Washington State Health Care Authority

Prescription Drug Affordability Drug (PDAB) meeting. October 20, 2023.

Washington State Health Care Authority

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Washington State Health Care Authority

Prescription Drug Affordability Board

Agenda

Friday, October 20, 2023

Cherry Street Plaza **9:00 – 4:00 PM**

Time	Agenda Topic	Presenter
9:00 – 9:20 a.m.	Welcome & Introductions	Mike Neuenschwander
9:20 – 10:20 a.m.	Review SB5532, state comparison, and the Board's Objectives • Board Q&A with HCA	Evan Klein Mike Neuenschwander
10:20 – 10:30 a.m.	Break	Group
10:30 a.m. – 12:00 p.m.	Presentations • Open Public Meetings Act and Robert's Rules of Order Training • Public Records Act Training • Agency Rulemaking Overview	Michael Tunick Catherine Taliaferro Wendy Barcus
12:00 – 1:00 p.m.	Lunch	Group
1:00 – 1:45 p.m.	Review Rules and Brief Overview of Policies	Mike Neuenschwander
1:45 – 3:00 p.m.	Set Next Meeting's Agenda and Meeting Cadence	Mike Neuenschwander
3:00 – 4:00 p.m.	Public Comment*	
4:00 p.m.	Adjourn	

** Stakeholders will be allowed 3 minutes for comments.*

The times noted are estimates and subject to change.

If you are a person with a disability and need a reasonable accommodation or have questions please email HCA_WA_PDAB@hca.wa.gov

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Prescription Drug Affordability Drug (PDAB) Welcome Packet

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Prescription Drug Affordability Board Welcome Packet

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Overview of HCA & PDAB

Health Care Authority Overview

The Washington State Health Care Authority (HCA) is committed to whole-person care, integrating physical health and behavioral health services for better results and healthier residents. HCA purchases health care for more than 2.5 million Washington residents through Apple Health (Medicaid), the Public Employees Benefits Board (PEBB) Program, the School Employees Benefits Board (SEBB) Program, and the COFA Islander Health Care Program. As the largest health care purchaser in the state, we lead the effort to transform health care, helping ensure Washington residents have access to better health and better care at a lower cost.

Agency Mission

Provide equitable, high-quality health care through innovative health policies and purchasing strategies.

Agency Vision

A healthier Washington.

Agency Values

- **People first.** We put the best interest of the people we serve and our employees first.
- **Diversity and inclusion.** We value work and life experiences while practicing cultural humility with the people we serve and each other.
- **Health equity.** We help ensure everyone has the opportunity to obtain whole-person health.
- **Innovation.** We develop creative solutions and put them into action to improve our processes, systems, and services.
- **Stewardship.** We are accountable for the use of resources entrusted to us as public servants.

Agency Strategic Goals

- Ensure equitable access to integrated, whole-person care
- Achieve value-based care through aligned payments and systems
- Build person- and community-centered systems

PDAB Overview

The PDAB's mission is to monitor prescription drug affordability and mitigate the impact of excess costs of prescription drugs for Washingtonians.

The PDAB is composed of three bodies:

- A board appointed by the Governor, with expertise in health care economics or clinical medicine
- A policy team within HCA tasked with advising and supporting the Governor's board
- Advisory groups composed of relevant stakeholders from across Washington, including patients, patient advocates, and experts

The PDAB was established following passage of SB 5532 by the Washington State Legislature in 2022, and it is codified under Chapter 70.405 RCW.
(https://app.leg.wa.gov/RCW/default.aspx?cite=70.405&full=true)

Board Members

MaryAnne Lindeblad, MPH, now retired, spent the majority of her career working in various health related positions for the Department of Social and Health Services and the Washington State Health Care Authority. She was appointed state Medicaid Director in 2012 and served in that role until her retirement in 2021. Her leadership spanned most aspects of health care including acute care, long-term care, behavioral health, oral health, senior care and services for individuals with disabilities.

In 2015, she was inducted into the Eastern Washington University Chapter of the Upsilon Phi Delta Society. And in 2019, she was honored by the University of Washington School of Nursing as one of 100 Distinguished Nurse Influencers in the state. In 2020, she received the Randy Revelle award for her advocacy in supporting those with behavioral health conditions achieve their full potential. She also chaired the executive committee for the National Academy for State Health Policy, and served on the board of the National Association of Medicaid Directors. Currently, she serves on the Board of the Arcora Foundation, and the Board of the Olympia Free Medical Clinic. In addition, she serves on Westminster Presbyterian Church's Hope Village committee which provides transitional housing and support to folks in the greater Thurston County. MaryAnne holds a Bachelor of Science in Nursing from Eastern Washington University and a Master of Public Health from the University of Washington.

Douglas Barthold, Ph.D., is a health economist and Research Assistant Professor in the Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute at the University of Washington School of Pharmacy. He joined the UW in 2018, after completing a postdoctoral fellowship at the Schaeffer Center for Health Policy and Economics at the University of Southern California. He received his Ph.D. in Economics from McGill University in 2015, with a specialization in empirical health economics. Dr. Barthold teaches a graduate-level class in health economics at the UW, and is broadly interested in the relationships between health policies, healthcare utilization, and health outcomes and inequalities. His current research examines the intersection between health policies, chronic disease management, and cognition, from mid-life to end-of-life. This includes the role of health policies in the pharmaceutical management of mid-life risk factors for Alzheimer's disease and related dementias (ADRD), as well as the value of care for conditions that influence healthy aging. For more information on Dr. Barthold's research and publications, please visit: https://sites.google.com/site/douglasbarthold/.

Hung Truong, PharmD, MBA, is currently the Executive Director of Madrona Health, LLC, a joint venture between Virginia Mason Franciscan Health and Confluence Health. He had held various leadership positions over the years at Virginia Mason Medical Center including oversight of the retail pharmacy division, ambulatory pharmacist team, drug regulatory compliance, and the self-funded health plan. In 2017, he launched the specialty pharmacy program which led to the formation of Madrona Health today. Truong earned his Pharm.D. from Washington State University and MBA from Western Governors University.

Eileen Cody, BS, earned an associate degree in nursing from the College of Saint Mary and a Bachelor of Science degree in nursing from Creighton University. Eileen retired after working at Kaiser Permanente (formerly Group Health Cooperative) in Seattle for the over forty years. She worked as a neuro-rehab nurse certified in both rehabilitation nursing and multiple sclerosis care. In addition to her work at Kaiser Permanente, Eileen is a founding member of District 1199 NW/SEIU Hospital and Health Care Employees Union.

First appointed and subsequently retained to the House of Representatives in 1994, she served constituents in first the 11th district and then the 34th district through 2022. Eileen dedicated her legislative career to achieving affordable, quality healthcare for all residents of Washington state. On her retirement from the legislature Eileen was appointed to Washington's Health Care Cost Transparency Board by Governor Inslee. She also serves as a

trustee for Harborview Hospital after being nominated and appointed by the King County Council and Executive.

Health Care Authority Staff Members

Donna Sullivan, **PharmD, MS,** is the Chief Pharmacy Officer at the Washington State Health Care Authority. She has over twenty years' experience in pharmacy benefit management and formulary design. Dr. Sullivan plays a major role in the development of a statewide pharmaceutical purchasing strategy and maintenance of an evidence-based prescription drug program that optimizes state resources and clinical effectiveness.

She is responsible for managing and administering the pharmacy benefits for the Public and School Employee Benefits Boards and the Washington Medicaid Apple Health program. Dr. Sullivan oversees $1.2 billion in biennial pharmaceutical expenditures for over 2 million individuals enrolled in Medicaid and the Public and School Employee Benefits programs.

