PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING
Monday, April 13, 2026
Virtual Meeting
Minutes

AGENDA ITEM 1

Call the Meeting to Order
Chair Van Mitchell called the meeting to order at 9:05 a.m.

Board Members present: Van Mitchell, Stephen Rockower, M.D., Georges C. Benjamin, MD, MACP, Julia F. Slejko, PhD., Gerard Anderson, PhD

AGENDA ITEM 2

Approve March 23, 2026 Meeting Minutes
Chair Van Mitchell stated that the approval of the March meeting minutes will be postponed until the regular May 18, 2026 PDAB meeting.

AGENDA ITEM 3

Opportunity for Public Comment
Four entities submitted written comments that have been provided to the Board and posted to the website. Three people registered to provide oral public comment:

1. Derek Flowers; Value of Care Coalition; Agenda Items 5, 6, and 7
2. Josh Spagnola; AstraZeneca; Agenda Item 6
3. Terry Wilcox; Patients Rising; Agenda Item 5

AGENDA ITEM 4

Updates to Cost Review Study Process and Policy Review Process (Staff Briefing)
Executive Director Andrew York presented a brief overview on the progress to the Cost Review Study Process and Policy Review.

AGENDA ITEM 5

Consideration of Proposed COMAR 14.01.06 - Implementation and Monitoring of Upper Payment Limits
Dr. York presented an overview of draft regulations COMAR 14.01.06 in a presentation entitled "Consideration of Proposed COMAR 14.01.06- Implementation and Monitoring of Upper Payment Limits." Dr. York reviewed the previous and current actions on the proposed regulations, the comments received on the posted draft regulations, staff responses, and recommended updates and revisions. The Board had the opportunity to ask questions and discuss. This presentation and the supporting documents, including the draft regulations, are posted on the Board page of the website.
Chair Mitchell asked for a motion to approve COMAR 14.01.06 as drafted and to authorize staff to submit the regulations for review and publication in accordance with the Administrative Procedure Act. Dr. Rockower made the motion, which was seconded by Dr. Anderson. Chair

Mitchell called for discussion on the motion; no discussion took place. Chair Mitchell called for a vote and the Board voted unanimously to approve COMAR 14.01.06 as drafted.

ACTION: Approve COMAR 14.01.06 as drafted and authorize staff to submit the regulations for review and publication in accordance with the Administrative Procedure Act; APPROVED.

AGENDA ITEM 6

Farxiga - Consideration of Final Cost Review Study Report, Policy Review, and UPL

a. Final Cost Review Study Report

Dr. Slejko recused herself from consideration of Farxiga.

Dr. York, using a presentation, gave an overview of the actions taken as a part of the Cost Review Study Process for Farxiga to date. For Farxiga, the Board was tasked with reviewing public comments, discussing the revised draft cost review study report, move, deliberate and vote on a final affordability challenge determination, and vote to approve the final cost review study report.

Dr. York reviewed the comments received on the draft cost review study report and staff's recommendations regarding those comments. One comment addressed certain market changes including a reduction in WAC and expiration of the primary patent which could allow generics to come to market. Dr. York explained that the affordability determination concerns whether use of a drug has or will create an affordability challenge; based on the data available at the time the Board made the preliminary determination that use of the drug *has* created an affordability challenge. Dr. Benjamin underscored the importance of keeping a historical record of the Board's thinking based on the data available when a determination is made, noting that historical findings do not change based on new data or information. This presentation and supporting documents are posted on the Board page of the website.

Chair Mitchell asked for a motion to adopt as final the determination that the use of Farxiga has created an affordability challenge to the State Health Care System under the three identified circumstances. Dr. Anderson made the motion and Dr. Rockower seconded. The Board voted 4-0 (Dr. Slejko, recused) to adopt the determination as final.

ACTION: Adopt as final that the determination that the use of Farxiga has created an affordability challenge to the State Health Care System under the three identified circumstances; APPROVED.

Staff will update the cost review study report to reflect the deliberations including that the report is a record in time and the historical findings do not change based on new information. Dr. York explained the various revisions and read into the record additional language for inclusion in the final cost review study report.

