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Agenda

Date: July 20, 2022 | Time: 9 a.m.

 Meeting name
 Prescription Drug Affordability Board

 Meeting location
 Virtual

 Zoom link
 Click here to register for the meeting

Board Members: Akil Patterson, Chair; Shelley Bailey, Vice Chair; Daniel Hartung; Richard Bruno; Robert Judge (A); Rebecca Spain (A)

*(A) denotes Alternate Member

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Melissa Stiles, administrative specialist; Joanna Tucker Davis, counsel; Pramela Reddi, counsel

Subject		Presenter	Time Allotted
	Call to order, roll call and approval of minutes	Chair Patterson	5 minutes
	Executive session for DOJ legal advice pursuant to ORS 192.660(2)(h). Not open to the public, with the exception of media and staff.	Joanna Tucker Davis and Pramela Reddi, counsel	20 minutes
	Return to open session: roll call	Chair Patterson	2 minutes
	Executive Director's program update	Ralph Magrish	5 minutes
	PDAB Policies and Procedures: PDAB Policy Amended PDAB Draft Delegation Policy	Ralph Magrish, Cortnee Whitlock	50 minutes
	Presentation of <u>Proposed Work Plan</u>	Cortnee Whitlock, Stephen Kooyman	20 minutes
	Announcements	Board Chair, Ralph Magrish	5 minutes
	Public comment	Board Chair	10 minutes
	Adjournment	Chair Patterson	2 minutes

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Next Meeting

August 3, 2022, at 9:30 a.m.

Accessibility

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made to Melissa Stiles by email at pdab@dcbs.oregon.gov or by phone at 971-374-3724, with at least 48 hours' notice.

Public Comment

Verbal Testimony

To sign up for public comment, email your request to the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov 24 hours before the meeting. Include your name, organization, and the related agenda item. Same-day requests will be considered by the board chair.

Written Testimony

Written comments need to be provided 72 hours prior to scheduled meeting. Any written comments after 72 hours will be included for board consideration at the next meeting. Include your name, organization, and the related agenda item.

Open and Closed Sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed, with the exception of news media and staff. Members of the news media are directed not to report on or otherwise disclose anything said during the executive session. No final actions will be taken in the executive session. When action is necessary, the board will return to an open session.



Oregon Prescription Drug Affordability Board Virtual Meeting Thursday, June 23, 2022 Draft Minutes

Call to Order and Roll Call

Executive Director Ralph Magrish called the meeting to order at 9:32 a.m. and called roll. **Board Members Present**: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Alternates Present: Robert Judge, Rebecca Spain

Welcome Remarks and Introductions

Oregon Sen. Rob Wagner, Sen. Deb Patterson, Rep. Rachel Prusak, and Alex Cheng, deputy director of the Division of Financial Regulation, welcomed board members to the inaugural meeting. Executive Director Magrish introduced board members and read their bios on Pages 2-3 in the agenda packet posted online: https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf

The executive director also introduced staff and counsel.

Executive Session

The board adjourned to executive session for legal advice pursuant to ORS 192.660(2)(f). The meeting was not open to the public with the exception of media and staff. No votes were taken.

Return to Open Session

The board returned to open session and a roll call was taken. All board members were present.

SB 844 Overview and Extension Request

Executive Director Magrish reviewed Senate Bill 844, which established the board, and reviewed the extension request for the annual reporting requirement. The Senate Bill can be found on Pages 9-17 and the letter on Pages 18-19 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf

Election of Board Chair, Vice Chair

Executive Director Magrish led the board through an election of a chair and vice chair. After nominations and roll call votes, the board elected Akil Patterson as chair and Shelley Bailey as vice chair.

Term Assignments

Executive Director Magrish led the board through the term requirements in Section 9 of Senate Bill 844 and presented the following recommendations for the board.

Board Position	Term Length	Expires On
Position 1 Chair	4 years	12/31/2026
Position 2 Vice Chair	4 years	12/31/2026
Position 3	3 years	12/31/2025
Position 4	3 years	12/31/2025
Position 5 (Vacant)	2 years	12/31/2024
Alternate Position 1	4 years	12/31/2026
Alternate Position 2	3 years	12/31/2025
Alternate Position 3 (Vacant)	2 years	12/31/2024

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Board Member Dr. Bruno said, since code does not specify, if the chair or vice chair step down from the position before their terms expire, will the board vote for a new chair or vice chair. Executive Director Magrish said they hope the board chair and vice chair can continue their roles through the duration of their terms. But if they resign, the board would elect a new chair and vice chair. He said a motion is needed to approve the recommended term assignments. He called on Chair Patterson to conduct business. Chair Patterson asked for a motion and Member Dr. Bruno so moved. Vice Chair Shelley Bailey provided a second. The chair called for a vote.

MOTION by Richard Bruno to approve the recommended board appointments. Board Roll Call Vote:

Yea: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Nay: None.

Motion passed.

