Oregon Prescription Drug Affordability Board

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Agenda

Date: **June 23, 2022** | *Time*: **9:30 a.m.**

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Click here to join the meeting

Board Members: Shelley Bailey; Daniel Hartung; Richard Bruno; Akil Patterson; 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 and roll call	Ralph Magrish	2 minutes
☐ Welcome remarks	Alex Cheng and invited legislators	10 minutes
☐ Introductions	Ralph Magrish	10 minutes
☐ Executive session for DOJ legal advice pursuant to ORS 192.660(2)(f). Not open to the public, with the exception of media and staff.	Joanna Tucker Davis and Pamela Reddi, counsel	30 minutes
☐ Return to open session: roll call	Ralph Magrish	2 minutes
☐ SB 844 overview, Extension Request	Ralph Magrish	10 minutes
☐ Election of board chair and vice chair; Vote to assign Board terms durations (refer to SB 844, Section 9)	Ralph Magrish	15 minutes
☐ PDAB Policies and Procedures: PDAB Draft Policy PDAB Draft Delegation Policy * Conflict of Interest Policy will be tabled until the July 20th meeting.	Ralph Magrish & Cortnee Whitlock	15 minutes
☐ Temporary Rule Overview & Adoption Temporary Filing Statement of Need & Justification OAR 925-100-0001: Model Rules for Rulemaking OAR 925-100-0002: Notice of Rulemaking OAR 925-100-0003: Public Records Requests	Cassie Soucy & Cortnee Whitlock	15 minutes
☐ Announcements & Board Calendar	Ralph Magrish	5 minutes
☐ Public comment	Board Chair	10 minutes

Next Meeting

July 20, 2022, at 9:00 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 Prescription Drug Affordability Board at pdab@dcbs.oregon.gov 24 hours before the meeting. Include your name, organization, and the related agenda item.

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. 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

Board Member Welcome Packet

Contents

Oregon Prescription Drug Affordability Board

Board Members

Shelley Bailey served as the CEO and co-owner of Central Drugs Pharmacy. Shelley is currently the CEO of Famlee, the nation's first and only 50-state virtual fertility care and treatment option (combining at-home labs with fertility telehealth and Rx delivery). Shelley has been involved in healthcare since she was a young girl and her grandparents owned a small, independent pharmacy in Portland's Mt. Tabor neighborhood. Under her leadership, Central Drugs was the largest contractor for the state's AIDS Drug Assistance Program (ADAP), serving Oregonians living with HIV and Hepatitis C. Shelley has experience with specialty pharmacy, wholesaler price negotiations, manufacturer negotiations, PBM contract negotiations, and 340B arrangements. Previously, Shelley served on the Oregon 2012 Pharmacy Benefit Manager Legislative Committee (HB 4122), the McKesson National Independent Advisory Board, and on state and national pharmacy advocacy committees. Shelley brings direct pharmacy knowledge into broader discussions on effectively saving money on prescription drug costs for the State and all Oregonians.

Richard Bruno, MD, MPH, is a double-boarded Family & Preventive medicine physician, practicing as the Senior Medical Director at Central City Concern, a federally-qualified health center in Portland that has an integrated 340B pharmacy. His main clinical focuses are on houselessness, HIV, gender-affirming care, obesity, and opioids, with involvement in community public health interventions and policies, including cooking classes for kids/seniors and legislation expanding access to medication for opioid use disorder. Dr. Bruno passionately believes no one should have to choose between life-saving medications and other necessities. As a primary care physician, he often runs into barriers trying to get his patients access to the medications they need and states it would be an honor to serve on the PDAB to look at drug pricing and make improvements for all Oregonians.