Chair Mitchell asked for a motion to adopt as final the cost review study report with the identified revisions and updates. Dr. Anderson made the motion and Dr. Rockower seconded the motion. The Board voted 4-0 (Dr. Slejko, recused) to approve the motion to adopt the final cost review study report.

ACTION: Adopt as final the cost review study report for Farxiga with identified revisions and updates; APPROVED.

b. Non-UPL Policies
Agenda items 6b and 6c were combined for discussion.

c. UPL Rules - COMAR 14.01.07.01
Chair Van Mitchell observed that several generics for Farxiga have come online. Noting that although the Board has ample information to move forward, Chair Mitchell suggested that it might be prudent for the Board to pause and let the marketplace work. Dr. Rochower noted that the manufacturers continue to make money even with the presence of generics. Dr. Anderson noted that the generic approvals announced by the FDA, as mentioned in the comment letter, did not necessarily guarantee that all those generics would come to market in a timely manner, noting the multi-year delay in bringing biosimilars to the U.S. market for Humira. Dr. Anderson also noted that some percentage of patients will always continue to use the name brand drug, Farxiga, and there is still an opportunity to protect those patients through policies, such as upper payment limits. Based on these observations, Dr. Anderson expressed an interest in continuing with the process to consider UPL and Non-UPL policies for Farxiga. Dr. Benjamin noted that a UPL is a ceiling, not a floor. Although generic drugs decrease costs for patients on the generic drug, it is unclear how the entry of generic drugs will impact the price and cost of the name brand drug. Dr. Benjamin saw no reason for delay unless it was for staff to address a specific question or concern. Dr. Benjamin expressed an interest in moving forward with upper payment limits. Dr. York reiterated staff's concerns that FDA approval of generics does not guarantee that the generics will enter the market; however, the information provided and status of the approvals seemed to indicate that there would be substantial generic competition in the near future. Dr. York noted that it was appropriate for the Board to consider the information related to the upcoming entry of generics in the context of evaluating policy solutions to the affordability challenges identified by the Board. Dr. York highlighted Dr. Anderson's observation that there is a group of patients that will always be on the name brand Farxiga, who could be protected by an upper payment limit. Chair Mitchell reiterated that the Board's current charge is to focus on state and local governments, which is a subset of the overall market.

Dr. Anderson made a motion to continue reviewing the UPL and Non-UPL policies for Farxiga. No Board member seconded that motion and the motion died.

Dr. Rockower suggested bringing Farxiga back for consideration in six months to review the data changes resulting from generic competition. Dr. Benjamin agreed. Dr. Anderson expressed concern that there would be no new data available to make a decision by November. Dr.York

suggested that by December information would be available about whether the formulary covered the brand or generic drug. Chair Mitchell mentioned that a motion could be made to defer Farxiga to the November 2026 meeting,; and staff could provide an update on the market status of Farxiga generics. Dr. Benjamin and Dr. Anderson commented on the data that might be available at that time.

No Board member moved to defer Board action.

Lacking a main motion and second, the Board concluded its consideration of the agenda items concerning the Non-UPL and UPL Policies for Farxiga, taking no action.

AGENDA ITEM 7

Jardiance - Consideration of Final Cost Review Study Report, Policy Review, and UPL
a. Final Cost Review Study Report

Dr. York, using a presentation, gave an overview of the actions taken as a part of the Cost Review Study Process for Jardiance to date. For Jardiance, the Board is tasked with reviewing public comments, discussing the revised draft cost review study report,move, deliberate and vote on a final affordability challenge determination, and vote for the final cost review study report. Dr. York reviewed the comments that were received on the draft cost review study report and staff's recommendations regarding those comments. This presentation and supporting documents are posted on the Board page of the website.

After the presentation, Chair Mitchell entertained a motion to adopt as final the determination that the use of Jardiance has created an affordability care system under the three identified circumstances. Dr. Rockower made the motion which Dr. Benjamin seconded. The Board voted unanimously to approve the motion.

ACTION: Adopt as final the determination that the use of Jardiance has created an affordability Care System under the three identified circumstances; APPROVED.