PDAB Policies and Procedures

PDAB Draft Policy: Executive Director Magrish said PDAB has received public comment that was shared with the board regarding the delegation policy, concerning government functions, adequate confidentiality protection, and fair notice of rules that may impact public policy. The draft policies for board review today provide general guidance and direction to address the objectives of the board. The policies provide that the board convenes under ORS 646A.693-697. There is nothing in these policies contrary to those or any other statutes, constitutional provisions, or relevant juridical decisions. These board operating policies are necessary for the board to function. Following staff presentation, board will have options for votes, to table, table individual portions, or adopt the polices as they have already been reviewed by the Department of Justice for legal sufficiency. He introduced Cortnee Whitlock, board policy analyst, who reviewed the draft PDAB Policy on Pages 20-24 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf

Chair Patterson asked for one of three motion options: table the policy; table individual parts of the policy; or accept staff recommendation and adopt the policy. Vice Chair Shelley Bailey moved to table all of the policy in light of public comments recently provided to the board. Chair Patterson asked for a second and hearing none, said the motion failed. Chair Patterson asked for other motions. Vice Chair Bailey made a motion to table the confidentiality piece for further review. Chair Patterson asked for a second. Board Member Dan Hartung provided a second for future discussion. Vice Chair Bailey said she would like reassurance for any vendors providing analysis to the board or to whom confidential information would be presented, that those contractors would have non-disclosure agreements with the state. Executive Director Magrish pointed to Section 17 of the PDAB Policy, confidentiality as it relates to staff, which can be found on Page 24 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf.

Vice Chair Bailey said she was referring to Senate Bill 844 Section 1 (18)(b),"Unless permission is granted by the board, a third party hired by the board may not release, publish or otherwise use any information to which the third party has access under its contract," on Page 10 of the agenda packet:

https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf. Vice Chair Bailey asked about the repercussions if this is not followed, since sensitive information is being provided to a vendor. Chair Patterson said the bill delegates authority from board to staff to contract with a third party. The chair asked if the third parties would be liable if they violated terms of the contract. Executive Director Magrish said any perimeters around prospective contractors would be included in the Request for Proposal and the final contract language, prior to execution, and would include the appropriate safeguards. Vice Chair Bailey thanked Mr. Magrish for the clarity on the issue. Chair Patterson asked for further comments and hearing none, said, because

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of the pending motion and second, the board needs to take a roll call vote. The chair called for a roll call vote to table a portion of the PDAB policy.

MOTION by Shelley Bailey to table a portion of the PDAB policy. Board Roll Call Vote:

Nay: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Yea: None.

Motion failed.

Chair Patterson asked for a motion to accept all of the PDAB policy recommendations and Member Dr. Bruno so moved. Member Daniel Hartung provided a second. Chair Patterson asked for a roll call vote.

MOTION by Richard Bruno to approve the PDAB policy.

Board Roll Call Vote:

Yea: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Nay: None.

Motion passed.

PDAB Delegation Policy: Cortnee Whitlock, board policy analyst, reviewed the delegation policy on Pages 25-28 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20220623-PDAB-document-package.pdf. Chair Patterson asked for a motion and said a concern was noted by stakeholders of interest which could take some deliberation or time to think about. Vice Chair Bailey moved to table the policy. Member Dr. Bruno provided a second. Chair Patterson asked for a roll call vote.

MOTION by Shelley Bailey to table the PDAB Delegation Policy. Board Roll Call Vote

Yea: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Nay: None.

Motion passed.

Chair Patterson said the policy has been tabled for a later date. He asked staff to move it to the July 20 meeting and staff agreed.

Appoint Rulemaking Coordinator

Executive Director Magrish said the board needs to appoint a rulemaking coordinator and move forward with temporary rules. He recommended the board appoint Karen Winkel from Department of Consumer Business Services to serve as rulemaking coordinator. Chair Patterson asked if anyone so moved. Member Richard Bruno made the motion and Member Daniel Hartung provided the second. Chair Patterson called for the vote.

MOTION by Richard Bruno to appoint Karen Winkel as rulemaking coordinator.

Board Roll Call Vote:

Yea: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Nay: None.

Motion passed.

Temporary Rule Overview and Adoption, Temporary Filing Statement of Need and Justification

Executive Director Magrish asked the chair's permission to extend the meeting 15 minutes to complete agenda items and limit public comment to 3 minutes. The chair agreed. Executive Director Magrish introduced Cassie

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Soucy, senior policy advisor, and Cortnee Whitlock, board policy analyst, as presenters for the next agenda item. Cassie Soucy provided an overview of the rulemaking process, filing temporary rules, the three proposed rules and the Statement of Need Justification on Pages 29-31 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/pdab-rural-app.pdf.

Model Rules for Rulemaking, Notice of Rulemaking, Public Records Requests, OAR 925-100-0001-0003 Cortnee Whitlock reviewed the temporary rules for public records requests on Pages 32-33 in the agenda packet. Chair Patterson asked for a motion to adopt these rules and Member Dr. Bruno so moved. Vice Chair Bailey provided a second. Chair Patterson asked for a roll call.

