Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, March 15, 2023
Minutes
Approved by the board on April 19, 2023

Chair Akil Patterson called the meeting to order at 9:32 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, Robert Judge (alternate), John Murray (alternate), Dr. Rebecca Spain (alternate).
Board members absent: None

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the Feb. 15, 2023, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230315-PDAB-document-package.pdf and there were none. **Vice Chair Shelley Bailey** moved to approve the minutes and **Daniel Hartung** provided a second.

MOTION by Shelley Bailey to approve the Feb. 15, 2023 minutes.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish said staff met with guests from Health Care for All Maryland and John Mullen, chair of the OregonCoalition for Affordable Prescritpions (OCAP), to talk about their coalition building experience. Ralph reported that legislative counsel is working on an amendment to Senate Bill 404, which includes the board's recommendations. Staff is recruiting for a data analyst position, which closes March 20. DCBS will hold a rulemaking advisory committee (RAC) for the PDAB rules on March 29. Chair Akil Patterson and Ralph Magrish met with the Pharmaceutical Care Management Association (PCMA) and have extended an invitation to present during a board meeting this summer. The Institute for Clinical and Economic Review (ICER) will give a presentation to the board in April about how they approach clinical evidence using available data sources. PDAB holds a user license with ICER and will use the information during the board's affordability review process. Staff is preparing a contract with Jane Horvath of Horvath Healthcare, a policy consultant who will provide technical assistance and knowledge to the board. Staff is also preparing a solicitation for a technical assistance contractor to help with the affordability reviews.

Marty Carty, governmental affairs director, Oregon Primary Care Association, gave a presentation from Pages 7-20 in the agenda document about federally-qualified health centers (FQHC) and shared a video about OPCA. In Oregon, 34 organizations operate 270 care delivery sites that provide integrated primary and behavioral health care. Last year they served 430,000 patients, 40 percent identifying as a racial or ethnic minority. Section 340B of the Public Health Services Act requires drug manufacturers who participate in the Medicaid program to offer certain outpatient drugs to covered entities at discounted prices and provide the drug to patients based on a sliding fee scale. The same drug purchased at a discount is reimbursed at full price by payers when a patient has insurance. Covered entities retain the difference. FQHCs are required by statute to reinvest that difference into services that directly benefit patients. Under the Affordable Care Act in 2010, hospital organizations were added to the program as eligible covered entities but do not have to reinvest the net dollars back into programs and

patients. OPCA recommends making it easier for FQHCs to operate retail pharmacies, increased PBM regulations, and more flexibility in using a contract pharmacy.

Questions from the board: Robert Judge said FQHCs play a critical role, especially in rural Oregon. Pharmacy benefit managers (PBMs) are involved in the third-party payer of insured patients. What are the pain points FQHCs are seeing? **Marty Carty** said PBMs contract with safety net providers, particularly 340Bs covered entities, and reimburse them at a different rate than they do others. Oregon statute prohibits this yet the practice continues. Congress created the 340B program as a way to pay for health care for underserved populations without public money. When outside entities retain some of those dollars the covered entity is entitled to, they are undermining the safety net. **Robert Judge** said the dilemma is who ultimately is responsible for the cost of medications and paying for those services. The safety net provides a critical role. It is a Gordian knot, he said.

John Murray said he is a board member for the Morrow County Health District, which operates a critical access hospital and school-based health care center in rural Oregon. He is also a pharmacy owner of two critical access pharmacies in Eastern Oregon. He understands about PBMs trying to reduce reimbursement for any 340B claims because he experiences this in his own contracting. It hurts no one but the covered entity to have a drastically-reduced difference in pricing. Critical access hospitals and school-based clinics provide equal care for those populations having a difficult time, usually the poor in the rural areas. He is concerned about covered entities and pharmacies being left out because they are not listed as an FQHC. **Marty Carty** said OPCA wants to protect all safety net providers, particularly FQHCs. He said OPCA would never do anything that would have a negative impact on access to care for underserved communities.

