Washington State Health Care Authority

Report to the Legislature

Prescription Drug Affordability Board Annual Report 2024

Second Substitute Senate Bill 5532; Section 8; Chapter 153; Laws of 2022

December 15, 2024

Washington State Health Care Authority
Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501
Phone: 360-725-0944
Email: hca_wa_pdab@hca.wa.gov
hca.wa.gov

Table of Contents

Executive Summary

The Prescription Drug Affordability Board (PDAB) was established following passage of SB 5532 by the Washington State Legislature in 2022. The PDAB's mission is to monitor and mitigate unsupported price increases of prescription drugs for Washingtonians. The PDAB is a five member board appointed by the Governor (four of the fives seats are currently filled, and we are working with the governor's offices to appoint the fifth) with expertise in health care economics and clinical medicine and staff support from the Health Care Authority (HCA). The PDAB is also permitted to establish advisory groups composed of relevant Washington stakeholders, including patients, patient advocates, and experts.

Each year, PDAB is tasked with submitting a report to the legislature outlining the Board's activities. In 2024, the Board's focus was on building and narrowing down an initial list of drugs that could be selected for affordability review. Highlights from 2024 include:

- Electing a Board Chair and Vice Chair and voting on Board Policies and Procedures related to administration of the board.
- Creating an Advisory Group to inform the Board's deliberations regarding drug selection for affordability review.
- Compiling an initial list of eligible drugs for review and determining a methodology for selecting drugs from this list for affordability review.
- Contracting with the Program on Regulation, Therapeutics, and Law at Harvard University to assist with the Board's activities and education.

Selecting a Board Chair, Vice Chair, and Ratifying Policies and Procedures

The Board elected MaryAnne Lindeblad as the Chair of the PDAB, and Eileen Cody as the Vice Chair.

The Board ratified policies and procedures for: the general operation of the board, the creation and management of an Advisory Group, and methodologies for drug selection. These policies can be found on the PDAB website.

They were ratified following a process that involved: initial drafting by HCA staff, sharing the policies with the PDAB members during an open public meeting, allowing time for the public to review and comment, and then voting to ratify the policies in a following meeting.

Creation of a PDAB Advisory Group

In 2024, the Board created a PDAB Advisory Group to inform the Board's deliberations regarding drug selection for affordability review, and to assist the Board in conducting affordability reviews.

The Advisory Group is a group of unpaid volunteers, serving 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, WAC 182-52, and in the PDAB Advisory Group Policies.

The Board appointed [INSERT FINAL NUMBER HERE] 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.

Core Advisory Group members are 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.

To the extent possible, the Board attempted to appoint Advisory Group members who 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.

In 2024, the Advisory Group provided input on how the Board should select drugs for affordability review. [PROVIDE MORE DETAILS ONCE THIS HAS HAPPENED].

In 2025, the Advisory Group will provide input on specific drugs that should be selected for affordability review, and the Board will appoint supplemental Advisory Groups to assist with each individual affordability review.

Developing an Initial Drug List

In 2024, HCA developed an initial drug list for the Board to review. This list is available on the PDAB website. Over the course of 2024, the Board discussed methods and specific data to examine in order to narrow down this list to select specific drugs for affordability reviews. In 2025, the Board will vote to select specific drugs, and then conduct affordability reviews on those drugs. In subsequent years, the Board may conduct affordability reviews of an additional 24 drugs per year.

The methodology for developing the initial drug list is described below.

PDAB is required by RCW 70.405.030 to identify prescription drugs that:

- Have been on the market for at least seven years
- Are dispensed at a retail, specialty, or mail-order pharmacy
- Are not designated by the United States Food And Drug Administration (FDA) under 21 u.s.c. sec. 360bb as a drug solely for the treatment of a rare disease or condition

The drugs must also meet the following thresholds:

1. Brand name prescription drugs and biologic products that:
    a. (a) Have a wholesale acquisition cost of $60,000 or more per year or course of treatment lasting less than one year; or
    b. (b) Have a price increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase over three years.
2. A biosimilar product with an initial wholesale acquisition cost that is not at least 15 percent lower than the reference biological product.
3. Generic drugs with a wholesale acquisition cost of $100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months.

The Board then narrowed down the drug list by [INSERT METHODOLOGY HERE AT THE END OF THE YEAR].

Contracting with the Program on Regulation, Therapeutics, and Law (PORTAL)

The Board contracted with the Program on Regulation, Therapeutics, and Law (PORTAL), a group of policy researchers at Harvard Medical School and Brigham and Women's Hospital who study how laws and regulations influence therapeutic innovation, product approval and use, and optimal delivery of care. PORTAL has worked closely with the National Academy for State Health Policy (NASHP) and other state PDABs as they have created initial drug lists, narrowed down those lists, and then selected drugs for affordability review.

The PORTAL team presented at PDAB meetings, provided access to white papers related to drug selection and conducting affordability reviews, and answered Board member questions regarding these topics.

PORTAL's presentations can be found on the Washington PDAB website, and their white papers can be found on the NASHP PDAB website.

Conclusion

In summary, the Board's activities in 2023 included:

- Electing a Board Chair and Vice Chair and voting on Board Policies and Procedures.
- Creating an Advisory Group to inform the Board's deliberations regarding drug selection for affordability review.
- Compiling an initial drug list and determining a methodology for selecting drugs from this list for affordability review.
- Contracting with the Program on Regulation, Therapeutics, and Law at Harvard University to assist with the Board's activities.

In 2025, the Board's objectives are to:

- Select drugs for affordability review.
- Begin work on the first affordability review.

The next annual report will be submitted in December 2025.

For any inquiries, please contact: hca_wa_pdab@hca.wa.gov.