MOTION by Richard Bruno to adopt model rules. Board Roll Call Vote:

Yea: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson.

Nay: None.

Motion passed.

Announcements and Board Calendar

Executive Director Magrish said the board is doing ground-breaking work. He thanked the board for patience and grace with the technology and process issues in today's meeting and said staff strives to do better going forward. He told the board this is rocky soil but the board is laying a foundation to promote important work and meaningful change for Oregonians in months and years to come. He is honored to work and serve with the board. He announced board vacancies for one full position and one alternate position. This is a recruitment for rural residents and positions are open to anyone who meets the perimeters of the legislation and represent the needs and interests of rural Oregonians. The board has established a monthly meeting calendar of the third Wednesday. Other than next month, when the meeting begins at 9:00 a.m., all future meetings will be held from 9:30 to 11:30 a.m. The board calendar and recruitment application can be found on the PDAB website: https://dfr.oregon.gov/pdab/Pages/index.aspx

Public Comment

Chair Patterson asked those providing public comments to stay within a three-minute time frame and asked the secretary to track time. He called on Dharia McGrew, director of state policy, PhRMA. She thanked the board for kicking off the first meeting of PDAB and said she appreciated the discussion of issues raised in her letter submitted to the board. She said the delegation policy is lacking and some of the policy delegates too much of Oregon's authority without adequate detail and protections. She said there is a lack of detail in the confidentiality policies. She appreciates the board's conversation today and urges members to consider these concerns and flesh out these policies further with more detail. Chair Patterson called on the next speaker. Executive Director Magrish said people requesting to provide public comment to the board must sign up in advance. Marybeth Guarino said she is the health care advocate for OSPIRG, which strongly supports SB 844 and the goals of the board. She has heard from consumers who met deductibles in the first month of their plan year because of prescription costs. She said there are Oregonians currently paying thousands of dollars a month for medications that will save lives, ease pain, and address symptoms of diseases. She said, along with filling prescriptions, these Oregonians must pay rent and buy food and clothes for their children. She urges the board to keep this in mind as they consider prescription costs and make recommendations. She thanked board members for their time and commitment to lowering prescriptions costs for all Oregonians.

Adjournment

There being no further business before the board, the chair moved to adjourn the meeting at 11:32 a.m.

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Prescription Drug Affordability Board Policy and Procedures

Policy Number: 01-AMENDED

Title: Policies and Procedures
Date Issued: <u>June 23, 2023</u>
Dates Reviewed: <u>June 23, 2023</u>
Date Adopted: <u>June 23, 2023</u>

Date Amended:

1. Statutory Authority.

The Prescription Drug Affordability Board is convened under ORS 646A.693 – 646A.697. Nothing in this document is intended to be contrary to these, or any, rules, statutes, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the rules, statutes, Constitution, and judicial decisions govern.

2. Purpose.

The Prescription Drug Affordability Board (the "Board") is established by statute to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state, and other stakeholders within the health care system in this state from the high costs of prescription drugs.

The Board is directed to collect and evaluate information concerning the cost of Prescription Drugs in Oregon; perform Affordability Reviews of those Prescription Drugs; study the entire prescription drug distribution and payment system in this state and polices adopted by other states and countries that are designed to lower the list price of prescription drugs; and make recommendations to the legislative assembly to make prescription drugs more affordable in the state

The Board is required to provide reports to the Legislative Assembly on the following schedules:

No later than June 1st of each calendar year, the Board shall submit a report to the legislative assembly on the generic drug marketplace.¹

No later than December 31st of each calendar year, the Board shall submit a report to both the Legislative Assembly and the Health Care Cost Growth Target program at the Oregon Health Authority that includes i. price trends for the list of drugs provided by DCBS to the Board; ii. the prescription drugs reviewed for affordability reviews²; and iii. any recommendations for legislative changes necessary to make prescription drugs more affordable in Oregon.

The Board has rulemaking authority to adopt criteria for drug affordability reviews and to provide consultation to DCBS in the adoption of annual fees to be paid by manufacturers to meet the cost of program and Board administration costs.

¹ Request submitted by PDAB Executive Director to Legislative Assembly on May 20, 2022 requesting delay of initial deliverable to December 31, 2022

² Request submitted by PDAB Executive Director to Legislative Assembly on May 20, 2022 requesting delay of affordability review results until December 31, 2023 based on rulemaking requirements

3. Board Member Selection Process

Individuals interested in serving on the Board may apply through the Oregon Boards and Commissions website. Applicants must be residents of Oregon with expertise in health care economics and clinical medicine. 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.

4. Term Length and Vacancies

For the initial Board, the Governor appointed five members and three alternate members on May 10, 2022, who are subject to Senate confirmation. Term durations for members will be determined based on election of the Board chairperson and member interest in term durations. Pending member choice, terms to the first appointed Board will be determined as follows:

- (1) One member and one alternate shall serve for a term ending December 31, 2024.
- (2) Two members and one alternate shall serve for a term ending December 31, 2025.
- (3) Two members, including the chairperson, and one alternate shall serve for a term ending December 31, 2026.

