

PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING

Monday, July 28, 2025

**Miller Senate Building, William Amoss Room, 4th Floor
11 Bladen Street, Annapolis, MD 21401
and Livestreamed Via Zoom**

MEETING MINUTES

AGENDA ITEM 1

Call the Meeting to Order

Chair Van Mitchell called the meeting to order at 2:01 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 Minutes

a. May 19, 2025 Meeting Minutes

Chair Mitchell asked for a motion to approve the May 19, 2025 meeting minutes. Dr. Anderson made the motion, which Dr. Rockower seconded, and the Board unanimously approved the minutes.

b. May 19, 2025 Closed Meeting Minutes

Chair Mitchell asked for a motion to approve the May 19, 2025 closed session meeting minutes. Dr. Anderson made the motion, which Dr. Rockower seconded, and the Board unanimously approved the minutes.

c. June 23, 2025 Meeting Minutes

Chair Mitchell asked for a motion to approve the June 23, 2025 meeting minutes. Dr. Anderson made the motion, which Dr. Rockower seconded, and the Board unanimously approved the minutes.

Action: All Minutes APPROVED.

AGENDA ITEM 3

Opportunity for Public Comment

The PDAB received four written comments, which were shared with the Board and posted to the website. Due to the global Microsoft disruption PDAB staff was not able to post the written comments to the Board's website prior to the meeting.

Three persons registered to provide oral public comment and the Board heard from:

1. Derek Flowers

Value of Care Coalition, Agenda Item 4: Cost Review Study Process

2. Dr. Harry Gewanter

Let My Doctors Decide, Agenda Item 4: Cost Review Study Process

3. George Huntley

Patient and Diabetes Patient Advocacy Coalition, Agenda Items 4 and 5: Farxiga and Jardiance Cost Review Studies

AGENDA ITEM 4

Staff Presentation

Overview of Cost Review Study Process and Policy Review Process

Executive Director York presented an overview of the cost review study process and the policy review process and provided an update concerning Farxiga and Jardiance. Executive Director York reviewed the procedures for making a preliminary determination and the actions following a preliminary determination. The Board had the opportunity to ask questions and provide feedback. This presentation is posted on the Board page of the website.

AGENDA ITEM 5

Farxiga - Cost Review Study

a. Staff Presentation of Dossier

Executive Director York provided a presentation on the Farxiga- Cost Review Study that tracked the data elements in the Farxiga Dossier and included summaries of public comments received concerning the draft dossier. The presentation included the factors that the Board can consider in making a preliminary determination. Confidential, trade secret and proprietary information will be discussed in closed session. The Board members made observations about the data contained in the lengthy Dossier, including the significant work that went into its development. The Board members asked questions about specific slides including slides 39, 52 (factor 7.5), and 47, and discussed the dossier content and certain inclusion criteria.

This presentation is posted on the Board’s website as meeting materials for July 28, 2025.

b. Closed Session-

Chair Mitchell asked for a motion to close the session to consider and discuss confidential, trade secret and proprietary information, under GP § 3-305(b)(13) and HG 21-2c-03(e)(1)(iv); and to consult with counsel and receive legal advice regarding the cost review study, under GP § 3-305(b)(7) in closed session.

Dr. Rockower moved to close the session and Dr. Anderson seconded the motion. All Board members voted to close the session; no member opposed the motion. The vote to close the session was taken at 3:09 p.m. The closed session commenced at 3:15 p.m. via a private conference room located nearby.

SUMMARY OF CLOSED SESSION

Pursuant to General Provisions, § 3-305(b)(13) and § 3-305(b)(7), Annotated Code of Maryland, on July 28, 2025 at 3:15 p.m. the Board met in closed session to receive advice of counsel regarding the mechanics and procedures for performing the cost review study, and to discuss proprietary, trade secret and confidential information concerning Farxiga.

Van Mitchell, Dr. Onukwugha, Dr. Anderson, Dr. Rockower, Dr. Levy, Assistant Attorney General McDonald (counsel), Dr. York (Executive Director), and Zeid El-Kilani (regulatory economist) attended the closed session.

AAG McDonald provided the Board with legal advice regarding the mechanics and procedures for performing the cost review study.

The Board reviewed and discussed certain proprietary, trade secret and confidential information concerning Farxiga.

Dr. Anderson moved that the Board make a preliminary determination that Farxiga has created an affordability challenge to the State healthcare system and identified as a circumstance: the percentage change in WAC over time is substantially larger than the percentage change in inflation. Dr. Rochower seconded the motion. The Board unanimously passed the motion.

