

Prescription Drug Affordability Board Policies and Procedures

| | |
|---|----|
| 1. Background..... | 3 |
| A. Statutory Authority | 3 |
| B. Purpose..... | 3 |
| 2. Definitions | 3 |
| 3. Board Members and Meetings | 4 |
| A. Board Member Selection Process | 4 |
| B. Term Length and Vacancies | 4 |
| C. Responsibilities of the Chair of the Board | 4 |
| D. Meetings..... | 5 |
| i. Meeting Agendas, Materials, and Notes | 5 |
| ii. Quorum, Decisions, and Voting..... | 6 |
| iii. Public Records and Open Meetings..... | 6 |
| iv. Executive Session | 6 |
| v. Meeting Attendance, Absences, and Participation | 7 |
| E. Conflicts of Interest | 8 |
| i. Policy Statement | 8 |
| ii. Actual Conflict of Interest | 8 |
| iii. Appearance of Impropriety | 9 |
| iv. Procedures for Identifying and Managing Conflicts of Interest | 9 |
| v. Annual Review | 9 |
| F. Member Resignation, Removal, and Replacement | 10 |
| G. Board Members are Public Representatives | 10 |
| H. Coordinating with other Entities | 10 |
| I. Interaction with the Media and Lobbyists | 11 |
| 4. Health Care Authority Staff | 11 |
| A. Board Meetings | 12 |
| B. Contracts | 13 |
| C. Administration | 13 |
| D. Support for Performance of Board Duties | 15 |
| 5. Advisory Groups | 16 |
| A. Advisory Group Member Selection Process | 16 |

| | | |
|------|---|----|
| B. | Term Length and Vacancies | 16 |
| C. | Responsibilities of the Advisory Group Members..... | 17 |
| D. | Meetings | 17 |
| E. | Conflicts of Interest | 17 |
| 6. | Affordability Review | 18 |
| A. | Identifying Prescription Drugs for Affordability Reviews | 18 |
| B. | Selection of Eligible Prescription Drugs for Affordability Review | 18 |
| C. | Conducting an Affordability Review | 19 |
| i. | Assembling and Presenting Required Information to the Board | 19 |
| ii. | Notice and Submissions of Information | 20 |
| iii. | Maintaining Confidential Information | 21 |

1. Background

A. Statutory Authority

The Prescription Drug Affordability Board is convened by HCA as required by § 70.405 RCW. 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 Washington Administrative Code (WAC), the statutes, Constitution, and judicial decisions govern.

B. Purpose

The Prescription Drug Affordability Board (the “Board”) is established by statute to protect Washington residents from excessive prescription drug costs. The purpose of the Prescription Drug Affordability Board (“Board”) is to conduct reviews of drug prices, perform drug affordability reviews, and to set upper payment limits for prescription drugs. The Board will be assisted in these functions by the Health Care Authority Staff (“HCA” or “Authority” or “Staff”). These policies and procedures outline the means through which the Board and the Authority will accomplish the Board’s mission as defined by statute, § 70.405 RCW, and in the rules adopted by HCA Chapter 182-52 WAC (“Chapter”).

2. Definitions

“Advisory Group” means the Washington Prescription Drug Affordability Advisory Group created in § 70.405 RCW.

“Chair” means Chair of the Prescription Drug Affordability Board

“Counsel” means any assistant attorneys general assigned by the Attorney General to provide legal counsel to the Board.

“HCA” and “Authority” means the Washington Health Care Authority.

“Member” means one of the five Board members appointed by the Governor.

“Staff” means any individual employed by HCA or a subcontractor providing support to or doing work on behalf of the Board.

3. Board Members and Meetings

A. Board Member Selection Process

Members are appointed by the Governor. Individuals interested in serving on the Board may apply through the Washington 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.

B. Term Length and Vacancies

Members will serve five-year terms.

Members seeking re-appointment for a second term should notify HCA 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 Governor's office.

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.

C. Responsibilities of 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 works with Staff to develop Board meeting agendas. The Chair also ensures Member compliance with the Conflict of Interest Policy.

The Chair is selected through a vote of the members of the Board. Members can nominate themselves or be nominated by other Members. Three members of the Board must vote affirmatively for a Member to be selected.

D. Meetings

The Board will determine the frequency of meetings but are required to hold a meeting at least every three months. The Chair may decide to cancel or postpone a meeting at their discretion. Examples of when a meeting may need to be postponed include, but are not limited to:

- when there are no prescription drugs to review whether as a result of incomplete data or the need for further analysis,
- when a quorum of the Board is unavailable, or
- other unforeseen events making it impractical to meet at that time.