5. Conflict of Interest

The Board's Conflict of Interest Policy is set forth in the Prescription Drug Affordability Board Policy No. Placeholder 03.

6. Responsibilities of the Chair of the Board and Vice Chair

The members of the Board will elect one member to serve as the Chair and one member to serve as the Vice Chair for the duration of their appointment to the inaugural 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 Vice Chair presides over a Board meeting in their absence. The Chair works with Board staff to develop Board meeting agendas as set forth in Section 8. The Chair also ensures member compliance with the Conflict of Interest Policy, Policy No. <a href="mailto:special-black-staff-place-black-staff-pla

7. Open Records and Open Meetings

The Board's activities are subject to the Oregon Public Meetings Law, ORS chapter 192 Consistent with those laws, the Board's activities generally will be conducted in public pursuant to public notice requirements, unless Public Meetings laws permit particular matters to be discussed in executive session to receive legal advice from the Department of Justice, to consider trade secret, confidential, or proprietary data that is not otherwise available to the public or other grounds found in ORS 192.660.

The Board's records are generally subject to the Oregon's Public Records Laws, subject to any exclusions from disclosure contained in ORS 192.340 through 192.390.

8. Meetings

The Board will hold meetings at least every six weeks. The Chair of the Board may decide to cancel or postpone a meeting when there are no prescription drugs to review whether as a result of incomplete data or the need for further analysis and no other Board business to conduct. 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 will provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally during the designated time. Persons giving oral comments should introduce themselves with their name and affiliation, if any. The Board is not obligated to respond to comments. The amount of time allocated for public comment will be determined by the Chair of the Board in consultation with Board staff.

Unless otherwise invited to speak or present by the Board, persons or organizations wanting to offer public comment shall identify themselves prior to the beginning of the comment period through a sign-up process administered by Board staff.

9. Meeting Agendas, Materials, and Notes

Board 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.

10. Quorum, Decisions, and Voting

A majority of the five (5) person Board constitutes a quorum. Voting will be conducted by a member roll call. Motions to conduct Board business should flexibly follow the processes set forth in Robert's Rules of Order (e.g. motion, second, discussion, vote).

Alternate Board appointees will participate in all aspects of Board activities, including participation in Executive Session, however they will not hold voting rights unless otherwise designated by the chair person in a member's absence or declaration of a conflict of interest on the issue or drug product brought to a vote by the Board.

The Board Chair will select an alternate member for voting privileges if a member is not in attendance or available, or if there is a vacant position until filled. The alternate will uphold the same responsibilities as voting members.

Alternates will be chosen based on the following criteria (1) an alternate who has a conflict of interest will not be chosen; (2) an alternate who has been present for more of the substantive discussions of the subjects under consideration will be given priority over an alternate who has been absent; (3) an alternate who can commit to attendance at future meetings if the appointment will continue beyond the current meeting will be given priority over an alternate who cannot and (4) priority will be given to an alternate who not been previously designated as a voting member over one who has been previously chosen. If, after applying the criteria in (1)-(4), there is no prioritized alternate, alternates will be chosen in alphabetical order by last name.

11. Executive Session

The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Oregon Department of Justice or as permitted by ORS 192.660. The board may-will-meet in executive session to discuss trade secret information. The

Board will not deliberate concerning whether to subject a prescription drug to an affordability review, 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 only be disclosed if required under the Public Records Law, ORS chapter 192.

12. Meeting Attendance, Absences, and Participation

Board members and alternate appointees 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 and Executive Director prior to the meeting. Under ORS 182.010, any member of a state board or commission appointed by the Governor who fails to attend two consecutive meetings of the board or commission, whether regular, adjourned or special, shall forfeit office unless the member is prevented from attending by the serious illness of a member or the family of the member or for any other cause that in the judgment of the Governor constitutes a valid reason for failing to attend. The Governor shall immediately appoint a successor.

13. Board Members are Public Representatives

Members of the Board are Public Representatives, appointed by the Governor to protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state and other stakeholders within the health care system in this state from the high costs of prescription drugs. Members accept appointment to the Board with the understanding that they will represent the public interest in their actions and decisions on the Board.

14. Use of State Email Accounts

State email accounts should be used only to send or receive information to or from the Board staff. When sending or replying to Board staff, members should not reply all so as to avoid a situation of appearance of Board business being discussed in a setting that should otherwise be public. If Board members receive communications from the public about board business, board member should forward those communications to the PDAB Executive Director Ralph Magrish at Ralph.M.Magrish@dcbs.oregon.gov

15. 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 Oregon consumers.

16. Interaction with the Media and Lobbyist

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 the PDAB Executive Director Ralph Magrish at Ralph.M.Magrish@dcbs.oregon.gov

17. Department of Consumer & Business Services Staff

Staff from the Department of Consumer & Business Services ("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, administrative rule development, drafting and filing, policy issue brief development, data analysis, and additional tasks as delegated by the Board.

The Staff may also provide support to the Board in preparing policy recommendations to the Legislative Assembly and preparation of annual reports to the Legislative Assembly (pursuant to ORS 646A.693 - 646A.697).

