Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, November 16, 2022
Minutes
Approved by the board on December 14, 2022

Call to Order and Roll Call
Chair Akil Patterson called the meeting to order at 9:33 a.m. and asked for the roll call.

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

Approval of the Minutes
Chair Akil Patterson asked if board members had any changes to the October 19, 2022, minutes on Pages 3-7 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. **Dr. Richard Bruno** moved to approve and **Vice Chair Shelley Bailey** provided a second.

MOTION by Shelley Bailey to approve the October 19, 2022, minutes.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Vice Chair Shelley Bailey, Chair Akil Patterson.
Nay: None.
Motion passed.

Program Update: Executive Director Ralph Magrish said staff would produce a quarterly newsletter beginning in December. He said the Drug Price Transparency program will hold a public hearing on Dec. 1, with details on Page 7 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. He will give a presentation during Legislative Days on Dec. 8 about the Prescription Drug Affordability Board and Drug Price Transparency program. He invited board members to provide a list of their requests for presentations in 2023 s at the December meeting. Ideas may include the Oregon State Pharmacy Association speaking on its recent report "Understanding Reimbursement Trends in Oregon: The High Cost of Low Prices," or the Oregon Primary Care Association speaking about 340B purchasing.

Patent Law: Ralph Magrish introduced **Tahir Amin**, founder and executive director of the Initiative for Medicines, Access & Knowledge (I-MAK), a nonprofit organization addressing structural inequities in how medicines are developed and distributed. Tahir Amin said when a drug company is developing a product, it takes out a patent in the research stages before a drug is approved for marketing. If something from the discovery is successful, the drug gets approved by the FDA. This step takes up the first eight years of the patent life. Once the drug gets to market, the company has 10-12 years of exclusivity, a limited monopoly in the marketplace when no one else can sell without consent. Most people think of 20-year patent terms, and once the patent ends, generic drugs, or biosimilar competition, will enter the market. His organization and other academics have found, however, that is not what is happening. He wants to shed light on how pharmaceutical companies are using the patent system to prolong that limited monopoly, holding on to exclusivity for longer, charge higher prices, and keeping competition at bay, all which leads to higher drug pricing. He discussed information from Pages 8-23 of the agenda document posted here: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. He recommends contacting congressional members and coordinating with other states to raise awareness about what drug companies are doing through the patent system.

Questions from the Board: Dr. Daniel Hartung asked about using marching rights to invalidate patents for publicly-funded drugs and other therapies. **Tahir Amin** said marching rights are when the government overrides patents of drugs that have received public fund, inviting competition. It is a struggle to get marching rights because it has never been used. In public-private partnerships, the signed contracts do not allow the government to use marching rights.

Dr. Rebecca Spain asked if Europe is a benchmark to compare with U.S. patents and if Europeans are happy with their patent system. **Tahir Amin** said he does not think Europe has the best patent system either. U.S. and Europe have the two biggest patent offices in the world. In Europe, companies cannot file applications repeatedly like they can in the U.S., accumulating patents used in litigation that suffocates people into settlements. Even in Europe, there is work to do because Europeans are paying high prices for drugs as well.

Chair Akil Patterson asked if patent games are an issue for the courts or the legislature. **Tahir Amin** said that, ultimately, it is with Congress. The courts became pro patent in the 1980s, a response to the tough economic times of the 1970s. Today, the courts are so patent friendly, it is very hard to get a patent challenge. The USPTO can make new rules, but ultimately, raising the bar to get a patent happens in Congress. A flurry of lobbying activity will follow to preserve the system, he predicts, but he is hopeful for the future.

Dr. Amy Burns asked if definitions around biosimilars have driven some of these challenges. **Tahir Amin** said there is a difference in how U.S. defines interchangeable versus non-interchangeable biosimilars. Many states look for a biosimilar that is interchangeable. A biosimilar company has to do extra effort in clinical trials in order to get that "interchangeable" status, as not every biosimilar approved by the FDA is interchangeable. In Europe, they do not have that same interchangeable criteria. It is not to say Europe is not doing enough trials, but there seems to be an extra level in the United States hindering competition to substitute a biosimilar for a biologic. In the generic space, showing bio-equivalency is more straightforward. Because it is so easy to file so many patents on a biologic drug given the nature of the product, it is rife with delays in getting these products to the market, he said. Many biosimilar companies do not want to participate in this process because it is too costly to get through patents and bureaucratic levels.

