

# **Prescription Drug Affordability Board DRAFT Meeting Minutes**

Friday, August 22, 2025; 10 am - 2 pm - Virtual Meeting

Meeting Recording

## **Meeting Attendance**

<b>Board Members</b>	Board Staff
Dr. Gail Mizner	Sophie Thomas
Dr. Justin VandenBerg	Kate Davidson
Dr. Amy Gutierrez	Bryan Fife
Dr. Sami Diab	Moroj Salih
Ms. Cathy Harshbarger	Sagun Sharma
	Callie Shelton
	Sara Stultz
	Rebecca Walker

### Agenda

- Call to Order and Roll Call, Board Member and Director Disclosures
- Approval of July 11, 2025 Meeting Minutes
- Director Updates
- Rulemaking Hearing: Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3:
   Upper Payment Limit for Enbrel
- Break
- Board Business
  - o APCD Data Validation Cosentyx Validated Data Addendum
  - UPL Implementation and Monitoring

# Call to Order, Roll Call, Board Member and Director Disclosures

Dr. Gail Mizner called the meeting to order at 10:06 am. Dr. Mizner, Dr. Amy Gutierrez, and Dr. Justin Vandenberg were present. Dr. Sami Diab joined the meeting at 10:44 am, and Ms. Harshbarger joined the meeting at 12:55 pm.

No Board members disclosed any stakeholder meetings. Board Director, Sophie Thomas, disclosed that staff met with Centennial State Prosperity, Chronic Care Collaborative, Colorado Department of Healthcare Policy and Financing, and Colorado Department of Personnel and Administration.

## **Approval of July 11, 2025 Meeting Minutes**

Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to approve the July 11, 2025 meeting minutes. Dr. Mizner, Dr. Gutierrez, and Dr. VandenBerg voted to approve the minutes. DECISION: July 11, 2025 meeting minutes are approved at 10:08 am.

### **Director Updates**



Ms. Thomas noted that today's meeting agenda may fluctuate in order to let the UPL rulemaking hearing for Enbrel continue beyond the allotted time if needed. Ms. Thomas also announced there will not be a general public comment session at today's meeting. Stakeholders may submit any written comments via <a href="mailto:dora\_ins\_pdab@state.co.us">dora\_ins\_pdab@state.co.us</a>. Additionally, Ms. Thomas noted that the Board is anticipating holding another rulemaking hearing on Enbrel's UPL on October 3, 2025. Finally, Ms. Thomas announced the three open positions on the Prescription Drug Affordability Advisory Council that the Board is currently recruiting for: representatives for labor unions, carriers, and consumer advocates.

# 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 10:10 am on PDAB Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel. Dr. Diab – who joined the meeting at 10:44 am – did not participate in the rulemaking hearing due to a conflict of interest with 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, including reviewing previously presented data, in addition to new data on:

- Age distribution of Enbrel utilizers by payer type,
- Drug shortage list, and
- Retail discount amounts.

At 10:50 am, Dr. VandenBerg moved, and Dr. Gutierrez 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. Vandenberg, Dr. Gutierrez, Dr. Mizner, and Dr. Diab voted to convene an executive session. Dr. Diab did not attend the session due to his conflict of interest with Enbrel.

DECISION: At 10:51 am, the Board convened 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 11:03 am. 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.

Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to convene an executive session to receive legal advice as to whether if MFP should go away, the Board could reconvene to reset the UPL criteria for Enbrel, pursuant to section 24-6-402(3)(a)(II), C.R.S. Dr. Vandenberg, Dr. Gutierrez, Dr. Mizner, and Dr. Diab voted to convene an executive session. Dr. Diab did not attend the session due to his conflict of interest with Enbrel.

DECISION: At 11:19 am, the Board convened an executive session to receive legal advice as to whether if MFP should go away, the Board could reconvene to reset the UPL criteria for Enbrel.



Executive session adjourned at 11:25 am. The Board received legal advice as to whether if MFP should go away, the Board could reconvene to reset the UPL criteria for Enbrel. The Board conducted no formal business within the session.

Dr. VandenBerg moved, and Dr. Gutierrez seconded a motion to convene an executive session to receive legal advice regarding consistency of the use of MFP in UPL decision-making, pursuant to section 24-6-402(3)(a)(II), C.R.S. Dr. Vandenberg, Dr. Gutierrez, Dr. Mizner, and Dr. Diab voted to convene an executive session. Dr. Diab did not attend the session due to his conflict of interest with Enbrel.