Dan Hartung PharmD, MPH, is a tenured professor of Pharmacy Practice in the College of Pharmacy at Oregon State University. Over the last two decades, he has conducted pharmaceutical health services research with an emphasis on substance use disorders and prescription drug policy. Dr. Hartung's work has been supported by CDC, AHRQ, and NIH (NIDA). He has published more than 100 papers in peer-reviewed medical literature. His research involves investigating the causes and consequences of rising prescription drug costs, with an emphasis on medications for multiple sclerosis (MS). He has developed a deep understanding about how the dysfunctional pharmaceutical ecosystem has contributed to rising prescription drug prices and expenditures. As a researcher and pharmacist, he is well positioned to serve on this board to help develop policy to address prescription drug affordability challenges for Oregonians.

Akil Patterson JD, MLS, PCM was involved in advocacy for the creation of PDABs in Oregon as a member of the Oregon Coalition for Affordable Prescriptions (OCAP) and in Maryland, where he previously resided. He is passionate in his advocacy that the poor and people of color have access to the same lifesaving medications as others. Mr. Patterson is former political organizer for the Oregon Nurses Association, where he led trainings around diversity and inclusion, and efforts to address the social determinants of health in health policy reforms. Currently Mr. Patterson serves as the City of Portland Social Equity and Educational Development Coordinator for the Cannabis Program. Mr. Patterson was awarded a Presidential Service Award in 2016 by President Barrack Obama for being a champion of social justice and racial equity issues. He has served in a number of leadership roles including the Maryland State Medical Society's Sugar-Free Kids Project and Aids Healthcare Foundation.

Alternate Members

Robert Judge is the Director of Pharmacy Services at Moda. In this role, Robert is responsible for managing Moda Health's pharmacy account services and data analytics teams for the company's fully insured, ASO and MCO clients. Robert also manages pharmacy programs, services and analytics for Moda Health's government clients and individuals enrolled in ArrayRx (formerly the Northwest Prescription Drug Consortium), a collaboration between the States of Oregon, Washington and Nevada to provide pharmacy solutions and affordable medications to residents in member states. He has expertise in payer pharmaceutical acquisition pricing, pharmacy benefit management services, pharmaceutical distribution, supply chain and public health service 340B program management.

Rebecca Spain MD, MSPH is an Associate Professor in the Department of Neurology at OHSU, Associate Director of Clinical Care for the, Multiple Sclerosis (MS) VA Center of Excellence West, and MS Regional Director for the VA Portland Health Care System. As a neurologist specializing in MS, she sees first-hand the devastating effects of high cost prescription drugs on patients and their families. Noting these effects result in poorer health outcomes, economic devastation, and a loss of social cohesion, Dr. Spain hopes to contribute to the PDAB with her knowledge, experience, and advocacy.

Counsel

Joanna Tucker Davis
Senior Assistant Attorney General
Oregon Department of Justice

Pramela Reddi
Assistant Attorney General
Oregon Department of Justice

Oregon Prescription Drug Affordability Board

Board Staff

Ralph Magrish, Executive Director
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Melissa Stiles, Board Administrative Specialist
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The Prescription Drug Affordability Board (PDAB) was established under Senate Bill 844 and supported by the Department of Consumer and Business Services (DCBS). The PDAB aims to protect residents of the State of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system of Oregon from the high costs of prescription drugs.

PDAB is a board with five members and three alternate members with expertise in health care economics and clinical medicine. The Senate appointed the Board in June 2022. The Board will conduct affordability reviews to determine whether a drug presents affordability challenges to Oregon residents, health systems, and health inequities for communities of color in Oregon.

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 offers strategic planning to help the Board comply with its statutory duties and responsibilities. The Vice-Chair presides over a Board meeting in the absence of the Chair. The Chair works with Board staff to develop Board meeting agendas and ensures member compliance.

Member term durations will be determined based on the 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.

Board members and alternate appointees are expected to make every effort to attend monthly Board meetings. Members may participate in a meeting in person, by telephone, or by any other means of electronic communication by which all persons participating in the meeting can hear each simultaneously. If a member is unable to attend a meeting, the member must notify the Chair and Executive Director prior to the meeting.

