Prescription Drug Affordability Board Advisory Group Overview

October 8, 2024

Washington State Health Care Authority

Agenda

- Prescription Drug Affordability Board (PDAB) Background
- PDAB Legislative History
- PDAB Advisory Group Mission
- PDAB Advisory Group Membership
- PDAB Advisory Group Responsibilities

Washington State Cost Transparency Efforts

- Rx Price Transparency (2019): RCW 43.71C
  - Reporting on cost and utilization
  - Applies to:
    - Health carriers
    - Pharmacy benefit managers (PBM)
    - Manufacturers
    - Pharmacy services administrative organizations (PSAO)
  - HCA submits annual report to the Legislature
- Health Care Cost Transparency Board (2020): RCW 70.390
  - 14-member Board staffed by HCA
  - Analyzing cost growth and cost drivers
  - Reports annually to Legislature
- Department of Health (DOH) hospital financial reports: RCW 43.70.052
- All-Payer Claims Database: RCW 43.371

Prescription Drug Affordability Boards

- Independent bodies empowered to analyze the high cost of drugs and suggest effective ways to lower costs
  - Maine
  - Maryland
  - New Hampshire
  - Oregon
  - Ohio
  - Colorado
  - Washington
  - Minnesota
- Certain state Boards are permitted to set upper payment limits (UPLs)
- Focused on cost transparency and containment
- Variation in price thresholds across states

Senate Bill 5532 (2022)

- History
  - Passed during the 2022 Legislative session
  - Prime sponsor: Senator Keiser
  - Based on NASHP model legislation, amended during the process
    - Delayed implementation of rules and UPLs
    - Increased threshold for affordability review and UPLs
- Board
  - Five-member board appointed by governor
  - Serve five-year terms
  - Conflicts of interest prohibited

Affordability reviews

- RCW 70.405.030-.040
- Drugs subject to the purview of the Board:
  - Brand names and biologics
  - Have a wholesale acquisition cost (WAC) of $60,000 or more
  - Price increase of 15 percent per year or 50 percent over three years
  - Biosimilars with initial acquisition cost not at least 15 percent lower than the reference product
  - Generics with a wholesale acquisition cost of $100 or more for a 30-day supply that increased 200 percent or more in the previous year

Affordability reviews (continued)

- Board may conduct affordability reviews of up to 24 drugs per year
- Must determine whether the drug led or will lead to excess costs to patients
- Must consider:
  - Relevant price factors
  - Average patient costs
  - Effects on access
  - Orphan drug status
  - Patient assistance programs
  - Therapeutic alternatives
  - Input from patients and medical experts

Upper payment limits

- RCW 70.405.050
- **UPLs apply to all drug purchases by any entity and reimbursements for a claim** for the drug by a health carrier.
  - Employer-sponsored self-funded plans may elect to be subject to UPLs
- HCA must adopt rules establishing UPL methodology
  - Rules and UPLs cannot take effect until 90 days after the next session
- Can set **UPLs on up to 12 drugs per year**, beginning in 2027
- Must consider:
  - Cost of administering the drug
  - Cost of delivering to patients
  - Status of the drug on the drug shortage list
  - Other relevant administrative costs related to production or delivery
- Must post notice of UPL and hold public comment 30 days before setting a UPL

PDAB Advisory Group Vision and Mission

- Vision
  - To aid the Board in conducting affordability reviews of selected drugs, by providing guidance and expertise.
- 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 a drug affordability review. The Advisory Group members will investigate each drug selected by the Board and will provide a written report to the Board with their findings. The Advisory Group members will follow the description of their roles and responsibilities laid out in 70.405 RCW and in WAC 182-52.

Membership

- 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.

Responsibilities

1. Attend bimonthly Advisory Group meetings, as well as bimonthly PDAB meetings
2. Submit a final report to the PDAB for each drug under review
3. Respond to ad hoc requests from the PDAB

Potential Topics to Inform Affordability Review

- The relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, and other price concessions;
- The average out-of-pocket cost for the drug;
- The effect of the price on consumers' access to the drug in the state;
- Orphan drug status;
- The dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug;
- The price and availability of therapeutic alternatives;
- Input from:
  - Patients affected by the condition or disease treated by the drug; and
  - Individuals with medical or scientific expertise related to the condition or disease treated by the drug;
- Any other information the drug manufacturer or other relevant entity chooses to provide;
- The impact of pharmacy benefit manager policies on the price consumers pay for the drug;
- Life-cycle management;
- The average cost of the drug in the state;
- Market competition and context;
- Projected revenue;
- Off-label usage of the drug; and
- Any additional factors identified by the board.

Next Steps

- Review drug list following PDAB meeting
- Draft recommendations for PDAB to shortlist / choose drugs for affordability review

Questions?

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