PRESCRIPTION DRUG AFFORDABILITY BOARD MEETING
Monday, November 17, 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 10:03 a.m.

Board Members present: Van Mitchell, Gerard Anderson, Ph.D., Eberechukwu Onukwugha, MS, Ph.D., Stephen Rockower, M.D.

AGENDA ITEM 2

Approval of minutes
Chair Mitchell asked for a motion to approve the September 29, 2025 meeting minutes as submitted. Dr. Rockower made the motion, which Dr. Onukwugha seconded. The Board unanimously approved the minutes.

Action: Motion Passed; Minutes APPROVED.

AGENDA ITEM 3

Opportunity for Public Comment
Thirteen entities submitted written comments that have been provided to the Board and posted to the website.

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

1. Rev. Melody Hession, Delaware-Maryland Synod of the Evangelical Lutheran Church in America, Agenda Item VIII: Policy Review Process
2. Rev. Ken Phelps Jr., Episcopal diocese of Maryland (Montgomery County, Prince George's County, and Charles County), Agenda Item VIII: Policy Review Process
3. Larry Zarzecki, Public Citizen, Agenda Item VIII: Policy Review Process
4. Denise Gilmore, ASPE Maryland Council 3, Agenda Item VIII: Policy Review Process
5. George Huntley, CEO of Diabetes Patient Advocacy Coalition, Agenda Item III: Opportunity for Public Comment

AGENDA ITEM 4

Staff Presentation
Overview of Cost Review Study Process and Policy Review Process
Executive Director Dr. York presented a verbal overview of the Cost Review Study Process and the Policy Review Process. 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

Ozempic - Cost Review Study

a. Staff Presentation on Dossier

Dr. York presented a powerpoint presentation that tracked the data elements in the Ozempic Dossier and included summaries of the public comments received concerning the draft dossier. The presentation included the factors (organization of data) that the Board may consider in making a preliminary determination. The Board members asked questions, made comments and discussed the data, presentation and Ozempic Dossier. This presentation is posted on the Board's website as meeting materials for November 17, 2025.

b. **Closed Session**

Chair Mitchell asked for a motion to close the meeting 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 § 21-2c-10. Dr. Anderson moved to close the session and Dr. Rockower 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 11:04 a.m. The closed session commenced at 11:10 a.m. via a private conference room located nearby.

Action: Motion passed; Board adjourned to closed session.

SUMMARY OF CLOSED SESSION

Pursuant to General Provisions, § 3-305(b)(13) and Health-General § 21-2c-03(e)(1)(iv) and § 21-2c-10, Annotated Code of Maryland, on November 17, 2025 at 11:10 a.m. the Board met in closed session to discuss proprietary, trade secret and confidential information. Van Mitchell, Dr. Onukwugha, Dr. Anderson, Dr. Rockower, Assistant Attorney General McDonald (Counsel), Dr. York (Executive Director), Zeid El Kilani (Regulatory Economist), Christina Shaklee (Health Policy Analyst), and Chidera Agwu (Health Policy Analyst) attended the closed session. The Board reviewed the closed session minutes for the July 28, 2025 meeting in which confidential, proprietary and trade secret material was considered. The Board unanimously approved the minutes. The Board then reviewed and discussed certain proprietary, trade secret and confidential information concerning Ozempic. The Board voted unanimously to make a preliminary determination that Ozempic has created an affordability challenge to the state healthcare system and high out-of-pocket costs for patients, and the circumstances under which use of the prescription drug product has led to an affordability challenge include: at the 90th percentile patient out-of-pocket cost to state and local government markets is disproportionate to the net cost paid by payors. The Board then adjourned the closed session.

c. Preliminary Determination

At 12:03 p.m., the open session resumed. The Chair explained that the Board would conduct a public discussion and would also ratify the actions taken in closed session. The Board then discussed the Ozempic data.