Dr. Sullivan received her Doctor of Pharmacy degree from Mercer University in Atlanta, GA and a Master's Degree in Pharmaceutical Outcomes Research and Policy from the University of Washington. She completed residency training in Ambulatory Care at the Veterans Affairs Medical Center in Atlanta GA and a two-year managed care pharmacy fellowship sponsored by Astra pharmaceuticals and the University of Washington. Prior to her current position Dr. Sullivan was the Director of Pharmacy Services for the Uniform Medical Plan, where she managed the $150 million pharmacy benefit for over 200,000 Washington State employees, retirees, and their dependents. Dr. Sullivan is also an Assistant Affiliate Instructor at the University of Washington, serving as a preceptor for third and fourth year doctor of pharmacy students.

Michael Neuenschwander, **MPA,** is the Prescription Drug Affordability Board (PDAB) Program Manager at the Washington State Health Care Authority. Michael was hired in March of 2023 to stand up the new PDAB program and oversees the administrative and support services required to assist the board with the selection and review of prescription drugs. Previously Michael worked for the Food and Drug Administration's Office of Regulatory Affairs and Center for Drug Evaluation and Research. His duties there included implementing and drafting legislation such as the Generic Drug User Fee Act and 21st Century Cures, as well as managing several of the agency's major internal process improvement projects. Most recently he also worked overseas as a US diplomat in Germany and Malaysia helping to facilitate foreign relations and implement programs abroad.

Michael has a Masters in Public Administration, speaks Spanish and Malay, and is married with four children.

Ryan Pistoresi, PharmD, MS, joined the Washington State Health Care Authority (HCA) in 2015 as the Assistant Chief Pharmacy Officer. Ryan's primary roles are to provide clinical support to the state's Apple Health (Medicaid), Public Employees Benefits Board (PEBB), and School Employees Benefit Board (SEBB) health plans and to the state's Drug Price Transparency (DPT) and Prescription Drug Affordability Board (PDAB) programs. Additionally, Ryan supports HCA with other legislative projects and priorities around pharmacy access, affordability, and purchasing, including the Total Cost of Insulin Work Group, Naloxone Bulk Purchasing and Distribution initiative, Bleeding Disorders Collaborative, Patient Out-of-Pocket Costs Taskforce, Opioid Prescribing Taskforce, and others. Ryan enjoys working on complex pharmacy issues to improve the state's overall wellbeing and for a healthier Washington.

Ryan graduated from the University of Washington School of Pharmacy with his Doctor of Pharmacy in 2014 and received his master's degree from the University of Washington Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute in 2015. Ryan serves as a Clinical Instructor for the University of Washington School of Pharmacy, helping precept student pharmacists and lecturing in the managed care elective class.

Jingping Xing, **Ph.D.** is the Cost & Quality Analytics Manager at the Washington State Health Care Authority. She oversees data analytics for the Health Care Cost Transparency program, Drug Price Transparency program, and Prescription Drug Affordability program. Dr. Xing has 10 years of experience conducting quantitative research regarding the efficacy of health care interventions and policy changes on health care utilization, cost, and outcomes. She received her PhD degree in Health Service Research & Policy from University of Rochester.

Kelly Wu, **MS,** is the Prescription Drug Affordability Board Data Analyst at the Washington State Health Care Authority (HCA). Kelly will provide data support to the Prescription Drug Affordability Board and help develop and implement analytic and research projects in support of drug price and affordability reviews.

Prior to joining HCA, Kelly worked as a research scientist with the AIDS Drug Assistance Program at the California Department of Public Health, and as an assistant statistician with the California Health Interview Survey at the UCLA Center for Health Policy Research. Kelly received her Bachelor of Science in

management science from the University of California, San Diego, and Master of Science in biostatistics from the University of California, Davis.

Marina Suzuki, **PharmD, PhD, BCPS, BCACP**, is the Health Economics Research Manager at the Washington State Health Care Authority. She received her PharmD from Oregon State University and PhD in Clinical Pharmaceutics from University of Florida. Prior to joining the Health Care Authority in 2023, she was in academia and had practiced as a board-certified ambulatory care pharmacist. Her practice setting included internal medicine and gastroenterology / hepatology clinics. Her research experience started with clinical trials in the area of pharmacokinetics and pharmacogenomics, and with collaborations with healthcare systems, she conducted real-world evidence research focusing on patient outcome data. Her current goal is to collect and analyze data to support the Prescription Drug Affordability Board and to provide cost effective care for patients in the state of Washington.

Nonye Connor, CPhT, is a Washington State Health Care Authority (HCA) project manager with the Pharmacy Unit. Nonye's current task is to help stand up the Prescription Drug Affordability Board. Nonye is a highly experienced Pharmacy Technician with over 15 years of experience and extensive pharmacy operations and procedures knowledge.

Simon Borumand, **JD, MPP** is the Prescription Drug Affordability Board Policy Analyst at the Washington State Health Care Authority (HCA). Simon will provide policy support to the Prescription Drug Affordability Board and support Mike Neuenschwander in executing the objectives of the board. Prior to joining HCA, Simon completed his Juris Doctor at the University of Washington and Master in Public Policy at the Harvard Kennedy School of Government. Prior to graduate school, Simon was a member of Mercer's Health Innovation LABS, where he evaluated new startups in health tech focused on the employer sponsored insurance market.

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Website and Contact Information

Find news, updates, meeting times and registration information, agendas and minutes at:

https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-board.

Questions about the Prescription Drug Affordability Board and Advisory Council can be sent to HCA_WA_PDAB@hca.wa.gov.

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Senate Bill Summary – PDAB Board Key Objectives

PDAB Mission

The Prescription Drug Affordability Board (PDAB) is a 5-member Board tasked with the following duties:

- Identify drugs that may be subject to an affordability review;
- Conduct affordability reviews on 24 selected eligible drugs each year;
- Determine whether a prescription drug is unaffordable for Washington consumers;
- If a drug is found to be unaffordable, the Board may set an upper payment limit starting in 2027.

Key Dates

- September 2023 – Identify initial drug list
- December 2023 – Submit Annual Report to the Legislature
- January 2024 – Submit methodology for calculating cost savings from upper payment limits to legislature
- January 2027 – Board may establish upper payment limits

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Board Meeting Schedule 2023

Meeting 1	Friday, October 20	9 AM – 4 PM
Meeting 2	Monday, December 11	9 AM – 3 PM

Frequently Asked Questions

What is a Prescription Drug Affordability Board (PDAB)?

The PDAB is a 5-member board tasked with the following duties:

- Identify drugs that may be subject to an affordability review;
- Conduct affordability reviews on selected eligible drugs;
- Determine whether a prescription drug is unaffordable for Washington consumers;
- If a drug is found to lead to excess costs, the board may set an upper payment limit.

The PDAB will be supported in this work by staff at the Washington State Health Care Authority and will receive input from relevant advisory groups composed of stakeholders from across Washington, including patients, patient advocates, and prescription drug pricing and treatment experts.

Why was it important for Washington to establish a Prescription Drug Affordability Board?

As prescription drug costs continue to skyrocket, Washingtonians are struggling to afford the medications they need. A prescription drug affordability board will give Washington an avenue to address these high costs and help ensure consumers can access the medications they need, when they need them. An affordability board will bring together diverse stakeholders, improve transparency, and address the cost of drugs for Washingtonians.

Who is on the board?

The board consists of five members with expertise in health care economics and/or clinical medicine. The board will be supported by HCA staff and advisory groups. No board member may be an employee of, a board member of, or a consultant to a prescription drug manufacturer, pharmacy benefit manager, health carrier, prescription drug wholesale distributor, or related trade association. Board members will recuse themselves from matters where they have a conflict of interest. The board will operate with the express task of bringing transparency to drug costs and helping Washingtonians afford the drugs they need.

When will the board investigate a drug?