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

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

No later than December 31 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:

1. Price trends for the list of drugs provided by DCBS to the Board;
2. The prescription drugs reviewed for the affordability reviews; and
3. Any recommendations for legislative changes are 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 the program and Board administration costs.

Oregon Prescription Drug Affordability Board

PDAB Public Website

https://dfr.oregon.gov/pdab/Pages/index.aspx

Questions about PDAB: pdab@dcbs.oregon.gov

Telephone: 971-374-3724

Proposed Board 2022 Schedule

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 17	9:30 – 11:30 a.m.
Meeting 4	Wednesday, September 21	9:30 – 11:30 a.m.
Meeting 5	Wednesday, October 19	9:30 – 11:30 a.m.
Meeting 6	Wednesday, November 16	9:30 – 11:30 a.m.
Meeting 7	Wednesday, December 14	9:30 – 11:30 a.m.

Enrolled
Senate Bill 844

Sponsored by Senator PATTERSON, Representative PRUSAK; Senator MANNING JR, Representatives CAMPOS, HUDSON, SCHOUTEN

CHAPTER .....

AN ACT

Relating to the price of prescription drugs; creating new provisions; and amending ORS 646A.689.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) The Prescription Drug Affordability Board is established in the Department of Consumer and Business Services 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.

(2) The board consists of five members and three alternates appointed by the Governor.

(3) The term of office of each member of the board is four years, but a member serves at the pleasure of the Governor. Before the expiration of the term of a member, the Governor shall appoint a successor whose term begins on January 1 next following. A member is eligible for reappointment. If there is a vacancy for any cause, the Governor shall make an appointment to become immediately effective for the unexpired term.

(4) The appointment of each member of the board is subject to confirmation by the Senate in the manner prescribed in ORS 171.562 and 171.565.

(5) A member of the board is entitled to compensation and expenses as provided in ORS 292.495.

(6) The members of the board must be residents of this state with expertise in health care economics and clinical medicine.

(7) A member of the board may not be an employee of, a board member of or a consultant to a manufacturer or a trade association of manufacturers.

(8) The board shall select one of its members as chairperson and another as vice chairperson, for terms and with duties and powers necessary for the performance of the functions of the offices as the board determines.

(9) A majority of the members of the board constitutes a quorum for the transaction of business.

(10) The department shall appoint an executive director for the board, may employ consultants, investigators or other staff and shall provide staff support to the board to carry out its duties.

(11) The board shall meet at least once every six weeks at a time and place determined by the chairperson. The chairperson may cancel or postpone a regular meeting if there is no prescription drug to review. The board may also meet at other times and places specified by the call of the chairperson or of a majority of the members of the board.

(12)(a) The following actions by the board shall be open to the public in accordance with ORS 192.610 to 192.690:

(A) Any deliberation on whether to conduct an affordability review of a prescription drug under section 3 of this 2021 Act; and

(B) Any decision or deliberation toward a decision on any matter before the board except as provided in paragraph (b) of this subsection.

(b) The board may meet in executive session to discuss trade secret information.

(13) The board shall:

(a) Provide public notice of each board meeting at least two weeks in advance of the meeting;

(b) Make materials for each board meeting available to the public at least one week in advance of the meeting;

(c) Provide an opportunity for public comment at each open meeting of the board; and

(d) Provide the public with the opportunity to submit written comments on any pending decision of the board.

(14) The board may allow expert testimony at board meetings, including when the board meets in executive session.

(15)(a) A member of the board shall recuse the member from decisions related to a prescription drug if the member, or an immediate family member of the member, has received or could receive any of the following:

(A) A direct financial benefit of any amount deriving from the result or finding of a study, review or determination by or for the board; or

(B) A financial benefit from any person that owns, manufactures, or provides prescription drugs, services or items to be reviewed by the board that in the aggregate exceeds $5,000 per year.

(b) For the purposes of paragraph (a) of this subsection, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings and any direct financial benefit deriving from the result or finding of a study, review or determination by or for the board.