The Board has discretion to set the time for its meetings. The Board may decide to adjourn a meeting and postpone agenda items until the next scheduled meeting. A Member can participate in person, by phone, or virtually. Board meetings are open public meetings, other than executive sessions and the Board meetings will abide by all requirements of the Open Public Meetings Act. Meeting times will be posted with the registrar by Staff.

The Board may provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally at the meeting during the designated time. When speaking, members of the public should introduce themselves with their name and affiliation, if any. The Board is not obligated to respond to comments. Public comments may be limited to a reasonable time per speaker, such as 3 minutes per speaker, unless otherwise established by the Chair.

i. Meeting Agendas, Materials, and Notes

Staff will post Board meeting minutes, agendas, and notices of upcoming meetings on the Prescription Drug Affordability Board web page. The meeting agenda will be designed, among other things, to ensure the Board meets its statutory obligations. The Board Chair in collaboration with Staff will prepare a draft agenda and provide it to the Members no less than one week prior to the Board meeting.

Each Member will review the draft agenda and notify the Staff of any potential conflict of interest at least one day before the meeting. Staff will notify the Chair if there is not quorum, at which point the Chair will cancel the meeting.

Prior to the meeting, Staff will provide each Member with a Board packet of items.

The Board packet may include materials, information, or analysis from the Advisory Group, Staff, and any third-party contractors necessary for the Board to make informed decisions. The agenda will be posted on the Board’s website no less than 24 hours prior to the Board meeting.

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

ii. Quorum, Decisions, and Voting

A simple majority of the five (5) Members constitutes a quorum. Decisions will be made by Member voting. Voting will be conducted by Member roll call, with at least three “yes” votes needed in order to pass. A meeting cannot be held with only one or two members.

Motions to conduct Board business should follow the processes set forth in Robert’s Rules of Order (e.g., motion, second, discussion, vote).

iii. Public Records and Open Meetings

The Board’s activities are subject to the Washington Public Records Act, § 42.56 RCW, and the Open Public Meetings Act, § 42.30 RCW. Consistent with those laws, the Board’s activities generally will be conducted in public pursuant to public notice, unless the Open Public Meetings Act permits particular matters to be discussed in executive session or as expressly required by § 70.405 RCW 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 Washington Public Records Act, subject to any exclusions from disclosure contained in that Act or exclusions provided under § 70.405 RCW. The Board adopts as its Washington Public Records Act policy HCA’s Washington Public Records Act policy contained in § 182-04 WAC. Under some circumstances, the Board may meet in Executive Session. Members who have a conflict must recuse themselves from any portion of the executive session where topics related to the conflict are discussed.

iv. Executive Session

The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Washington Office of the Attorney General as permitted by § 42.30 RCW. The Board may retire into executive session to discuss confidential information pursuant to section § 70.405 RCW.

- To enter executive session, the Chair will state the topic for discussion in the executive session, the statutory provision which authorizes the Board to meet in executive session, and when the executive session will conclude.
- Upon a majority vote in favor of the motion, the open meeting will be adjourned, public attendees are required to leave the meeting before 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.
- If additional time is required to complete the deliberations of the executive session, the Board will adjourn the executive session, reconvene the open public meeting, then announce the need to return to executive session, following the steps listed above.

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.

v. Meeting Attendance, Absences, and Participation

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 Staff at least one day prior to the meeting. If a Member misses meetings without informing Staff, the Board may vote to recommend to the Governor that Member be removed.

E. Conflicts of Interest

i. Policy Statement

Members must disclose all conflict of interest for which the 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 Member's participation in a Board activity does not constitute a conflict of interest. All Member applicants must disclose conflicts of interest when being considered for appointment or re-appointment to the Board.

To ensure impartiality, each 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 of interest. Individual Staff may be required to recuse themselves from any Board activity in which the individual has a conflict of interest. The Board and HCA will ensure Members and Staff disclose conflicts of interest in accordance with this policy and its requirements.

ii. Actual Conflict of Interest

Members may have an actual conflict of interest or the appearance of a conflict of interest. An actual conflict of interest occurs when a Member is in a position to derive personal benefit, financial or otherwise, direct or indirect, from actions or decisions made in the course of the performance of official duties, or when a Member's private or personal interest impairs their independent and impartial judgement in the exercise of official duties. Conflicts of interest include situations that have the potential to bias or appear to bias an individual's decisions in matters related to the Board or the activities of the Board.

iii. Appearance of Impropriety

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 § 70.405.020(4) RCW, 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.

iv. Procedures for Identifying and Managing Conflicts of Interest

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

Prior to each Board meeting, 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 Member determines they have a conflict of interest, the Member must recuse themselves. The Member will also notify 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 Members may seek the advice of the assistant attorney(s) general assigned to the Board.

v. Annual Review

The Board will review the Conflict of Interest Policy at least annually.