Statute determines how drugs are selected for an affordability review. HCA will produce a list of drugs that exceed certain thresholds in list prices or price increases that vary by drug category. The board can select drugs from this list and begin an investigative process where they collect information, evaluate data, and discuss whether the drug is affordable for consumers in Washington. The affordability review may result in the board taking action, or not, depending on the specific circumstances of each drug reviewed.

Where will the board get its data? How will proprietary information be protected?

The board will have the ability to evaluate any publicly available information on prescription drug costs that already exists in Washington and in other states. Additionally, the board may request information directly from manufacturers, carriers, or pharmacy benefit managers. Proprietary information is protected from public disclosure. The board will be able to go into executive session when discussing proprietary information.

What is an upper payment limit?

An upper payment limit (UPL) is a limit on what purchasers within the state of Washington will be able to pay for specific drugs identified by the Board; it will not take away the power of payers and drug manufacturers to negotiate below the limit or for drugs outside the board's purview. The upper payment limit is optional for employer-sponsored self-funded health plans.

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PDAB Legislative History Presentation

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Prescription drug affordability legislative history

Prescription Drug Affordability Board meeting

October 20, 2023

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Agenda

- Background on health care costs
- Overview of national and state cost transparency efforts
- Prescription Drug Affordability Board (PDAB) background
- PDAB legislative history
- Next steps

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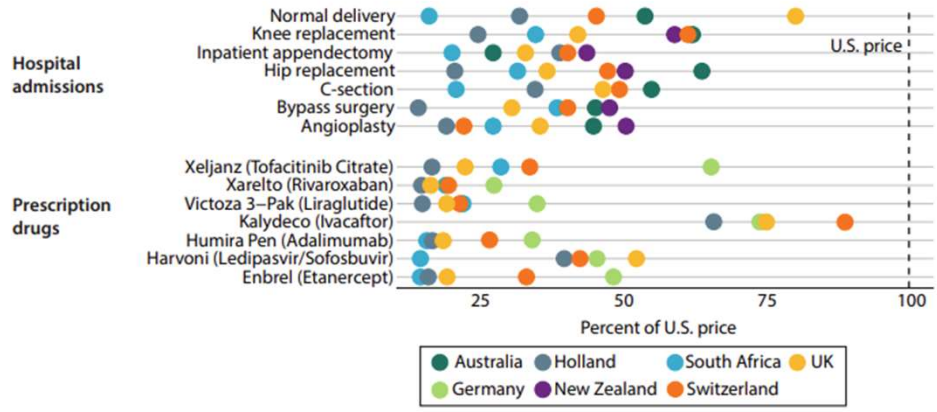
Snapshot of international health care prices

FIGURE 8.
Prices of Services and Prescription Drugs, by Country



3

National prescription drug costs

- Overall pharmacy expenditures in the U.S. grew 9.4 percent from 2021 to 2022
- Total U.S. expenditure in 2022: $633.5 billion
- Anticipated increase in drug spending between 6-8 percent in 2023

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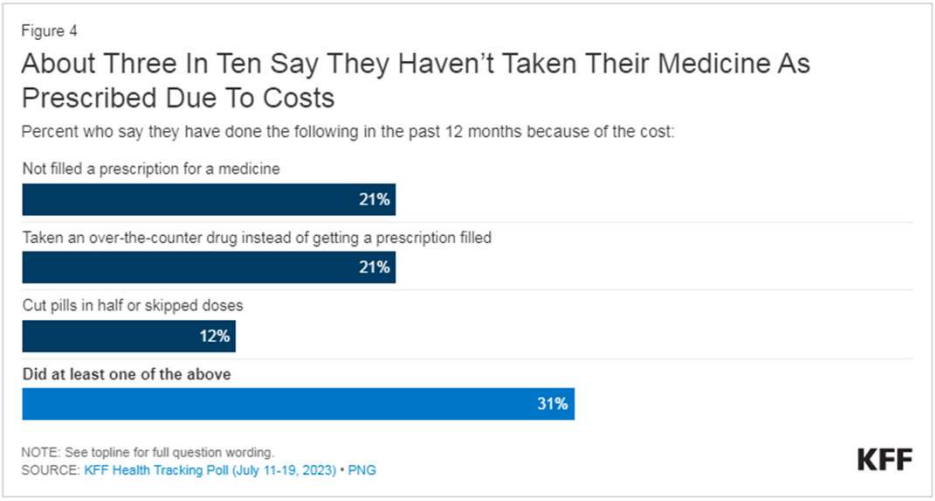
National prescription drug costs (continued)



https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

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National cost transparency efforts

- All-Payer Claims Databases
- Cost boards and growth benchmarks
- The No Surprises Act
- Inflation Reduction Act
  - Medicare prescription drug negotiation
    - https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf
- Hospital and payer price transparency
  - https://www.cms.gov/priorities/key-initiatives/healthplan-price-transparency
  - https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency

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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

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Prescription drug affordability boards

- Independent bodies empowered to analyze the high cost of drugs and suggest effective ways to lower costs
  - Maine
  - 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

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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

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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

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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

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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

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Next steps

- HB 1269, HCA sponsored bill last session: Failed
- No HCA proposals for the 2024 session
- Continuing partnership with Legislature and sister agencies to advance affordability efforts, including:
  - Advancing work of the Health Care Cost Transparency Board
  - Cross-agency report on health care affordability, led by Office of the Insurance Commissioner (OIC) and Attorney General's Office (AGO)
  - Annual reporting to Legislature

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Questions?

Evan Klein
Special Assistant
Legislative & Policy Affairs
evan.klein@hca.wa.gov

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PDAB in Other States Presentation

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Prescription Drug Affordability Efforts in Other States

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General Trends

- National Academy for State Health Policy
  - NASHP drafted template PDAB legislation
  - Adopted in Colorado, Maine, Maryland, New Hampshire, Oregon, Washington, and most recently, Minnesota
  - Colorado, Oregon, Washington, and Maryland have the authority to implement upper payment limits

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General Trends

- Other state efforts
  - Massachusetts implemented enhanced negotiating authority Medicaid programs
    - Allows the state to directly negotiate supplemental rebate agreements with drug manufacturers
  - New York implemented Medicaid drug benefit budget cap
    - Allows the state to negotiate with drug manufacturers for supplemental rebates if spending on a drug is expected to exceed the Medicaid drug cap or if a newly launched drug meets certain thresholds to be considered high cost

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Colorado PDAB

- Goals
  - Study information concerning the cost of prescription drugs sold to Colorado consumers
  - Perform affordability reviews of prescription drugs
  - Establish upper payment limits on select drugs
  - Make policy recommendations to the Colorado legislature to improve the affordability of prescription drugs

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Colorado PDAB (continued)

- Current efforts
  - Selected five drugs for affordability reviews
    - Enbrel
    - Genvoya
    - Cosentyx
    - Stelara
    - Trikafta
  - Released eligible drug dashboard
    - Tool for displaying data regarding the selection of drugs for affordability reviews

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Oregon PDAB

- Goals
  - Evaluate the cost of prescription drugs and determine whether they present an affordability challenge for consumers and health systems in Oregon
  - Identify 9 drugs and at least one insulin product per year to conduct an affordability review

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Oregon PDAB (continued)

- Current efforts
  - The Oregon Legislature acted on the board recommendations by passing Senate Bill 192 in June 2023, requiring:
    - PBMs to annually report to the Dept. of Consumer and Business Services information about rebates, fees, price protection payments, and other payments received from drug manufacturers
    - PDAB to develop a plan for establishing upper payment limits on certain drugs
  - PDAB released a report on the generic drug market in 2023

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Maryland PDAB

- Goals
  - Study the entire pharmaceutical distribution and payment system in Maryland
  - Research policy options being used in other states and countries to lower the list price of pharmaceuticals
  - Recommend legislative actions, including:
    - Setting upper payment limits
    - Using reverse auction marketplaces
    - Implementing a bulk purchasing process