(c) A conflict of interest shall be disclosed:

(A) By the board when hiring board staff;

(B) By the Governor when appointing members and alternate members to the board; and

(C) By the board, when a member of the board is recused in any final decision resulting from a review of a prescription drug.

(d) A conflict of interest shall be disclosed at the earlier of:

(A) Prior to the first board meeting after the conflict is identified; or

(B) Within five days after the conflict is identified.

(e) A conflict of interest disclosed under this section shall be posted on the website of the board unless the chairperson of the board recuses the member from any final decision resulting from a review of a prescription drug.

(f) A posting under paragraph (e) of this subsection shall include the type, nature and magnitude of the conflict of interest of the member involved.

(16) Members and alternate members of the board, staff and third parties that contract with the board may not accept any gift or donation of services or property that creates a potential conflict of interest or has the appearance of biasing the work of the board.

(17)(a) The board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board.

(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.

(18) In accordance with applicable provisions of ORS chapter 183, the board may adopt rules necessary for the administration of sections 1 to 3 of this 2021 Act.

SECTION 2. **(1) The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar quarter a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted to the department under ORS 743.025 and a list of insulin drugs marketed in this state during the previous calendar year. Each calendar year, the board shall identify nine drugs and at least one insulin product from the lists provided under this subsection that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board by rule, including but not limited to:**

(a) Whether the prescription drug has led to health inequities in communities of color;

(b) The number of residents in this state prescribed the prescription drug;

(c) The price for the prescription drug sold in this state;

(d) The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review;

(e) The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices;

(f) The estimated price for therapeutic alternatives to the drug that are sold in this state;

(g) The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives;

(h) The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the United States Food and Drug Administration and recognized standard medical practice;

(i) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

(j) The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;

(k) The estimated average patient copayment or other cost-sharing for the prescription drug in this state;

(L) Any information a manufacturer chooses to provide; and

(m) Any other factors as determined by the board in rules adopted by the board.

(2) A drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review under subsection (1) of this section.

(3) The board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition.

(4)(a) If the board considers the cost-effectiveness of a prescription drug in criteria adopted by the board under subsection (1) of this section, the board may not use quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. For any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability.

(b) As used in this subsection:

(A) "Health utility" means a measure of the degree to which having a particular form of disease or disability or having particular functional limitations negatively impacts the

quality of life as compared to a state of perfect health, expressed as a number between zero and one.

(B) "Quality-adjusted life-year" is the product of a health utility multiplied by the extra months or years of life that a patient might gain as a result of a treatment.

(5) To the extent practicable, the board shall access pricing information for prescription drugs by:

(a) Accessing pricing information collected by the department under ORS 646A.689 and 743.025;

(b) Accessing data reported to the Oregon Health Authority under ORS 442.373;

(c) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

(d) Accessing other publicly available pricing information.

(6) The information used to conduct an affordability review may include any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

(7) The department and the board shall keep strictly confidential any information collected, used or relied upon for the review conducted under this section if the information is:

(a) Information submitted to the department by a manufacturer under ORS 646A.689; and

(b) Confidential, proprietary or a trade secret as defined in ORS 192.345.

SECTION 3. (1) The Department of Consumer Business Services shall adopt by rule, in consultation with the Prescription Drug Affordability Board, annual fees to be paid by manufacturers that sell prescription drugs in this state. The fees shall be established in amounts necessary to meet the costs of the department and the board in administering sections 1 to 3 of this 2021 Act. The fees shall be imposed based on a manufacturer's share of gross revenue from sales of prescription drugs in this state.

(2) Fees collected under this section shall be deposited in the Prescription Drug Affordability Account established in section 4 of this 2021 Act.

SECTION 4. The Prescription Drug Affordability Account is established as a subaccount in the Consumer and Business Services Fund created in ORS 705.145, consisting of moneys collected under section 3 of this 2021 Act and moneys that may be appropriated for deposit into the Prescription Drug Affordability Account by the Legislative Assembly. Interest earned on the account shall be credited to the account. Moneys in the account are continuously appropriated to the Prescription Drug Affordability Board to carry out sections 1 to 3 of this 2021 Act.

