

Prescription Drug Affordability Board Meeting

May 23, 2025

May 23 Meeting Agenda

Call to Order, Roll Call, Member Updates, Minutes Approval	10:00 - 10:05 am
Board Member & Director Updates	10:05 - 10:10 am
Public Comment <i>Comments will be limited to 2 minutes per person or organization.</i>	10:10 - 10:30 am
Board Business <ul style="list-style-type: none">General Assembly ReportBoard Approval of Data Submission Guide (DSG)APCD Data Validation - Enbrel Validated Data Addendum	10:30 - 11:40 am
Break	11:40 - 11:55 am
Rulemaking Hearing Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.2.C. Upper Payment Limit for Enbrel/Etanercept <ul style="list-style-type: none">Rule IntroductionEnbrel Data Presentation from staff <i>Executive Session: The Board may meet in Executive Session to discuss confidential, trade-secret, or proprietary information pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.</i>Witness TestimonyBoard Deliberation <i>The Board may meet in Executive Session to discuss confidential, trade-secret, or proprietary information pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.</i> <i>The Board may meet in Executive Session to receive legal advice pursuant to section 24-6-402(3)(a)(II), C.R.S.</i> <i>If you are in need of an accommodation to access PDAB meetings or materials, please notify staff at dora_ins_pdab@state.co.us.</i>	11:55 am - 1:00 pm

Call to Order Roll Call Minutes Approval

April 11 Meeting Minutes

Board Member Updates & Director Updates

Public Comment

- *Comments will be limited to 2 minutes per person or organization.*
- *Please sign up via the link in the chat.*
- *Please keep your comments civil. Personal attacks against Board members, Division staff, stakeholders, or other individuals will not be recognized.*

Board Business

General Assembly Report Discussion

Board Approval of Data Submission Guide

APCD Data Validation - Enbrel Validated Data Addendum

Board Business

General Assembly Report Requirements

10-16-1414: On or before July 1, the Board shall submit a report to the Governor, the Health and Insurance Committee of the House, and the Health and Human Services Committee of the Senate summarizing the activities of the Board during the preceding calendar year. At a minimum, the report must include:

- Publicly available data concerning price trends for Rx drugs,*
- The number of Rx drugs subjected to an affordability review, including results of the affordability review and the number and disposition of any appeals or judicial reviews,*
- A list of each Rx drug for which the Board established a UPL,
- Impact of any UPLs on health care providers, pharmacies, and patients' ability to access the Rx drug,
- Summary of any appeals of Board decisions,
- Description of each conflict of interest disclosed to the Board,*
- A description of any violations, including an indication of any enforcement action taken in response to any such violations,
- Any recommendations the Board may have for the General Assembly concerning legislative and regulatory policy changes to increase the affordability of Rx drugs and reduce the effects of excess costs on consumers and commercial health insurance premiums in the state.*

*more information on the next slide

Board Business

General Assembly Report - 2024 Activities Summary

Publicly available data concerning price trends for Rx drugs

- Prescription Drug Rebates in Colorado (CIVHC, 2024)
- Reducing Prescription Drug Costs in Colorado (HCPF, 2021)
- Annual Cost Review Report (Maryland PDAB, 2024)
- Prescription Drug Distribution System and Generic Drug Report (Oregon PDAB, 2024)
- Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans (Assistant Secretary for Planning and Evaluation on behalf of DHHS, 2024)

The number of Rx drugs subjected to an affordability review

- The Board conducted 4 affordability reviews in 2024 for the selected 5 drugs in 2023: Enbrel, Genvoya, Stelara, and Cosentyx.

Description of each conflict of interest disclosed to the Board

- Per Section 10-16-1402, the Board members, Council, staff members, and contractors of the board are required to disclose any conflict of interest to the board.

Board Business

General Assembly Report - PDAB Policy Recommendations

Following are the policy recommendations for the General Assembly to increase the affordability of prescription drugs and reduce the effects of excess costs on consumers and commercial health insurance premiums in the state:

1. Strengthen consumer input:

- The Board recommends the General Assembly consider revising section 10-16-1406(1), C.R.S. to allow for consumers to identify prescription drugs for consideration for affordability reviews.

2. Change eligibility thresholds:

- The Board recommends reducing the threshold for identified brand name drugs below the current \$30,000/yr threshold.

