Oregon Prescription Drug Affordability Board

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

Agenda

Date: **August 17, 2022** | *Time*: **9:30 a.m.**

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

Board Members: Chair Akil Patterson; Vice Chair Shelley Bailey; Dr. Daniel Hartung; Dr. Richard Bruno; Robert Judge (A); Dr. 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 Director's program update	Ralph Magrish	5 minutes
☐	**PDAB Policies and Procedures:** PDAB Draft Public Comment Policy and Form	Cortnee Whitlock	15 minutes
☐	**Presentation of Outlines for:** Rx Generic Drugs Report Rx Distribution and Payment System Report Price Trends for List of Rx Recommendations from Rx List	Cortnee Whitlock	50 minutes
☐	Announcements	Ralph Magrish	5 minutes
☐	Public comment	Chair Patterson	10 minutes
☐	Adjournment	Chair Patterson	2 minutes

Next Meeting

September 21, 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

Oral 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.

Written Testimony

Email your written testimony to the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov 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

Oregon Prescription Drug Affordability Board Meeting
Wednesday, August 3, 2022
Draft Minutes

Call to Order and Roll Call
Chair Akil Patterson called the meeting to order at 9:38 a.m. and called for the roll.

Board Members and Alternate Members Present: Richard Bruno, Akil Patterson, Robert Judge (alternate), Rebecca Spain (alternate).
Board Members Absent: Shelley Bailey (excused), Dr. Daniel Hartung (excused)

Appointing Alternate Members for Voting
Pursuant to board policies and because members are absent, the chair has the ability to select members to be alternates. In this case, the chair appointed Rebecca Spain and Robert Judge to be alternate voting members for the duration of this meeting.

Approval of the Minutes
Chair Akil Patterson asked if board members had any changes to the July 20, 2022 minutes on Pages 3-6 in the packet posted online: https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf. Hearing none, the chair asked for a motion to approve the minutes. Dr. Bruno moved to approve and Robert Judge provided a second. The chair called roll.

MOTION by Richard Bruno to approve the July 20, 2022 minutes.
Board Voice Vote:
Yea: Richard Bruno, Robert Judge, Rebecca Spain, Akil Patterson.
Nay: None.
Motion passed.

Program Update
Executive Director Ralph Magrish summarized proposed legislation before the U.S. Senate that will give the federal government the ability to negotiate drug prices with drug manufacturers for Medicare Part D, the prescription drug benefit program approved by Congress in 2003 for Medicare beneficiaries. By 2025, there would be a cap for maximum out-of-pocket cost at $2,000. By 2024, it will eliminate a 5 percent copay on expensive drugs for catastrophic coverage for patients with cancer, hepatitis C, multiple sclerosis, or other serious diseases. According to the Kaiser Family Foundation, it would eliminate the 5 percent co-insurance above the Part D catastrophic threshold for more than 14,000 Oregonians, establish a $2,000 out-of-pocket spending cap for Part D for more than 20,000 Oregonians, expand income eligibility for Part D subsidies for 5,300 Oregonians, and eliminate cost sharing for adult vaccines covered under Medicare Part D for nearly 70,000 Oregonians. Beginning in 2023, drug companies would be required to pay rebates if drug prices rise faster than inflation. The first negotiated prices would take effect on 10 drugs in 2026, 15 additional drugs in 2027, 15 more in 2028, and 20 more in 2029. The bill is expected to equal a net revenue for the federal government of $288 billion over 10 years. Manufacturers have suggested this will limit industry's will and ability to pursue new innovations. Congressional Budget Office models show the impact is likely to be a modest reduction of 15 drugs coming to market out of an expected 1,300 over 30 years. Negotiated prices will only apply to a narrow category of expensive drugs with no generic competition. Negotiations on new drugs will not be permitted until 9 to 13 years after launching. Drug companies would face financial penalties if they raise

prices faster than the rate of inflation. Insulin would not be covered under the negotiation provision because it has generic competition.

Mr. Magrish also mentioned the Senate Parliamentarian was requested to add back in the bill the $35 cap on copays for consumer purchases on insulin. Medicare pricing is only one piece of a much larger bill that would go through the reconciliation process if passed by the Senate. He hopes board members will watch the progressing legislation as the board pursues its mission of protecting Oregonians from the high cost of prescription drugs.