SECTION 5. No later than December 31 of each year, the Prescription Drug Affordability Board shall report to the Health Care Cost Growth Target program established in ORS 442.386 and to the interim committees of the Legislative Assembly related to health, in the manner provided in ORS 192.245, the following information:

(1) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services under section 2 (1) of this 2021 Act;

(2) The prescription drugs that were reviewed under section 2 of this 2021 Act; and

(3) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state.

SECTION 6. (1) As used in this section, "generic drug" means:

(a) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. 355(j);

(b) An authorized generic as defined by 42 C.F.R. 447.502; or

(c) A drug that entered the market before 1962 that was not originally marketed under a new drug application.

(2) The Prescription Drug Affordability Board shall annually conduct a study of the operation of the United States market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians, including:

(a) The prices of generic drugs on a year-to-year basis;

(b) The degree to which generic drug prices affect insurance premiums;

(c) Annual changes in health insurance cost-sharing for generic drugs;

(d) The potential for and history of generic drug shortages;

(e) The degree to which generic drug prices affect annual spending in the state medical assistance program; and

(f) Any other topic the board considers relevant to the cost of generic drugs.

(3) No later than June 1 of each calendar year, the board shall report to the Legislative Assembly the findings of the board's study in the manner provided in ORS 192.245.

SECTION 7. (1) The Prescription Drug Affordability Board shall 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 including but not limited to the following options:

(a) Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain;

(b) Using a reverse auction marketplace for the purchase of prescription drugs by state and local governments; and

(c) Implementing a bulk purchasing process for state and local governments to purchase prescription drugs.

(2) No later than December 31, 2022, the board shall complete the study described in subsection (1) of this section and report to the interim committees of the Legislative Assembly related to health in the manner provided in ORS 192.245:

(a) The board's findings including findings for each option described in subsection (1) of this section; and

(b) Recommendations for policies to lower the list prices of prescription drugs sold in this state and for legislative changes necessary to implement the policies.

SECTION 8. ORS 646A.689 is amended to read:

646A.689. (1) As used in this section **and sections 1 to 3 of this 2021 Act**:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than March 15 of each year, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in ORS 646A.692, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) In accordance with section 2 of this 2021 Act, the department shall provide to the Prescription Drug Affordability Board established in section 1 of this 2021 Act:

(a) Each calendar quarter, a list of prescription drugs included in reports submitted under subsections (2) and (6) of this section; and

(b) Access to pricing information submitted to the department under subsections (3), (6) and (7) of this section.

[*(11)*] **(12)** The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

[*(12)*] **(13)** The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

[*(13)*] **(14)** No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 9. Notwithstanding the term of office specified by section 1 of this 2021 Act, of the members first appointed to the Prescription Drug Affordability Board:

(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.

SECTION 10. There is appropriated to the Department of Consumer and Business Services, for the biennium beginning July 1, 2021, out of the General Fund, the amount of $1,786,192 for the purpose of carrying out the provisions of sections 1 to 7 of this 2021 Act.

Passed by Senate June 24, 2021

.....
Lori L. Brocker, Secretary of Senate

.....
Peter Courtney, President of Senate

Passed by House June 25, 2021

.....
Tina Kotek, Speaker of House

Received by Governor:

.....M.,....., 2021

Approved:

.....M.,....., 2021

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2021

.....
Shemia Fagan, Secretary of State

Oregon
Kate Brown, Governor

Department of Consumer and Business Services
Division of Financial Regulation
350 Winter St. NE, Room 410
P.O. Box 14480
Salem, OR 97309-0405

May 20, 2022

To: Senate Health Care Committee Chair, Deb Patterson
House Health Care Committee Chair, Rachel Prusak

Re: Prescription Drug Affordability Board (PDAB) Deliverable Extension Request

Honorable Senator Patterson and Representative Prusak,

I am writing in follow up to my letter dated April 5, notifying you of anticipated delays in several deliverables required under SB 844 (2021). As you may recall, it took us longer to get positions approved and posted, including my own. That has correspondingly slowed the board recruitment and appointment process and led to the need for the request for deliverable timeline adjustments outlined below.