Dr. Onukwugha made a comment concerning utilization data. She observed that summing the utilization data in the slide for factor 4.1 showed that spending on Ozempic represents 4.87% of the total gross spend for state and local governments. Chair Mitchell asked whether Dr. Onukwugha wanted to add this as a

finding – that is, whether this is a circumstance for finding an affordability challenge and Dr. Onukwugha indicated that it was.

After some procedural discussion with counsel, Chair Mitchell called for a motion to adopt the finding proposed by Dr. Onukwugha that use of Ozempic has created an affordability challenge to the state healthcare system, and the circumstances under which use of the prescription drug product has led to an affordability challenge include total gross spending for Ozempic exceeds 4.87% of gross prescription drug spend for state and local governments.

Dr. Rockower moved the motion, which Dr. Anderson seconded. The Board unanimously passed the motion.

Action: Motion passed; Board makes a preliminary determination that use of Ozempic has created an affordability challenge to the state healthcare system under the following circumstance: total gross spending for Ozempic exceeds 4.87% of gross prescription drug spend for state and local governments.

Chair Mitchell then discussed ratifying, by resolution, the closed session action and the action taken in open session. Assistant Attorney General McDonald read the draft Resolution 2025-03, which read in part:

It is hereby **RESOLVED** that:

The Board makes a preliminary determination that use of Ozempic:

Has created an affordability challenge for the State health care system and an affordability challenge in the form of high out-of-pocket costs to patients; and

That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice.

The circumstances under which the prescription drug product has led to an affordability challenge include:

- At 90th percentile patient out-of-pocket cost to state and local government markets is disproportionate to the net cost paid by payors (closed session); and
- Total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session).

Chair Mitchell asked for a motion to adopt Resolution 2025-03 for Ozempic. Dr. Rockower made the motion which was seconded by Dr. Onukwugha. The Board voted unanimously to approve Resolution 2025-03.

Action: Motion passed; Resolution 2025-03 (Preliminary Determination Cost Review Study of Ozempic) ADOPTED.

AGENDA ITEM 6

Trulicity - Cost Review Study

a. Staff Presentation on Dossier and Staff Recommendation to Amend List of Approved NDCs

Dr. York presented a powerpoint presentation that tracked the data elements in the Trulicity Dossier and included summaries of public comments received concerning the draft dossier. The presentation included the factors (organization of data) that the Board may consider in making a preliminary determination. Executive Director York further advised that the list of approved NDCs also need to be amended to include an additional seven NDCs. This presentation is posted on the Board's website as meeting materials for November 17, 2025.

Chair Mitchell invited the Board to comment on the data and to propose any findings based on public-facing data at this time before going into closed session. Dr. Onukwugha applauded the multiple opportunities for public input but inquired whether the Board should seek input about the process concerning patient engagement where the opportunities for patient engagement are underutilized or undersubscribed.

Dr. Onukwugha observed that the Trulicity utilization data in Tables 7a-7d (Factor 4.1) reflects total gross spending of 2.27% for state and local governments for Trulicity. Dr. Onukwugha proposed that this level of total gross spending (2.27%) for state and local governments reflects an affordability challenge.

Dr. Anderson observed that Table 19 reflects a wide variation in patient out-of-pocket costs. For example, the commercial market ranges from $200 to $4000, state and local governments range from $220 to $280, Medicare ranges from $39 to $1400.

Dr. Onukwugha recommended that the Board make a preliminary determination that use of Trulicity has created an affordability challenge to the state healthcare system, based on the circumstances that total gross spending for Trulicity exceeds 2.27% of gross prescription drug spend for state and local governments.

Chair Mitchell asked for a motion to include Dr. Onukwugha's proposed preliminary determination in the Board's resolution. Dr. Rockower made the motion, which Dr. Onukwugha seconded.

Action: Motion passed; Board to include in its Resolution a preliminary determination that use of Trulicity has created an affordability challenge to the state healthcare system under the following circumstance: total gross spending for Trulicity exceeds 2.27% of gross prescription drug spend for state and local governments.

