

**PRESCRIPTION DRUG AFFORDABILITY BOARD**  
**VIRTUAL MEETING**  
**Monday, July 26, 2021**  
**Minutes**

Chair Van Mitchell called the meeting to order at 2:01 p.m.

**Board Members present:** Van Mitchell, Joseph Levy, PhD, Eberechukwu Onukwugha, MS, PhD, Gerard Anderson, PhD, and George Malouf, MD.

**AGENDA ITEM 1.**

**Approval of minutes**

Chair Mitchell asked for a motion that the May 24, 2021, minutes be approved as submitted. Dr. Anderson made a motion to approve the minutes, which was seconded by Dr. Onukwugha and unanimously approved.

**AGENDA ITEM 2.**

**Approval of minutes**

Chair Mitchell asked for a motion that the June 8, 2021, minutes be approved as submitted. Dr. Anderson made a motion to approve the minutes, which was seconded by Dr. Onukwugha and unanimously approved.

**AGENDA ITEM 3.**

**Update on Board Composition**

Andrew York introduced the Board's newest member, Dr. Renee Bovellev. Dr. Bovellev replaces Dr. Malouf following his decision to step away from the Board. Dr. Bovellev also addressed the Board to introduce herself and stated that she was looking forward to working with the other Board members.

**No Action Needed**

**AGENDA ITEM 4.**

**Policy Review, Presentation, and Discussion**

Next, the Board received a presentation from the Maryland Tech Council's Martin Rosendale and MIT's Mark Trusheim about Maryland's life sciences industry and novel payment models. Mr. Rosendale explained that the MD Tech Council represents about 500 corporate members who work in the life sciences and biotechnology sectors. Mr. Rosendale then introduced Mr. Trusheim to review various novel payment models.

Mr. Trusheim began by introducing his work with MIT NEWDIGS and FoCUS. FoCUS is involved in developing durable therapies that are accessible, innovative, and affordable. This includes creating precision financing solutions for these therapies. Next, Mr. Trusheim noted that the emerging durable therapy pipeline is plagued by three issues: very high up-front costs,

performance risks regarding both effectiveness and durability, and the possibility of encountering one of the diseases that requires these durable therapies for smaller payers.

Next, Mr. Trusheim walked through the following five precision financing models to address these challenges:

- Short-term Milestone-based Contracts – Effectiveness is measured in the short-term, and if the therapy doesn't work then the payor doesn't pay or receives some discount.
- Multi-year Performance-based Annuities – Similar to short-term milestone-based contracts but measured over a term of years. The annuities can be set up as rebates or as prospective payments where, at annual anniversaries, a decision is made as to whether a patient or patient population has met some pre-determined clinical milestone. If so, the payment is released, or a rebate is delivered. This is utilized by other countries and will be tested in the U.S. in 2022.
- Orphan Reinsurer and Benefit Manager (ORBM) and Risk Pools – A pooling approach where members can pay a per-member, per-month fee to receive access to a list of certain therapies/therapy coverage. Provides stability, budget-able number, and potentially savings.
- Subscription Model – Often referred to as the “Netflix Model,” the payer pays a fixed amount each year and receives unlimited drug supply. This approach, which has been tried in a couple of states, is meant to increase access for patients, and align public health, payer, and manufacturer incentives.
- Warranty Model – A relatively newer approach to financing, this approach requires the payer to pay upfront, but provides a direct rebate back to the payer and/or pays for alternative/replacement therapies in the event of therapy failure.

Mr. Trusheim also noted that most of these novel approaches are just beginning to be rolled out and are still being updated. He also noted concerns and limitations related to patient mobility and data collection, risk sharing, as well as legal/regulatory hurdles like Medicaid drug price reporting, anti-kickback laws, and FDA guidelines for clinical tests. Still, Mr. Trusheim explained that these issues are solvable, and stakeholders continue to address these problems as they arise.

**No Action Needed**

## **AGENDA ITEM 5.**

### **Administrative Updates**

Mr. York next addressed the Board regarding staffing and administrative updates. Mr. York noted that Kris Vallecillo will be transferring to a permanent PIN position, PDAB staff plan to convert the pharmacist PIN to an economist position, and the next hire will be an Assistant Attorney General followed by an administrative assistant.

Next, Mr. York provided an update to the analytics contracts approved during the June Meeting, noting that PDAB staff has entered into the contracts and is meeting with the group weekly to discuss the work that will end up in the Board's December 2021 report.

**No Action Needed**

**AGENDA ITEM 6.**

**End of FY 2021 - Report**

Mr. York informed the Board that for FY21, the Board spent slightly more than \$206,000 of its FY21 budget of slightly more than \$748,000. Mr. York informed the Board that PDAB staff has learned that it's preferred to receive an amended appropriation for FY22 than to encumber the FY21 funds into FY22.

For FY22, the Board has been appropriated slightly more than \$763,639. Mr. York noted that the Board has also been allocated an appropriation code, an important achievement which will allow the Board to create its own budget.

**No Action Needed**

**AGENDA ITEM 7.**

**Prescription Drug Affordability Fund - Update**

Mr. Vallecillo provided the Board with an update on the Prescription Drug Affordability Fund. Mr. Vallecillo explained that, following the May Board Meeting, the Board authorized the PDAB staff to submit the proposed regulations for publication. The proposed regulations were published in the July 2 Issue of the Maryland Register. Mr. Vallecillo provided an overview of the procedural process for the proposed regulations, including the AELR committee and DSD review, the 45-day window, and 30-day comment period. Mr. Vallecillo explained that the earliest the Board could vote to adopt the regulations would be August 17, 2021. PDAB staff informed the public that a meeting would be held at 9:00am on August 17 to vote on whether to advance the proposed regulations for final notice and publication. If approved during that meeting, Mr. Vallecillo explained that the regulations would then be published in the August 27 Issue of the Register.

**No Action Needed**

**AGENDA ITEM 8.**

**Memoranda of Understanding - Update**

Mr. York provided the Board with an update on the possible MOUs the Board may enter with the Maryland Health Care Commission and the Maryland Health Benefit Exchange. As the PDAB staff intends to remain lean, the Board will need to partner with peer agencies to perform support services. Currently, the Board works closely with MHCC to augment its own staff for certain services such as HR, Accounting, Budget, Procurement, and IT. Mr. York explained that PDAB staff is pursuing an MOU with MHCC to continue these services until FY23, when the Board will have independent access and control over its own budget.

Mr. York noted that the PDAB will still need these support services, and explained that the Board would begin working with MHBE pending the approval of an MOU with that agency. The MOU would begin partly in FY22 for accounting services, and more comprehensively in FY23 for HR, Budget, Accounting, IT, and communications services.

**No Action Needed**

**AGENDA ITEM 9.**

**Opportunity for Public Comment**

No person or group reached out to PDAB staff to register for an opportunity to provide public comment.

**No Action Needed**

**AGENDA ITEM 10.**

**Chair's Update**

The Chair began his update by thanking Trevor Coe, an AAG from the Maryland Health Benefit Exchange, for his time and work supporting the PDAB over the previous months. The Chair then highlighted the progress that has been made over the previous several weeks for PDAB staff, and how this administrative work allows the Board to pursue its statutory mandate and legislative purpose. He also formally welcomed Dr. Bovellet to the Board.

Finally, the Chair noted the dates for two upcoming meetings: the August 17 meeting to vote on proposed regulations, and the September 27 regularly scheduled meeting.

**No Action Needed**

**Adjourned** at 3:14 p.m.