Generic marketplace report

As required under Section 6 of SB 844, PDAB shall annually conduct a study of the operation of the U.S. market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians. The PDAB shall report to the Legislative Assembly its findings no later than June 1 of each calendar year.

As advised by Oregon Department of Justice, PDAB cannot transact business, including the issuance of reports, until board members are appointed by the governor and confirmed by the senate. Confirmation hearings are scheduled for June 1. Therefore, I am requesting an extension until Dec. 31, 2022 to include this report as a part of our required deliverables under Section 6 of SB 844.

Drug affordability reviews

PDAB is required to report to both the Legislative Assembly and the Health Care Cost Growth Target Program at the Oregon Health Authority no later than December 31 of each calendar year. Requirements under Section 5 of SB 844 include:

- Price trends for the list of prescription drugs provided to the board by the DCBS under section 2(1);
- (2) The prescription drugs that were reviewed under section 2; and
- (3) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state.

Sec 5(1): There will not be any impediments to reporting requirements under Section 5(1) as this information is already collected by our Drug Pricing Transparency program.

Sec 5(2): Because reporting on the affordability reviews in (2) must be conducted based on criteria adopted by the board by administrative rule, the PDAB will not make this deadline. With support from PDAB staff, board members will need to first develop and approve methodologies for evaluating each affordability criteria defined in Section 2(1) including receiving public comment, and then conduct rulemaking activities prior to using the criteria. As a transparent rulemaking process takes between 4-6 months including requirements in HB 2993 (2021), I am asking for an extension on the deliverable date. Given the depth and breadth of analysis and decision making involved, I believe it will take the board the remainder of this calendar year to develop draft criteria for the rulemaking required prior to conducting the affordability reviews. PDAB expects to adopt administrative rules specifying criteria for affordability reviews no later than June 1, 2023.

Given the reality that we are approximately a year away from having rules in place around affordability reviews, PDAB will not complete its review of nine drugs and at least one insulin product that it determines may create affordability challenges until December 31, 2023.

Sec 5(3): Once seated, the PDAB will begin conversations about potential recommendations for legislative changes to make prescription drugs more affordable in this state. No extension is requested.

I am happy to discuss any questions you may have relating to this request and look forward to working with you to advance the goals and objectives of the board.

Sincerely,

Ralph Magrish
Executive Director, Oregon Prescription Drug Affordability Board

CC: Senator James Manning Junior
Representative Wlnsvey Campos
Representative Zach Hudson
Representative Sheri Schouten
Representative Rob Nosse
Tony Lapiz, Office of Governor Kate Brown
Andrew Stolfi, DCBS Director
TK Keen, DCBS-DFR Administrator
Alex Cheng, DCBS – DFR Deputy Administrator
Theresa Van Winkle, DCBS Legislative Director
Sarah Bartelmann, Cost Growth Target Program Manager, OHA

Prescription Drug Affordability Board Policy and Procedures
Policy Number: 01-DRAFT PENDING BOARD APPROVAL

Title: Policies and Procedures
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, 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 reviews[2]; 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>.

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. <Placeholder>.

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.

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 meet in executive session to discuss trade secret information member. 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 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.

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

a. 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.
j. 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 any procurement policies developed by DCBS, 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:
    i. 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. Equity and cultural responsiveness related to the Board's activities; and
    vi. 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.

TEMPORARY FILING
INCLUDING STATEMENT OF NEED & JUSTIFICATION
For internal agency use only.