Executive Director York asked whether the Board had additional deliberations responsive to the comments to add the final report. Dr. Slejko appreciated the observation that the report is a historical document reflecting the data available and considered to that point. However, in future reports, Dr. Slejko would like to include updated data on market dynamics and market competition. Dr. York explained that the patent expiration information is included in the dossier but the expiration of a patent does not mean that the generics have actually come to market. Executive Director York explained the various revisions and read into the record additional language for inclusion in the final cost review study report.

Chair Mitchell then asked for a motion to adopt as final the cost review study report with the identified revisions and updates. Dr. Rockower made the motion and Dr. Benjamin seconded the motion. The Board voted unanimously to approve the motion.

ACTION: Adopt as final the cost review study report for Jardiance with identified revisions and updates; APPROVED

b. Non-UPL Policies

Dr. York presented an overview of the Non-UPL policy recommendations for the Board's consideration including: WAC inflation penalty, patient navigator program, and delinking PBM compensation from WAC increases. This presentation and supporting documents are posted on the Board page of the website. Dr. Benjamin shared his experience with the Department of Health's prior efforts to address affordability in rural communities, including certain navigator and patient assistance programs. He observed multiple challenges including how to make such programs sustainable, the use of patient assistance programs by manufacturers to promote certain drugs, and the significant burden of substantial paperwork associated with the programs. He noted a collaboration between the hospital system and the health departments in western Maryland. Chair Mitchell noted the low cost and effectiveness of Kentucky's program and the possibility of duplicating this model. Dr. Slejko noted the patient navigator program addresses patient out-of-pocket costs. Dr. Slejko discussed the report submitted by EACH/PIC noting the way financial assistance programs interact with other programs or requirements. Dr. Anderson also noted that the broad sweep of information collected by manufacturers in order to qualify for certain patient assistance programs.

Chair Mitchell entertained a motion to adopt, as a slate, the proposed Non-UPL policies for Jardiance. Dr. Rockower made the motion which Dr. Anderson seconded. The Board unanimously voted to approve the motion.

ACTION: Adopt Slate of Proposed Non-UPL Policies for Jardiance; APPROVED

c. Proposed UPL Rules - COMAR 14.01.07.02

Chair Mitchell clarified that COMAR 14.01.07.02 is now COMAR 14.01.07.01 given that the Board did not propose an upper payment limit for Farxiga.

Using a presentation, Dr. York walked the Board through the consideration of an upper payment limit for Jardiance. Dr. York explained the UPL chronology, as well as the UPL decision structure. Dr. York reviewed the public comments received on the draft UPL regulation, COMAR 14.01.07.02, and staff's recommendations regarding those comments. Dr. York walked the Board through guiding principals and criteria for the Board to consider when deciding to set an upper payment limits (slides 10-24). This presentation and supporting documents are posted on the Board page of the website.

Chair Mitchell entertained a motion to establish an Upper Payment Limit for Jardiance by adopting COMAR 14.01.07.01 as drafted and authorizing staff to submit the regulation for review and publication in accordance with the Administrative Procedure Act. Dr. Benjamin made the motion which Dr. Rockower seconded. Dr. Rochower observed that Jardiance would be

going off patent in the near future which may prompt revisiting the issue. Dr. Slejko inquired about the time period over which the estimated savings would be achieved. Dr. York explained that the ballpark estimate was per year for eligible state and local government entities. The Board voted to approve the motion 4-0 (Dr. Anderson, absent).

ACTION: Establish an Upper Payment Limit for Jardiance by adopting COMAR 14.01.07.01 as drafted and authorizing staff to submit the regulation for review and publication in accordance with the Administrative Procedure Act; APPROVED

AGENDA ITEM 8

Administrative Update

No administrative update was presented.

AGENDA ITEM 9

Chair's Update

- Chair Mitchell advised that the Board had granted the Maryland Hospital Association an extension to submit the data requested for the 340B report, which is due to the General Assembly on July 1, 2026..
- The next PDAB meeting is scheduled for May 18, 2026. It is undetermined if it will be in person or virtual.

AGENDA ITEM 10

Adjournment

Chair Mitchell adjourned the meeting.

Adjourned at 11:11 a.m.