

Prescription Drug Affordability Board

Advisory Group

Charter and Operating Procedures

The purpose of this charter is to clarify the responsibilities of and expectations for the Advisory Group as established by the Prescription Drug Affordability Board (PDAB).

I. Vision and Mission

A. Vision

To aid the Board in conducting affordability reviews of selected drugs, by providing guidance and expertise.

B. Mission

The Advisory Group serves at the direction of the Board. The goal of the Advisory Group is to provide guidance to the Board on the different components of drug affordability in Washington. The Advisory Group members will investigate each drug selected by the Board and will provide a written report to the Board with their findings as to the drug's affordability. The Advisory Group members will follow the description of their roles and responsibilities laid out in 70.405 RCW and in WAC 182-52.

II. Advisory Group Duties and Responsibilities

A. Membership and Term

The Board will appoint up to nine core Advisory Group members, including experts in:

- The pharmaceutical business model;
- Supply chain business model;
- The practice of medicine or clinical training;
- Health care consumer or patient perspectives;
- Health care cost trends and drivers;
- Clinical and health services research;

- The state's health care marketplace.
- A representative of the prescription drug industry;

For each specific drug affordability review, the Board will appoint up to five supplemental Advisory Group members, including experts in:

- Patients and/or patient advocates for the condition being treated;
- Health care providers who specialize in treating the condition for the drug being reviewed.

To the extent possible, Advisory Group members will have experience serving underserved communities and reflect the diversity of the state with regard to race, ethnicity, immigration status, income, wealth, disability, age, gender identity, sexual orientation, and geography.

B. Recruiting and Appointment

The opportunity to apply for Advisory Group membership will be posted to the Prescription Drug Affordability Board's web page. The call for applications will be shared by HCA through a GovDelivery announcement when the opportunity is posted to the Board's web page. Nominees will need to complete a basic application about the individual, their background/expertise to participate, and why they want to participate on the Advisory Group. Nominees will also submit their most recent resume. The posting and opportunity to complete an application will be available for at least thirty (30) days which may be extended to sixty (60) days if needed to allow for additional applicants.

All application materials will be shared with the Board. The top three (3) most qualified applicants will be presented to the Board. The Board will then appoint Advisory Group members based on HCA's recommendation.

Advisory Group members must complete a conflict of interest form before being appointed. Vacancies among the Advisory Group members will be filled by the Board with HCA's assistance.

Core Advisory Group members will be appointed for 2-year staggered terms. The members of the inaugural Advisory Group may be appointed for longer or shorter terms to allow for staggered tenures. Supplemental Advisory Group members will be appointed for the duration of a specific drug affordability review.

C. Advisory Group Member Responsibilities

Members of the Advisory Group agree to fulfill their responsibilities by serving at the direction of the Board, attending and participating in the Advisory Group meetings, and studying the available information. As directed by the Board, the Advisory Group members agree to participate in the development of the Advisory Group report, as well as respond to ad hoc inquiries made by the Board during the affordability review.

The Advisory Group members provide guidance to the Board. The Board will consider the Advisory Group guidance in its decision making while conducting affordability reviews and while considering the enactment of upper payment limits. Outside subject matter experts may be invited to present to the Advisory Group at their meetings on a singular or recurring basis. However, outside subject matter experts will not be official members of the Advisory Group.

Members of the Advisory Group agree to participate in good faith and to act in the best interests of the Board and its charge. The Advisory Group members are expected to consider a range of issues and options to address them, discuss the pros and cons of the issues or options, and present them to the Board, while keeping in mind the impact of those options on patients. The Advisory Group will include the rationale behind each recommendation provided to the Board.

The Advisory Group will meet between Board meetings on a bimonthly basis. This schedule will continue until the Board deems it appropriate to revise the Advisory Group's meeting schedule, or the Advisory Group completes its goals. The Advisory Group members should review materials before meetings and attend meetings.

Specific Advisory Group member responsibilities include:

1. Attending the Advisory Group meetings and reviewing materials provided in advance of the meeting.
2. Reviewing background materials, including:
 - i. The Board's regular meeting materials to understand issues under consideration by the Board and any decisions the Board has made.
 - ii. The Board's annual reports to the Legislature.
3. Working collaboratively with one another to explore issues as directed by the Board.
4. Hearing from invited outside subject matter experts, as needed.
5. Developing a final report with guidance to the Board regarding conducting an affordability review of a specific drug.

6. Some of the following areas could be assigned by the Board for guidance, including but not limited to:
 - i. The relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, and other price concessions;
 - ii. The average out-of-pocket cost for the drug;
 - iii. The effect of the price on consumers' access to the drug in the state;
 - iv. Orphan drug status;
 - v. The dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug;
 - vi. The price and availability of therapeutic alternatives;
 - vii. Input from:
 - o Patients affected by the condition or disease treated by the drug; and
 - o Individuals with medical or scientific expertise related to the condition or disease treated by the drug;
 - viii. Any other information the drug manufacturer or other relevant entity chooses to provide;
 - ix. The impact of pharmacy benefit manager policies on the price consumers pay for the drug;
 - x. Life-cycle management;
 - xi. The average cost of the drug in the state;
 - xii. Market competition and context;
 - xiii. Projected revenue;
 - xiv. Off-label usage of the drug; and
 - xv. Any additional factors identified by the board.