F. Member Resignation, Removal, and Replacement

Any Member who can no longer perform the responsibilities of the Board must notify the Chair (unless that Member is the Chair), 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.

Members serve at the will of the Governor, and a Member may be removed by the Governor at the Governor's discretion. Reasons for removal may include but are not limited to the following:

- Multiple absences from Board meetings;
- Conflict of interest or appearance of impropriety;
- Upon recommendation by the Authority;
- Upon a simple majority vote of the remaining members of the Board;
- Acting in a way that explicitly goes against or frustrates the purpose of the authorizing statute, WAC rules, or policies and procedures of the Board;

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

G. Board Members are Public Representatives

Members of the Board are Public Representatives, appointed by the Governor, with the purpose of protecting Washington 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 of the Board. As such, it is imperative Members do not engage in any activity of the Board where there is a conflict of interest.

H. 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 Washington consumers.

I. Interaction with the Media and Lobbyists

The Board operates as a single entity when communicating with external parties. If Members receive media requests related to their Board work and participation, they should notify HCA_WA_PDAB@hca.wa.gov, and the request will be routed to the proper HCA staff.

4. Health Care Authority Staff

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.

Staff may also provide support to the Board in preparing policy recommendations to the Legislature and preparation of annual reports to the Legislature (pursuant to § 70.405.080 RCW). The Authority 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.

Staff may be reached at HCA_WA_PDAB@hca.wa.gov. These policies will be posted

on the HCA PDAB website: <https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-Board>.

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 Member.

A. Board Meetings

- Facilitate meetings of the Board and advisory group meetings, including scheduling meetings, arranging meeting platforms and/or locations, and sending calendar invitations and Board-related notices.
- Provide public notice of Board meetings and agenda items on the Board's website.
- Develop agendas for Board meetings in coordination with the Chair.
- Serve as the Recording Secretary for the Board and prepare meeting minutes for consideration by the Board.
- Prepare Board materials.
- Distribute agenda and materials in support of the Board's agenda to each Member.
- Review meeting materials and agenda items with Counsel prior to the Board meeting.
- Record all meetings.
- Record and securely store recordings of all executive sessions entered into by the Board during Board meetings.

B. Contracts

- Pursuant to “Chapter”, and in compliance with any procurement policies, 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 on time.
- In order to carry out its powers and duties, the Board authorizes the Authority to contract on its behalf for work deemed necessary.

C. Administration

- Custodian of record for the Board.
- 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.
- 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.
- Receive and respond to requests made pursuant to the Washington Public 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.
- The Program Director or any other Staff may accept service on behalf of the Board.
- 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.

- Receive and maintain documents and correspondence addressed or submitted to the Board and ensure Board review of such materials, if necessary.
- Draft reports and memoranda pertaining to work completed by or on behalf of the Board.
- Maintain the Board's public webpage and ensure the webpage contains the following:
 - Reports prepared pursuant to section 70.405.080 RCW.
 - Notice of Board meetings and hearings.
 - All agendas, non-confidential and non-privileged meeting materials, and Board-approved meeting minutes.
 - List of Members.
 - List of Advisory Group Members.
 - Instructions for submitting materials for the Board's consideration.
 - Contact information for submitting requests pursuant to the Washington Public Records Act.
 - Policies and procedures adopted by the Board.
 - Resolutions, Orders, and any other memorialized decisions by the Board.
 - Findings, reports, and studies conducted by the Board, redacted for confidential information as necessary.
 - Notices of proposed rulemaking and rulemaking hearing information.
 - List of all prescription drugs the Board selects for an affordability review.
 - List of all prescription drugs the Board determines to be

unaffordable.

- List of all upper payment limits established by the Board.
- Any material specifically requested by the Board.

D. Support for Performance of Board Duties

- Facilitate rulemaking, policies, and drafting of methodologies and other deliverables for review by the Board.
- Provide and collect conflict of interest forms to the Board:
 - Distribute conflict of interest forms and coordinate completion of disclosures by prospective and active Members, Staff, prospective and active Advisory Group members, and Counsel.
 - Seek legal advice on behalf of the Board from Counsel concerning analysis related to conflicts of interest.
- Draft reports required by section 70.405.080 RCW, and present drafts to the Board for review, amendment, and approval as part of HCA's report writing and publication process.
- Coordinate with legislative staff regarding legislative hearings or presentations.
- Coordinate data and information collection on behalf of the Board, including by working with other state agencies, stakeholders, and Advisory Groups, 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.
- 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 Public Meetings Act, Washington Public Records

Act, confidentiality of information received by the Board, Board meetings and agenda items, executive session, and Board proceedings.

- Recruit potential Advisory Group members for consideration by the Board.
- Request notification and copies of any notices of withdrawal received by the Office of the Insurance Commissioner pursuant to section 70.405.070 RCW.
- 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 addressed in these policies.