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Maryland PDAB (continued)

- Current efforts
  - Updating their regulations
  - Receiving introductory presentations on upper payment limits
  - Will conduct initial drug cost reviews next year
  - Released an annual cost review report in December 2022
  - Released a report on the operation of the generics drug market in June 2022

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Maine PDAB

- Goals
  - Determine annual spending targets for prescription drugs purchased by Maine public payers and make recommendations to achieve targets
  - Spending targets will be based on a 10-year rolling average of the medical care services component of the Dept. of Labor consumer price index plus a reasonable percentage for inflation and minus a spending target determined by the board for pharmacy savings
  - Spending targets will be determined on specific prescription drugs that may cause affordability challenges to enrollees

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Maine PDAB (continued)

- Current efforts:
  - Recommended that the Maine Legislature institute international reference rates alongside Medicare reference rates
  - Released annual reports in 2022 and 2021

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New Hampshire PDAB

- Goals
  - Determine annual spending targets for prescription drugs purchased by New Hampshire public payers and make recommendations to achieve targets
  - Spending targets will be calculated using a similar formula to Maine's PDAB
  - Spending targets will be achieved through a variety of policy approaches, including:
    - Negotiating specific rebate amounts
    - Changing a formulary or establishing a common formulary for public purchasers
    - Bulk purchasing agreements within the state and with other states

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New Hampshire PDAB (continued)

- Current efforts
  - Received presentations on pharmaceutical supply chains (PBMs, Medicaid prescription expenditures, etc.)
  - Finalized PDAB regulatory framework
  - Released annual reports in 2022 and 2021 describing:
    - The 25 costliest prescription drugs
    - The 25 most frequently prescribed drugs
    - The 25 drugs with the highest year-over-year cost increases

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Robert's Rules of Order and Open Public Meetings Act Presentation

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ROBERT'S RULES OF ORDER

- PARLIAMENTARY PROCEDURE -

Presented to the Prescription Drug Affordability Board

October 20, 2023

By Michael R. Tunick, Assistant Attorney General

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OVERVIEW

- General Overview of Parliamentary Procedure and How Robert's Rules Fit In
- Meeting Basics
- Motions, Debate, Voting
- Types of Motions
- Executive Session, Public Comment

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2

PARLIAMENTARY PROCEDURE

Principles of parliamentary procedure:

1. One subject at a time
2. Every subject gets fully debated
3. Rights equal to every other board member
4. Majority rule
5. Respect

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AUTHORITIES GOVERNING THE BOARD

(FROM HIGHEST TO LOWEST IN PRIORITY)

- **Law:** Certain rules are prescribed by applicable law
  - Open Public Meetings Act
  - Ethics in Public Service Act
  - Laws specific to the Board, *e.g.*, RCW Chapter 70.405
- **Bylaws/Charter:** Govern the structure and operation of the organization
- **Rules of Order:** Special Rules of Order specific to your organization and Parliamentary Authority adopted by your organization (*e.g.*, Robert's Rules)
- **Common Practice or Custom:** Not in written rule

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INFORMAL PROCEDURES IN SMALL BOARDS

With smaller boards (typically fewer than twelve members), such as PDAB, more informal procedures may be followed:

- Member may raise hand to obtain floor instead of standing
- The Chair and members may remain seated when speaking or voting
- Members may speak more than twice during debate
- Subjects may be discussed informally even if no motion is pending
- Chair may participate in debate, make motions, and vote without giving up the chair

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MEETING BASICS

- **Presiding Officer**
  - Chair, or if not present, Vice-Chair.
- **Quorum (or not)**
  - Three is the minimum number of members who must be present to conduct business. RCW 70.405.020.
- **Agenda/Order of Business**
  - Order of Business is determined by the agenda, which is circulated prior to meeting.
- **Minutes**
  - Minutes summarize significant action taken by the Board. At subsequent meetings, the minutes of prior meeting get approved.

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MOTIONS, DEBATE, AND VOTING

Six steps to motion practice:

1) **Motion is made** – Formal proposal made by a member at a meeting that the group take certain action.
2) **Seconded** – Another member must second a motion to bring it before the entire group.
3) **Chair "States" the Question** – Repeats the exact words of the motion or resolution.
4) **Debate** – Discussion of the merits of a pending motion or resolution.
5) **Chair "Puts" the Question** – After debate has closed, the Chair "puts" the motion or resolution to a vote.
6) **Chair Announces Result**

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MOTION PRACTICE

Types of Motions

- Main Motion
- Secondary Motions
  - Amend
  - Lay on the Table
  - Point of Order
  - Parliamentary Inquiry
- Motions that Bring a Question Again Before the Assembly
  - Take from the Table
  - Reconsider
  - Rescind or Amend Something Previously Adopted
  - Renewal

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MOTION TO AMEND

- Methods of Amending

Insert	"I move to insert . . ." or "I move to amend by inserting . . ."
Strike	"I move to strike . . ." or "I move to amend by striking . . ."
Strike and insert	"I move to strike out the words '*[X, Y, Z]*' and insert the words '*[T, U, V, W.]*'"

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MOTION TO AMEND, cont'd
(Insert or Add Text)

Original Sample Pending Motion:
"I move that we buy a new sign."

You Want the Motion to Read:
"That we buy a new sign ***not to exceed $50 dollars***."

You Would Say:
"*I move to amend by adding the phrase 'not to exceed $50 dollars' at the end of the motion.*"

10

10

MOTION TO AMEND, cont'd
(Strike Text)

Original Sample Pending Motion:
"I move that we buy a new sign."

You Want the Motion to Read:
"That we buy a ~~new~~ sign."

You Would Say:
"*I move to amend by striking out the word 'new.'*"

11

11

MOTION TO AMEND, cont'd
(Strike and Insert Text)

Original Sample Pending Motion:
"I move that we buy a new sign."

You Want the Motion to Read:
"That we buy a new ~~***sign***~~ ***billboard***."

You Would Say:
"*I move to amend by striking out the word 'sign' and inserting the word 'billboard.'*"

12

12

MOTION TO AMEND, cont'd

- Restrictions on Making Amendments:
  - Germane
  - Cannot defeat main motion
  - No third-degree amendments
- The Amendment Process:
  - Debate is limited to the desirability of the amendment not the merits of the motion being amended
  - Voting determines whether the text of the main motion is changed not whether the main motion is adopted

13

13

OTHER SECONDARY MOTIONS

Kind of Motion	Objective
Lay on Table	clear the floor for more urgent business
Point of Order	call attention to violation of the rules
Parliamentary Inquiry	obtain information on parliamentary procedure

14

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MOTIONS THAT BRING A QUESTION BEFORE THE BOARD, AGAIN

Kind of Motion	Objective
Take from the Table	resume consideration of a motion laid on the table
Reconsider	reconsider the vote on a motion
Rescind or Amend	change something previously adopted by repeal or changing part of it
Renew	place a motion before the Board again

15

15

REPORTS

- Two legislative reports required every year
- Members decide what other reports they want
- Should be listed on the agenda/order of business

16

PUBLIC COMMENT

- Must be allowed for regular meetings where final action is taken
- If allowed, is still under the control of the Chair
- Limitations on time and subject relevance may be imposed

17

EXECUTIVE SESSION

- Part of a regular or special meeting that is closed to the public
- Limited to specific purposes by the Open Public Meetings Act
  An executive session may be held to address such matters as:
  - To consider confidential information collected by the Prescription Drug Affordability Board
  - Discuss Enforcement Actions and Litigation with Legal Counsel
- Purpose of the closed meeting and the time it will end must be announced by the presiding officer
- No voting.

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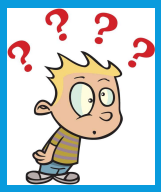
THE END

- Any Questions?