Dr. Levy moved that the Board make a preliminary determination that Farxiga has created an affordability challenge to the State healthcare system and identified as a circumstance: at the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors. Dr. Rochower seconded the motion. The Board unanimously passed the motion.

Chair Mitchell asked for a motion to adjourn the closed session. Dr. Onukwugha moved to adjourn and Dr. Anderson seconded the motion. The Board unanimously approved adjourning the closed session and returning to the open session.

c. Preliminary Determination

At 4:39 p.m., the open session resumed. The Chair explained that the Board would have a discussion regarding actions taken in the closed session and a public discussion.

Dr. Anderson stated the Board had observed that the WAC price had increased substantially faster than overall inflation.

To clarify the current posture, AAG McDonald explained that during the closed session the Board considered confidential, trade secret and proprietary information, and after discussion and deliberation, made a preliminary determination that use of Farxiga created an affordability challenge finding two circumstances. One of the circumstances was just stated by Dr. Anderson.

AAG McDonald further explained that the Board would ratify the preliminary determination and the identified circumstances that utilized proprietary data in open session by Board resolution.

Referencing the closed session, Dr. Levy identified one circumstance under which use of Farxiga had created an affordability challenge as: at the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors.

The Chair noted that those two circumstances be included in the Board resolution.

Dr. Anderson noted another circumstance under which Farxiga has created an affordability challenge—that the total spending for state and local government employees for Farxiga is greater than 1%, representing a significant portion of drug spending. The public data presented in the cost review dossier presentation underpins this circumstance.

The Board members engaged in an extended discussion of the drug, its comparative effectiveness, that a single product represented so much of the drug spend, the limited utilization of Farxiga among Medicaid patients in the public data, additional data that could be useful, other more expansive definitions of out-of-pocket costs and how such data could be used, how the effectiveness of the drug informs the use of pricing comparison to therapeutic alternatives, the prevalence of diabetes in Maryland (the need), coinsurance and suggested further work on benefit design.

AAG McDonald asked for clarification from Dr. Anderson concerning the third circumstance identified in the open session.

While AAG McDonald was drafting the resolution, the Chair asked Executive Director York to provide the administrative update.

Administrative Update (AGENDA ITEM 7 - taken out of order)

At the Chair's request, Agenda Item 7 was heard while AAG McDonald prepared the Board resolution. Executive Director York provided the following updates:

- The PDAB is continuing to work on the next two dossiers for Ozempic and Trulicity.
- The next PDASC meeting is on August 25, 2025.
- The PDAB currently has two open staff positions. The State entered a hiring freeze on July 1, 2025.
- The PDAB budget closeout was successful and the PDAB was under budget for FY25.
- The PDAB sent FY 24 and FY 25 unpaid fee assessment invoices to collections.

Board Resolution 2021-01

AAG McDonald read the draft Board Resolution 2025-01 into the record.

Chair Mitchell moved that the resolution be adopted; Dr. Rockower seconded the motion. The Chair called for a roll call vote: Anderson - agree (aye); Levy - agree (aye) ; Onukwugha - agree (aye); Rockower - agree (aye); Mitchell - affirmative (aye). Motion passed and resolution adopted.

Action: Board Resolution 2025-01 adopted.

AGENDA ITEM 6

Jardiance - Cost Review Study

a. Staff Presentation on Dossier

Executive Director York provided a presentation on the Jardiance- Cost Review Study that tracked the data elements in the Farxiga Dossier and included summaries of public comments received concerning the draft dossier. The presentation included the factors that the Board can consider in making a preliminary determination. Confidential, trade secret and proprietary information will be discussed in closed session. The Board asked questions and provided feedback.

This presentation is posted on the Board's website as meeting materials for July 28, 2025.

Correction/Amendment to Resolution 2025-01

AAG McDonald identified an issue with Board Resolution 2025-01 and requested further clarification. After discussion, Chair Mitchell moved that the Resolution on page two, third circumstances be corrected/amended to read: "total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments (public session)." Dr. Anderson seconded the motion, which the Board unanimously approved.

Board Action: Resolution 2025-01 corrected/amended

Point of Personal Privilege

Delegate Cullison requested a point of personal privilege to address the Board.

b. Closed Session- To Consider and Discuss Confidential, Trade Secret and Proprietary Information, under GP § 3-305(b)(13) and HG 21-2c-03(e)(1)(iv); and to Consult with Counsel and Receive Legal Advice Regarding the Cost Review Study, under GP § 3-305(b)(7).

