Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, February 15, 2023
Minutes
Approved by the board on March 15, 2023

Chair Akil Patterson called the meeting to order at 9:33 am and asked for the roll call.

Board Members present: Chair Akil Patterson, Vice Chair Shelley Bailey, Dr. Richard Bruno, Dr. Amy Burns, Dr. Daniel Hartung, John Murray (alternate), Robert Judge (alternate)
Board members absent: Rebecca Spain (alternate)

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the Jan. 18, 2023, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230215-PDAB-document-package.pdf and there were none. **Vice Chair Shelley Bailey** moved to approve the minutes and **Richard Bruno** provided a second.

MOTION by Shelley Bailey to approve the Jan. 18, 2023 minutes.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson
Nay: None.
Motion passed.

Ben Rome, MD, MPH, and Adam Raymakers, PhD, PORTAL BWH Harvard gave a presentation from Pages 7-40 in the agenda document. They walked through what the PDAB affordability review process would look like based on Senate Bill 844, PDAB's founding legislation. It begins with the board receiving a list of expensive drugs every quarter. PORTAL reorganized and consolidated the criteria from the statute into four buckets shown on Page 16. Drug prices (WAC) increased by 5.9 percent per year and net spending per patient and payers increased by 4.8 percent. To determine how to measure a drug's benefit compared to therapeutic alternatives, the board could consider asking how well does the drug works relative to other drugs treating similar conditions, what are the side effects, impact of the drug on health care resources, and utilization. A medicine for heart failure that reduces hospitalizations down the road can cost less money in the long run and improve a patient's well-being. Other questions: how easy is the drug to administer? An injectable might be less preferred than a drug that is orally administered at a patient's home. Drug trial information can be a good source of data. He recommended consulting with experts, clinicians and patients, because there may be factors about a drug therapeutic benefit over alternatives not captured in the data. If a drug offers some benefit over what is already out there, the board can ask how much are they willing to pay for that incremental benefit. Many drugs are used to treat many different conditions. When the board does these assessments, they should do them separately for each indication. When the board thinks about measuring how well a drug works, they could consider whether it makes patients live longer or live healthier, increasing longevity or improving quality of life, including reducing pain, improving mobility or cognitive function.

Adam Raymakers talked about cost-effectiveness analysis and how it can be used in decision making and in price negotiations. By Oregon statute, the board may not use quality of life years (QALYs), formulas that consider a patient's age or severity of illness or disability when determining a drug's cost effectiveness. The

board must weigh the value of the quality of life equally for all patients. He discussed how QALYs are used in the industry. He showed other ways to capture benefit, include life years gained, equal value life year gained, and natural units shown on Page 31. He explained efficiency frontiers on Pages 32-33, which compares price and effectiveness of a new drug relative to its therapeutic alternatives.

Ben Rome said high costs may limit access to medications as shown on Pages 36-39, which shows the relationship of copayments and health inequities. He cited a study that showed how eliminating medication copayments reduces disparities in cardiovascular care.

Questions from the board: Robert Judge thanked Portal for the informative presentation. He said getting data seems to be the easy side but the hard part is the qualitative assessment. Affordability is looking at the costs and funneling it through these criteria to determine qualitative value. If SB 844 legislation precludes the board from using quality of life factors, are there other options? Does the board need to focus its attention on competitive assessments versus qualitative assessments? **Ben Rom**e said there are many ways to measure benefits of the product and the board does not have to measure it using QALYs. The board could measure it in any unit of measure, such as dollars per life year, where there is more literature.