Michael R. Tunick, Assistant Attorney General
Attorney General's Office
Michael.Tunick@atg.wa.gov

Washington State Health Care Authority

Public Records Act Presentation

Washington State Health Care Authority

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Public Records Preservation and Disclosure

Prescription Drug Affordability Board

Washington State Health Care Authority

1

OVERVIEW

- Public Records
- Preservation of Public Records
- Disclosure of Public Records

Washington State Health Care Authority

2

Public Record

"Public record" includes any writing containing information relating to the conduct of government or the performance of any governmental or proprietary function prepared, owned, used, or retained by any state or local agency regardless of physical form or characteristics.

Washington State Health Care Authority

3

Preservation of Public Records

- The Secretary of State's Office, Division Archives and Records management, are responsible for setting the standards and providing guidance relating to the preservation of public records.
- State and local agencies are required to preserve public records in accordance with an approved records retention schedule.
- State agency records retention schedules can be located on the Secretary of State's website.

Washington State Health Care Authority

4

Records Retention Schedules

- State Government General Records Retention Schedule – Covers records that represent the operations of all state agencies.
- Agency Unique Records Retention Schedules - Covers records that represent the operations unique to the specific agency.

Washington State Health Care Authority

5

Record Series

DISPOSITION AUTHORITY NUMBER (DAN)	DESCRIPTION OF RECORDS	RETENTION AND DISPOSITION ACTION	DESIGNATION
GS 10004 Rev. 1	***Governing/Executive/Policy-Setting Body Records*** Records documenting the actions, meetings, and membership of the agency's governing body, executive management team, and other policy-setting/decision-making boards, committees, commissions, councils, task forces, etc. Also includes interagency/national/external policy-setting/decision-making bodies for which the agency acts as secretary/keeper of the official records. Includes, but is not limited to: • Agendas, meeting/agenda packets (briefs, reference materials, etc.); • Speaker sign-up, written testimony; • Audio/visual recordings and transcripts of proceedings; • Minutes; • Reports/correspondence/communications sent/received on behalf of the body; • Orders, resolutions, etc.; • Appointment, reappointment, and termination correspondence/communications; • Selected images/photographs showing the committee membership at particular points in time (such as board/committee portraits, etc.) and/or significant stages of the board/committee's life. Excludes appointment records of the Office of the Governor and other records covered by: • *Advisory Body Records (DAN GS 10015);* • *Meeting Arrangements (DAN GS 09024);* • *Meeting Materials – Members' Copies/Notes (DAN GS 09026).*	**Retain** for 6 years after end of calendar year *then* **Transfer** to Washington State Archives for permanent retention.	**ARCHIVAL** (Permanent Retention) **ESSENTIAL** (for Disaster Recovery) OPR

Washington State Health Care Authority

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Records Series – Members' Copies

DISPOSITION AUTHORITY NUMBER (DAN)	DESCRIPTION OF RECORDS	RETENTION AND DISPOSITION ACTION	DESIGNATION
GS 09026 Rev. 0 / GS2016-007 Rev. 0	***Meeting Materials – Members' Copies/Notes*** Individual members' meeting materials from participating in advisory, governing/ executive/policy-setting, internal/external committees (including national/external bodies), provided the Committee's records are retained by the secretary/responsible agency/member. Includes, but is not limited to: • Copies of agendas, meeting packets, minutes, etc.; • Working notes/drafts, etc.; • Related correspondence/communications.	**Retain** until no longer needed for agency business *then* **Destroy**.	NON-ARCHIVAL NON-ESSENTIAL OFM

Washington State Health Care Authority

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Email Correspondence (records)

- Emails containing information relating to work of Prescription Drug Affordability Board are public records.
- All emails of the Prescription Drug Affordability Board are preserved within HCA's Enterprise Email Management system.

Washington State Health Care Authority

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Public Records Act (PRA)

The people of this state do not yield their sovereignty to the agencies that serve them.

The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know.

The people insist on remaining informed so that they may maintain control over the instruments that they have created.

The Act shall be liberally construed, and its exemptions narrowly construed to promote this public policy and to assure that the public interest will be fully protected.

Washington State Health Care Authority

9

When responding to a request

- Agencies must provide timely responses to public disclosure requests for public records.
- Agencies must perform a reasonable search to identify all responsive records.
- When withholding a public record or specific information within a public record, there must be an exemption authorized in law.

Washington State Health Care Authority

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Enforcement & Penalties

- The Public Records Act is enforced by the courts.
  - The court can impose statutory penalties to be awarded to requestor.
  - The court will order payment of requestor's attorneys fees & costs.
  - The court can also order disclosure of all or part of withheld record, or non-disclosure of part or all of record.

Washington State Health Care Authority

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QUESTIONS

Thank you!

Catherine Taliaferro, HCA Records Officer
catherine.taliaferro@hca.wa.gov

Washington State Health Care Authority

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Washington State Health Care Authority

Rulemaking Overview Presentation

Washington State Health Care Authority

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Washington State Health Care Authority

Rulemaking Overview

Division of Legal Services/
Office of Rules & Publications (ORP)

1

Consists of 7 parts

- Part I – General Provisions
- Part II – Public Access to Agency Rules
- Part III – **Rule-Making Procedures**
- Part IV – Adjudicative Proceedings
- Part V – Judicial Review and Civil Enforcement
- Part VI – Legislative Review
- Part IX – Technical Provisions

2

Administrative Procedures Act (APA)

RCW 34.05

Enacted in 1988,
to clarify the existing laws of administrative procedure,
to achieve greater consistency with other states and federal government in administrative procedure,
and to provide greater public and legislative access to administrative decision making.

2

Washington State Health Care Authority

How does rulemaking start?

- Contact the office responsible for the agency's rulemaking
- In HCA, contact the Rules Coordinator in the Office of Rules & Publications
- After deciding if rulemaking is necessary, ORP staff manages the process to ensure compliance with the Administrative Procedures Act (APA)

3

3

RCW 34.05
Part III –
Rule-Making Procedures

3 Steps (Filings) in
Standard Rulemaking Process

Prenotice inquiry (CR101)
Proposed rule (CR102)
Rule-Making Order (CR103P)

4

Standard Rulemaking Process

4

Preproposal Statement of Inquiry (CR–101)

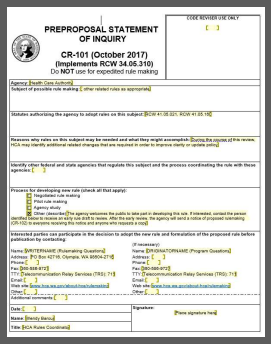
5

Starts the **official rulemaking process.**

First notice to the public of the agency's intent to conduct rulemaking on a subject.

No text included.
No expiration.