D. Role of the Washington Health Care Authority (HCA)

HCA assists the Board and shall assist the Advisory Group by facilitating meetings, conducting research, distributing information, helping draft reports, and advising the Advisory Group members.

E. The Advisory Group Lead's Role

The Advisory Group Lead will be designated by the Board. The Advisory Group Lead will encourage participation by the Advisory Group members in all aspects of the process, assist in creating guidance for the Board, and ensure all participants abide by the expectations for discussion processes and behavior.

The Advisory Group Lead will develop meeting agendas, organize invitations to outside experts, and otherwise ensure an efficient decision-making process. The Advisory Group

Lead will also serve as the liaison between the Advisory Group and the Board, including presenting to the Board the Advisory Group's guidance.

III. Operating Procedures

A. Protocols

All participants agree to act in good faith in all aspects of the Advisory Group's discussions. This includes being honest and refraining from undertaking any actions that will undermine or threaten the deliberative process. It also includes behavior outside of meetings. Expectations include the following:

- i. Members should attend and participate actively in all meetings. If members cannot attend a meeting, they are requested to advise HCA staff. After missing a meeting, the member should contact staff for a recording of the meeting, or if not available, then a meeting summary and any available notes from the meeting.
- ii. Members agree to be respectful at all times of other Advisory Group members, Board members, staff, and audience members. They will listen to each other and seek to understand the other's perspectives, even if they disagree.
- iii. Members agree to make every effort to bring all aspects of their concerns about issues related to drug affordability into this process.
- iv. Members agree to refrain from personal attacks, undermining the process of the Advisory Group or the Board, and publicly criticizing or misstating the positions taken by any other participants during the process.
- v. Any written communications, including emails, blogs, and other social networking media, will be mindful of these procedural ground rules and will maintain a respectful tone even if highlighting different perspectives.
- vi. Members are advised that email, blogs, and other social networking media related to the business of the Advisory Group or the Board are considered public documents. Emails and social networking messages meant for the entire group must be distributed via HCA staff.
- vii. Requests for information made outside of meetings will be directed to HCA staff. Responses to such requests will be limited to items that can be provided within a reasonable amount of time.

B. Communications

1. Written Communications

Members agree that transparency is essential to the Advisory Group's discussions and the Board's deliberations. In that regard, members are requested to include both the Advisory Group lead and HCA staff in written communications

commenting on the Advisory Group's discussions or the Board's deliberations from/to interest groups (other than a group specifically represented by a member); these communications will be included in the public record as detailed below and copied to the Advisory Group and the full Board as appropriate.

Written comments to the Advisory Group, from both individual Advisory Group members and from agency representatives and the public, should be directed to HCA staff.

Written comments will be distributed by HCA staff to the Advisory Group and the full Board in conjunction with distribution of meeting materials or at other times at HCA's discretion. Written comments will be posted to the Board's webpage.

2. Media

Advisory Group members agree to defer to HCA for all media communications related to the Advisory Group or the Board's process and its work. Advisory Group members agree not to negotiate through the media, nor use the media to undermine the Advisory Group or the Board's work.

Advisory Group members agree to raise all their concerns, especially those being raised for the first time, at an Advisory Group meeting or to the Advisory Group lead and not in or through the media.

C. Conduct of the Advisory Group Meetings

1. Conduct of the Advisory Group Meetings

For the near future, the Advisory Group will meet by videoconference bi-monthly unless changed by the Board.

Meetings will be conducted in a manner deemed appropriate by the Board and the Advisory Group Lead to foster collaborative discussion. Robert's Rules of Order will be applied.

2. Conflict of Interest

In the event that an Advisory Group member has a conflict of interest, the Advisory Group member must disclose the interest to HCA staff and will be ineligible to vote on guidance to the Board.

3. Documentation

All Advisory Group meetings shall be recorded, and written summaries prepared. The meeting recordings shall be posted on the Board's public webpage. Meeting agendas, summaries, and supporting materials will also be posted to the Board's webpage.

Interested parties may receive notice of the Advisory Group meetings and access the Advisory Group materials on the website, or via GovDelivery.

D. Public Status of the Advisory Group Meetings and Records

The Prescription Drug Affordability Board meetings are conducted under the provisions of Washington's Open Public Meetings Act (Chapter 42.30). Though the Advisory Group meetings are open to the public, meetings are not conducted under the provisions of Washington's Open Public Meetings Act (Chapter 42.30). Members of the public and legislators may testify before the Advisory Group at the time designated for public testimony. In the absence of a quorum, the Advisory Group may still receive public testimony.

Advisory Group records, including formal documents, discussion drafts, meeting summaries and exhibits, are public records. Communications of the Advisory Group members are not confidential because the meetings and records of the Advisory Group are open to the public. "Communications" refers to all statements and votes made during the meetings, memoranda, work products, records, documents, or materials developed to fulfill the charge, including electronic mail correspondence. The personal notes of individual Advisory Group members will be public to the extent they relate to the business of the Board and/or the Advisory Group.

E. Amendment of Operating Procedures

These procedures may be changed by an affirmative vote of most of the Board members, but at least one day's notice of any proposed change shall be given in writing, which can be by electronic communication, to each Board member.