Chair Mitchell asked for a motion to amend the list of approved NDCs for Trulicity. Dr. Anderson made the motion, which was seconded by Dr. Rockower. The Board unanimously approved the motion.

Action: Motion passed; Amended list of Approved NDCs for Trulicity- APPROVED

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 § 21-2c-10. Dr. Anderson made the motion, which Dr. Onukwugha seconded. Before a vote, counsel noted that there are some additional bases for closing the meeting. Chair Mitchell then added an additional reason to close the

session to his request for a motion: to consult with counsel and receive legal advice regarding the cost review study, under GP § 3-305(b)(7). Dr. Onukwugha moved to close the session and Dr. Rockower 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 12:38 p.m. The closed session commenced at 12:50 p.m. via a private conference room located nearby.

Action: Motion passed; Board adjourned to closed session.

SUMMARY OF CLOSED SESSION

Pursuant to General Provisions, § 3-305(b)(13) and § 3-305(b)(7), and Health-General § 21-2c-03(e)(1)(iv) and § 21-2c-10, Annotated Code of Maryland, on November 17, 2025 at 12:50 p.m. the Board met in closed session to receive advice of counsel regarding certain mechanics and procedures for performing the cost review study, and to discuss proprietary, trade secret and confidential information. Van Mitchell, Dr. Onukwugha, Dr. Anderson, Dr. Rockower, Assistant Attorney General McDonald (counsel), Dr. York (Executive Director), Zeid El Kilani (regulatory economist), Christina Shaklee (health policy analyst), and Chidera Agwu (health policy analyst) attended the closed session. AAG McDonald provided the Board with legal advice regarding the procedures for performing the cost review study. The Board then reviewed and discussed certain proprietary, trade secret and confidential information concerning Trulicity. The Board voted unanimously to make a preliminary determination that Trulicity has created an affordability challenge to the state healthcare system, and the circumstances under which use of the prescription drug product has led to an affordability challenge include: the percentage change in WAC over certain periods is substantially larger than the percentage change in inflation (rate of increase in inflation). The Board then adjourned the closed session.

c. Preliminary Determination

At 1:50 p.m., the open session resumed. Assistant Attorney General McDonald read Resolution 2025-04, ratifying actions taken in the closed and open sessions, and making a preliminary determination. Resolution 2025-04 reads in part:

It is hereby **RESOLVED** that:

The Board makes a preliminary determination that use of Trulicity:

Has created an affordability challenge for the State health care system; and

That the use creating the affordability challenge was consistent with the labeling approved by the FDA or standard medical practice.

The circumstances under which the prescription drug product has led to an affordability challenge include:

- The percentage change in WAC over certain periods is substantially larger than the percentage change in inflation (rate of increase in inflation) (closed session); and
- Total gross spending for Trulicity for state and local governments exceeds 2.27% of gross prescription drug spend for state and local governments (public session).

Chair Mitchell asked for a motion to adopt the Resolution 2025-04. Dr. Anderson made the motion, which was seconded by Dr. Rockower. The Board unanimously approved Resolution 2025-04.

Action: Motion passed; Resolution 2025-04 (Preliminary Determination Cost Review Study of Trulicity) APPROVED.

Amendment to Actions Taken Under Agenda Item 6
Chair Mitchell observed that, based on calculations and methods used when analyzing and discussing Trulicity in closed session, it was apparent that resolution 2025-03 should be amended. Chair Mitchell asked for a motion to amend resolution 2025-03 (Preliminary Determination Cost Review Study of Ozempic) as follows: by striking the 8th and 9th "whereas" paragraphs, striking and rescinding the finding that Ozempic created an affordability challenge based on the following circumstance: at the 90th percentile patient out-of-pocket cost in state and local government markets is disproportionate to the net cost paid by payors. The sole remaining preliminary determination of an affordability challenge is based on the circumstance that total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session). The resolution, as amended, reads in part:

It is hereby **RESOLVED** that:

The circumstances under which the prescription drug product has led to an affordability challenge include:

> Total gross spending for Ozempic for state and local governments exceeds 4.87% of gross prescription drug spend for state and local governments (public session).