RCW 34.05.310



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

[ ]

Agency: [Health Care Authority]

Subject of possible rule making: [other related rules as appropriate]

Statutes authorizing the agency to adopt rules on this subject: [RCW 41.05.021, RCW 41.05.160]

Reasons why rules on this subject may be needed and what they might accomplish: [During the course of this review, HCA may identify additional related changes that are required in order to improve clarity or update policy]

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: [ ]

Process for developing new rule (check all that apply):
- [x] Negotiated rule making
- [ ] Pilot rule making
- [ ] Agency study
- [x] Other: [describe] The agency welcomes the public to take part in developing this rule. If interested, contact the person identified below to receive an early rule draft to review. After the early review, the agency will send a notice of proposed rulemaking (CR-102) to everyone receiving this notice and anyone who requests a copy.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

[PRIMARY]
Name: [WRITTENNAME (Rulemaking Questions)]
Address: [PO Box 42716, Olympia, WA 98504-2716]
Phone: [ ]
Fax: [360-586-9727]
TTY: [Telecommunication Relay Services (TRS): 711]
Email: [ ]
Web site: [www.hca.wa.gov/about-hca/rulemaking]
Other: [ ]
Additional comments: [ ]

[ALTERNATE]
Name: [ORIGINATORNAME (Program Questions)]
Address: [ ]
Phone: [ ]
Fax: [360-586-9727]
TTY: [Telecommunication Relay Services (TRS): 711]
Email: [ ]
Web site: [www.hca.wa.gov/about-hca/rulemaking]
Other: [ ]

Date: [ ]	Signature: [Have signature here]
Name: [Wendy Barcus]	
Title: [HCA Rules Coordinator]	

5

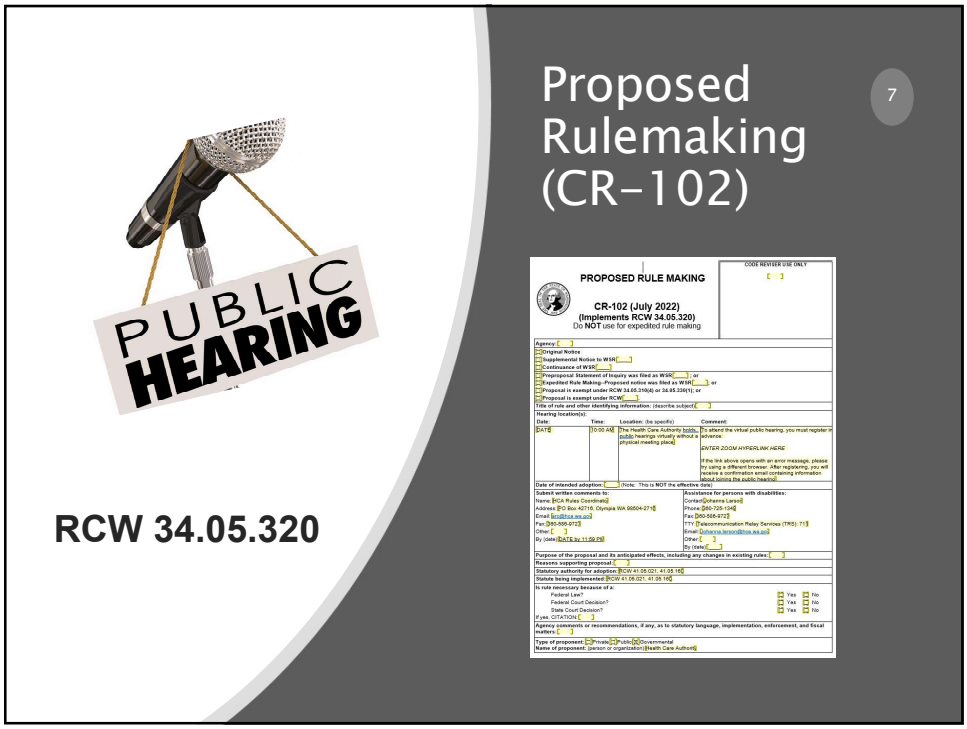
Washington State Health Care Authority

Reviewing drafts

- HCA sends drafts to **internal program staff** to make them aware of the draft rule.
- HCA complies with the APA requirements in RCW 34.05.310(2) & (3)(a) for **public input** by sending the draft rule to interested stakeholders who have expressed an interest in the subject of the rule.
- HCA documents and responds to all comments.
- After a final draft is agreed on the rule is ready for the **public hearing**.

6

6



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Washington State Health Care Authority

Proposed rulemaking (CR-102)

- **HCA Rules Coordinator reviews** the CR-102 for completeness and files with the Code Reviser.
- Once filed, the **CR-102 shows the public hearing date**, which is set by the Code Reviser's office
- **HCA notifies the public** by sending an HCA Rulemaking Notice via GovDelivery. HCA also publishes the CR102 and hearing dates/times on HCA's **Upcoming Public Hearing web page**.

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Washington State Health Care Authority

Public rulemaking hearings

- Up to **two** public hearings a month
- Dedicated **WAC email in box** for written comments
- Rules Coordinator **conducts public hearing**
- HCA **conducts Public Hearings virtually** using Zoom. Registration is required.
- Any interested person may register and attend the hearing and provide verbal testimony (RCW 34.05.325(2)).
- Public hearings are **recorded and transcribed**

9

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Washington State Health Care Authority

After public hearing

Comments are reviewed and discussed. Program staff decide if changes are necessary based on the comments received.

If the changes are substantial, a 2nd Public Hearing is required.

If not, the comments are compiled into a **Concise Explanatory Statement (CES)** (as required in RCW 34.05.325)

CR103P – Permanent Rulemaking is prepared

10

10

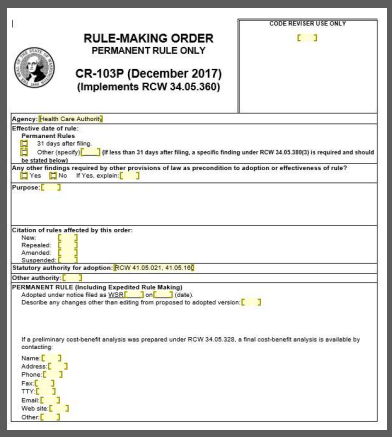
Permanent rulemaking (CR-103P)

11

Finalizes proposed rule.
Sets effective date.
Includes final text.

FINISHED

RCW 34.05.360



RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

Agency: [Health Care Authority]

Effective date of rule:
Permanent Rules
31 days after filing.
Other (specify):[ ] (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?
Yes No If Yes, explain:[ ]

Purpose:[ ]

Citation of rules affected by this order:
New: [ ]
Repealed: [ ]
Amended: [ ]
Suspended: [ ]

Statutory authority for adoption: [RCW 41.05.021, 41.05.160]

Other authority: [ ]

PERMANENT RULE (Including Expedited Rule Making)
Adopted under notice filed as WSR[ ] on[ ] (date).
Describe any changes other than editing from proposed to adopted version:[ ]

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:[ ]
Address:[ ]
Phone:[ ]
Fax:[ ]
TTY:[ ]
Email:[ ]
Web site:[ ]
Other:[ ]

Permanent rulemaking (CR-103P)

12

This is the final stretch

Writer finalizes **Concise Explanatory Statement** (**CES**) and sends to commenters

Rules Coordinator files the permanent rule (CR103P)

Permanent rules are **effective 31 days after the filing date**, or a date beyond 31 days may be chosen

HCA informs the public of the permanent rule filing through HCA Rulemaking Notice (GovDelivery) and HCA Rulemaking web page.

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Official Rulemaking Files

HCA's Office of Rules & Publications (ORP):

- Maintains the **official rulemaking files** for the Health Care Authority (as required in RCW 34.05.370)
- Manages and maintains **HCA's rulemaking web pages** (as required in RCW 34.05.270)
- Publishes a **Semi-Annual Rulemaking Agenda** (as required in RCW 34.05.314)

13

13

Questions?

Wendy Barcus, HCA Rules Coordinator
Wendy.barcus@hca.wa.gov

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Washington State Health Care Authority

Draft Policies

Washington State Health Care Authority

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Prescription Drug Affordability Board Policies and Procedures

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 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 the board Chapter 182-52 WAC.

2. Definitions

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

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

"HCA" means the Washington Health Care Authority.

"Staff" means any individual employed by HCA providing support to and/or doing work on behalf of the Board.

3. Board Members and Meetings

A. Board Member Selection Process

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

The initial Board was appointed by the Governor by 08/24/2023. Board members will serve five-year terms and may serve no more than two 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 Board staff to develop Board meeting agendas. The Chair also ensures Member compliance with the Conflict of Interest Policy.