PDAB Policies and Procedures

PDAB Conflict of Interest Policy: Cortnee Whitlock, policy analyst, reviewed the policy and form on Pages 7-11 of the agenda packet posted here: https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf. She reviewed the policy's supporting Oregon Revised Statutes. Board members will complete and submit the form by email to the PDAB office. Executive Director Magrish said the board received public comment about this policy and the individual has signed up to speak today. Mr. Judge moved to approve the conflict of interest policy and Member Dr. Richard Bruno provided a second. The chair asked for discussion. Mr. Judge asked how best to determine a conflict of interest since he works in an insurance industry covering prescription drugs. His company sees a financial benefit and he gets involved with decisions about drugs on a daily basis. He asked if there is a financial threshold for personal benefit related to a recusal statement. Joanna Tucker Davis, board counsel, said the Oregon Government Ethics Commission has resources and board members are welcome to call them to talk about any potential conflicts. Chair Patterson encouraged board members to seek guidance from the ethics commission for each prescription drug the board may be covering. The chair asked for the roll call.

MOTION by Richard Bruno to approve the PDAB conflict of interest policy and form.
Board Roll Call Vote:
Yea: Richard Bruno (indicated by thumbs up due to audio difficulty), Rebecca Spain, Robert Judge, Akil Patterson.
Nay: None.
Motion passed.

PDAB Draft Public Comment Policy and Form: Cortnee Whitlock, policy analyst, presented the draft public comment policy and form on Pages 13-14 posted online here: https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf. Chair Patterson said there was a public comment letter submitted about this policy. He asked for a motion so the board could begin a dicussion. Alternate Member Robert Judge moved and Member Dr. Rebecca Spain provided a second. Chair Patterson said he believes there should be changes to the policy form with more inclusive language around affiliation, such as health care industries, supply chain, patient advocacy, interested stakeholder, or everyday citizen. The language could be strengthened so the board is not pointing out anyone directly but understanding who the individual is and what their connection is. While the policy asks for 72 hours for the board to review comments, it does not preclude anyone from signing up 24 hours before to give oral statements and at the same time, submitting written statements, which would be reviewed by the board at the following meeting, he said. The board is giving the community enough time to register and let their voice be heard while making sure the board has adequate time to review, he said. Alternate Member Robert Judge agreed with the language changes, noting the board is trying to get everyone's input. The chair asked for a motion to accept the policy with the amendments. Mr. Judge said he would like to see the draft as amended before voting. The chair said the board will table the policy and staff will bring back a draft for board to review on August 17. The chair said a roll call vote must be taken because of the motion and second. He called for the vote.

MOTION by Robert Judge to approve the PDAB Public Comment Policy and Form.
Board Roll Call Vote
Yea: None.
Nay: Richard Bruno, Rebecca Spain, Robert Judge, Akil Patterson.
Motion failed.

Presentation of Proposed Work Plan
Cortnee Whitlock, policy analyst, reviewed the proposed work plan presented to the board at the July 20 meeting, found on Pages 21-22 of the agenda packet posted here: https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf. She asked board members for topic ideas as she develops outlines and structures for these reports. Dr. Rebecca Spain asked if the board would review a different drug list than any drugs identified at the federal level as a result of the proposed legislation. Executive Director Magrish said the Drug Price Transparency program housed at DCBS will provide the board a list of drugs on a quarterly basis, based on staff analytics and reporting from manufacturers and carriers, and an insulin product as well. Alternate Member Robert Judge asked if the generic drug report goal is to identify prices at the point of sale in retail pharmacy in the form of a co payment, or what payers or pharmacies pay for those drugs. When looking at the supply chain of generic drugs from manufacturers on out, he asked if the goal is to also explore wholesalers or PBMs or other participant roles in the supply chain. Member Dr. Richard Bruno said as a primary care physician at a federally-qualified health center with a 340B contract pharmacy, often times generic medications he prescribes for patients are non-formulary, but still require copay. He recommends looking at non-opioid pain therapies in this report. He said this is a good section of generic medications to study because prices are still very high for patients who would benefit from them. Alternate Member Robert Judge said, to clarify his original request, the report needs to look at the role of middle men in supply chains as it relates to generic drug prices. Chair Patterson recommends the report address the following questions: Where do added costs come from, the PBM's ability to negotiate, a hospital's increased cost, inflation? What is the impact of marketing budgets on the overall supply chain and how do consumers find out about medications? What is the direct cost of research in these mechanisms? Consider looking at systems that have addressed brand manufacturer pay-for-delay tactics, where brand manufacturers reach agreements with generic companies to not manufacture generic equivalents. What are the impacts on generic prices between 340B clients and other non-covered health care entities?