Board Business

Deliberate and Vote - General Assembly Report



Board
Action Item

Board deliberates

Board may vote to:

- Approve the General Assembly Report, pending no additional changes made before submitting to the General Assembly on July 1, 2025.

Board Business

General Assembly Report Discussion

Board Approval of Data Submission Guide

APCD Data Validation - Enbrel Validated Data Addendum

Board Business

Data Submission Guide Overview

Upper Payment Limit Data Submission Guide (DSG)

The draft DSG provides guidance for stakeholders interested in submitting information for the PDAB's consideration for a drug's UPL rulemaking. Includes:

- Timeline for submitting information prior to a UPL rulemaking hearing,
- Instructions and requirements for how stakeholders can submit data and information,
- Research and methods that use a dollars-per-QALY, and
- Types of data requested from different stakeholder groups.

Stakeholders may still submit additional information not outlined in the DSG for the Board's consideration.

Board Business

Data Submission Guide - PDAAC Feedback

Staff asked PDAAC members to provide recommendations on the draft DSG and the members provided feedback over two rounds. Staff have since made edits incorporating relevant feedback.

PDAAC Recommendations

PDAAC members suggested that staff could make the following edits to the DSG:

- Provide a glossary of common terms for stakeholders,
- Staff and Board contractors could review any data submitted with dollars-per-quality adjusted life year (QALY), and
- Clarify the confidential data submission process:
 - Include step-by-step instructions on communication and data confidentiality.
 - Clarify how stakeholders can join executive session during a rulemaking hearing.



The following slides highlight edits to the DSG per Advisory Council suggestions.

While staff have read and considered all recommendations, only those relevant to the Board's current UPL work were included.

Board Business

Data Submission Guide - PDAAC Feedback

Impact to Older Adults and Persons with Disabilities

- Language edits:
 - Clarify precisely what is meant by the impacts on older adults and persons with disabilities
 - Provide a “person first” approach
- Add section requesting information on patient assistance programs
- Clarification that submissions can be written or verbal testimony

Research and Methods that Employ a Dollars-per-QALY

- Add that staff and Board contractors will review submissions for QALYs before the information is shared with the Board.
- *Note: Any submission using QALYs will not be used by the Board during UPL rulemaking, pursuant to section 10-16-1407(4)(a), C.R.S.*

Board Business

Data Submission Guide - PDAAC Feedback



Manufacturer Submissions

- “Average price charged” was added to the data points requested from manufacturers.



Wholesaler Submissions

- Rebates and discounts are not an accurate description of the relationship between manufacturers and wholesalers so that description was changed to “chargebacks” in this section.



Pharmacy/Provider Submissions

- Additional questions were added to this section, including:
 - Is the drug is purchased directly from the manufacturer or from a distributor?
 - Do any prescriptions for the drug have to be transferred due to being out-of-network?

Board Business

Data Submission Guide - PDAAC Feedback



Confidential Information Submission Process

Staff has created a separate document that provides guidance for stakeholders to submit confidential information for the PDAB's consideration during UPL rulemaking.

The document provides the following information:

- Timeline for submitting confidential information to the Board,
- Process for requesting access to the secure File Transfer Protocol (FTP),
- How the Board will receive confidential information,
- How to request to join an executive session to answer questions from the Board about confidential information, and
- Colorado Open Records laws and the Division's policy on confidential information.

Board Business

Data Submission Guide - Board Approval

Board Deliberation

The Board may approve the DSG after deliberating any potential changes and may request that staff:

- Incorporate any changes suggested by the Board, and
- Upload the DSG on PDAB's website for public use ahead of the 2nd rulemaking hearing on July 11

Board Business

General Assembly Report Discussion

Board Approval of Data Submission Guide

APCD Data Validation - Enbrel Validated Data Addendum

Board Business

APCD Data Validation - Recap from April

On April 11, the Board discussed the miscategorization of commercial and Medicare claims data by a PBM. Staff presented the corrected data on:

Price & Cost Statistics

Annual Utilization & Expenditures

After reviewing the data, the Board directed staff to add an addendum to the affordability review summary report (ARSR). This addendum includes the corrected tables and figures impacted by the data miscategorization. Staff has confirmed the eligibility of Enbrel. The following slide details the addendum for Enbrel.