D. Meetings

The Board will hold meetings at least every three months. The Chair of the Board 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 meetings may be referred to as meetings or hearings depending on what types of business the Board plans to conduct. The Board has discretion to set the time for its meetings. The Board may decide to adjourn a meeting or hearing to the next available day because a meeting or hearing is running long or for any other reason. A Member can participate in person, by phone, or virtually. Board meetings are broadcast live over the internet, other than executive sessions.

The Board may provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally 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 2 minutes per speaker.

i. Meeting Agendas, Materials, and Notes

HCA staff will post Board meeting minutes, agendas, and notices of upcoming meetings on the Prescription Drug Affordability Board website. The meeting agenda will be designed, among other things, to ensure the Board meets its statutory obligations. The Board Chair in collaboration with the Staff will prepare a draft agenda and provide it to the Members prior to the Board meeting or hearing.

Each Member will review the draft agenda and notify the assigned Assistant Attorney(s) General at the Washington Office of the Attorney General of any potential conflict of interest. Counsel will notify the Staff of whether Members have recused themselves from certain agenda items.

Prior to the meeting or hearing, the Staff will provide each Member with a Board packet of items, excluding materials related to any agenda item from which a Member has recused themselves. The Board packet may include materials, information, and/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 prior to the Board meeting or hearing.

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) person Board constitutes a quorum. Decisions will be made by Member voting. Voting will be conducted by a Member roll call, with at least three votes needed in order to pass. If only three board members are present for a vote, the vote must be unanimous

in order to pass. If only four members are present, then three votes will be required 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.

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, a Member will state the topic for discussion in the executive session and the statutory provision which authorizes the Board to meet in executive session. Upon a majority vote, the open meeting will be adjourned and 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. 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

Board 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 the Chair prior to the meeting. If a Member misses more than three consecutive meetings without informing the Chair, the Board may vote to recommend to the Governor that Member be removed.

E. Conflicts of Interest

i. Policy Statement

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

The Board will strive to ensure that it acts impartially. To ensure impartiality, each Board 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. To further ensure impartiality, staff and contractors of HCA engaged in a Board Activity may be required to recuse themselves from any Board Activity in which the individual has a Conflict. The Board and HCA will ensure Board Members, staff, and contractors disclose Conflicts in accordance with this policy and its requirements.

ii. Actual Conflict of Interest

Board Members may have an actual Conflict of Interest or the appearance of a Conflict of Interest. An actual Conflict of Interest occurs when a Board 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 Board 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

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

For all other Board activities, Board members will not participate in any Board activity in which a Board member has a Conflict of Interest. Prior to each Board meeting where the Board will engage in a Board activity, Board 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 Board member determines they have a Conflict of Interest, the Board Member must disclose the conflict in an open meeting and recuse themselves. The Board Member will also notify Board 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 Board Members may seek the advice of the assistant attorney(s) general assigned to the Board.

As required by sections § 70.405.020(4) RCW, the Board will disclose Conflicts of Interest for the Board, Advisory Group, Board staff, and contractors working on behalf of the Board on its page of HCA's website and in the annual report to the Governor and respective committees in the Legislature. The Board will identify Conflicts of Interest on its website by identifying the person with the Conflict and the Prescription Drug or Pharmaceutical Company for which they have a Conflict and have recused. The Board will not identify the nature of the Conflict of Interest on the website.

v. Annual Review

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

F. Member Resignation, Removal, and Replacement

Any Board Member who can no longer perform the responsibilities of the Board must notify the Chair (unless that Member is the Chair), Board 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 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;
- Any other reason not listed here.

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 on 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

Unless otherwise delegated to them by a majority vote of the Board, individual Board Members do not have the authority to speak on behalf of the Board. The Board operates as a single entity when communicating with external parties. If Board 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 from HCA ("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.

The 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). HCA, on behalf of the Board, 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.

The Staff may be reached at HCA_WA_PDAB@hca.wa.gov. The Board's standing authorization to HCA may also be found at https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-board. The Board may also delegate particular tasks to HCA on a case-by-case basis to perform its duties. These particular delegations may be found at 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 Board Member.

A. Board Meetings

- Facilitate meetings of the Board and ad hoc committees, 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 Board 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 Board 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 at Board meetings.

B. Contracts

- Pursuant to Chapter 70.405 RCW, and in compliance with any procurement policies developed by the Board, 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.

- The Board determines that to necessarily carry out its powers and duties, HCA is authorized to contract on its behalf for work related to the following:

    - Data identification, collection, and analysis related to pharmaceutical markets and supply chains, prescription drug pricing, and other state and federal programs related to prescription drug pricing;

    - Data, research, analysis, and supporting materials to inform the process for and conducting of affordability reviews;

    - Data, research, analysis, and supporting materials to inform the methodology and process for and consideration of whether to set an upper payment limit;

    - Data, research, analysis, and initial recommendations related to the development of a formula to calculate savings pursuant to section 70.405.060 RCW;

    - Equity and cultural responsiveness related to the Board's activities; and

    - Data, research, analysis, and supporting materials for the Board's consideration in identifying potential policy recommendations to the Governor and Legislature and compiling the Board's recommendations.

C. Administration

- Serve as the 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 for the Board 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.

- Collect and distribute any moneys received for the Board.

- Maintain the Board's public webpage and ensure the webpage contains the following:

    - Conflicts of interest disclosed to the Board pursuant to sections § 70.405.020(4) RCW.

    - 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 Board 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.
- Regulations and guidance adopted by the Board.
- 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 conducted by the Board, including but not limited to:
  - Draft rules for consideration by the Board.
  - Effectuate publication and/or filing of notices of draft proposed regulations on specific topics authorized by the Board, and adopted rules in the Washington Code Reviser and to the HCA website.
  - Submit requests for Attorney General opinions regarding adopted rules.
  - Compile the official rulemaking record for all rulemaking conducted by the Board, including receipt and inclusion of any public comments.
- Collect and provide conflicts of interest to the Board:
  - Distribute conflict of interest forms and coordinate completion of disclosures by prospective and active Board Members, Staff, contractors of HCA, 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 the Advisory Group, 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 selected by HCA staff through an open application process. Applications will be submitted through the HCA website. Applications will be reviewed, candidates interviewed, and group members selected by HCA staff. HCA staff will endeavor to seat group members who meet the qualifications listed in Chapter 182-52 WAC.

B. Term Length and Vacancies

Advisory group members will serve for the duration of each current affordability review. The duration of each affordability review is variable, and will be determined by the Board and subject to change.

Advisory group members removed from the advisory group by HCA will be notified of their removal from the advisory group and 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 182-52 WAC.

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.). 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. The Board will also consider any Council member conflicts disclosed to the Board pursuant to § 70.405.020(4) RCW, the Board will disclose Conflicts of Interest for the Board, Council, staff, and contractors working on behalf of the Board on its page of HCA's website and in the annual report to the Governor and respective committees in the Legislature.

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 182-52 WAC.

Once Staff has compiled the list of eligible prescription drugs as delegated by the Board, Staff will present the list to the Board. The Board will review the list and vote on whether to approve the list.

To the extent that Staff develops methodologies or draws from existing data sources to identify the drugs, the methodologies and sources will be publicly presented to the Board, or presented in executive session, as applicable.

