MARYLAND PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL VIRTUAL MEETING Monday, August 28, 2023 Minutes

Agenda Item 1

Call to Order: Co-Chair Lorriane Diana called the meeting to order at 2:00 PM

(Roll Call) Stakeholder Council Members present: Shawn Brown, Steven Chen, Lorraine Diana, CRNP, Babette Edgar, Pharm. D., John Elliot, Jim Gutman, Deron Johnson, Barry Lipsy, Eric Morse, Marc Nicole, Shaun O'Brien, Hayley Park, Pharm. D., Mandi Poplawski, Pharm.D., Beth Rada, Kimberly Robinson, Glenn Schneider, MPH, Kelly Schultz, Sean Tunis, MD, MSc

Agenda Item 2

Opportunity for Public Comment

PDAB staff member Christina Shaklee advised that no person requested to provide comment at the Stakeholder Council meeting today and that a written comment was received and provided to the co-chairs.

Agenda Item 3

Regulations-chapters COMAR 14.01.01 and COMAR 14.01.04- Update

- Executive Director Andrew York provided an overview of COMAR 14.01.01.-.05 (General Provisions Chapter) and COMAR 14.01.04.01-.05 (Cost Review Study Process Chapter), the comments received, revisions to the draft regulations, and an overview of the process.
- Dr. York explained that there have been two comment periods and summarized the comments received by the Board. Major themes included updated definitions, selection process, eligibility criteria, consideration of treatment of rare disease, and protection of confidential and proprietary information. Dr. York also provided a summary of the revisions proposed to the most recent draft regulations based on the comments received.
- Dr. York detailed the updated comment process (COMAR 14.01.01.05) and selection process (COMAR 14.01.04.03).
- Dr. York reported that:
 - The Board unanimously approved COMAR 14.01.01.01-.05 General Provisions as submitted. The proposed regulations have been submitted to the Maryland Register for publication.

- The Board also unanimously approved COMAR 14.01.04.01-.05 Cost Review as submitted and amended. The proposed chapter of new regulations was submitted to the Maryland Register for publication.
- Once these regulations are published in the Maryland Register there will be another 30-day comment period.
- There was a short Q&A after Executive Director York's presentation.
- The slide deck for this presentation is posted on the Board's website on the Stakeholder Council page.

Agenda Item 4

Upper Payment Action Plan Update and Presentation

- Dr. York provided an overview of Maryland's statutory scheme governing UPLs, and identified key decision points in developing the UPL Action Plan.
- Dr. York discussed the framework for setting UPLs through value assessment, budget assessment, rate of return, and additional considerations.
- There was an opportunity for comments and questions throughout the presentation.
- The slide deck for this presentation is available on the Board's website at the Stakeholder Council's page.

Agenda Item 5

Approval of Meeting Minutes

Co-Chair Diana asked for a motion to approve the June 26, 2023 meeting minutes as submitted. Jim Gutman made the motion, which Deron Johnson seconded and the Stakeholder Council unanimously approved the minutes with no opposition, one member abstaining.

Action: Minutes APPROVED

Agenda Item 6

Administrative Update

- Executive Director York provided an update on an AARP letter that the Board Chair, Van Mitchell received, which was shared with the other Board members. The Board has not discussed expansion of UPLs and it is not expected to be an upcoming agenda item. The Board does owe a report in 2026 in regards to the expansion of UPLs.
- Ms. Shaklee provided an update on appointments to the Stakeholder Council and advised that PDAB staff will continue to work closely with the appointing authorities to address expired appointments.

Agenda Item 7

Co-Chair's Update

- Co-Chair Diana introduced new Stakeholder Council members: Steven Chen (representing hospitals), Kelly Schulz (representing biotechnology companies), and Dr. Renee Bovelle (representing physicians).
- Co-Chair Diana reminded the Council of the process for addressing topics and issues at the Stakeholder Council. Council members who would like to discuss a topic at a meeting should reach out to the co-chairs to propose a matter as a possible agenda item.
- Co-chair Diana further advised that the next Stakeholder Council meeting will be held virtually on October 23, 2023 at 2:00pm.

Agenda Item 8

Adjournment

Co-Chair Diana asked for a motion to adjourn the meeting. Deron Johnson made the motion to adjourn, which was seconded by Jim Gutman at 3:12 pm.

Adjourned at 3:12 PM