Board Business

APCD Data Validation - Enbrel Validated Data Addendum

The addendum to the affordability review summary report for Enbrel includes the following corrected tables and figures:

<i>Tables</i>	<i>Figures</i>
Table 2: Utilization of Enbrel	Figure 1: Enbrel Utilization by Payer Type
Table 5: Utilization of Enbrel and Identified Therapeutic Alternatives	Figure 2: Insurance Information
Table 6: Enbrel's 2022 Price & Cost Per person Statistics	Figure 4: Insurance Information for Therapeutic Alternatives
Table 7: Enbrel's 2022 Statewide Price & Cost Statistics	Figure 5: Average Commercial Out-of-Pocket Cost Comparison
Table 8: Average Monthly Commercial Out-of-Pocket Cost Information in 2022	Figure 6: Changes in Copay Amounts by Year and Drug 2019-2022
Table 10: Annual Utilization and Expenditures	Figure 9: Monthly Utilizers for Enbrel and Therapeutic Alternatives
	Figure 10: Monthly Total Paid and Average Total Paid

Board Business

APCD Data Validation - Enbrel Validated Data w/ Percent Changes

Table 10 - Annual Utilization and Expenditures

Table 10 shows the percent change in the Annual Utilization and Expenditures for Enbrel in 2019-2022.

	Percent Change			
	2019	2020	2021	2022
Patient Count	-30%	-27%	-26%	-24%
Total Paid	-26%	-24%	-23%	-20%
Average Paid Per Person	6%	5%	4%	5%
Total Patient Paid	-41%	-37%	-31%	-30%
Average Out-of-Pocket (OOP)	18%	16%	36%	54%

Board Business

Deliberate and Vote - Enbrel Validated Data Addendum



Board Action Item

Board deliberates

Board may vote to:

- Approve the addendum to Enbrel's Affordability Review Summary Report and,
- Confirm Board's findings on February 16, 2024, that Enbrel is unaffordable to Colorado consumers.

Board Business

Deliberate and Vote - Begin UPL Rulemaking Hearing for Enbrel



Board
Action Item

Board deliberates

Board may vote to:

- Begin rulemaking to establish an upper payment limit (UPL) for Enbrel.

