

Prescription Drug Affordability Board DRAFT Meeting Minutes

Friday, May 23, 2025; 10 am - 1 pm - Virtual Meeting Meeting Recording

Meeting Attendance

Board Members

Dr. Gail Mizner Dr. Justin VandenBerg Dr. Amy Gutierrez Dr. Sami Diab

Absent Ms. Cathy Harshbarger

Board Staff

Lila Cummings Sophie Thomas Kate Davidson Moroj Salih Callie Shelton Sagun Sharma Sara Stultz Rebecca Walker

Agenda

- Call to Order, Roll Call, Board Member and Director Disclosures
- Approval of April 11, 2025 Meeting Minutes
- Board & Director Updates
- Public Comment
- Board Business
 - General Assembly Report Discussion
 - Board Approval of Data Submission Guide (DSG)
 - APCD Data Validation Enbrel Validated Data Addendum
- Break
- Rulemaking Hearing: Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel

Call to Order, Roll Call, Member Updates

Dr. Mizner called the meeting to order at 10:00 am. Four of the five Board members were present; Ms. Harshbarger was absent. No Board members disclosed any stakeholder meetings. Board Director, Sophie Thomas, disclosed that staff met with Colorado Bioscience Association (CBSA), Biotechnology Innovation Organization (BIO), and Centennial State Prosperity.

Approval of April 11, 2025 Meeting Minutes

Dr. VandenBerg moved, and Dr. Gutierrez seconded the motion to approve the April 11, 2025 meeting minutes. The four Board members present at the meeting voted to approve the minutes.

DECISION: April 11, 2025 meeting minutes were approved at 10:02 am.



Board and Director Updates

Ms. Thomas informed the Board about healthcare-related bills that were passed during the most recent Colorado legislative session. These bills will likely be presented in more detail at upcoming Board meetings.

Public Comment

Starting at 10:03 am, the following individuals offered public comment to the Board:

- Harry Gewanter Pediatric Rheumatologist
- Ranier Simons Community Access National Network (CANN)
- Amy Goodman CBSA
- Tiffany Westrich-Robertson Ensuring Access through Collaborative Health (EACH) Coalition and Patient Inclusion Council (PIC)
- Primo Castro BIO
- Scott Burns Johnson & Johnson
- Brett Johnson Amgen

Board Business

General Assembly Report Discussion

At 10:19 am, Ms. Thomas presented a summary of the General Assembly Report that summarizes PDAB's activities in 2024 and provides policy recommendations to the General Assembly from the Board. The Board discussed having a consumer representative on the Board. The Board recommended the legislature consider the pros and cons of adding a consumer representative to the Board, along with defining the expertise and educational qualifications the representative must have to be appointed to the Board. Dr. Gutierrez moved, and Dr. Diab seconded to add this recommendation to the General Assembly Report. DECISION: At 10:49 am, the four Board members present at the meeting voted to add the recommendation that the General Assembly consider the pros and cons of adding a consumer representative to the Board to the General Assembly Report.

Dr. VandenBerg moved, and Dr. Gutierrez seconded to approve the General Assembly Report as amended, pending no additional changes made before submitting to the General Assembly on July 1, 2025.

DECISION: At 10:52 am, the four Board members present at the meeting voted to approve the General Assembly Report as amended, pending no additional changes made before submitting to the General Assembly on July 1, 2025.

Board Approval of Data Submission Guide (DSG)

Staff presented the DSG to the Board that included suggested edits from the Prescription Drug Affordability Advisory Council (PDAAC). The Board suggested adding additional questions to fully gather the scope of patient assistance programs. Dr. VandenBerg moved, and Dr. Gutierrez seconded to approve the DSG as amended and have staff post it on the PDAB's website for public use before the July 11, 2025 rulemaking hearing.

DECISION: At 11:18 am, the four Board members present at the meeting voted to approve the DSG as amended and post it on PDAB's website before the July 11, 2025 rulemaking hearing.