5. Advisory Groups

A. Advisory Group Member Selection Process

Advisory group members will be established by the Board with the assistance of the Staff. Staff will select advisory group members through an open application process, following the selection of drugs for affordability reviews. Applications will be submitted through the Board website. Applications will be reviewed, candidates interviewed, and group members selected by Staff. Staff will endeavor to seat group members who meet the qualifications listed in “Chapter”.

B. Term Length and Vacancies

Advisory group members will serve for the duration of the affordability review for which they were selected to be a member. The duration of each affordability review is variable, and will be determined by the Board and subject to change.

Members removed from the advisory group will be notified with the reasons for their removal. Removals will be effective immediately, from the moment that notice is sent by HCA to the advisory group member. Advisory group members can be

removed for any of the reasons listed in “Chapter”.

Vacancies on the advisory group will be filled using the same process as the original appointment of the advisory group: through an application and selection process facilitated by HCA staff.

C. Responsibilities of the Advisory Group Members

The advisory group is established by statute to provide stakeholder input to the Board regarding the affordability of prescription drugs. Advisory group members may be tasked with the production of a report or series of reports, and may be asked to respond to specific Board inquiries.

Board members may consider advisory group opinions, reports, and analyses in the formulation of the affordability review, but are not required to follow the advisory group’s guidance.

D. Meetings

Advisory group members will meet at a cadence determined by the Board. Meetings will be facilitated by HCA staff and will be open to the public. Meeting materials will be posted to the PDAB website and distributed to the advisory group prior to advisory group meetings.

E. Conflicts of Interest

The rules and policies regarding Board member conflicts of interest apply to Advisory group members, with the exception that one member of the advisory group may be a representative from the prescription drug industry (e.g., an employee, consultant, or Board member of a prescription drug manufacturer or related trade association.). The advisory group member who is a representative from the prescription drug industry cannot be an employee, consultant, or Board Member of a manufacturer whose drug is being reviewed, or a competitor of that manufacturer. All advisory group members must complete a conflict of interest form before serving.

The Board appoints the members of the Advisory Group and will ensure that all

potential Advisory Group 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 Group.

6. Affordability Review

A. Identifying Prescription Drugs for Affordability Reviews

Staff will prepare a list of prescription drugs that meet the criteria set forth in section 70.405.030 RCW, and “Chapter” to be considered by the Board for an affordability review.

Once Staff has compiled the list of eligible prescription drugs, Staff will present the list to the Board for review.

Methodologies used to extract data from existing data sources to identify the drugs that are eligible for an affordability review will be publicly presented to the Board, or presented in executive session, as applicable.

B. 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 set forth in 70.405.040 RCW and “Chapter”.

To the extent permissible, the Board will publicly deliberate over the selection criteria. The Board will deliberate over any information relating to the selection criteria containing confidential data that is not otherwise available to the public in executive session. The Board may 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. All drugs for which the Board has determined to conduct an affordability review will be posted on the Board's website.

C. Conducting an Affordability Review

i. Assembling and Presenting Required Information to the Board

Staff shall compile information to support each of the factors identified in sections 70.405.040 RCW and "Chapter". Staff may compile the information through internal analysis, engaging contractors, 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. 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. 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 Washington 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 may take and consider public comment regarding its deliberations concerning whether a prescription drug is unaffordable for Washington consumers. When the Board determines it has sufficiently considered the information, the Board

will 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. Staff will present the final report at the next Board meeting, where the Board may then vote to adopt the final report. The final report will be made available to the public on the Board's website.

ii. Notice and Submissions of Information

On an annual basis, Staff may 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 70.405.040 and 050 RCW. All interested parties may 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. 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.

Persons submitting information for the Board's consideration shall have 60 days from the date of the Board's selection 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) 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.

Staff may seek pricing information from manufacturers, carriers, and PBMs pursuant to section 70.405.040 RCW. Staff will request information provided under section 70.405.040 RCW, in writing (by mail or electronic mail). Staff will inform the Board in the event a manufacturer, carrier, and/or PBM fails to provide the requested pricing information. Manufacturers, carriers, and PBMs must provide the requested information to the Board within 30 days of Staff's request. If the

information is not provided within this timeframe, the Board may conduct the affordability review without the requested information.

iii. 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. "Confidential information" for the purposes of these policies means: (a) Specific information collected by the authority that is not publicly available for the purposes of "Chapter"; or (b) Is proprietary data provided by manufacturers in accordance with "Chapter" that is not subject to public disclosure.

If confidential information has been submitted for the Board's consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential information. To the extent the Board deliberates such confidential information, the deliberations may take place in executive session. The Board will not disclose confidential 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.

The Board will comply with the Washington Public 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.