Ralph Magrish asked Portal to speak to some of the potential challenges of drugs for treatment of rare diseases and other indications. When the board is looking at a funnel of several hundred drugs, if each of those could be approved for three to ten other indications, how should the board compartmentalize that information and tie to data and claims in diagnosis? **Ben Rome** said the operational challenge is figuring out what is the purpose of excluding drugs that treat rare diseases. Another operational challenge is understanding if the drug is better than therapeutic alternatives. It is important to study a drug for a particular treatment. The board will have to analyze comparative costs and benefits at the indication level. The board may choose to only focus on FDA-approved indications. Many drugs will have more than one indication. It also poses a quantity of data challenge to sift through all of that and it is not easy to pull data, especially for pharmacy drugs. When a primary care doctor sends a prescription, there is no obligation to tell the pharmacy why the medicine is being prescribed. The board may not always have the data to know why medicine is used.

Robert Judge said another factor to consider is what happens when a drug is being investigated for a preferred drug list. The board could learn how Oregon establishes its criteria or evaluates drugs as they go through their preferred drug list (PDL) analysis.

Ben Rome said that is a good point and the board would not have to start from scratch There are a lot of folks doing this type of work for new products. When a new drug comes on the market, there is less information about it. But the board will also look at top-selling products that might have been on the market for ten or more years, with a wealth of information about the drugs benefits. There will also be more therapeutic alternatives which makes things more complicated.

Vice Chair Shelley Bailey asked about ways to link the cost of some of these high-cost medications with the offset to the medical community, whether it is a hospitalization or other offsets. She asked about other data sources to track this journey of a high-cost drug versus the medical offset, in addition to the All Payers All Claims database.

Ben Rome said these studies are done using a combination of real data and modeling. The clinical trials for new drugs are short, lasting six months or a year. The board might want to think about the costs and offsets over a five-year period, or even over a lifetime. Health economists model out what those are going to be. There are data sources of such models done both by industry and academics.

Dr. Daniel Hartung: In terms of gathering information about value and cost-effectiveness, are there high-performing institutions or organizations the board should look to first for best sources of data?

Adam Raymakers recommended Canadian Institute for Health Information (CIHI), an agency in Canada with publicly-available reports on the assessment of the clinical effectiveness and the relative comparators. National Institute for Health and Care Excellence (NICE) in the UK does a review of clinical and economic evidence. **Ben Rome** said ICER in the U.S. does this most comprehensively here. Even if ignoring their methods for cost effectiveness, they often do these meta analyses and consolidate a large amount of clinical data down to a drug rating system. The board should find out how the data collection is funded and who is doing the research.

Program update: Executive Director Ralph Magrish said Dr. Dan Hartung has pioneered research on copays as it relates to the Medicaid population. His work resulted in removal of copays as a barrier to medications. He wanted to recognize that work and how fortunate it is to have him on the PDAB board. There will be a hearing at the Capitol from 1 to 2:30 pm Monday. on legislative action to lower prescription drug prices. Presenters will include National Academy of State Health Policy (NASHP), Oregon Health Authority, Andy York of Maryland PDAB and a state legislator from Colorado. Ralph will speak on the board recommendations and John Mullen from the Coalition of Affordable Prescription Drugs will speak on next steps. Senate Bill 404-1-1 will be heard in committee next week. The amendment includes board recommendations and a proposal to expand the board to eight full voting members. This came from consultation with the board attorney who has never seen a state board model with alternate members. Ralph Magrish said board members appointed as alternates expend the same amount of time, energy, and effort in their volunteer roles and should have the right to vote. He reminded board members, when testifying before the legislature, they cannot advocate on behalf of the board without prior consent of the board and the governor's office. Board members should not leverage their position on the board to give additional weight to their testimony. PDAB staff has begun posting public comments on the website. Board members will soon receive iPads with keyboards and state email addresses to use for board business. Board staff will meet with guests from Health Care for All Maryland next week, after an invitation extended by the board. They were instrumental in the passage of Maryland's PDAB legislation and will be speaking on community listening sessions. John Mullen, the chair of the Working Coalition, will attend.

Board discussion on rulemaking – fee structure and affordability reviews: Cortnee Whitlock presented concepts for the draft fee structure, for collecting gross revenues from manufacturers, shown on Pages 32-42 of the agenda packet. She also discussed the draft affordability review criteria on Pages 37-38.