Cortnee Whitlock thanked board members for their knowledgeable feedback and moved to distribution of payment systems report, a one-time report due this year, shown on Page 22 of the proposed work plan posted online here: https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf. Though Oregon doesn't have upper payment limits, she said the board needs to study other states that have adopted it to see what impacts it has on the system.

Member Robert Judge recommended exploring data resources from The National Academy for State Health Policy's Drug Pricing Center. He also asked staff to look at what other states are doing, including Utah's efforts to address prescription drug costs. Executive Director Magrish said staff will be watching those states implementing upper payment limits or those doing bulk purchasing. Member Dr. Richard Bruno asked about inviting PDAB staff from other states to speak to the board. Mr. Magrish said he participated in a multi-state panel and would be glad to invite them to Oregon when time permits. He also said staff looks forward to receiving technical assistance from the National Academy of State Health Policy as a grantee of theirs in the coming weeks.

Chair Patterson said he would like to see PDAB work with minority health policy folks to give the board an idea how this impacts different diversity groups, Latinx, non-recognized indigenous communities, those who are at

great risk for falling into medical debt. It is important to make sure board recommendations to the legislature have an equity focus built into them. The board must ensure it is uplifting its commitment to equity, whether it is geographical equity, equity of thought, financial equity, and racial and gender equity as well. Alternate Member Robert Judge additionally recommended reaching out to states that have done reverse auctions to see their experiences, such as New Jersey, Minnesota, and he will provide staff with a resource.
Cortnee Whitlock moved to the next report under Section 5, where the board reviews nine drugs. As the board starts preparing for that work, staff will provide information from the Drug Pricing Transparency program on price trends for identified drugs. Executive Director Magrish said the Drug Pricing Transparency Program is analyzing data and anticipates having a draft report by Thanksgiving. Mr. Judge said that report will be helpful as the board makes recommendations. Member Dr. Rebecca Spain said it would be helpful to know the number of generics that exist for each of these drugs, an important factor in bringing down the list price. As generic availability for brand products varies, including biosimilar products, this information will help the board in making recommendations, she said. Chair Patterson called for a motion to approve the-2023 roadmap in the proposed work plan. Dr. Richard Bruno moved and Dr. Rebecca Spain seconded.

MOTION by Richard Bruno to approve the PDAB 2023 road map in the proposed work plan.
Board Roll Call Vote:
Yea: Richard Bruno, Rebecca Spain, Robert Judge, Akil Patterson.
Nay: None.
Motion passed.

Announcements
Chair Patterson said the next board meeting will be August 17 at 9:30am. Executive Director Magrish said they submitted the names of two rural applicants to the governor's office for the vacant board positions and anticipate those individuals being notified in the next several weeks, with Senate confirmations in September. Staff received a strong pool of applicants for the two PDAB data analytics staff positions and will be reviewing and scheduling interviews soon. The August 17 draft agenda is posted to the website and staff will send an amended version to address public comment form revisions. Staff will present outlines for report deliverables for the legislature and the cost growth target team at the Oregon Health Authority. The PDAB and OHA teams have begun to work together to identify opportunities for collaboration and shared analysis given the alignment between the two program mandates.