Department of Consumer & Business Services, Division of Financial Regulation			925
Agency and Division Name			Administrative Rules Chapter Number
Karen Winkel		karen.j.winkel@dcbs.oregon.gov	503-947-7694
Rules Coordinator		Email	Telephone
Karen Winkel	350 Winter Street NE, Salem, OR 97301	karen.j.winkel@dcbs.oregon.gov	503-947-7694
Filing Contact	Address	Email	Telephone

FILING CAPTION

Model Rules for Rulemaking and Public Records Requests

Not more than 15 words.

Agency Approved Date: June 24, 2022

Effective Date: June 24, 2022 through December 21, 2022

RULEMAKING ACTION

ADOPT: OAR 925-100-0001, OAR 925-100-0002, and OAR 925-100-0003

Secure approval of new rule numbers (Adopted or Renumbered) with the Rules Coordinator prior to filing.
List each rule number separately (000-000-0000). Attach clean text for each rule at the end of the filing.

STATUTORY/OTHER AUTHORITY: ORS 646A.693 through 646A.697

STATUTES/OTHER IMPLEMENTED: SB 844 (2021) and 183.325 through 183.410

RULE SUMMARY:

OAR 925-100-0001 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

OAR 925-100-0002 defines requirements for notification of rulemaking by the PDAB.

OAR 925-100-0003 adopts requirements found in Oregon's Public Records Law (ORS 192) into PDAB rules.

STATEMENT OF NEED AND JUSTIFICATION

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 rule 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.

Authorized Signer	Printed name	Date

Draft Procedural Rules for PDAB

OAR 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.

{ED. NOTE: 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 http://arcweb.sos.state.or.us/pages/rules/oars_100/oar_137/137_001.html.}

Statutory authority: ORS 646A.693 through 646A.697
Statutes implemented: ORS 183.325 through 183.410

OAR 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 authority: ORS 646A.693 through 646A.697
Statutes implemented: ORS 183.335 and ORS 84.022

OAR 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.

(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 authority: ORS 646A.693 through 646A.697
Statutes implemented: ORS 192.324 (Formerly ORS 192.440)

Oregon
Kate Brown, Governor

Department of Consumer and Business Services
Division of Financial Regulation
350 Winter St. NE, Room 410
P.O. Box 14480
Salem, OR 97309-0405

Active recruitment for Rural Oregonian Applicants – Prescription Drug Affordability Board
Oregon Prescription Drug Affordability Board overview and potential applicant information

Recruitment: The Oregon Prescription Drug Affordability Board is now accepting applications from rural Oregonians for one vacant board and one alternate board appointment. Applicants must have expertise in health care economics and clinical medicine. Appointees may not be an employee of, a board member of, or a consultant to a manufacturer or a trade association of manufacturers.

Purpose: 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 Oregon from the high costs of prescription drugs.

Composition: The board consists of five members and three alternates appointed by the governor.

Terms: The term of each appointment are defined in statute but will be no less than two years, however members serve at the pleasure of the governor. Appointment is subject to confirmation by the senate.

Application deadline: Interested parties must complete the application process in its entirety **no later than 5 p.m. on Tuesday, July 5, 2022,** for consideration. Applications are submitted through Workday and must include the following:

- Uploaded resume (PDF only)
- Uploaded short personal bio (PDF only)
- Responses to the three General Application Question Responses to Background Questions
- Responses to the subsequent Gender Identity, Personal Information, and Public Records Disclosure tasks that come up directly after you submit your application

Board functions: Study of the entire prescription drug distribution and payment system in Oregon and polices adopted by other states and countries that are designed to lower the list price of prescription drugs including:

- Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to determine the upper payment limit.
- Using a reverse auction marketplace for the purchase of prescription drugs by state and local governments.
- Implementing a bulk purchasing process for state and local governments to purchase prescription drugs.

Based on information provided to the board by the Drug Pricing Transparency (DPT) program, it will identify nine drugs and at least one insulin product that it determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board.

