# PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING Monday, April 18, 2022 Meeting Held Via Video Conference (Zoom) Minutes

Chair Van Mitchell called the meeting to order at 2:00 p.m.

#### **Board Members present:**

Van Mitchell, Chair Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Joseph Levy, Ph.D.

Also present: Andrew York, Executive Director, PDAB Michelle Robinson, Health Policy Analyst Advanced, PDAB Christina Shaklee, Health Policy Analyst Advanced, PDAB Sydne Robinson, Administrative Specialist, PDAB Michele McDonald, General Counsel, Assistant Attorney General

#### **AGENDA ITEM 2**

#### **Approval of minutes**

Chair Mitchell asked for a motion to approve the January 23, 2023 meeting minutes as submitted. Dr. Anderson made the motion, which Dr. Levy seconded, and the Board unanimously approved the minutes.

#### Action: Minutes APPROVED.

#### **AGENDA ITEM 3**

#### **Opportunity for Public Comment**

No persons registered for an opportunity to provide public comment.

#### **AGENDA ITEM 4**

#### **Draft Regulations**

AAG McDonald presented an overview of the pre-proposal regulations comment process and an overview of three sets of draft regulations: COMAR 14.01.01.01 General Provisions (definitions), COMAR 14.01.02.02 Prescription Drug Affordability Fund (fee assessment amendments), and COMAR 14.01.03.01-05 Cost Review Process (all new).

The presentation and draft regulations are available on the Board's website.

Public written comments for COMAR 14.01.01.01 (Definitions), 14.01.02.02 (Fee Assessment), and 14.01.03 (Cost Review) are requested by May 2, 2023. Additional draft regulations are currently in development including COMAR 14.01.01.02 (Rules of Construction), COMAR 14.01.01.03 (Open Meetings), COMAR 14.01.01.04 (Confidential, Proprietary and Trade-Secret Information). These drafts will be posted shortly. Public written comments for these regulations are requested by May 5, 2023. The Board solicits and encourages public comment.

The regulations presentation concluded at 2:38 pm. Dr. York then facilitated the Board's discussion of the draft cost review process. Dr. York will provide a summary of the comments received by the Board and any proposed revisions to the draft regulations.

No action taken.

# **AGENDA ITEM 5**

# Administrative Update

- Legislative Session Review: Health Policy Analyst Christina Shaklee provided a review of the bills affecting PDAB.
  - SB202/HB279 This bill recodified the Board's Upper Payment Limit authority, which had previously sunset. The Governor signed the bill into law on April 11, 2023. PDAB supported the bill.
  - HB382 This bill requires the Maryland Department of Health (MDH) and PDAB to study prescription drug claim payments in the Maryland Medical Assistance Program including the total amount managed care organizations paid pharmacies for prescription drug claims in 2021 and 2022 and how to address inconsistencies in the amounts studied. This bill was sent to the Governor's Office for signature.
  - HB456/SB940 Among other things, this bill directs MDH to submit a report on the potential process for, and costs of, implementing enhanced professional dispensing fees for providing accessible labels and compliant packaging to blind, visually impaired, and otherwise print disabled individuals. PDAB may be asked to assist with this report. This bill was sent to the Governor for signature.
  - Budget Bill: HB200 For FY 24, PDAB received an appropriation of \$1.4 million in special funds and an additional \$1 million in general funds for operating expenses.
- Chair Mitchell advised that PDAB will confer with the Department of Budget and Management (DBM) concerning expenditure of the general fund appropriation.
- Executive Director York explained that the Center for Medicare (CMS) issued guidance on the implementation of the negotiation provisions of the Inflation Reduction Act (IRA) and sought public comment on this guidance. A comment letter was submitted by the National Academy of State Health Policy (NASHP) on behalf of the states identifying areas of concern and opportunities for the states to leverage this work including sharing

data to reduce reporting burden, utilizing the infrastructure, and employing similar methodologies for consistency. Dr. York will share that letter with the Board.

• Executive Director York also advised that PDAB made its first payment to the Maryland Health Care Commission (MHCC) in the amount of \$176,000 to reimburse that agency for operational expenses it incurred in supporting PDAB. Repayment is scheduled to occur over three years.

No action taken.

# AGENDA ITEM 6

# Chair's Update

- Ms. Shaklee serves as the primary staff person for the Stakeholder Council.
- The next PDAB Board Meeting is scheduled for May 22, 2023 at 2:00 p.m. Chair Mitchell expects to be able to hold in-person meetings by the Fall.

No action taken.

# **AGENDA ITEM 7**

# **Closed Session**

The Chair asked for a motion to close the session under General Provisions § 3-305(b)(7), Annotated Code of Maryland, to receive legal advice from counsel and maintain confidentiality and attorney client privilege in closed session.

Dr. Anderson moved to close the session and Dr. Levy seconded the motion. Chair Mitchell, Dr. Anderson, Dr. Onukwugha, and Dr. Levy voted to close the session. No Board member opposed the motion. Closed session commenced at 3:04 p.m. via Zoom breakout session.

# SUMMARY OF CLOSED SESSION

Pursuant to General Provisions § 3-305(b)(7), Annotated Code of Maryland, on April 18, 2023 at 3:04 p.m. the Board met in closed session to receive legal advice from counsel concerning the draft regulations.

Chair Mitchell, Dr. Anderson, Dr. Onukwugha, Dr. Levy, AAG McDonald, and Board staff Dr. York, Ms. Shaklee, Dr. Robinson, and Ms. Robinson attended the closed session. AAG McDonald provided the Board with legal advice concerning the draft regulations.

No actions and no votes were taken in the closed session.

# Adjournment

Public session was reconvened. Chair Mitchell requested a motion to adjourn. Dr. Anderson made the motion to adjourn, which Dr. Levy seconded. The Board adjourned at 3:34 p.m.