PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING
Monday, May 22, 2022
Meeting Minutes

Chair Van Mitchell called the meeting to order at 2:02 p.m.

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Joseph Levy, Ph.D., Stephen Rockower, M.D.

AGENDA ITEM 2

Approval of minutes
Chair Mitchell asked for a motion to approve the April 18, 2023 meeting minutes as submitted. Dr. Anderson made the motion, which Dr. Rockower seconded, and the Board unanimously approved the minutes.

Action: Minutes APPROVED.

AGENDA ITEM 3

Opportunity for Public Comment
No persons registered to provide public comment.

Executive Director York advised that the Board received one written comment concerning PDAB's budget to which the Board provided a written response.

The Chair exercised his prerogative to deviate from the order of the agenda and introduce the Senate President's Office appointee to the Board, Dr. Stephen Rockower. Dr. Rockower introduced himself and stated that he was happy to be a part of the Board.

AGENDA ITEM 4

Presentation: Harvard Medical School and Brigham & Women's Hospital Program On Regulation, Therapeutics And Law (PORTAL)
Chair Mitchell welcomed the PORTAL team and Executive Director York invited them to make presentation to the Board. The presentation is available on the Board's website. .
Presenting PORTAL Team : Dr. Benjamin Rome and Adam Raymakers, PhD, with comments by Dr. Jerry Avorn

Dr. Benjamin Rome provided a brief introduction and overview of PORTAL. Dr. Rome explained that the presentation is intended to open a dialogue to identify key issues in evaluating

prescription drug costs.PORTAL's presentation was structured in two sections: Conducting Cost Reviews and Considerations for Upper Payment Limits. Dr. Rome identified three key topics in conducting cost reviews: comparative effectiveness, cost effectiveness and budget impacts. This discussion included identifying the factors and possible data sources for each topic. Dr. Anderson asked several questions concerning data sources.

Dr. Raymakers provided information regarding economic evaluation as a tool to identify the best course of action and as an input in a health technology assessment. Dr. Raymakers also explained what QUALYS are and how they can be used as an incremental/comparative measure of a benefit. Dr. Jerry Avorn commented on some objections to QUALYS.

Dr. Raymakers addressed some additional analytical frameworks and metrics used to mitigate some of the concerns around QUALYS. He also discussed other methods of analysis and the respective benefits and limitations of those methods. Dr. Levy inquired whether any researcher or entity is using these additional metrics.

Dr. Raymakers discussed budget impact analysis and impact to the health system. Dr. Anderson commented on the difficulty in incorporating some of these approaches. Dr. Rome suggested a framework of the components and assessment of available data in qualitative and quantitative analyses. Dr. Avorn observed that this is similar to what a practicing physician does.

Dr. Rome observed that the Maryland statute does not provide much guidance concerning upper payment limits. Dr. Rome discussed Colorado's factors in setting a UPL and the Medicare four-step process under the Inflation Reduction Act. He explained that other countries have developed methods for evaluating and negotiating/setting reimbursement prices. He further explained Colorado's approach is to apply the UPL to the reimbursement level (consumer purchase) and to the supply chain purchases. Dr. Levy asked whether the reimbursement perspective is the same as net price? Dr. Rome explained that Colorado's approach is that the reimbursement price is at the point of sale. This approach has different implications for high rebate and low rebate drugs.

Dr. Rockower noted that this is driven by patient out-of-pocket costs. Dr. Rome explained patient OOP cost is linked to point of sale price. Chair Mitchell asked whether CMS has issued any guidance on how the maximum fair price works with 340B? Dr. Rome also discussed implications for Medicaid best price, and opportunities for cost-shifting. Dr. Levy asked how entities at this level evaluate budget impact?

Dr. York asked whether UPLs can work and save money? Dr. Rome suggested they can and in cases where there are no rebates UPLs will clearly impact cost. For each drug the effectiveness of UPL as a policy solution may be different.

Chair Mitchell asked whether anyone has identified a formula or score for quantifying savings? Dr. Rome advised that the scoring depends on the ceiling price but there are overpriced drugs with less expensive alternatives—low hanging fruit. Massachusetts has seen savings by identifying drugs and asking for additional rebates. Dr. Avorn observed that there are many drugs that are very expensive.

Dr. Onukwugha asked whether PORTAL has found any consensus around evidence ranking? Dr. Rome advised that other countries have but states have other considerations that are both different and complicated.

