

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING

Monday, July, 27 2026 at 9:00 AM

Virtual Meeting

AGENDA ITEM 1

Call Meeting to Order

Chair Van Mitchell called the meeting to order at 9:01 am

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Stephen Rockower, MD, Julia F. Slejko, PhD.

AGENDA ITEM 2

Approve Meeting Minutes

- a. May 18, 2026
- b. June 30, 2026

Chair Mitchell requested a motion to approve the May 18, 2026 and June 30, 2026 meeting minutes. Dr. Rockower made the motion and Dr. Anderson seconded. The Board voted unanimously to approve the motion.

ACTION: Adopt May 18, 2026 and June 30, 2026 Meeting Minutes- APPROVED

AGENDA ITEM 3

Opportunity for Public Comment

The PDAB received five written comments. These comments were shared with the Board and posted to the website. There was one request for oral public comment:

- 1. Derek Flowers, Value of Care Coalition, Agenda items IV, V and VII

AGENDA ITEM 4

Consideration of Proposed Revisions to COMAR 14.01.04 Cost Review Study Process

Executive Director Andrew York provided a presentation on proposed revisions to COMAR 14.01.04 Cost Review Study Process. Dr. York explained the extensive process and drafts provided in revising COMAR 14.01.04. Dr. York reviewed overarching comment themes with the Board and key changes based on comments and staff suggestions. Dr. York clarified that the public reporting of drug affordability issues has been moved to 14.01.04.06- Reporting of Drug Affordability Issues, a new proposed chapter in COMAR 14.01.04 and was not removed. 14.01.04.01 now provides- Circumstances Under Which Use of a Drug May Create an Affordability Challenge.

The presentation is posted on the Board page of the website as well as the supporting documents. Dr. York explained that staff requests board approval of the proposed revisions to COMAR 14.01.04, as drafted, and authorize the staff to submit this information for review and publication in accordance with the Administrative Procedures Act.

Chair Mitchell then proceeded to allow the Board the opportunity to discuss. Dr. Slejko had some questions around the catch-all provisions and the Board had a discussion around that theme. No changes were made.

Dr. Anderson then proceeded to suggest six specific revisions by page number. Discussion took place on those proposed changes. Three of the six proposed changes moved forward as amendments.

Per request of the Chair, this agenda item was delayed while Counsel drafted the motion for the proposed changes.

AGENDA ITEM 5

Consideration of Proposed Revisions to COMAR 14.01.01.05 General Provisions- Public Comment Procedures

Dr. York explained a revision to COMAR 14.01.01.05- General Provisions- Public Comment Procedures. That revision allows for a comment period of at least 15 days when the Board requests comment by posting notice on its website. Executive Director York also noted a scrivener's error that needs correcting. The supporting document is posted on the Board page of the website.

Dr. York explained that staff would like the Board to consider proposed revisions to COMAR 14.01.01.05 as drafted and to authorize staff to submit this for review and publication in accordance with the Administrative Procedure Act.

Chair Mitchell asked for a motion which was made by Dr. Anderson. Dr. Rockower seconded the motion. The Board has no comments for discussion. The Board unanimously approved the motion, 4-0.

ACTION: Adopt Proposed Revisions to COMAR 14.01.01.05 as drafted and to authorize staff to submit this for review and publication in accordance with the Administrative Procedure Act- APPROVED

AGENDA ITEM 6

Dupixent- Staff Update on Dossier

Dr. York provided a verbal update that the draft Duxpient dossier will be posted for a 15 day public comment period. The final dossier will then be posted for a subsequent Board meeting. The Board is continuing to finalize the rest of the Cost Review Studies by the end of this year.

AGENDA ITEM 7

Proposed COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits- Staff Update on Comments Received Following Maryland Register Posting

Dr. York explained that COMAR 14.01.06- Implementation and Monitoring of Upper Payment Limits was posted in the DSD register and staff received and reviewed the comments from the 30 day public comment period. These comments were shared with the Board. Comments on COMAR 14.01.07.01 Upper Payment Limit- Jardiance and 14.01.07.02 Upper Payment Limit- Ozempic were also posted in the DSD register and comments on those regulations are due July 27, 2026.

AGENDA ITEM 8

Administrative Update

- Dr. York thanked everyone for their comments and communications regarding the recent decision of the United States District Court for the District of Columbia. In that decision, which was issued July 1, 2026, the district court granted Amgen's request for a preliminary injunction finding that the "price cap" established by the Colorado PDAB was preempted by federal patent law. The Maryland PDAB is watching developments in Colorado, and throughout the country, closely. Please be reminded, however, that a decision of the federal district court in Colorado is not binding precedent here in Maryland.
- Dr. York explained the budget closeout process for the PDAB.
- The PDAB completed its first audit and staff were appreciative of OLA's feedback and guidance. The report will be available in due time.
- There are no current updates on the office lease.
- PDAB is excited to work with the new MHBE Director, Johanna Fabian-Marks.
- The next PDASC meeting will be on August 24, 2026 at 2:00 PM.
- The PDAB will have a new website by DoIT on a different platform updated to improve the user interface. The new PDAB website should be available next month.
- Chair Mitchell requested that Dr. York provided a high level budget update at the next PDAB meeting.

AGENDA ITEM 4 - CONTINUED- OUT OF ORDER

The Chair exercised his prerogative to finalize agenda item 4, out of order. Dr. Anderson made a motion for COMAR 14.01.04- Cost Review Study Process, to amend draft proposed changes to read as follows:

COMAR 14.01.04.02D

(1) Aggregated Spending and Pricing Data:

(b) The 100 prescription drug products, with the highest total gross spending per patient in the most recent available calendar year *by prescription drug product, with a breakdown by NDC;*

(c) The 100 prescription drug products, with the highest percent change increase in WAC over the most recent available calendar year *by prescription drug product, with a breakdown by NDC;*

(2) Patient Out-of-Pocket Costs:

(a) The 100 prescription drug products, with the highest total patient out-of-pocket costs in the most recent available calendar year *by prescription drug product, with a breakdown by NDC; and*

(b) The 100 prescription drug products, with the highest average patient total out-of-pocket costs in the most recent available calendar year *by prescription drug product, with a breakdown by NDC;*

and finally,

COMAR 14.01.04.03B

(1) FDA Approval:

(b) If applicable, the date of the *initial primary patent and* last patent expired or will expire.

Assistant AAG clarified the language “breakdown” in the amendments.

Dr. Rockower seconded the motion. The Board had the opportunity to discuss the motion, but no discussion took place.

The Board unanimously voted to approve the motion, 4-0.

ACTION: Adopt Proposed Revisions to COMAR 14.01.04, with additional amendments and to authorize staff to submit this for review and publication in accordance with the Administrative Procedure Act- APPROVED

AGENDA ITEM 9

Chair's Update

- Dr. York presented a proclamation to express the PDAB's gratitude to Board Chair Van Mitchell for his service to the Maryland PDAB for the past six years.
- Chair Mitchell provided some final words of gratitude to the Board and Staff.

AGENDA ITEM 10

Adjournment

Chair Mitchell entertained a motion to adjourn the meeting. Dr Anderson made the motion, which Dr. Rockower seconded.

Adjourned at 10:19 a.m.