The Department of Consumer & Business Services 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 contractors are required to enter into a nondisclosure agreement to protect trade secret, confidential, or proprietary information.

The Board may also delegate particular tasks to the Department of Consumer & Business Services on a case-by-case basis to perform its duties.

18. Annual Review

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

Prescription Drug Affordability Board Delegation Policy Policy Number: 02-DRAFT PENDING BOARD APPROVAL

Title: Board Delegation Policy

Date Issued: Dates Reviewed: Date Adopted:

1. Statutory Authority

The Prescription Drug Affordability Board is convened under ORS 646A.693 - 646A.697. 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.

2. Purpose

- a. To clarify when staff within the Department of Consumer and Business Services (DCBS) may perform work on behalf of the Prescription Drug Affordability Board (Board)
- b. To provide guidance to the Board regarding their duties and responsibilities with respect to Staff.

3. Board Support

Staff from the Department of Consumer & Business Services (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, Administrative rule development and drafting, policy issue brief development, data analysis, and additional tasks as delegated by the Board.

Staff may also provide support to the Board in preparing policy recommendations to the Legislative Assembly and preparation of annual reports to the Legislative Assembly pursuant to ORS 646A.696 – 646A.697.

DCBS, on behalf of the with the approval from 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 agree to contractual provisions that address confidentiality and non-disclosure to protect trade-secret, confidential, or proprietary information. Third party contractors are to disclose any conflict of interests prior to entering into contract agreement and if any conflicts occur under the time of the contract.

The Board may also delegate particular tasks to DCBS on a case-by-case basis to perform its duties.

4. Policy Statement

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 delegation of any of these duties to an individual Board Member.

Board Meetings Pursuant to Oregon Public Meetings Law, ORS chapter 192

- Facilitate Public Meetings and Board Executive Sessions, including scheduling meetings, arranging meeting platforms and/or locations, and sending calendar invitations and Board-related notices.
- b. Provide public notice of Board meetings and agenda items on the Board's website and Oregon Transparency website.
- c. Develop agendas for Board meetings in coordination with the Board Chair.
- d. Serve as the recording secretary for the Board and prepare meeting minutes for consideration by the Board.
- e. Prepare Board materials.
- f. Distribute agenda and materials in support of the Board's agenda to each Board Member.
- g. Review meeting materials and agenda items with Counsel prior to the Board meeting.
- h. Record all meetings.
- i. Provide minutes of Board meetings on the Board's website.
- Record and securely store recordings of all executive sessions entered into by the Board at Board meetings.

Contracts

- a. Pursuant to and in compliance with <u>state law and any</u>-procurement policies <u>developed by DCBS</u>, 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.
- b. The Board determines that to necessarily carry out its powers and duties, DCBS 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;
 - ii. Data, research, analysis, and supporting materials to inform the process for and conducting of affordability reviews;
 - iii. Data, research, analysis, and supporting materials to inform the methodology and process for and consideration of whether to set an upper payment limit;
 - iv. Data, research, analysis, and initial recommendations related to the development of a formula to calculate savings;
 - v.iii. Equity and cultural responsiveness related to the Board's activities; and
 - <u>vi.iv.</u> Data, research, analysis, and supporting materials for the Board's consideration in identifying potential policy recommendations to the Legislative Assembly and compiling the Board's recommendations.

Administration

- a. Serve as the custodian of record for the Board in accordance with Oregon Public Records law (ORS chapter 192).
- b. 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.
- c. 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.
- d. Receive and respond to requests 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.
- e. The Executive Director or any other Staff for the Board may accept service on behalf of the Board.
- f. 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.
- g. Receive and maintain documents and correspondence addressed or submitted to the Board and ensure Board review of such materials, if necessary.
- h. Draft reports and memoranda pertaining to work completed by or on behalf of the Board.
- i. Maintain the Board's public webpage and ensure the webpage contains the following:
 - i. Conflicts of interest disclosed to the Board pursuant to ORS 646A.693.
 - ii. Reports prepared for the Health Care Cost Growth Target program pursuant to ORS 646A.696.
 - iii. Reports prepared for the Legislative Assembly pursuant to ORS 646.697.
 - iv. Notice of Board meetings and hearings.
 - v. All agendas, non-confidential and non-privileged meeting materials, and Board-approved meeting minutes.
 - vi. List of Board Members.
- vii. Instructions for submitting materials for the Board's consideration.
- viii. Contact information for submitting requests pursuant to Oregon Public Meetings Law, ORS chapter 192.
- ix. Policies and procedures adopted by the Board.
- x. Resolutions, Orders, and any other memorialized decisions by the Board.
- xi. Findings, reports, and studies conducted by the Board, redacted for confidential information as necessary.
- xii. Notices of proposed rulemaking and rulemaking hearing information.
- xiii. Regulations and guidance adopted by the Board.
- xiv. List of all prescription drugs the Board determines to be unaffordable.
- xv. Any material specifically requested by the Board.