The presentation ended at 2:45 pm.

AGENDA ITEM 5

Draft Regulations

a. Presentation on Draft Regulations

Executive Director York provided an overview of the changes to the draft Fee Assessment Regulations COMAR 14.01.02 noting that the Board had received one substantive comment regarding life insurers not being subject to assessment. The definition of carrier was revised to reflect the understanding that carriers that do not provide health benefits plans are not subject to assessment.

b. COMAR 14.01.02 Fee Assessment

i. Motion to Approve

Chair Mitchell asked for a motion to approve the draft amendments to COMAR 14.01.02. . Dr. Anderson made the motion which Dr. Rockower seconded. Chair Michell then entertained discussion on the motion.

Discussion

Dr. Levy asked if this would be applied retroactively, and Executive Director York explained that it would be effective in FY24 and applied to the next round of fee assessments.

Dr. Anderson asked if the Board would consider increasing assessment rates at any time. Executive Director York explained that the fee assessment process is evolving and that the Board has the opportunity to reevaluate its projected budgetary needs and the fee assessment annually..

Chair Mitchell reminded the Board that the legislature graciously increased the PDAB budget for FY24 so it would not be appropriate to ask for a fee increase for this year. PDAB will still continue to have the flexibility to raise rates in the future.

ii. Vote on Motion

With no opposition, the Board unanimously approved COMAR 14.01.02 Fee Assessment as submitted. **Action: COMAR 14.0.02 Fee Assessment APPROVEDas submitted.**

c. COMAR 14.01.03 Public Information Act (PIA)

Assistant Attorney General Michele McDonald provided a regulation by regulation overview of chapter COMAR 14.01.03 Public Information Act, implementing the Maryland Public Information Act, and explained the difference between the model PIA regulations and the proposed PDAB PIA regulations. AAG McDonald also provided a summary of the two written comments received concerning this regulation.

i. Motion to Approve

Chair Mitchell asked for a motion to approve the draft regulations COMAR 14.01.03 . Dr. Rockower made the motion which Dr. Anderson seconded. Chair Michell then entertained discussion on the motion.

Discussion

Dr. Anderson asked how the Board would respond to a PIA request for drug data. AAG McDonald explained that if the Board received a PIA request for drug pricing data, the Board would deny the request pursuant to the statute that makes certain information received by the Board is not subject to disclosure,

ii. Vote on Motion

With no opposition, the Board unanimously voted to approve COMAR 14.01.03 Public Information Act.

Action: COMAR 14.01.03 Public Information Act APPROVED as submitted.

AGENDA ITEM 6

Draft COMAR 14.01.04 Cost Review Regulations Presentation

Executive Director York explained that the Board received 12 comments by the May 2 deadline on the definitions and cost review process and 4 subsequent comment letters addressing the rules of construction and confidential, trade secret and proprietary information regulations. Executive Director York provided a high level overview of the themes in those comments. PDAB staff is continuing to work through the comments on the Cost Review Regulations and another draft will be posted for further public comment. These drafts for comment will be pushed out through Gov Delivery and posted on the PDAB website. All comments received thus far have been posted on the Board's website.

Dr. Anderson asked if there was going to be an interim meeting prior to the July 24th Board meeting.Executive Director York said he would follow up regarding that but wanted to ensure there was adequate time for the public to comment on the revised drafts.

AGENDA ITEM 7

Administrative Update

Executive Director York advised that there were no administrative updates but noted that this meeting is the last scheduled in fiscal year 2023.

Chair Mitchell asked Christina Shaklee to provide an update on the Stakeholder Council. Ms. Shaklee advised that the next Stakeholder meeting is Monday June 26, 2023. The agenda for that meeting will be forthcoming.

AGENDA ITEM 8

Chairs Update

Chair Mitchell again welcomed Dr. Rockower and noted a correction to the agenda – the next PDAB Board meeting is on July 24, 2023.

Chair Mitchell asked the Board members if they had any other comments.

Dr. Anderson reiterated he would like another meeting possibly before the July 24, 2023 meeting to move the regulations along.

AGENDA ITEM 9

Adjournment

Chair Mitchell asked for a motion to adjourn. Dr. Anderson made the motion which Dr. Rockower seconded.

The meeting was adjourned at 3:37 PM.