federal Employee Health Benefits program.

Methodology to Establish Upper Payment Limits

Upper Payment Limit Methodology: Staff will prepare the following information, to the extent it is available, for the Board to utilize to establish an upper payment limit. This information will be submitted to the Board as part of the rulemaking record for the rule establishing the upper payment limit for the prescription drug. To the degree the Board has identified whether certain factors in the methodology should be weighted, Staff will reflect this weighting in documents and data presented to the Board when establishing an upper payment limit.

1. Prescription Drug Costs: To approximate the cost of administering, dispensing, and distributing prescription drugs, as well as other relevant prescription drug costs, Staff may compile the following price and cost metrics for the Board's review. Staff may provide information on current metrics, metrics at the time when the prescription drug was identified as a prescription drug eligible for an affordability review, and historical information. Metrics include but are not limited to:

    a. Wholesale Acquisition Cost: obtained via a third-party vendor or contractor.

    b. Average Sales Price: if the prescription drug has an Average Sales Price (ASP), as reported by the Center for Medicare and Medicaid Services (CMS).

    c. National Average Drug Acquisition Cost: if the prescription drug has a NADAC, as reported by CMS.

    d. Out-of-pocket spending: Information regarding out-of-pocket costs for the prescription drug will be based on:

        i. APCD data, and

        ii. Other data sources that approximate out-of-pocket costs not captured in APCD data.

    e. Carrier paid amounts: Information regarding carrier paid amounts will be based on APCD data.

    f. Retail discount amounts: Information regarding retail discounting for the prescription drug from sources including Pharmacy Checker, Good Rx, and others.

    g. Public program fee schedules: Information regarding public program fee schedules may include fee schedules from: Colorado Medicaid, Colorado Children's Health Plan Plus, Medicare, Veterans Affairs, and other state and national fee schedules.

    h. Estimates of manufacturer net-cost and net-sales amounts: To the extent the Board has funding, information may be prepared from an external database regarding estimated rebates, discounts, and price concessions for the prescription drug under review.

i. Medicare's Maximum Fair Price: Information regarding the price negotiated as determined by section 42 U.S.C. § 1320f(c)(3).

j. Cost information voluntarily provided by a wholesaler, pharmacist, or provider.

2. Drug Shortage List: Staff will prepare information regarding a prescription drug's status on the Drug Shortage List on the day the Board adopts an upper payment limit for the prescription drug, as reported by the Food and Drug Administration (FDA) and the American Society for Health System Pharmacists.

3. Impact to Older Adults and Persons with Disabilities: Staff will prepare information related to the impact of the upper payment limit methodology to older adults and persons with disabilities and shall not place a lower value on their lives.

   a. Impact to Older Adults: The Board will consider the following metrics for individuals 65 years and older: =

      i. To the extent such information is available in the APCD:

         (a) Utilization of the prescription drug;

         (b) Cost of the prescription drug; and

         (c) Insurance coverage type for individuals utilizing the prescription drug; and

      ii. Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to older adults. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age. When applicable, stakeholders will disclose if cost-per-QALY or similar measure was used in research submitted.

   b. Impact to Persons with Disabilities: The Board will consider the following metrics for persons with disabilities:

      i. Therapeutic classification of the prescription drug, including the prescription drug's therapeutic purpose and any conditions or diseases the prescription drug may treat,

      ii. To the extent it is known that any conditions or diseases the prescription drug may treat are considered disabilities and to the extent such information is available in the APCD, the Board may consider:

         (a) Utilization of the prescription drug;

         (b) Cost of the prescription drug; and

(c) Insurance coverage type for individuals utilizing the prescription drug; and

iii. Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to persons with disabilities. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age. When applicable, stakeholders will disclose if cost-per-QALY or similar measure was used in research submitted.

4. Reasonable Pharmacy Fees: Staff will prepare information regarding the requirement to ensure an upper payment limit established by the Board does not preclude a pharmacist or pharmacy (as defined by section 12-280-103(43), C.R.S.) licensed by the State Board of Pharmacy to charge reasonable fees, to be paid by the providing health benefit plan of the consumer, for dispensing or delivering a prescription drug for which the Board has established an upper payment limit.

5. Research and Methods that Employ a Dollars-per-QALY: Staff will prepare information regarding the requirement that the Board shall not consider research or methods that employ a dollars-per-QALY or similar measure in estimating impact to older adults and persons with disabilities, or in any other upper payment limit methodology considerations.

6. Stakeholder Input: The Board shall receive stakeholder information submitted through an upper payment limit rulemaking, containing information relevant to any of these considerations that the Board may take into account in establishing an upper payment limit. Stakeholders are encouraged to disclose to the Board which type of stakeholder they are and/or whether they are affiliated with an entity or organization that may have experience with or an interest in a specific position related to the prescription drug.

