Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Meeting
Wednesday, July 19, 2023
Minutes
Approved by the board on August 23, 2023

Vice Chair Shelley Bailey called the meeting to order at 9:34 am and asked for the roll call.

Board members present: Vice Chair Shelley Bailey, Dr. Amy Burns, Dr. Richard Bruno, Dr. Daniel Hartung, Robert Judge (alternate), Dr. Rebecca Spain (alternate), John Murray (alternate)
Board members absent: Chair Akil Patterson, excused
Vice Chair Bailey appointed Robert Judge to vote in today's meeting due to a board member absence.

Approval of the minutes: Vice Chair Shelley Bailey asked if board members had any changes to the June 21, 2023, minutes on Pages 3-5 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230719-PDAB-document-package.pdf and there were none. **Dr. Amy Burns** moved to approve the minutes and **Robert Judge** provided a second.

MOTION by Amy Burns to approve the June 21, 2023 minutes.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Robert Judge, Vice Chair Shelley Bailey
Nay: None.
Motion passed.

Board Member John Murray declared a potential conflict of interest due to his ownership of Murray Drugs Incorporated, three independent pharmacies in Eastern Oregon with pharmacy services contracts with PBMs and insurance companies in Oregon.

Program update: Executive Director Ralph Magrish said staff signed a contract with the Program on Regulation, Therapeutics, and Law (PORTAL) at the Harvard Medical School and Brigham & Woman's Hospital to provide technical assistance. The effective date of the contract is today. Ralph and Chair Patterson sent a letter to legislative leadership on July 13th requesting an extension to complete drug affordability reviews with recommendations to the Legislature by June 30, 2024. Ralph noted his desire to have all work completed by the end of March 2024. He reviewed the updated timeline on Page 8 of the agenda packet.

Sarah Bartelmann, **Oregon Health Authority Cost Growth Target Program Manager,** said the PDAB, the Drup Price Transparency (DPT) program and Cost Growth Target program share the goal of targeting health care costs and market oversight. She shared data from recent reports. The Oregon goal is for health care spending is to grow no more than 3.4 percent per year. The program annually looks at key drivers of healthcare costs, including growth in Medicaid and commercial plans, price, utilization, hospital services, and pharmacy costs. They report the information on their website and hold public hearings. Last year the Cost-Growth Target Committee endorsed the Prescription Drug Affordability Board's recommendations and strategies. She reviewed the cost growth drivers between 2013 and 2019 based on claims, data, administrative claims, data from Oregon's, all-payer, all claims database, shown on Pages 9-32 in the agenda packet. The report identified pharmacy costs as a main driver. Pharmacy costs grew almost 200 percent in the Medicare market and almost 80 percent in the commercial market. The claims data does not include pharmacy rebates. **Amy Burns** asked if this considers the state rebates for Medicaid and Sarah Bartelmann said yes, one reason why Medicaid claims are so much higher. Sarah Bartelmann said the report showed growth every year, even with rebates. Pharmacy costs increased 7.6

percent, well above the 3.4 percent target and the 5 percent national trend. Since 2018, per person spending has increased about 11.5 percent. The report showed pharmaceutical spending totaled more than $1 billion by 2021. **Daniel Hartung** asked, on Slide 16, how much of the increase was due to growth in enrollment versus changes in prescription spending. Sarah Bartelmann said most of it was due to utilization and enrollment, particularly for Medicaid. **Daniel Hartung** asked about the non-claim circle on Slide 16. Sarah Bartelmann said it captures money a health plan pays to a provider outside of a claim, including value-based payments for performance and quality incentives.

Robert Judge noted Slide 20 shows rebate contribution reducing gross spending by about 20 percent for the Medicare Advantage and commercial markets. He asked what rebate portion payers receive and Sarah Bartelmann said it is unknown. **Robert Judge** asked how this rebate offset data compares with other states and Sarah Bartelmann said Colorado and Massachusetts have seen similar trends. **Shelley Bailey** asked if the 2013-2019 reports reflect market anomalies such as Covid and the new blockbuster drugs to treat Hepatitis C and Sarah Bartelmann said yes. They hope to have a website dashboard for looking up specific data to help sort out big markers like blockbuster drugs. **Shelley Bailey** asked about data lag times and Sarah Bartelmann said the next data submission is due in September. The program will collect data for 2022 in September and publish it in early 2024. **Amy Burns** said rebates tend to suppress the market because of preferring one medication over another and asked if the Cost Growth program would be watching for this. Sarah Bartelmann said yes and agreed that protecting market share is a motivation to offering deep rebates and trying to prevent disruption. She invited the board to attend the public hearing on September 14.