Chair Mitchell asked for a motion to close the session to consider and discuss confidential, trade secret and proprietary information, under GP § 3-305(b)(13) and HG 21-2c-03(e)(1)(iv); and to consult with counsel and receive legal advice regarding the cost review study, under GP § 3-305(b)(7) in closed session. Dr. Anderson moved to close the session and Dr. Levy seconded the motion. At 5:25 p.m., all Board members voted to close the session; no member opposed the motion. Closed session commenced at 5:30 p.m. via a private conference room located nearby.

SUMMARY OF CLOSED SESSION

Pursuant to General Provisions, § 3-305(b)(13) and § 3-305(b)(7), Annotated Code of Maryland, on July 28, 2025 at 5:30 p.m. the Board met in closed session to receive advice of counsel regarding the mechanics and procedures for performing the cost review study, and to discuss proprietary, trade secret and confidential information concerning Jardiance.

Van Mitchell, Dr. Onukwugha, Dr. Anderson, Dr. Rockower, Dr. Levy, Assistant Attorney General McDonald (counsel), Dr. York (Executive Director), and Zeid El-Kilani (regulatory economist) attended the closed session.

AAG McDonald provided the Board with legal advice regarding the mechanics and procedures for performing the cost review study.

The Board reviewed and discussed certain proprietary, trade secret and confidential information concerning Jardiance.

Dr. Anderson moved that the Board make a preliminary determination that Jardiance has created an affordability challenge to the State healthcare system and identified as a circumstance: the percentage change in WAC over time is substantially larger than the percentage change in inflation. Dr. Rochower seconded the motion. The Board unanimously passed the motion.

Dr. Levy moved that the Board make a preliminary determination that Jardiance has created an affordability challenge to the State healthcare system and identified as a circumstance: at the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors. Dr. Rochower seconded the motion. The Board unanimously passed the motion.

Chair Mitchell asked for a motion to adjourn the closed session. Dr. Onukwugha moved to adjourn and Dr. Anderson seconded the motion. The Board unanimously approved adjourning the closed session and returning to the open session.

c. Preliminary Determination

At 5:52 p.m., the open session resumed.

The Chair explained that during the closed session the Board considered proprietary and confidential information received through the Request for Information process and through licensing and data use agreements. The Board's counsel will work on a Board resolution.

Dr. Levy identified the disproportionate patient OOP cost as a circumstance underpinning the affordability challenge. At the 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors.

AAG McDonald again explained that during the closed session the Board considered confidential, trade secret and proprietary information, and after discussion and deliberation, made a preliminary determination that use of Jardiance created an affordability challenge finding two circumstances. One of the circumstances was just stated by Dr. Levy – at the 90th percentile, patient out-of-pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors.

Noting the confidential WAC data, Dr. Anderson identified as a circumstance the observation that the WAC price increased substantially faster than the rate of inflation.

AAG McDonald stated that in closed session the Board had made a preliminary determination that use of Jardiance had created an affordability challenge noting the two circumstances just cited, and that the counsel would draft a Board resolution ratifying those determinations and circumstances in open session.

The Chair then engaged the Board in discussion concerning public facing data.

Citing the data in factors 41. Through 4.4, Dr. Onukwugha observed that spending on Jardiance represents 1.8% of the overall prescription drug spend for state and local governments, which would create an affordability challenge.

The Board members discussed the effectiveness of the drug, including the comparative effectiveness, and observed that the Board does not want to impede patient access to the drugs. The Board also made some suggestions for consolidating data to facilitate review and identified other data of interest. The Board members referenced copay programs and issues surrounding benefit design.

Board Resolution 2021-02

AAG McDonald read the draft Board Resolution 2025-02 into the record.

Chair Mitchell moved that the resolution be adopted; Dr. Anderson seconded the motion. The Chair called for a roll call vote. Rockower - aye; Onukwugha - aye; Levy - aye; Anderson - aye; Mitchell - affirmative (aye). The motion passed unanimously and the resolution was adopted.

Action: Board Resolution 2025-02 adopted.

AGENDA ITEM 7 (out of turn)

AGENDA ITEM 8

Chair's Update

Chair Mitchell thanked staff, the Board, and the Department of Legislative services staff for their hard work.

AGENDA ITEM 9

Adjournment

Chair Mitchell asked for a motion to adjourn the meeting. Dr. Anderson made the motion and Dr. Onukwugha seconded. The Board unanimously passed the motion.

Adjourned at 6:08 PM.