Staff will utilize methodologies, including the following where practicable, to identify prescription drugs eligible for affordability reviews:

- For all prescription drugs:
    - Wholesale Acquisition Costs (WAC), where the initial WAC means the earliest listed WAC for a prescription drug in the relevant database.
- For a brand-name drug or biological product:
    - Legend drugs and biological products will be identified utilizing National Drug Code (NDC) identifications. Legend drugs and biological products will be identified for eligibility by identifying, consolidating, and listing NDCs with the same brand name and active ingredient.
    - Twelve-month supply and course of treatment will be determined by multiplying the initial WAC/unit for a prescription drug by a measure of central tendency (e.g., mean, median, mode) as calculated from utilization data in the Washington State All Payer Claims Database (APCD). Staff may provide additional utilization statistics from other sources to provide more context regarding how actual utilization compares to common understandings of a twelve-month supply or course of treatment.
- For a biosimilar product:
    - Biosimilar products will be identified utilizing National Drug Code (NDC) identifications. Biological products will be identified for eligibility by identifying, consolidating, and listing NDCs for FDA-approved biosimilar drugs by manufacturer, brand name, and active ingredient.
    - Initial WAC amounts for biosimilars will be compared to the corresponding biological product's most recent WAC listed before the date when the initial biosimilar WAC was listed.
- For a generic drug:

- Generic drugs will be identified utilizing National Drug Code (NDC) identifications. Generic drugs will be identified for eligibility by identifying, consolidating, and listing NDCs by manufacturer and active ingredient.

- Current WAC means the WAC listed in the relevant database as reported in January of the year for which the affordability review is being conducted.

- For each generic drug for which the WAC cost increased by 200% or more during the immediately preceding twelve months from the current WAC, a review of FDA labeling will be done to determine if the FDA labeling:

    - Recommends a more than 30-day supply: In this case, calculate the WAC for a 30-day supply using the current WAC;

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 182-52 WAC**.**

Staff will prepare the following information, to the extent it is available, for the Board's consideration and deliberation as part of the selection process:

1. Identifying the initial date of FDA approval of the eligible prescription drug, including whether the prescription drug was approved through an expedited pathway, and evaluating the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale by gathering:

    a. Information on the class of the prescription drug, as identified in the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) Classification, US Pharmacopeia (USP) Drug Classification System, or other similar classification system.

    b. Information on whether there are any therapeutically equivalent prescription drugs:

        i. Are approved: therapeutic equivalent prescription drugs will be identified by examination of the FDA Orange Book, FDA Purple Book, or other therapeutic equivalence databases.

        ii. Are for sale: information on the availability of therapeutic equivalents for sale, as opposed to therapeutic equivalents that are FDA approved but not currently marketed, will be gathered by examining information regarding utilization of the therapeutic equivalent prescription drug

within the previous 12 months, in aggregate and by payer, as well as additional information gathered from experts regarding whether the therapeutically equivalent drug is for sale.

2. The following aggregated data sources may be utilized:

    a. Pricing Information: Including WAC pricing trends over time, Average Sales Price trends over time, and National Average Drug Acquisition Cost trends over time.

    b. Expenditures: APCD data showing spending amounts by payers, by consumers, and by total amounts.

    c. Utilization: APCD data showing claim counts, unit counts, and per person utilization.

    d. Combined expenditure and utilization aggregated data: APCD data that incorporates both expenditure and utilization (e.g., cost per person, per member per month expenditure, etc.).

    e. Health equity impact: information showing whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations, as such conditions are identified from sources like the Washington Health Care Authority's Health Equity Office, the Centers for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion, and other sources.

    f. Information estimating manufacturer net-cost and net-sales amounts of an eligible drug.

    g. Aggregated data analyses will examine up to five years of data for all categories and all prescription drugs.

3. Input from the Prescription Drug Affordability Advisory Group:

    a. After presenting the list of identified prescription drugs to the Board, Staff will email the list to the Advisory Group and convey Board requests.

    b. Before the next Board meeting, Staff will assist in convening an Advisory Group meeting to gather Advisory Group input.

    c. Staff will present the Advisory Group input to the Board.

    d. Nothing in this policy precludes the Advisory Group from identifying additional methods for delivering input to the Board (e.g., Advisory Group written or verbal reports directly to the Board).

4. Average patient's out-of-pocket cost for the prescription drug for up to five years for each prescription drug based on:

    a. APCD data, in aggregate and by payer type, for out-of-pocket costs, and

    b. Other data sources that approximate out-of-pocket costs not captured in APCD data.

5. The Board may use information from selection criteria to prioritize affordability goals in the selection of prescription drugs for an affordability review. Examples of affordability goals the Board may want to consider prioritizing in selecting prescription drugs for an affordability review include:

    a. Price increases that exceed reasonable levels, as such levels are identified by the Board,

    b. Consumer costs that threaten Washingtonians' economic well-being,

    c. Costs that contribute significantly to rises in health-care costs and health insurance premiums that threaten financial and physical health of Washingtonians,

    d. Costs for prescription drugs for conditions and disease that disproportionately impact priority populations, and/or

    e. Excessive costs that contribute significantly to rising state budget costs.

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 182-52 WAC. 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. Compiling Supporting Evidence and Information for Required Factors

Evidence and information used to conduct an affordability review may include:

1. Wholesale Acquisition Cost: Information regarding the initial WAC, the current WAC, and changes to WAC over time.

2. Therapeutic Alternatives: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research.

   Information prepared for the Board's consideration includes:

a. The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;

b. The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and

c. Rebate data for the therapeutic alternative(s) by examining external databases.

3. Price Effect on Washington Consumer Access: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information may also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:

   a. When therapeutic alternative(s) were available;

   b. Changes to patents; and

   c. Changes in rebate amounts for the prescription drug or therapeutic alternative.

4. Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services cost. This may be done by reviewing research that is:

   a. Publicly available;

   b. To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or

   c. Is voluntarily provided by manufacturers.

5. Patient Copayment or Other Cost Sharing: Information from:

   a. APCD data, in aggregate and by payer, for out-of-pocket costs;

   b. Other data sources that approximate out-of-pocket costs not captured in APCD data; and

   c. Out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs.

6. Orphan Drug Status: Information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414),

including:

a. Reviewing the Orphan Drug List for the quarter during which the affordability review begins.

b. Designation date of the prescription drug on the orphan drug list.

c. Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.

d. Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available.

7. Input from Specified Stakeholders

   a. Staff may gather input from patients and caregivers through outreach and holding a public meeting(s).

      i. Patients and caregivers may continue to provide input via verbal public comment and written public comment.

      ii. During the following Board meeting(s), Staff will present input provided by patients and caregivers and will report such information in their final report.

   b. Staff may gather input from individuals who possess scientific or medical training through outreach and holding a public meeting(s).

      i. Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.

      ii. During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report.

8. Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration.

   After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the Advisory Group, by posting on its website, of the ability to submit information if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities.

9. Additional Factors:

    a. Rebates, Discounts, and Price Concessions: To the extent such information is available, information may be prepared from an external database regarding estimated manufacturer net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Staff may also prepare information regarding manufacturer coupons to pharmacies and/or consumers.

    b. Health Equity Factors: Staff may prepare information regarding changes in utilization as compared to changes in WAC and changes in expenditures as identified in APCD data, attempting to understand changes in utilization across differing factors related to health equity.

    c. Non-adherence and Utilization Management Information: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug.

iii. Compiling Supporting Evidence and Information for Permissive Factors

1. The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

    a. Life-cycle management;

    b. Average cost of the prescription drug in Washington;

    c. Market competition;

    d. Projected revenue;

    e. Estimated cost-effectiveness of the prescription drug; and

    f. Off-label usage of the prescription drug.

2. The Board may access pricing information for prescription drugs by:

    a. Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.

b. Accessing available pricing information from the APCD and from state entities.

c. Staff may review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.

d. Staff may review pricing information available from state entities and provide such information to the Board.

e. Accessing information that is available from other countries. Staff may review pricing information from other countries and provide such information to the extent it is available.

iv. 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.

After determining there is no publicly available pricing information, 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 voluntarily provide the requested pricing information. The Board will consider

information provided within 30 days of the request from Staff. The Board will then conduct the affordability review without the requested information.

v. 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 182-52 WAC; or (b) Is proprietary data provided by manufacturers in accordance with Chapter 182-52 WAC 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 may choose not to 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.