Support for Performance of Board Duties

a. Facilitate rulemaking conducted by the Board, including but not limited to:

- i. Draft rules for consideration by the Board.
- ii. Effectuate publication and/or filing of notices of draft proposed regulations approved by the Board, and adopted rules in the Oregon Bulletin, on the Oregon Secretary of State's website.
- iii. Submit requests for advice from Oregon Department of Justice.
- iv. Compile the official rulemaking record for all rulemaking conducted by the Board, including receipt and inclusion of any public comments.
- b. Collect and provide conflicts of interest to the Board:
 - i. Distribute conflict of interest forms and coordinate completion of disclosures when required by law.
- c. Draft reports required by ORS 646A.696 and ORS 646A.697, and present drafts to the Board for review, amendment, and approval.
- d. Coordinate with legislative staff regarding any legislative hearings or presentations.
- e. Coordinate the secure collection of and access to data and information on behalf of the Board pursuant ORS 646A.694, ORS 646A.696, and ORS 646A.697, including by working with other state agencies, stakeholders, and presenting material received to the Board, and entering into memoranda of understanding or data use agreements as needed and approved by the Board.
- f. Request notification and copies of any notices of membership withdrawal received by the Board pursuant to ORS 646A.693.
- g. Assist in the collection and presentation of data, information, or analysis necessary for the Board to perform its duties related to affordability reviews and as may be further specifically addressed in other Board policies.





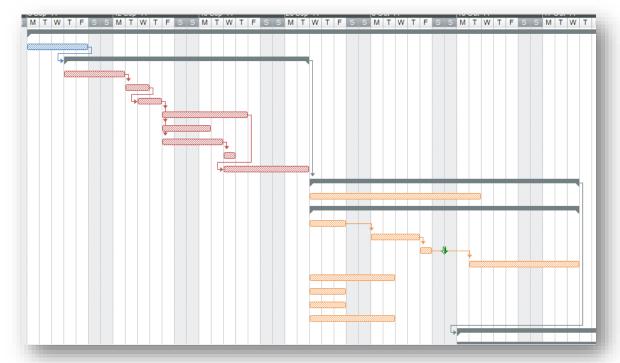
Prescription Drug Affordability Board

Proposed Work Plan 2022 - 2023

Proposed Work Plan

PDAB's work plan tracks the milestones and deliverables need to support the board's responsibilities:

- Board Meeting Schedule
- Annual Studies
- Annual Reports
- Rules Development





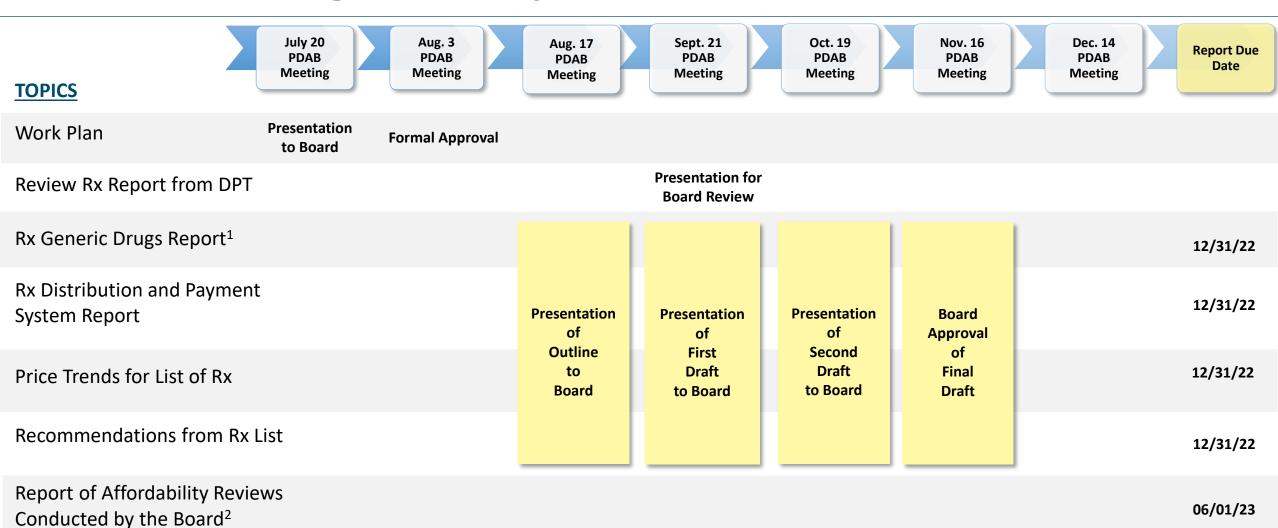
Board Meetings through 2022







Board Meetings and Topics









¹Originally due June 1, now December 31, 2022

² Originally due December 31, 2022, now due June 1, 2023

PDAB ROADMAP for 2022

APR

Review Reports from DPT

- Rx list of Carriers
- New Rx list of Manufacturers

Studies

- Rx Distribution and Payment System
- Generic Drugs
- Price trends for list of Rx
- Recommendations from Rx list