Dr. Onukwugha made the motion, which was seconded by Dr. Rockower. The Board unanimously approved Resolution 2025-03 as amended.

Action: Amended Resolution 2025-03 APPROVED.

AGENDA ITEM 7

Lunch Break
The lunch break was combined with the closed session from 12:38 p.m to 1:50 p.m.

AGENDA ITEM 9 - OUT OF ORDER

Administrative Update
The Chair exercised his prerogative to consider the administrative update (Agenda Item 9) out of order.

- Dr. York introduced the new PDAB Health Policy Analyst, Chidera Agwu.
- Dr. Georges Benjamin was appointed to the Prescription Drug Affordability Board as the new Board member replacing Dr. Levy.
- The next Board meeting is on December 8, 2025 at 9:00 a.m.
- The next PDASC meeting will be on December 15, 2025 at 2:00 p.m.

AGENDA ITEM 8

Policy Review Process:
a. Upper Payment Limit Framework- Farxiga (Staff Presentation)

Dr. York presented a powerpoint presentation concerning the criteria for setting UPL and guiding principles, policy review process for establishing a UPL, and potential frameworks.

Dr. York presented an overview of the potential frameworks for setting a UPL for Farxiga. He also presented frameworks recommended by staff including domestic reference pricing under COMAR 14.01.05.06B(5) - Medicare Maximum Fair Price (MFP) and staff-recommended contextual information under COMAR 14.01.05.06C. Dr. York also provided savings estimates. The presentation and framework are posted on the Board page of the website.

Chair Mitchell exercised his prerogative to order the discussion, questions and vote. Chair Mitchell stated that the Board would discuss Farxiga, hear staff's presentation on Jardiance and discuss Jardiance, and then proceed to any vote.

The Board then discussed the UPL frameworks and the staff-recommended framework.

b. Upper Payment Limit Framework- Jardiance (Staff Presentation)
Dr. York presented an overview of the potential frameworks for setting a UPL for Jardiance. He also presented staff's recommended framework of domestic reference pricing under COMAR 14.01.05.06B(5) - Medicare Maximum Fair Price (MFP), and staff-recommended contextual information under COMAR 14.01.05.06C. Dr. York also provided savings estimates.

The presentation and framework are posted on the Board page of the website. The Board then discussed the UPL frameworks and the staff-recommended framework.

Staff Request for Direction from Board
Dr. York asked for direction from the Board regarding whether staff should develop and publish a methodology for the staff-recommended upper payment limit framework of Medicare Maximum Fair Price (MFP), for which there would be public comment, and utilize the staff-recommended contextual information.

Chair Mitchell asked for a motion to direct staff to move forward with the staff-recommended framework (domestic reference pricing under COMAR 14.01.05.06B(5) - Medicare Maximum Fair Price (MFP)) and contextual information for Farxiga. Dr. Anderson made the motion, which Dr. Rockower seconded. The motion passed 3-1. Dr. Anderson, Dr. Rockower, and Dr. Onukwugha voted in favor; Chair Mitchell voted against.

Action: Motion passed; Staff to move forward with the staff-recommended framework and contextual information for Farxiga.

Chair Mitchell asked for a motion to direct staff to move forward with the staff-recommended framework (domestic reference pricing under COMAR 14.01.05.06B(5) - Medicare Maximum Fair Price (MFP)) and contextual information for Jardiance. Dr. Anderson made the motion which Dr. Onukwugha seconded. All Board members approved the motion.

Action: Motion passed; Staff to move forward with the staff-recommended framework and contextual information for Jardiance.

AGENDA ITEM 10

Chair's Update

- Chair Mitchell gave Board members the opportunity to reflect on the meeting.

AGENDA ITEM 11

Adjournment

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

Adjourned at 2:46 p.m.