DECISION: At 11:27 am, the Board convened an executive session to receive legal advice regarding consistency of the use of MFP in UPL decision-making.

Executive session adjourned at 11:30 am. The Board received legal advice regarding consistency of the use of MFP in UPL decision-making. The Board conducted no formal business within the session.

At 11:46 am, Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to amend Section E of PDAB Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel by adding the following language: "The upper payment limit for Enbrel (Etanercept) is set at \$583.59 per unit, which is the current Maximum Fair Price for Enbrel. This price per unit will be reviewed and updated annually." Dr. Mizner, Dr. Gutierrez, and Dr. VandenBerg voted to approve the proposed amendments.

DECISION: The motion to amend PDAB Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel passed at 11:47 am.

The Board directed Board staff to post the amended UPL rule for Enbrel on the PDAB website for public comment prior to the October 3, 2025 Board meeting.

### **Break**

Dr. Mizner called for a break from 11:48 am to 12:00 pm.

The rulemaking hearing for Enbrel continued at 12:03 pm. Board staff provided a brief explanation of how the Board's UPL amendments were calculated based on the Maximum Fair Price.

Beginning at 12:08 pm, the following individuals offered testimonies to the Board on PDAB Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel:

- Vanessa Lathan Patient Inclusion Council (PIC)
- Tiffany Westrich Roberston AiArthritis, Ensuring Access through Collaborative Health (EACH) Coalition, and Patient Inclusion Council (PIC)
- Katelin Lucariello Pharmaceutical Research and Manufacturers of America (PhRMA)
- Primo Castro Biotechnology Innovation Organization (BIO)
- Bethany Pray Colorado Center on Law and Policy (CCLP)
- Amy Goodman Colorado Bioscience Association (CBSA)
- Derek Flowers Value of Care Coalition
- Austin Blumenfeld Centennial State Prosperity



- Candace DeMatteis Partnership to Fight Chronic Disease
- Bridget Seritt Advocates for Compassionate Therapy Now (ACT Now)
- Ranier Simons Community Access National Network (CANN)
- Emily Zadvorny Colorado Pharmacists' Society

Ms. Cathy Harshbarger joined the meeting at 12:55 pm.

Dr. Gutierrez moved, and Dr. VandenBerg seconded a motion to continue the rulemaking hearing on Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel to October 3, 2025. Dr. Mizner, Dr. Gutierrez, Ms. Harshbarger, and Dr. Vandenberg voted to continue the rulemaking hearing.

DECISION: At 1:28 pm, the Board continued the rulemaking hearing on Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel to October 3, 2025.

## **Board Business**

# APCD Data Validation - Cosentyx Validated Data Addendum

At 1:30 pm, Board staff presented, and the Board deliberated on the addendum to Cosentyx's 2023 Affordability Review Summary Report (ARSR) with corrected data. Dr. Diab had a conflict of interest with Cosentyx and recused himself from the deliberation and vote. Staff confirmed the continued eligibility of Cosentyx for selection of an affordability review. Dr. VadenBerg moved, and Ms. Harshbarger seconded to adopt the updated Cosentyx ARSR to include the validated data addendum. Dr. Mizner, Dr. Gutierrez, Ms. Harshbarger, and Dr. Vandenberg voted to adopt the addendum.

DECISION: At 1:44 pm, the Board adopted the addendum to the Cosentyx ARSR.

Dr. Gutierrez moved, and Dr. VandenBerg seconded to confirm the Board's findings on June 14, 2024, that Cosentyx is unaffordable to Colorado consumers. Dr. Mizner, Dr. Gutierrez, Ms. Harshbarger, and Dr. Vandenberg voted to confirm the Board's findings. DECISION: At 1:45 pm, the Board confirmed the Board's findings on June 14, 2024, that Cosentyx is unaffordable to Colorado consumers.

Ms. Harshbarger moved, and Dr. VandenBerg seconded to begin rulemaking for Cosentyx's upper payment limit (UPL). Dr. Mizner, Dr. Gutierrez, Ms. Harshbarger, and Dr. Vandenberg voted to begin rulemaking.

DECISION: At 1:46 pm, the Board began rulemaking for Cosentyx's UPL rule.

### **UPL** Implementation

Board staff presented a draft UPL implementation and monitoring plan.

Dr. Mizner adjourned the meeting at 1:01 pm. The next PDAB meeting will be held on Friday, October 3, 2025 at 10:00 am MT.