Richard Bruno said he works at FQHCs through Central City Concern in Portland. Central City uses the 340B programs extensively to ensure they can get the right medications to their patients. Often times, those folks have extreme poverty and sometimes can't even afford a sliding scale $20 copay. Central City tries to provide medications at no cost through the 340B program, knowing the importance of patients getting their insulin or anti-diabetic medications. Central City is always thinking about how, as an organization and 340B pharmacy, to make this sustainable. He asked about the stability of the 340B program.

Marty Carty said he thinks the 340B program is on unstable footing. The New York Times and Washington Post published uncomfortable stories around the 340B program, though those were not FQHCs in those stories. When Congress created the 340B program, it did not authorize Health Resources and Service Administration power to promulgate rules, leaving it up to interpretation by consumers, or even Pharma, to create the rules of the road, he said. This program benefits the safety net, underserved communities and Congress needs to figure out a way to shore it up in a way that makes sense, he said.

Vice Chair Shelley Bailey said related to 340B and contract pharmacy relationships, sometimes there are unintended consequences for the pharmacy. As PBMs go through their contracting process and with the National Association of Boards of Pharmacy (NABP) that registers pharmacies, part of the registration process now is asking pharmacies if they participate in 340B programs. If a pharmacy attests they participate in 340B, they can see a reduced payment, not only in the drugs identified as 340B, but also for their entire book of business. **Marty Carty** agreed that discrimination is happening.

Chair Akil Patterson thanked OPCA for providing this insight. He said he has been a huge supporter of the 340B program around FQHCs, particularly in marginalized communities, disenfranchised communities, and rural communities. Sometimes FQHCs are the only access to care.

Ralph Magrish said the board has the responsibility to make recommendations to the Legislature each calendar year. Some things the board heard today could potentially shape 340B-specific recommendations.

Fee Structure Rule Discussion: Cortnee Whitlock discussed the draft fee structure rule on Page 21 of the agenda packet. She said this is a work in progress and staff is finalizing the proposed methodology and billing process to present to the board at future meetings. **Shelley Bailey** said she looks forward to hearing stakeholder input during the RAC. She said, when talking about gross revenue, the board wants to make sure, to the extent possible, to include when a manufacturer is selling things at the 340B price or sub 340B price or giving discounts to contract pharmacy partners and payers.

Quarterly Drug List: **Ralph Magrish** said the board's enabling legislation differs from other states that have to construct their own methodology and build a feeder list for affordability reviews. The Oregon Drug Price Transparency program per statute produces these lists for reporting requirements from manufacturers and carriers. Staff is directed to present these lists to the board on a quarterly basis. Feedback will be about the process, not about the drugs per se. He discussed the annual price increase list from Page 22 of the agenda packet. Manufacturers are required annually to submit pricing reports to the Drug Price Transparency. Reports received in 2022 reflect increases of average drug prices 2020-2021. In 2022, the program received 102 annual price increase reports, each one for a different National Drug Code Directory (NDC) designation, from 21 different manufacturers. This is a decrease from 143 reports received in 2021. On the generic side, the program received price increase reports for 22 generic drugs from five manufacturers. Staff also received reports for 27 brand name drugs from 16 manufacturers. Patient assistance programs were reported for 10 of those brand drugs from six manufacturers. The median price increase was 19.9 percent for generic drugs and 13.4 percent for brand drugs.

Robert Judge asked if the board is limited to looking at the DPT price increase drugs or can the board look at drugs for which the state of Oregon spends a large amount of money. Ralph said the board is limited to looking at the DPT list. **Dr. Bruno** asked if it is possible to get a breakdown of dosing formulation these are referring to. **Vice Chair Bailey** asked about quantity. Ralph Magrish said he will ask counsel how much detail can be shared publicly.

Cortnee Whitlock showed Page 23 of the agenda packet, highlighting the top drugs that were injectables versus suppositories. She asked board members if this was a helpful way to break down the information. **Chair Akil Patterson** said yes, it is helpful to organize by administered injectables, an important distinction for someone who has a disease such as Crohn's and physically goes in an office to see a medical professional to get the medication. **Rebecca Spain, Amy Burns, Shelley Bailey** agreed.