Board discussion of draft reports: **Cortnee Whitlock**, policy analyst, discussed the draft reports and sought board member feedback. The reports are located on Pages 24 – 74 in the agenda document: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf. Here is the board's feedback:

Generics and DIRs

Dr. Rebecca Spain recommended distinguishing between generics and biologicals. **Dr. Amy Burns** suggested including physician-administered medications because of the difference in cost and distribution through the system**. Vice Chair Shelley Bailey, John Murray, Robert Judge, and Dr. Dan Hartung** recommended including a section about the impact on pharmacies of direct and indirect remuneration fees (DIR). **Robert Judge** said DIRs seem to be a revenue source for PBMs. **John Murray** said pharmacists try to do everything right to hit DIRs fees, whether it is drug evaluation or patient consultation, or generic implementation. The bar always moves, is always raised, and they never seem to hit it. He said it is more of a PBM profit motive than trying to improve actions at a pharmacy leveled. **Dr. Dan Hartung** recommended including rebates, which are also part of DIRs.

Fee for service and CCOs

Vice Chair Shelley Bailey recommended highlighting what percent of Medicaid claims in Oregon are fee for service (FFS) versus CCOs. Dr. **Daniel Hartung** recommends clarifying about the mental health carve out, which is included in the FFS section. Another important part of the Medicaid supply chain is the Federal Medicaid rebate.

The inflationary rebate, which is the new model for the Medicaid legislation, is an impotent discussion point because it differentiates Medicaid from the other sectors of the pharmacy market. **Robert Judge** said it would be beneficial to have discussions on Medicaid FFS and Medicaid CCO. Although CCOs are funded through state funds, it is mostly administered in the pharmacy arena through commercial PBMs that support the CCOs.

Ralph Magrish asked the chair about extending the meeting to accommodate the remaining agenda items. **Chair Akil Patterson** asked for a motion. **Vice Chair Shelley Bailey** moved to extend the meeting time and **Dr. Daniel Hartung** provided the second. **Dr. Amy Burns** said she cannot stay for the extended meeting time.
MOTION by Shelley Bailey to extend the meeting time.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey.
Nay: None
Abstain: Akil Patterson
Motion passed.

Independent Pharmacy, Commercial Insurance
Vice Chair Shelley Bailey recommended changing the term "independent pharmacy" to "small chain and independent pharmacy." She said, when it comes to access and equity, small chain pharmacies closures are just as impactful to communities as an independent pharmacy because they are often the only pharmacy provider in certain geographic areas. **Dr. Amy Burns** suggested changing the heading employer-sponsored health insurance to commercial so it also includes individual or small group market. **Chair Akil Patterson** agreed about defining terms. **Robert Judge** said the report describes three markets – Medicaid, Medicare and commercial markets. **Vice Chair Shelley Bailey** agreed, but added a fourth area, separating out fee for service Medicaid versus managed Medicaid. **Chair Akil Patterson** suggested having a key with definitions and terminologies.

Prior Authorizations (PA)
Robert Judge recommended giving equal time to the reason PAs exist, making sure that right therapies get to right individuals at the right time at the right cost. **Dr. Amy Burns** agreed. Dr. **Rebecca Spain** said she was writing this portion from her prescribing perspective. She knows it is important to have cost containing measures. Prior authorizations sometimes do not make sense, she said. A solution would be to have subject experts on the diseases be part of creating prior authorization chains or tier chains. She gave an example of trying to prescribe a certain drug to a patient who now needed a less aggressive drug with lower risk ratio, but did not tolerate the one on the insurance formulary. She said it was very difficult to find a medication with a lower risk that would be paid for by the patient's insurance. The easiest thing to do would be to continue a higher risk drug because it was on their system. Physicians get into these nonsensical situations even though the system is set up with good intentions. **John Murray** said, as a pharmacist, he deals with the other half of it, when a patient comes in the pharmacy, the pharmacist explains the PA to the frustrated patient. Hopefully, the PA process is being improved or streamlined with technology. He understands the need and importance of step therapy to minimize cost and that use of generics is important. But he also understands the frustration. **Robert Judge** recommended the report give equal time to patient assistance programs and copay coupons.

Impact on underserved and disadvantaged populations
Robert Judge and John Murray suggested this section include the criticality of community pharmacies, small chain pharmacies in areas of the state that are underserved, especially in Eastern Oregon, where there are growing "pharmacy deserts" without adequate services. **Dr. Richard Bruno** recommended changing the title to

under-resourced to be more consistent. **Chair Akil Patterson** recommended being specific when it comes to issues impacting race, ethnicity, and age. Pharmacy deserts may also impact aging populations in rural communities and tribal communities who depend on rural pharmacies, including people on unrecognized tribal lands. He said it is important to recognize these aspects of the rural community discussion.