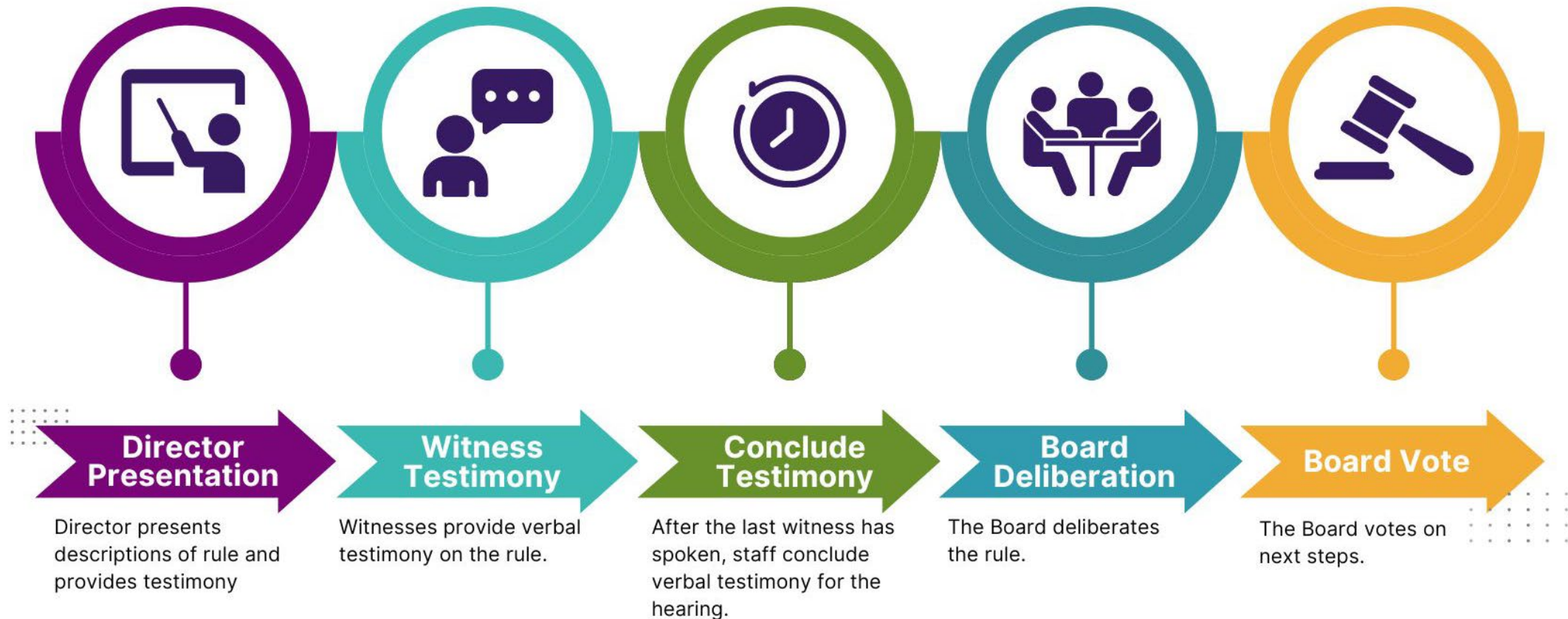
Break

The meeting will resume after a 15-minute break.

Rulemaking Hearing

*Prescription Drug Affordability Board Rule 3 CCR 702-9:
Part 4.2.C. Upper Payment Limit for Enbrel/Etanercept*

Rulemaking Hearing Overview



Rulemaking Hearing

*Staff Presentation of Prescription Drug Affordability Board Rule 3
CCR 702-9: Part 4.2.C. Upper Payment Limit for
Enbrel/Etanercept*

UPL Rulemaking Hearing

Enbrel - Definition

Enbrel (Etanercept)

- First approved by the United States Food and Drug Administration in 1998
- A tumor necrosis factor (TNF) inhibitor.

It is used to treat:

- Rheumatoid Arthritis (RA)
- Ankylosing Spondylitis (AS)
- Plaque Psoriasis (PsO)
- Psoriatic Arthritis (PsA)
- Juvenile Psoriatic Arthritis (JIA)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)

UPL Rulemaking Hearing

Enbrel - Price & Cost Metrics



Metrics & Year	Data Source	Collected By	Confidentiality
Average Sales Price (ASP) - 2024	CMS/ ASP pricing	PORTAL	Non-confidential
Carrier Paid Amounts - 2023	All-Payer Claims Database (APCD)	Board Staff	Non-confidential
Public Health Care Program Fee Schedules: FSS, Big Four, and VA Prices - 2024	VA & OPAL	PORTAL	Non-confidential
Maximum Fair Price (MFP) - 2024	CMS/ Medicare Drug Price Negotiation Program	PORTAL	Non-confidential
National Average Drug Acquisition Cost (NADAC) - 2025	CMS	PORTAL	Non-confidential
Retail Discount Amounts (Average Acquisition Cost - AAC) - 2023 for some biosimilars & 2024	CO HCPF	PORTAL	Non-confidential
Out-of-Pocket (OOP) Spending - 2023	All-Payer Claims Database (APCD)	Board Staff	Non-confidential
Wholesale Acquisition Cost (WAC) - 2025	First DataBank, Analysource	PORTAL	Confidential
Net Price -2024	SSR Health	PORTAL	Confidential

UPL Rulemaking Hearing

Enbrel - Standardization of Data

Annual calculations and common indications:

Per-unit prices were converted to price per year based on the recommended dosing for adult rheumatoid arthritis (RA). Adult RA was selected because it is one of three indications shared between Enbrel and all its therapeutic alternatives, alongside ankylosing spondylitis (AS) and adult psoriatic arthritis (PsA).

Annual calculations are used so that all benchmark data is compared on the same basis. If the board sets a UPL, it will be set on a per unit basis, which can be determined based on the annual units used.

*See memo for detailed methodology

UPL Rulemaking Hearing

Enbrel - Dosing

FDA recommended dosage by indication

Drug Name	Indication	FDA Recommended Dosage
Enbrel	Rheumatoid Arthritis (RA)	50 mg once weekly
	Polyarticular Juvenile Idiopathic Arthritis (pJIA)	0.8 mg/kg weekly with a max of 50 mg per week
	Psoriatic Arthritis (PsA)	50 mg once weekly
	Ankylosing Spondylitis (AS)	50 mg once weekly
	Plaque Psoriasis (PsO)	50 mg twice weekly for 3 months, followed by 50 mg once weekly

UPL Rulemaking Hearing

Enbrel - Data from Staff

- Excel Workbook: presents the UPL price and metric data applicable for the Enbrel UPL rulemaking hearing.
- Graph Packet: visualizes the cost and price metrics for Enbrel and its therapeutic alternatives (TAs).

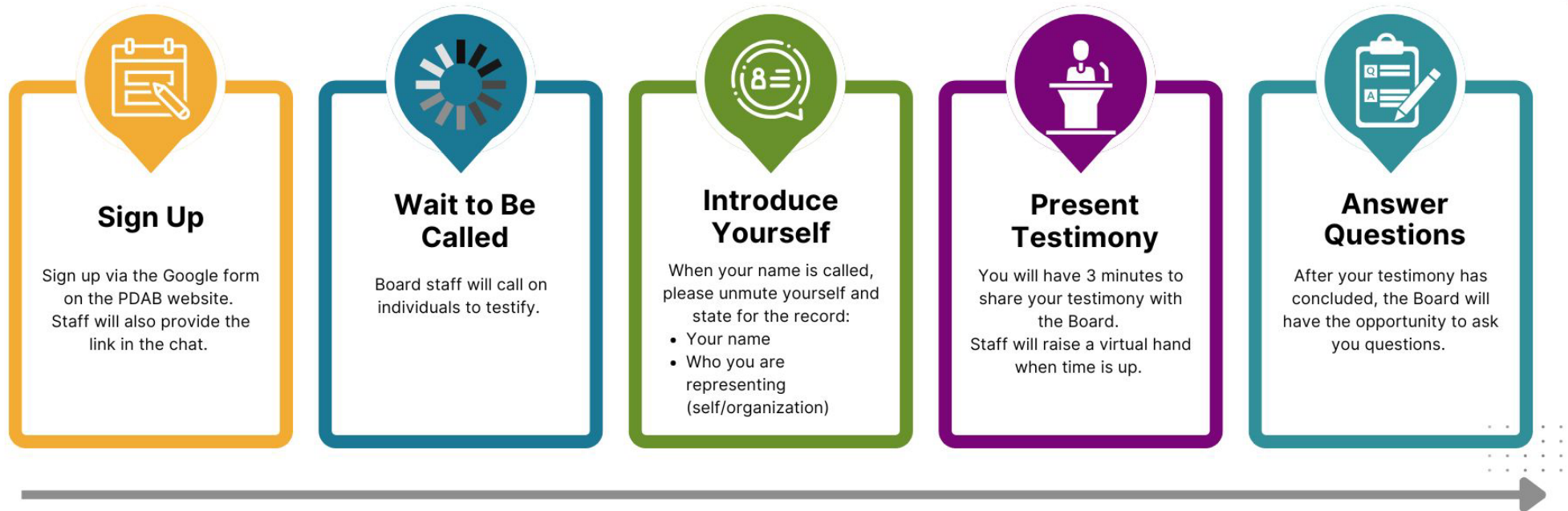
UPL Rulemaking Hearing

Enbrel - Data Presentation

Staff will now present the data on Enbrel UPL benchmarks in Tableau and Excel.

UPL Rulemaking Hearing

Providing Testimony During Today's Rulemaking Hearing



Reminders

- The purpose of the rulemaking hearing is for Board members to gather information about proposed amendments to the affordability review rule, rather than discuss previous Board deliberations and actions.
- Testimony is a time to provide feedback on the affordability review rule only. Stakeholders are asked to reserve other comments for the public comment period of the meeting.

UPL Rulemaking Hearing

Board Deliberation & Vote - Continue the UPL Rulemaking Hearing



Board
Action Item

Board deliberates

Board may vote to:

- Continue the UPL rulemaking hearing for Enbrel at its next meeting on July 11, 2025.

Upcoming Meetings

PDAB Meeting: July 11 at 10 am MT

For meeting minutes, agendas, and general information about PDAB, visit <https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board>

Questions about the Prescription Drug Affordability Board and Advisory Council can be sent to dora_ins_pdab@state.co.us.



The Prescription Drug Affordability Board is in Executive Session

The Board may meet in Executive Session to receive legal advice pursuant to section 24-6-402(3)(a)(II), C.R.S.



The Prescription Drug Affordability Board is in Executive Session

The Board may also meet in Executive Session to discuss confidential, trade-secret, or proprietary information pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.