Ralph Magrish showed Page 24- 27 for specialty drug reporting requirements. Manufacturers are required to submit a new prescription drug report to DPT within 30 days of introducing a new product with the list price of $670 or more for a 30-day supply or for a course of treatment, shorter than one month. The reporting period on this data was between Oct. 4, 2021, and Aug. 31, 2022. The program received 530 new high-cost drug reports, each one for a different NDC. These reports were submitted by 114 different manufacturers. We received new high cost drug reports for 173 generics from 54 different manufacturers, and also received reports for 84 brand name drugs that came from 66 manufacturers.

Cortnee Whitlock said the lists on Pages 24-27 are divided by drug name and therapy class. She asked if the board members prefer these categories. **Robert Judge** said it is always easier for him to start with a therapy category and then the drugs within the therapeutic category

Ralph Magrish said the lists on Pages 28-31 are from information the health insurance carriers are required to report to DCBS each year as part of the rate filing process. Health insurance companies report lists from their top 25 most prescribed drugs, top 25 drugs with the highest total health plan spending and the top 25 with the greatest increase of year-over-year plan spending. **Cortnee Whitlock** said the COVID-19 vaccination will fall off as new reporting numbers start coming in. She said these lists are examples to show what lists will look like for choosing drugs for the affordability review. **Robert Judge** asked if the year-over-year column is independent of a change in utilization of a drug and reflective of inflation or is there a way to break out use versus inflation? **Ralph Magrish** said the column likely represents the dollars and cents aspect. He said staff could discuss whether there would be data points in the All Payers All Claims database to do analysis about use trends.

Amy Burns recommended flagging drugs that show up on multiple lists with an increase of more than 10 percent or more than $100. It will not tell the whole story but it will tell the utilization numbers that Robert Judge is talking about, she said. **Robert Judge** asked if there is any way to get to net cost in the reporting? **Ralph Magrish** said he suspects the answer is no because the rebate reporting is aggregated by the Drug Price Transparency program. **Robert Judge** said the board may need to call that out to be fully transparent. **Dr. Rebecca Spain** said understanding the utilization increase versus the price increase is important information, particularly if the board recommends fixes. Dr. Burns' suggestion of cross referencing the various pieces of information so they have more context is a great start. If it is going up in price, the board can guesstimate a calculation about utilization. Maybe there is additional information that can give the board that trend over time.

Cortnee Whitlock showed the insulin lists on Pages 32-34 and asked the board if they have preferences on how they would like the data organized or structured in a meaningful way. **Richard Bruno** recommending sorting the three pages of insulin by price to help the board quickly find those with high cost.

Draft Affordability Review: Cortnee Whitlock said board members provided the following feedback and questions about the draft affordability review on Page 35:
* Expand the criteria to include extended pathway approval for orphans, fast track, priority review, accelerated approval, and breakthrough therapy designations.
* Use therapeutic alternatives instead of equivalents.
* Could expenditures include gross per prescription and per course of therapy?
* Is it possible to find the cost of therapy per individual who is using the drug?
* Look at the estimated average monetary price concessions as a percentage.
* Is there information, outside of fee for service, showing how drugs are capturing 340B pricing through the safety net, and how much of that is being passed through to help consumers?
* Look at average patient cost and whether a product is supported by manufacturer assistance or coupons.
Robert Judge said coupons and other patient assistance programs help people afford high-cost medications, but have a bearing on overall costs. It would be helpful to capture coupon information, if possible. **Ralph Magrish** said they would find out if that data is available from OHA. He asked board members to think about a methodology to study drugs with multiple approved indications. **Cortnee Whitlock** said staff will bring a red-line version of the draft affordability review to next month's meeting after the conversation with the RAC.

Public comment: The chair allocated three minutes for public comment. Asher Lisec, regional vice president PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230315-PDAB-public-comments.pdf

Adjournment: The meeting was adjourned at 11:24 a.m. by Chair Akil Patterson, with a motion by **Amy Burns** and a second by **Richard Bruno**.