Generic Drug Report
Vice Chair Shelley Bailey and Dr. Amy Burns suggested adding PBM fees and administrative costs to the payor net cost portion on Page 7. **Vice Chair Shelley Bailey, John Murray, and Dr. Amy Burns** recommended adding a sentence about maximum allowable cost (MAC) and the lack of transparency, which is challenging for pharmacies.

Recommendations: Chair Akil Patterson said members would discuss recommendations before taking a vote on each. He said if board members have a potential conflict of interest, the chair will appoint an alternate to vote instead. Here are highlights of the discussion:

Recommendation 1: **Robert Judge** said he was uncomfortable with setting an upper limit payment because it is unexplored territory that needs further study. He is concerned about what it might do to pharmacies who get reimbursed for the drugs. **Dr. Richard Bruno** said he feels comfortable with upper payment limits based on the speakers who presented to the board last month. **Vice Chair Shelley Bailey** said she is also concerned about potential impacts. **Chair Akil Patterson** believes the board should have the authority to set upper payment limits, but it is a legislative decision. He thinks the board should send back the legislature's original language about upper payment limits, which was removed from the current SB 844. **John Murray** said if granted authority, the board does not have to use it if the board determines it is harmful to the overall supply chain. He does not want to damage an already fragile system, especially for urban or rural disadvantaged populations. **Dr. Rebecca Spain** said the board should give the best recommendations to the legislature. It does not mean it will be implemented. She trusts this board to make good recommendations. **Chair Akil Patterson** asked for a motion. **Dr. Richard Bruno** moved to approve the upper payment limit section as written and **Dr. Amy Burns** provided the second.
MOTION by Richard Bruno to approve Recommendation 1 Upper Payment Limits.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Akil Patterson.
Nay: Shelley Bailey.
Motion passed.

Recommendation 2: **Robert Judge** proposed adding the phrase GPO, which are group purchasing organizations used or owned by PBMs, because GPOs create another layer of opacity in the rebate supply chain. **Vice Chair Shelley Bailey** made a motion to approve Recommendation 2 with the added language. **Dr. Amy Burns** provided the second.
MOTION by Shelley Bailey to approve Recommendation 2 transparency in supply chain rebates with the amendment of GPOs.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 3: **Dr. Amy Burns** left the meeting and **Chair Akil Patterson** appointed **Robert Judge** as the alternate member to vote. **Vice Chair Shelley Bailey** moved to approve Recommendation 3 as is and **Robert Judge** provided the second.

MOTION by Shelley Bailey to approve Recommendation 3 DPT expand reporting requirements for patient assistance programs.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 4: **Robert Judge** said he would abstain from voting due to a potential conflict of interest. The chair appointed alternate **Dr. Rebecca Spain** to vote. **Vice Chair Shelley Bailey** moved to approve Recommendation 4 as is and **Dr. Daniel Hartung** provided the second.
MOTION by Shelley Bailey to approve Recommendation 4 DPT expand reporting to more insurers.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Rebecca Spain, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Recommendation 5: **Robert Judge** said he would return to voting. **Vice Chair Shelley Bailey** moved to approve Recommendation 5 as proposed and **Dr. Daniel Hartung** provided the second.
MOTION by Shelley Bailey to approve Recommendation 5 require patient advocacy groups to disclose funding sources.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey.
Nay: None
Abstain: Akil Patterson
Motion passed.

Final Rule Making Approval: Cortnee Whitlock, policy analyst, reviewed the model rule process shown on Page 75 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-document-package.pdf.
Vice Chair Shelley Bailey moved to approve the final model rules and **Robert Judge** provided the second.

MOTION by Shelley Bailey to approve the final model rules.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Public Comment: The chair allocated three minutes for public comment. He called on the people who signed up in advance to speak, Tonia Sorrell-Neal, Pharmaceutical Care Management Association, and Dharia McGrew, PhRMA. Both provided testimony to the board.

Adjournment: The meeting was adjourned at 12:10 p.m. **Vice Chair Shelley Bailey** made the motion, and **Robert Judge** provided the second.

MOTION by Shelley Bailey to adjourn the meeting.
Board Voice Vote
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Vice Chair Shelley Bailey, Chair Akil Patterson.
Nay: None.
Motion passed.