Robert Judge asked if the report should include the trend of branded generics, which are relabeled branded products after the patent has expired and sold at higher prices.

Dr. Daniel Hartung agreed it would be helpful to include in the report authorized generics, where branded companies contract to produce the same drug by a generic firm essentially to out compete other generics. **Cortnee Whitlock** said yes and she would reach out to board members for additional input for the report.

Vice Chair Shelley Bailey asked if one of the board's data sources to measure inflation and pricing in Oregon will be the Myers and Stauffer reports on average actual acquisition costs. Myers and Stauffer is the contractor hired by the state to survey pharmacies and publish results, which are publicly available. It would be a helpful piece of real-time pricing to show what is going on in the inflation market, she said. **Ralph Magrish** said staff can talk to colleagues at the Oregon Health Authority and thanked her for the recommendation.

Robert Judge asked where will the board capture therapeutic classes? **Ralph Magrish** said the team has discussed whether there is a gold standard or recognition of a therapeutic class definition. Staff will come back

to the board with this topic. **Robert Judge** asked if the affordability review includes prescriptions dispensed under both outpatient pharmacy as well as hospital inpatient. **Ralph Magrish** said the board will consider both drugs distributed through retail pharmacy as well as physician-administered drugs. Staff will bring prescription drug lists to the board in March for the first quarterly review as part of the board mandate to look at drugs that create affordability challenges for both the health care system and high, out-of-pocket costs for patients.

Chair Akil Patterson asked about including patent expiration dates as part of the criteria. **Amy Burns** said FDA approval and patent expiration date are unclear sometimes. There are multiple approvals depending on indications. A manufacturer can come back with additional requests for FDA approvals. Some drugs might be applicable for review but have multiple indications, including orphan drug indications. It would be helpful to have clear and relevant language. **Chair Akil Patterson** asked the board if they are better off keeping this language or striking it? **Dr. Richard Bruno** said it would be helpful to keep this information, including U.S. drug patents, expiration dates, multiple approval dates for multiple indications, to give an overall context of the drug and its place in the lexicon. **Robert Judge** said it makes the project more complex for the board, but something the board has to live with. As discussed earlier, when pharmacies are filling and dispensing medication, they might not know what the drug is being used for. **Amy Burns** said FDA approval records, number of approvals, and timelines for additional approvals is all publicly available on the FDA drug website. The board could change the wording to "dates of FDA approval." **Dr. Daniel Hartung** said it would be helpful to delineate indications the drug is approved for and when those were approved. He agreed with Amy Burns that the information is easy to gather for indication approval day, expedited status, orphan status. **Chair Akil Patterson** asked staff to adjust the language and bring back to the board. **Dr. Daniel Hartung** asked to change the language to therapeutic alternatives because therapeutic equivalence has a very specific definition. He asked what is manufacturing net cost and does that data come from manufacturers. **Ralph Magrish** said manufacturers could submit the information to the Drug Price Transparency program and it would be part of the reports provided the board. **Cortnee Whitlock** asked the board to look through the document and provide feedback by email to staff.

Announcements: Chair Akil Patterson said the next board meeting will be on March 15, 2023, 9:30am. Ralph Magrish said staff is hoping to hire a contractor to provide both clinical and technical assistance and will update the board in March.

Vice Chair Shelley Bailey asked to add to the 2023 list of board speakers someone from Pharmacy Benefit Managers Association (PBMA) and groups that work with PBMA. **Ralph Magrish** and **Chair Patterson** said the board priority is first inviting Oregon-based groups most impacted by these policies and regulations.

Public comment: The chair allocated three minutes for public comment. Dharia McGrew, state policy director, PhRMA, provided testimony to the board. Her written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230215-PDAB-public-comments.pdf

Adjournment: The meeting was adjourned at 11:30 a.m. by Vice Chair Shelley Bailey, with a motion by **Amy Burns** and a second by **Richard Bruno**.