Senate Bill 192: **Ralph Magrish, executive director,** discussed the main achievements of Senate Bill 192 as shown on Pages 33-40 of the agenda packet. This bill contains the board's recommendations. The bill achieves:

- New reporting requirement for pharmacy benefit managers (PBMs) in Oregon.
- The board will develop an implementation plan for upper payment limits, including a methodology, an analysis of resources needed, how it would be enforced, and potential savings to the state.
- Allows a combined fee structure for PDAB and the Drug Price Transparency program.
- Makes alternates full board members.

Health insurer data template review: **Cortnee Whitlock**, policy analyst, reviewed the updated timeline on Page 42 of the agenda packet. **Amanda Claycomb**, research analyst, reviewed the data call template on Pages 50-60 that will be sent out by Department of Consumer and Business Services (DCBS). **Vice Chair Shelley Bailey** asked about adding a basis of cost determination field to request from payers NDC code and 340B information. **Robert Judge** said it is an elective field for pharmacies and not required to pay a claim. It would provide some insight but not for decision making. **Shelley Bailey** said she thinks it is an important data point to be able to observe and would provide helpful information. **Ralph Magrish** said they would consult with the Oregon Health Authority.

Dr. Rebecca Spain said she appreciates the columns about step therapy and prior authorization requirements for access on Page 59. She wonders if data is available to add another column for the lag time or delay between prescription submission and actual delivery of drugs. She said it would be nice to know the impediment to access. **Amy Burns** said it would be challenging to determine whether it is a true correlation of prior authorization and dispense date. The board could look at it, but not be able to draw conclusions from it. **Robert Judge** agreed. He also asked when the board would discuss therapeutic alternatives, which are very different from therapeutic equivalents. **Ralph Magrish** said staff will discuss with PORTAL when they meet soon.

PDAB hearing update: **Cortnee Whitlock** provided a summary of the comments from the rulemaking hearing held on June 22, including feedback from BIO and PhRMA. She reviewed Pages 43-46 of the agenda packet.

Affordability review rule updates: **Cortnee Whitlock** reviewed the proposed changes in the affordability review rule on Pages 47-49. **Shelley Bailey** asked, since pharmacies do not have to submit a diagnosis code for transactions, how will the board determine when a drug is being used to treat a rare disease and when it is not. **Ralph Magrish** said staff doesn't know specifically how to make that determination but they want to keep it as an option for the board's affordability reviews after consulting with the Department of Justice. **Robert Judge** confirmed medical claims include a diagnosis but not pharmacy claims. **Cortnee Whitlock** reviewed the wording for therapeutic alternatives and asked the board for feedback about BIO's proposed definition provided during the rulemaking hearing. **Robert Judge** asked if there would be a reason not to use the U.S. Department of Human Resources (DHS) definition. **Cortnee Whitlock** said the proposed is based on the DHS definition but not identical. **Rebecca Spain** said she prefers the proposed definition because it is more flexible and at the same time more rigorous by showing how something will be defined equivalent through peer-reviewed studies. **Daniel Hartung** said he is not comfortable with the wording about FDA approved for the same indication because many off-label drugs without FDA approval are used consistent with standard medical practice. **Amy Burns** suggested adding a clause about compendia recognized for off-label use for the same indication, which is line with Medicare. **Dr. Richard Bruno** said he agreed about adding a phrase for off label use and suggested moving the last line up.. Board members proposed amending this section of the rule andand agreed it was ready for approval with the following amendments:

- A prescription drug that is designated by the United States Food and Drug Administration (FDA), under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to an affordability review. *Added to section (1)(m)*
- In addition to the criteria in subparagraph (1)(m): A prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications. *Added to section (2)(n)*
- Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically-equivalent dose. *Revised definition for (2)(c).*

Approval of the affordability review rule: Vice Chair Shelley Bailey asked for a motion to approve the affordability review rule on Pages 74-78 in the agenda packet with the above amendments. **Dr. Amy Burns** moved to approve the rule and **Richard Bruno** provided a second.

MOTION by Amy Burns to approve the affordability review rule with amendments.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Robert Judge, Vice Chair Shelley Bailey
Nay: None.
Motion passed.

Staff member touch base meetings: **Cortnee Whitlock** reviewed Pages 79-83 of the agenda packet. There are 46 data points to consider for the affordability review process. Staff and board members will meet one on one for consultation about the data points and bring discussion items back to the public board meetings.

Public comment: The vice chair allocated three minutes for public comment. Dharia McGrew, state policy director, PhRMA, provided testimony to the board.

Adjournment: The meeting was adjourned at 11:23 a.m. by **Vice Chair Shelley Bailey**.