Process for Establishing an Upper Payment Limit Through Rulemaking

1. The Board will establish upper payment limits through rulemaking, in compliance with sections 10-16-1407(5) and 24-4-103, C.R.S.

2. The Board will publicly deliberate over which prescription drugs it has determined to be unaffordable pursuant to section 10-16-1406, C.R.S. and part 3 of the Board's rules to select for establishment of an upper payment limit.

3. The Board will take and consider public comment regarding its selection of eligible prescription drugs to be subject to an upper payment limit prior to voting whether to select a prescription drug for establishment of an upper payment limit.

4. The Board will select a prescription drug for establishment of an upper payment limit by a majority vote to initiate rulemaking to establish an upper payment limit for that drug. The upper payment limit will be established through the Board's adoption of a rule that identifies the upper payment limit for that prescription drug.

5. The Board will not vote whether to set an upper payment limit for a prescription drug in executive session, as required by section 10-16-1404(3)(a), C.R.S.

6. All drugs for which the Board has determined to establish an upper payment limit and filed notice for rulemaking with the Colorado Secretary of State will be posted on the Board's website.

7. Once a notice of rulemaking has been filed with the Colorado Secretary of State, Staff will make available the Affordability Review Report for that prescription drug.

8. Stakeholders can submit written comments to the Board at dora_ins_pdab@state.co.us or provide testimony at the noticed rulemaking hearing for that prescription drug in accordance with the Colorado Administrative Procedures Act. Subject to any confidentiality, all written stakeholder input will be published and become part of the rulemaking record.

9. The Board will encourage stakeholders to identify which of the considerations set forth above and in Part 4 of its rules the submitted information will assist and/or inform the Board of in its deliberations.

10. Nothing precludes the Board from terminating a rulemaking to establish an upper payment limit.

Process for Prescription Drug Availability Inquiries and Reporting

1. Withdrawal Information from Manufacturers:

    a. Inquiry process:

        i. For any upper payment limit established, the Board shall inquire of manufacturers:

            (a) Whether the manufacturer is able to make the prescription drug available for sale in the State of Colorado, and

            (b) The rationale for the manufacturer's response.

        ii. Manufacturers shall have 30 days to respond.

    b. Notification to Consumers: If the Board receives notification that a manufacturer intends to withdraw a prescription drug for which the Board has established an upper payment limit from the sale or distribution within Colorado, the Board will notify consumers within ten days, as required by section 10-16-1412(2), C.R.S.

2. Reporting to the General Assembly: The Board shall submit the manufacturer's inquiry response annually to the Health and Human Services Committee of the Senate and the Health and Insurance Committee of the House of Representatives, or to any successor committees.

Confidentiality

Staff will employ reasonable efforts to ensure confidential information can be securely submitted and maintained for the Board's consideration and is only accessible to authorized persons pursuant to sections 10-16-1404(3) and 10-16-1406(5), C.R.S. A person submitting information for the Board's consideration pursuant to Part 4 of the Board's rule shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary as

"confidential". Staff will not disclose information marked as "confidential" in public Board materials, including public meeting packets. Staff will not share confidential information except with Board members, legal counsel, and qualified third-party contractors subject to a nondisclosure agreement pursuant to section 10-16-1406(5), C.R.S.

If information marked as confidential has been submitted for the Board's consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential, trade secret, or proprietary information. The Board may also determine that information submitted to it is confidential, trade secret, or proprietary. To the extent the Board deliberates such confidential information, the deliberations will take place in executive session pursuant to sections 10-16-1404(3) and 10-16-1407(7), C.R.S. The Board will not disclose confidential, trade secret, or proprietary information in an open meeting or its public meeting materials. To the extent practicable, Staff will identify the need for an executive session for the Board's discussion and/or deliberation of trade-secret, proprietary, and confidential materials in advance of a public Board meeting as required by section 10-16-1404(3), C.R.S., and section 10-16-1407(7), C.R.S.

The Board will comply with the Colorado Open Records Act and all applicable state and federal laws in determining whether information is confidential. The Board, through Staff will independently determine whether information otherwise identified as "confidential" by a party submitting the information is confidential pursuant to state and federal law for purposes of responding to requests for information or documents.

In responding to any requests for information or documents, Staff may request additional information from the person asserting confidentiality or, to the extent Staff is able to determine who created the document or information, the person who created the document or information, regarding the nature of the confidentiality. Staff may seek legal advice on behalf of the Board related to confidentiality of documents.