Rules

Develop Structure:

Affordability Criteria

Fee Structure

Draft Annual Reports

- Rx Distribution and Payment System
- Generic Drugs
- Price trends for list of Rx
- Recommendations from Rx list

Rules

Present Proposed Structures:

- Fee Structure
- · Affordability Criteria

OCT

Oregon Prescription Drug Affordability Board

Identify 9 Rx & Insulin

Review list for 2023 review

Annual Reports Due

- Rx Distribution and Payment System
- Generic Drugs
- Price trends for list of Rx
- Recommendations from Rx list

DEC

MAY JUN JUL AUG SEP

Q4

NOV

Q3

JAN FEB MAR

Q1



PDAB ROADMAP for 2023

Rules

- Begin rulemaking for Fee Structure
- Develop draft Rules for Affordability Criteria

Studies

- Generic Drugs
- Rx for Affordability Reviews

Report from DPT

New Rx list of Manufactures

Rules

Begin rulemaking for Affordability Criteria

Annual Reports

- Generic Drug
- Health Care Cost Growth for Rx review

Rules

- Implement Fee Structure
- Implement Affordability Criteria

Studies

- Price trends for list of Rx
- Affordability of Rx
- Recommendations from Rx list

Report from DPT

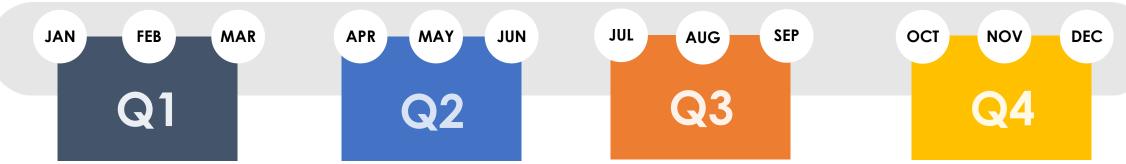
Rx list of Carriers

Identify 9 Rx & Insulin

Review list for 2024 review

Annual Reports

- Price trends for list of Rx
- Report of Affordability Reviews conducted by the Board
- Recommendations from Rx list









2022 Prescription Drug Affordability Board Calendar

Meeting 1	Thursday, June 23	9:30 – 11:30 a.m.
Meeting 2	Wednesday, July 20	9:00 – 11:00 a.m.
Meeting 3	Wednesday, August 3	9:30 – 11:00 a.m.
Meeting 4	Wednesday, August 17	9:30 – 11:30 a.m.
Meeting 5	Wednesday, September 21	9:30 – 11:30 a.m.
Meeting 6	Wednesday, October 19	9:30 – 11:30 a.m.
Meeting 7	Wednesday, November 16	9:30 – 11:30 a.m.
Meeting 8	Wednesday, December 14	9:30 – 11:30 a.m.

OFFICE OF THE SECRETARY OF STATE

SHEMIA FAGAN SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK DIRECTOR

800 SUMMER STREET NE SALEM, OR 97310 503-373-0701

FILED

06/27/2022 11:18 AM ARCHIVES DIVISION

SECRETARY OF STATE

& LEGISLATIVE COUNSEL

TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

PDAB 1-2022

CHAPTER 925

DEPARTMENT OF CONSUMER AND BUSINESS SERVICES

PRESCRIPTION DRUG AFFORDABILITY BOARD

FILING CAPTION: Model Rules for Rulemaking and Public Records Requests

EFFECTIVE DATE: 06/27/2022 THROUGH 12/23/2022

AGENCY APPROVED DATE: 06/27/2022

CONTACT: Karen Winkel 350 Winter Street NE Filed By:

503-947-7694 Salem,OR 97301 Karen Winkel

karen.j.winkel@dcbs.oregon.gov Rules Coordinator

NEED FOR THE RULE(S):

These rules are necessary for the operation of the Prescription Drug Affordability Board (PDAB) to promulgate administrative rules consistent with its authority under SB 844 (2021).

JUSTIFICATION OF TEMPORARY FILING:

This temporary rulemaking is needed because failure to act promptly will result in serious prejudice to the public interest as the PDAB's statutory mandate is to protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state and other stakeholders within the health care system in this state from the high costs of prescription drugs. The PDAB is unable to proceed without these rules in place.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft rules are available from the Rules Coordinator, Division of Financial Regulation, located at 350 Winter St. NE, P.O. Box 14480, Salem, OR 97301-0405, and are available on the division's website: dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

RULES:

925-100-0001, 925-100-0002, 925-100-0003

ADOPT: 925-100-0001

RULE SUMMARY: Provides a legal framework for the Prescription Drug Affordability Board (PDAB) to engage in rulemaking as authorized by SB 844 (2021), consistent with authorities granted under ORS 183.341.