APCD Data Validation - Enbrel Validated Data Addendum

At 11:20 am, staff presented, and the Board deliberated on the addendum to Enbrel's 2023 Affordability Review Summary Report (ARSR) with corrected data. Dr. Diab has a conflict of interest with the drug, thus recused himself from the deliberation and vote. Dr. Gutierrez moved, and Dr. VandenBerg seconded to adopt the updated Enbrel ARSR to include the addendum. DECISION: At 11:32 am, Dr. Mizner, Dr. Gutierrez, and Dr. Vandenberg voted to adopt the addendum to the Enbrel ARSR.

After staff confirmed the continued eligibility of Enbrel for selection of an affordability review, Dr. Gutierrez moved, and Dr. VandenBerg seconded to confirm the Board's findings on February 16, 2024, that Enbrel is unaffordable to Colorado consumers.

DECISION: At 11:33 am, Dr. Mizner, Dr. Gutierrez, and Dr. Vandenberg voted to confirm the Board's findings on February 16, 2024, that Enbrel is unaffordable to Colorado consumers.

Dr. VandenBerg moved, and Dr. Gutierrez seconded to begin rulemaking for Enbrel's upper payment limit (UPL).

DECISION: At 11:34 am, Dr. Mizner, Dr. Gutierrez, and Dr. Vandenberg voted to begin rulemaking for Enbrel's UPL rule.

Break

Dr. Mizner called for a 16-minute break from 11:34 to 11:50 am.

Rulemaking Hearing: Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel

The PDAB was in session for a rulemaking hearing at 11:52 am on PDAB Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel.

Board staff outlined the procedure for the rulemaking hearing. Ms. Thomas, presented the description of the rule, followed by staff-presented data for Enbrel related to ten data benchmarks. The Board deliberated regarding these benchmarks.

At approximately 12:05 pm, Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to convene an executive session to discuss confidential, trade-secret, or proprietary information related to Enbrel's wholesale acquisition cost (WAC) and net price pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S. The motion failed, as not enough Board members were present to vote to convene an executive session.

At approximately 12:23 pm, Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to convene an executive session to discuss confidential, trade-secret, or proprietary information related to Enbrel's wholesale acquisition cost (WAC) and net price pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S. Dr. Diab voted to convene an executive session but did not attend the session due to his conflict of interest with Enbrel. DECISION: At 12:24 pm, the four Board members present at the meeting voted to convene an executive session to discuss confidential, trade-secret, or proprietary information related to Enbrel's wholesale acquisition cost (WAC) and net price.



Executive session adjourned at 12:35 pm. The Board discussed only confidential, trade-secret, or proprietary information related to Enbrel's wholesale acquisition cost (WAC) and net price. The Board conducted no formal business within the session.

At approximately 12:37 pm, Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to convene an executive session to receive legal advice regarding maintaining confidentiality of proprietary information and setting a price range for an upper payment limit, pursuant to section 24-6-402(3)(a)(II), C.R.S. Dr. Diab voted to convene an executive session but did not attend the session due to his conflict of interest with Enbrel.

DECISION: At 12:37 pm, the four Board members present at the meeting voted to convene an executive session to receive legal advice regarding maintaining confidentiality of proprietary information and setting a price range for an upper payment limit.

Executive session adjourned at 12:45 pm. The Board received legal advice regarding maintaining confidentiality of proprietary information and setting a price range for an upper payment limit. The Board conducted no formal business within the session.

Due to time constraints, the Board did not hear witness testimony.

Dr. Gutierrez moved, and Dr. VandenBerg seconded to continue the rulemaking hearing on Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel to July 11, 2025.

DECISION: At 12:56 pm, Dr. Mizner, Dr. Gutierrez, and Dr. Vandenberg voted to continue the rulemaking hearing on Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel to July 11, 2025.

Dr. Mizner adjourned the meeting at 12:57 pm. The next PDAB meeting will be held on Friday, July 11, 2025 at 10 am MT.