Public Comment
The Chair said the board will move into the public comment portion of the agenda. He would like to make sure the community is aware the board is here to listen to stakeholders and the community. The board received two advance written comments and one request to provide oral testimony. The chair called on Asher Lisec of PhRMA. Asher Lisec thanked the chair and board members for allowing her to substitute in for Dharia McGrew, who was out sick. She summarized the letter PhRMA submitted about the draft conflict of interest policy and public comment policy and form. She thanked the board for the changes they suggested in today's meeting and looks forward to reviewing the draft before the next meeting. She said adding additional stakeholders is a step in the right direction. For the conflict of interest policy and form, she asked the board to consider third party contractors along with individual board members.

Adjournment
There being no further business before the board, the chair asked for a motion to adjourn the meeting at 9:53 a.m. Dr. Richard Bruno moved to adjourn, and Mr. Robert Judge provided a second.

MOTION by Richard Bruno to adjourn the meeting.

Board Voice Vote
Yea: Akil Patterson, Richard Bruno, Dr. Rebecca Spain, Robert Judge.
Nay: None.
Motion passed.

Prescription Drug Affordability Board
Policy Number: 04-DRAFT PENDING BOARD APPROVAL

Title: Public Comment
Date Issued:
Dates Reviewed:
Date Adopted:

1. Purpose

The opportunity for public comment will be provided at each Prescription Drug Affordability Board meeting.

2. Policy Statement

The Prescription Drug Affordability Board welcomes public comment during Board meetings. Board members generally will not respond to public comments during a meeting. Public comments may be submitted in writing or given orally during the designated time by completing the PDAB Public Comment form provided on the PDAB website.

The form's purpose is 1) to sign up to provide comments, 2) to assist board staff with time allotments for meeting agenda items, and 3) to disclose interest or affiliation.

Having an interest or affiliation does not prevent written or oral comments from being provided, but is included on the form for transparency purposes. Prior to the public comment, the Board Chair will state whether the form has been completed and any interest or affiliation of the speaker.

Written Comments
The Board will receive written public comments and the PDAB Public Comment form through the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov. The form includes fields for the name, organization and topic item for persons submitting written testimony. Written public comments submitted less than 72 hours before a board meeting will be considered at the following meeting.

Oral Comments
Persons interested in providing oral public comments may sign up by completing the PDAB Public Comment form and emailing it to pdab@dcbs.oregon.gov no later than 24 hours before the meeting. Anyone who did not sign up before the deadline will have the opportunity to speak at the next meeting after completing the PDAB Public Comment form. Speakers will be called to speak in the order in which they sign up. The Board Chair will ask the speakers to introduce themselves with their name and affiliation if any.

The amount of time allocated for oral public comment will be determined by the Board Chair in consultation with Board staff. When there are multiple requests to comment on a particular topic, the Board Chair may limit or expand the total time for comment or reduce the time allotted for each speaker. Any changes will be announced at the beginning of the public comment agenda item.

Oregon Prescription Drug Affordability Board

PDAB Public Comment Form

The purpose of this form is to sign up to provide public comment orally or in writing and to disclose an interest or affiliation. Having an interest or affiliation does not prevent written or oral comments from being provided, but is included on the form for transparency purposes. Failure to complete this form does not disqualify a speaker from commenting. However, persons who opt not to complete the form should be advised it will be publicly stated prior to their oral testimony.

Instructions: Please read all information. Questions marked with an asterisk (*) are required fields. Please email the form for public comment to pdab@dcbs.oregon.gov no later than 24 hours before the PDAB meeting. If providing written comments, please fill out this form and email it to pdab@dcbs.oregon.gov no later than 72 hours before PDAB meeting. If you need assistance completing or emailing this form, please call the PDAB office at 971-374-3724 or send an email to pdab@dcbs.oregon.gov.

COMMENTER INFORMATION

*Name:	*Date:
*Organization, if applicable:	*Topic/Drug:
Email Address:	Phone Number:

Are written comments submitted with this form? **Yes** ☐ **No** ☐

*Are you an employee, or volunteer of, or a lobbyist for, a pharmaceutical manufacturer, trade association, the health care industry, prescription drug supply chain, ~~patient~~ advocacy group, or other? **Yes** ☐ **No** ☐
*If **yes**, please identify the entity / organization:

*~~Are you an advocate, advocacy organization, or foundation that~~ Do you receive funding from a pharmaceutical manufacturer, trade association, the health care industry, prescription drug supply chain, ~~patient~~ advocacy group, or other? **Yes** ☐ **No** ☐
*Have you been asked to provide comments? **Yes** ☐ **No** ☐
*If **yes**, please identify the entity / organization:

*If you are a researcher or clinician, do you currently receive grants or other funding from any pharmaceutical entity, advocacy group, or other? **Yes** ☐ **No** ☐
*If **yes**, please identify the entity:

*Are you involved in or have you been involved in any research funded directly or indirectly from any pharmaceutical entity, advocacy group, or other? **Yes** ☐ **No** ☐
*If **yes**, please describe the type of compensation:

Is there any other information about yourself that the Board should know ~~(e.g. direct ownership and control of investments in a pharmaceutical manufacturer, membership health care or patient advocacy board)~~?

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Proposed Outlines
for
2022 Reports

Rx Generic Drugs Report (SB 844, Section 6 (2))

Annually by June 1, the Board conducts a study of the operation of the US market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians, including:

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

For 2022 reporting, Section 6 (2) will be submitted to the Legislative Assembly by 12/31/2022.

Board Feedback

- Purpose of Generic Drug Report
- Who are involved and their roles?
- Where does the pricing for generic drugs come from?
- Looking at marketing budget, does it impact the supply chain?
- What is the cost of research for generic drugs?
- Are generic manufactures taking financial incentives from name brands to not bring product to market due to competition?
- How generic drugs are reflected on formulary and the impact they have on 340B pharmacies
- What are other non-opioid therapies?
- What are the cost savings with generic drugs?

Outline Sections for Generic Drug Report

Background of Generic Drugs

- What are generic drugs?
- What are their purpose?

Generic Drug Pricing, Cost and Utilization

- How are generic drug prices set?
- Research cost associated with generic drugs?
- Cost savings with generic drugs
- Utilization of generic drugs

4

Outline Sections for Generic Drug Report (Cont.)

Study of Generics

- The prices of generic drugs 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 drug

Impacts on Generic Drug Market

- Players involved in generic drug marketplace and their roles
- Anticompetitive practices impacting generic drug availability
- Marketing impacts on the supply chain and cost

Recommendations

Rx Distribution and Payment System Report (SB 844, Section 7)

(1) 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 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;

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

(2) No later than December 31, 2022, PDAB shall report to the interim committees of the Legislative Assembly:

(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.

Board Feedback

How would upper payment limits be monitored?

Where is Oregon with bulk purchasing options?

How does the system impact communities of color and underserved populations?

Does the system impact underserved populations that may fall into medical debt?

What have other states done that have done reverse auction? What were the main take-aways?

Outline Sections Rx Distribution and Payment System Report

Prescription Drug (Rx) Distribution and Payment System in Oregon

- Market Based vs. Regulatory Strategies

Polices in Other States and Countries Designed to Lower the List Price of Rx

- Upper Payment Limits
- The methodology used to determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain

Reverse Auction Marketplace for the Purchase of Rx by State and Local Governments

Bulk Purchasing Process for Oregon and Local Governments to Purchase Rx.

Impact on Underserved and Disadvantaged Populations

Recommendations

SB 844, Section 5 (1) & (3)

By December 31 of each year, the PDAB shall report to the Health Care Cost Growth Target program and to the interim committees of the Legislative Assembly.

For 2022, Section 5 (1) and (3) will be reported by 12/31/2022. Section 5 (2), for the prescription drugs that were reviewed under Section 2 of SB 844, will be reported by 06/01/2023.

(1) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services

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

9

Board Feedback

List of generic drugs that are associated with brand names by class

List of top drugs by cost and utilization

What are the price trends?

Outline Section

Background of SB 844

- Program overview

Top drugs by cost and utilization

Generic drugs that are associated with brand names by class

Recommendations

Section 5 vs Section 7 Recommendations

Section 5 (3)

PDAB to provide recommendations if any, for legislative changes necessary to make prescription drug products more affordable in this state.

Section 7 (2)

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

Next Steps

PDAB board members should send any report suggestions or references to pdab@dcbs.oregon.gov

Next Board Meeting on Sept. 21 will be the presentation of report first drafts