CHANGES TO RULE:

925-100-0001

Model Rules for Rulemaking

The Model Rules for Rulemaking, OAR 137-001-0005 through 137-001-0100, in effect on Jan. 1, 2008, adopted

by the Oregon Department of Justice under ORS 183.341, are adopted as the rules of procedure for rulemaking actions of the Prescription Drug Affordability Board. The full text of the Model Rules is available from the Department of Justice, the Prescription Drug Affordability Board, or on the Oregon State Archives website at https://arcweb.sos.state.or.us/pages/rules/oars-100/oar-137/137-001.html.

Statutory/Other Authority: ORS 646A.693 - 646A.697 Statutes/Other Implemented: ORS 183.325 - 183.410 ADOPT: 925-100-0002

RULE SUMMARY: Defines requirements for notification of rulemaking by the PDAB.

CHANGES TO RULE:

925-100-0002

Notice of Rulemaking

(1) Except when adopting a temporary rule, the Prescription Drug Affordability Board will give prior public notice of the proposed adoption, amendment, or repeal of any rule by:¶

(a) Publishing notice of the proposed rulemaking action in the Secretary of State's Oregon Bulletin at least 21 days before the effective date of the rule;¶

(b) Notifying interested people and organizations on the Prescription Drug Affordability Board's notification lists of proposed rulemaking actions under ORS 183.335; and ¶

(c) Providing notice to legislators as required by ORS 183.335(15).¶

(2) A person or organization may elect to receive email or hard-copy notification of proposed rulemaking actions of the Prescription Drug Affordability Board.¶

(a) A person or organization may elect to subscribe to the Prescription Drug Affordability Board's email notification service at

https://public.govdelivery.com/accounts/ORDCBS/subscriber/new?topic id=ORDCBS 732.¶

(b) A person or organization may elect to receive hard-copy notification by sending a request in writing, including the person or organization's full name and mailing address, to the following address:¶

Rules Coordinator¶

Prescription Drug Affordability Board¶

350 Winter St. NE¶

P.O. Box 14480¶

Salem, OR 97309-0405

Statutory/Other Authority: ORS 646A.693 - 646A.697 Statutes/Other Implemented: ORS 183.335, ORS 84.022 ADOPT: 925-100-0003

RULE SUMMARY: Adopts requirements found in Oregon's Public Records Law (ORS 192) into PDAB rules.

CHANGES TO RULE:

925-100-0003

Public Records Requests

(1) Oregon's Public Records Law (ORS 192) provides that every person has a right to inspect any public records of a public body, except records that are exempt from disclosure.¶

(2) A public record request may be submitted in person, by U.S. Mail, fax or by email to the Prescription Drug Affordability Board (Board). The written request must include:¶

(a) The name and address of the person requesting the public record;¶

(b) The telephone number or other contact information of the person requesting the public record; ¶

(c) A sufficiently detailed description of the record(s) requested to allow the Board to search for and identify responsive records; and the ¶

(d) Date and signature of the person requesting the public record.¶

 $(3) \ Public \ records, \ except \ those \ exempt \ from \ disclosure, \ will \ be \ made \ available \ upon \ request \ for \ review \ and \ copies \ will \ be \ provided \ at \ a \ fee \ reasonably \ calculated. \P$

(4) The Oregon Public Records Law allows agencies to recover their actual costs in fulfilling a public records request including actual costs for supplies, research, compilation, postage, shipping and staff time.¶

(5) Fees will be payable prior to fulfilling a public records request. If the fee is estimated to be greater than \$25:¶

(a) The Board staff will provide the requestor with a written notice of the estimated amount of the fee. ¶

(b) The public records request will not be fulfilled until the requestor confirms in writing that the requestor wants to proceed with the request.¶

(6) Standard fees for Public Records:¶

(a) Per page fees reflect current Oregon Department of Administrative Services policy;¶

(b) \$5.00 for each true notarized certification;

(c) Other applicable fees: actual costs or best estimate of costs; and ¶

(d) Miscellaneous fees may include archive retrieval costs, costs of software companies/contracts; other third party costs.¶

(e) No charge for the first 30 minutes of staff time for processing request. The hourly rate charged for additional staff time is based on the level of skill or expertise required to complete the work performed not the employee-level of the individual actually fulfilling the request.¶

(f) Clerical labor charges are \$25.00 per hour; Managerial labor charges are \$40 per hour; Professional (IT, HR, high-level Analyst) \$75.00 per hour; and DOJ, special attorney and other applicable legal fees: at the actual hourly rate charged for Public Records Request-related services. Fees are subject to statutory limitation described in ORS 192.324.¶

(7) The Board may furnish copies of public information without charge or at a reduced fee if it is determined that the waiver or reduction of fees is in the public interest because providing access primarily benefits the general public under ORS 192.324.¶

(8) A person desiring a waiver or reduction in fees must submit a written request for a waiver. ¶

(9) The Board Executive Director will consider each request on a case-by-case basis based on the information provided by the requestor and the totality of the circumstance at the time of the request.¶

(10) The Board Executive Director will make fee waiver or reduction decisions based on the guidelines outlined in the Oregon Department of Administrative Services Statewide Standardized Fee Process.

Statutory/Other Authority: ORS 646A.693 - 646A.697

Statutes/Other Implemented: ORS 192.324