

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING

September 10, 2024

Minutes

AGENDA ITEM 1

Call Meeting to Order

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, MD

AGENDA ITEM 2

Approve July 22, 2024 Meeting Minutes

Chair Mitchell asked for a motion to approve the July 22, 2024 meeting minutes as submitted. Dr. Anderson made the motion, which Dr. Onukwugha seconded. The Board unanimously approved the minutes.

Action: Minutes APPROVED

AGENDA ITEM 3

Opportunity for Public Comment

Christina Shaklee, Health Policy Analyst, advised that one written comment was received, which was provided to the Board and posted to the website. One person provided oral public comment.

1. Tiffany Westrich-Robertson, AiArthritis, Agenda Item V

AGENDA ITEM 4

Supply Chain Report – Approve as Final with Corrections (Health-General Art. § 21-2C-07)

Executive Director York asked the Board to approve the Supply Chain Report- Health- General Article § 21-2C-07 (Supply Chain Report) as final with corrections. At the January 24, 2024 Board meeting, the Board approved the Supply Chain Report and allowed edits for typographical and scrivener's errors. PDAB staff have made further copy edits and requested approval of this final version of the supply chain report.

Chair Mitchell asked for a motion to approve the Supply Chain Report as final, as submitted. Dr. Rockower made the motion which was seconded by Dr. Anderson. Chair Mitchell opened the floor for discussion.

Dr. Anderson noted that this is a comprehensive report that should alleviate concerns brought up by written comments received by the PDAB about assessing policy solutions outside of upper payment limits (UPLs) in which Dr. Rockower agreed.

The Board unanimously approved the Supply Chain Report (Health-General Art. § 21-2C-07).

Action: Supply Chain Report (Health-General Art. § 21-2C-07) – APPROVED as Final

AGENDA ITEM 5

UPL Action Plan

a. Upper Payment Limit Action Plan (Staff Presentation)

Dr. York provided a robust presentation on the Upper Payment Limit Action Plan (UPL Action Plan). This presentation can be found on the Board page of the website. Dr. York allowed questions and discussions through certain points of the presentation.

The presentation gave an overview of the process after the Board makes a preliminary determination on affordability after a cost review study process. Dr. York explained that there is an extensive policy review process which will determine if a UPL or a Non-UPL policy is warranted. Dr. York went over the criteria for setting UPLs, sample methodologies, and contextual information for setting UPLs. Dr. York explained that the PDASC provided feedback and asked questions at their August 26, 2024 meeting on the UPL Action Plan. Many comments were received on the UPL Action Plan (available on the Board website) and all Board members and staff reviewed the comments and changes were applied to the draft based on these comments, where necessary. Dr. York gave a high level overview of the comments received and PDAB work, up to this point, on the UPL Action Plan.

Board members expressed appreciation for the written comments that were received and expressed that addressing these comments is a priority. The Board also clarified that the methodologies to calculate a potential UPL for a drug will be on a per-drug basis.

b. Adopt Upper Payment Limit Action Plan

Chair Mitchell asked for a motion to approve the UPL Action Plan. Dr. Anderson made the motion which was seconded by Dr. Levy, with an amendment to include staff changes for typographical and scrivener's errors. The UPL Action Plan was unanimously passed with no opposition.

Action: Upper Payment Limit Action Plan- APPROVED as Final

After passing the UPL Action Plan, Dr. York explained that the UPL Action Plan will be sent to the Legislative Policy Committee, who may approve the UPL Action Plan within the next 45 days. If approved, the Board will establish the process through regulations.

AGENDA ITEM 6

Emergency Regulations (COMAR 14.01.04.05 Cost Review Study Process)

a. Staff presentation

Assistant Attorney General Michele McDonald gave a presentation on proposed technical amendments to COMAR 14.01.04.05 Cost Review Study Process. This presentation is posted on the Board page of the website. The proposed amendments to COMAR 14.01.04.05 Cost Review Study Process include establishing a preliminary determination of affordability, clarifying analyses and data sources, providing additional factors considered in the cost review study, and additional amendments to allow for the cost review study process to incorporate the Policy Review Process outlined in the UPL Action Plan. These regulations are also being submitted as emergency regulations.

b. Adopt Proposed Emergency Regulations

Chair Mitchell asked for a motion to adopt the proposed Emergency Regulations (COMAR 14.01.04.05 Cost Review Study Process). Dr. Onukwugha made the motion which was seconded by Dr. Rockower. The proposed Emergency Regulations (COMAR 14.01.04.05 Cost Review Study Process) were approved with no opposition.

Action: Proposed Emergency Regulations (COMAR 14.01.04.05 Cost Review Study Process)- ADOPTED

AGENDA ITEM 7

Procurement–University of Maryland School of Pharmacy Agreement

Executive Director York gave a brief overview of the Procurement- University of Maryland School of Pharmacy Agreement.

The Cost Review Study Process has a series of analyses that require clinical expertise, including selection, assessment, and evaluation of therapeutic alternatives, and analyses in the Cost Review Study Process that require clinical input. Staff was seeking approval of funds to enter into a

University Agreement Agreement between two state entities, where they will provide specific services including analytics capabilities that require certain expertise. Board Staff requested approval for a not-to-exceed amount of \$63,000 for a University Agreement with the University of Maryland School of Pharmacy to conduct analyses for the 6 drugs that the Board selected for the Cost Review Study Process.

Board Members asked some clarifying questions. Chair Mitchell asked for a motion to approve the procurement for the University of Maryland School of Pharmacy Agreement. Dr. Levy made the motion to adopt and Dr. Anderson seconded the motion. Dr. Onukwugha recused themselves from the vote. The Board approved the Procurement–University of Maryland School of Pharmacy Agreement.

**Action: Procurement–University of Maryland School of Pharmacy Agreement-
APPROVED**

AGENDA ITEM 8

Cost Review Update (staff presentation)

Dr. York provided an update on the Cost Review Study Process. This presentation is posted on the Board page of the website. This presentation specifically covered the Request for Information process.

AGENDA ITEM 9

Administrative Update

- Ms. Shaklee explained that the October PDASC meeting date will be finalized soon.

AGENDA ITEM 10

Chair’s Update

- The next Board meeting on October 28, 2024 will be virtual.
- The November 25, 2024 Board meeting will be in person.

AGENDA ITEM 11

Adjournment

Chair Mitchell asked for a motion to adjourn the meeting. Dr. Anderson made the motion to adjourn, which was seconded by Dr. Onukwugha.

Adjourned at 3:38 PM