This criteria will include, at a minimum:

- Whether the prescription drug has led to health inequities in communities of color;

- The number of residents in Oregon prescribed the prescription drug;
- The price for the prescription drug sold in Oregon;
- The estimated average monetary price concession, discount, or rebate the manufacturer provides to health insurance plans in Oregon or is expected to provide to health insurance plans in Oregon, expressed as a percentage of the price for the prescription drug under review;
- The estimated total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager registered in Oregon for the prescription drug under review, expressed as a percentage of the prices;
- The estimated price for therapeutic alternatives to the drug that are sold in Oregon;
- The estimated average price concession, discount, or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in Oregon for therapeutic alternatives;
- The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the U.S. Food and Drug Administration and recognized standard medical practice;
- The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in Oregon;
- The relative financial impacts to health, medical, or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;
- The estimated average patient copayment or other cost-sharing for the prescription drug in Oregon;
- Any information a manufacturer chooses to provide;
- Any other factors as determined by the board in rules adopted by the board.

Rulemaking input

- Consultation to DCBS on annual fees paid by manufacturers that sell prescription drugs in Oregon to meet program and board operating costs based on the manufacturer's gross revenue from sales in Oregon.
- Criteria development for identifying drugs that create affordability challenges for the health care system or high out-of-pocket cost for patients.

Reporting requirements: Annual report to the Health Care Cost Growth Target program at the Oregon Health Authority and the legislature which includes:

- Price trends for the list of prescription drugs provided to the board;
- The prescription drugs that were reviewed;
- Recommendations to the legislature on changes necessary to make prescription drugs more affordable in Oregon.

An annual study of the generic drug marketplace in the U.S. for drugs dispensed by pharmacists and drugs administered by physicians including:

- Generic drug prices on a year-to-year basis;
- The degree to which generic drug prices affect insurance premiums;
- Annual changes in health insurance cost-sharing for generic drugs;
- The potential for and history of generic drug shortages;
- The degree to which generic drug prices affect annual spending in the state medical assistance program;
- Any other topic the board considers relevant to the cost of generic drugs.

Areas of review for study and recommendation: The prescription drug distribution and payment system in Oregon and polices adopted by other states and countries that are designed to lower the list price of prescription drugs including but not limited to:

- Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain;
- Using a reverse auction marketplace for the purchase of prescription drugs by state and local governments;
- Implementing a bulk purchasing process for state and local governments to purchase prescription drugs.

Findings will be presented to the legislature with policy recommendations made by the board to lower the list prices of prescription drugs sold in this state and for legislative changes necessary to implement the policies.

Meeting details: The following board actions will be open to the public:

- Deliberation on whether to conduct an affordability review of a prescription drug;
- Any decision or deliberation toward a decision on any matter except discussion of trade secret information, which shall occur in executive session;
- Opportunity for public comment will be afforded and the public can submit written comments on any pending board decisions;
- The board may allow expert testimony at board meetings, including when the board meets in executive session;
- A board member shall recuse themselves from decisions relating to a prescription drug if the member or their immediate family has received a financial benefit deriving from the result or finding of a study, review or determination by or for the board;
- Any real or perceived conflicts of interest shall be declared by the member.

Time commitment: The board will meet at least once every six weeks. Meeting cadence will be determined by a chairperson to be selected by the membership.

Mileage reimbursement: Board members are entitled to compensation and expenses as defined in statute.

For information about applying for board appointment, please contact Ralph Magrish, executive director of the Oregon Prescription Drug Affordability Board at Ralph.M.Magrish@dcbs.oregon.gov or 971-375-7591.

The Oregon Prescription Drug Affordability Board was created by Senate Bill 844 during the 2021 regular session and is viewable here: https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB0844/B-Engrossed

Oregon Prescription Drug Affordability Board

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 17	9:30 – 11:30 a.m.
Meeting 4	Wednesday, September 21	9:30 – 11:30 a.m.
Meeting 5	Wednesday, October 19	9:30 – 11:30 a.m.
Meeting 6	Wednesday, November 16	9:30 – 11:30 a.m.
Meeting 7	Wednesday, December 14	9:30 – 11:30 a.m.

350 Winter Street NE, Salem, OR 97309-0405 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab