

Advisory Group Proposal

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Objectives

Today's Objective:

1. Discuss an overarching structure for drug affordability review advisory groups.
2. Discuss the size, roles, and expertise desired for advisory groups.
3. Discuss an administrative structure for sharing and receiving input from the advisory groups (e.g. meeting cadence, expected deliverables, communication methods).

Looking Ahead:

1. Develop operating policies and open applications for advisory group roles.

Background: Legislative Mandate

RCW 70.405.020 – General Mandate

- ▶ (5) **The board shall establish advisory groups consisting of relevant stakeholders**, including but not limited to patients and patient advocates for the condition treated by the drug and one member who is a representative of the prescription drug industry, **for each drug affordability review conducted by the board pursuant to RCW 70.405.040**. Advisory group members are immune from civil liability for any official act performed in good faith as a member of the group.
- ▶ (6) **The authority shall provide administrative support to the board and any advisory group of the board** and shall adopt rules governing their operation that shall include how and when the board will use and discuss confidential information that is exempt from public disclosure. The rules adopted under this subsection may not go into effect until at least 90 days after the next regular legislative session.

Background: Legislative Mandate (continued)

RCW 70.405.020 – Conflicts of Interest

- ▶ (3) No board member or advisory group member may be an employee of, a board member of, or consultant to a prescription drug manufacturer, pharmacy benefit manager, health carrier, prescription drug wholesale distributor, or related trade association, **except that a representative from the prescription drug industry serving on an advisory group may be an employee, consultant, or board member of a prescription drug manufacturer or related trade association** and shall not be deemed to have a conflict of interest pursuant to subsection (4) of this section.
- ▶ (4)(a) Board members, advisory group members, staff members, and contractors providing services on behalf of the board shall recuse themselves from any board activity in any case in which they have a conflict of interest.
- ▶ (4)(b) For the purposes of this section, a conflict of interest 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 activities of the board.

Background: WAC Mandate

- ▶ (a) Advisory groups will consist of patients and patient advocates for the condition treated by the drug and one representative of the prescription drug industry. Additional group members, as selected by the board may include, but are not limited to, relevant stakeholders and experts in the following subject matters:
 - ▶ (i) The pharmaceutical business model;
 - ▶ (ii) Supply chain business model;
 - ▶ (iii) The practice of medicine or clinical training;
 - ▶ (iv) Health care consumer or patient perspectives;
 - ▶ (v) Health care cost trends and drivers;
 - ▶ (vi) Clinical and health services research;
 - ▶ (vii) The state's health care marketplace; or
 - ▶ (viii) Health care provider who specializes in treating the condition for the drug being reviewed.

Background: WAC Mandate (continued)

- ▶ Members are chosen by HCA
- ▶ Members must complete a conflict of interest check
- ▶ To the extent possible, members will have experience in developing policies for underserved communities
- ▶ One member can be a representative from the prescription drug industry
- ▶ Participation is uncompensated

Structure: Overview of Advisory Group Structure Proposal

- ▶ Follow the Advisory Group model developed by other HCA boards to establish a core advisory group
- ▶ Use of consistent core advisory group, with supplemental experts added for each drug under review

Structure: Core Advisory Group with Supplemental Experts

- ▶ Determine which types of supplementary advisors will be needed for each drug
- ▶ As drugs are selected for Affordability Review, open applications and select supplementary advisors
- ▶ Invite guest speakers to specific Advisory Group meetings to augment the group's expertise

Structure: Core Advisory Group with Supplemental Experts

▶ Advantages

- ▶ **Knowledge Retention:** Consistent core advisory group will be able to carry over lessons learned from earlier affordability reviews to future affordability reviews
- ▶ **Lower Administrative Burden:** Managing one group for multiple affordability reviews vs. establishing and administering up to 24 different groups each year

Members: Group Size, Roles, and Expertise

- ▶ Up to 7-member Core Advisory Group, composed of 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.
- ▶ Up to 6-member Supplemental Advisory Group for each drug under review:
 - ▶ Patients and/or patient advocates for the condition being treated;
 - ▶ A representative of the prescription drug industry*;
 - ▶ Health care providers who specialize in treating the condition for the drug being reviewed.

Administration: Basics

▶ Administration:

- ▶ Report to and are staffed by HCA.
- ▶ A Chair will be chosen from the core advisory group to assist HCA in facilitation of advisory group meetings.

▶ Deliverables:

- ▶ The prescription drug affordability board (PDAB) advisory groups provide stakeholder input to the board regarding the affordability of prescription drugs.
- ▶ A comprehensive report will be drafted by the advisory group and submitted to the PDAB before the close of the affordability review.
- ▶ The components of the report will be determined by the PDAB and communicated to the advisory group before work on the report commences.
- ▶ The advisory group will also be expected to respond to specific questions and inquiries from the PDAB over the course of the affordability review.

Administration: Basics

- ▶ Meeting cadence
 - ▶ Meet between PDAB meetings for 2-4 hours
 - ▶ Will need to commit 4-6 additional hours for meeting preparation
- ▶ Communication methods
 - ▶ HCA will communicate via email and in meetings
 - ▶ Advisory group will communicate to the Board through structured reports, through HCA, and during the advisory group meetings
- ▶ Term duration
 - ▶ Core advisory group members: 2-year term; staggered to maintain consistency
 - ▶ Supplemental advisory group members: serve the length of each specific drug affordability review

Administration: Recruiting

- ▶ Candidate outreach
 - ▶ Posts on the [PDAB webpage](#) and State Government Jobs site
 - ▶ Gov delivery listservs
 - ▶ Announcements during PDAB meetings
 - ▶ NASHP postings and announcements
 - ▶ Direct outreach to experts in the field and relevant stakeholders
- ▶ Application components
 - ▶ Basic information on the individual
 - ▶ Information on their expertise and background
 - ▶ Conflict of interest form
 - ▶ Brief explanation of why they want to participate on the board
- ▶ Application review
 - ▶ All application materials will be shared with the board
 - ▶ HCA staff will review applications and may conduct interviews of candidates to narrow down the list
 - ▶ The board will then appoint nominees to the PDAB advisory group based on the recommendations of HCA staff

Looking Ahead – Next Steps

- ▶ Develop operating policies and open applications for advisory group roles.



Questions?

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