Prescription Drug Affordability Board Meeting

January 17, 2025

COLORADO
Prescription Drug Affordability Board
Division of Insurance

January 17 Meeting Agenda

Call to Order, Roll Call, Member Updates, Minutes Approval **10:00 – 10:10 am**

Director Updates & Board Business **10:10 – 11:30 am**

- *Revisions to PDAB Policy and Procedures: Policy No. 4 (Affordability Review Policy and Procedure)*
- *Draft Upper Payment Limit Data Submission Guidance*

Public Comment **11:30 – 11:50 am**

Comments will be limited to 2 minutes per person or organization.

Executive Session **11:50 am – 1:00 pm**

The Board may meet in Executive Session to conduct mandatory annual training and receive legal advice regarding section 24-4-103(4)(a), C.R.S., pursuant to section 24-6-402(3)(a)(II), C.R.S.

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

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.

Call to Order
Roll Call
Member Updates
Minutes Approval

December 6 Meeting Minutes

Director Updates and Board Business

- *Revisions to PDAB Policy and Procedures: Policy No. 4 (Affordability Review Policy and Procedure)*
- ***Draft Upper Payment Limit Data Submission Guide***

Director Updates & Board Business
Draft UPL Data Submission Guide

During a drug's UPL rulemaking, the Board will consider:

Data outlined in statue/rule + Stakeholder information

- Staff has drafted a UPL DSG to provide guidance for stakeholders that are interested in submitting information to the PDAB for consideration prior to a drug's UPL rulemaking.
- Stakeholders may still submit additional information not outlined in the DSG for the Board's consideration.

Requested Data & Information

Impact to Older Adults and Persons with Disabilities

Supply Chain Entities

- Manufacturers
- Wholesalers
- Carriers
- PBMs, and
- Pharmacies/providers

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Draft UPL Data Submission Guide

Submissions Regarding Impact to Older Adults and Persons with Disabilities

- Qualitative and quantitative analyses on the impact of the drug on older adults and/or persons with disabilities,
- Effectiveness of the drug and its therapeutic alternatives,
- Any differences in the drug's effects for older adults or persons with disabilities,
- Stakeholders should describe if an indication treated by the drug is a disability and provide their reasoning (e.g., the condition is listed as a disability by the SSA, lived experience with the condition requires an accommodation, etc.),
- Any other information you would like the Board to know regarding the drug's impact on older adults and/or persons with disabilities.

The Board will not accept or consider any research that uses a QALY or similar measure, in accordance with 10-16-1407(3). Please ensure that all submitted information is well cited and does not contain QALYs or similar measures.

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Draft UPL Data Submission Guide

Submissions from Supply Chain Entities

To help the Board understand the impact of a potential UPL on supply chain entities:

- What factors would affect your decision to sell and/or purchase the prescription drug in question?
- How would a UPL impact patients, specifically in the form of lower premiums or out-of-pocket amounts?

Transactions

Details on transactions between entities that purchase, sell, reimburse, or otherwise participate in the prescription drug supply chain, including sales information and utilization information.

Rebates and Discounts

Details regarding any rebates or discounts an entity receives or grants another entity that lowers the overall cost of the prescription drug.

Plan Design

Details regarding decisions on health plan coverage, copayments, coinsurance, deductibles, and cost-sharing.

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For each of the requested data elements, please provide both:

- Current data for each category, and
- Projections on how the data may be impacted after a specific dollar amount UPL is set. Provide an explanation for your projection.

Additionally, for the requested data elements below, please:

- Provide multiple years of data and indicate which years you are reporting,
- Describe data sources, including line of business and payer type (e.g., Medicare, Medicaid, commercial) as applicable,
- Show calculations, and
- Outline methodologies and assumptions as needed to better understand data provided.

Please specify if data is presented at the NDC level, aggregate level, or another level for the selected drug.

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Draft UPL Data Submission Guide

Manufacturer Submissions

Transactions

Sales, Purchases, and Reimbursements

- **Total sales in Colorado:** *separated by sales to wholesalers and direct purchasers, if applicable.*
- **Average price charged:** *The average price charged to purchasers, separated by wholesalers and direct purchasers if applicable. Information should include minimum, maximum, median, and mean.*

Units and Utilization

- **Total units sold in Colorado:** *separated by sales to wholesalers and direct purchasers, if applicable.*

Rebates & Discounts

- **Net prices in Colorado:** *The net price of the drug after discounts and rebates. Information should include minimum, maximum, median, and mean.*
- **Average rebates and discounts in Colorado:** *The average rebates and discounts provided to commercial payers for the drug in Colorado, excluding 340B discounts.*
- **Percent of sales of the drug sold in Colorado to 340B providers**
- **Assistance programs offered by the manufacturer:** *Any documents explaining manufacturer assistance programs (if any) offered for the drug 1 and how this program helps patients with cost-sharing. Please include the following: Who is eligible for the assistance program? How is the assistance program designed? How do patients apply, and what is the application process? How is the assistance provided (e.g., co-pay card, reimbursement)?*

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Draft UPL Data Submission Guide

Wholesaler Submissions

Transactions

Sales, Purchases, and Reimbursements

- **Total sales in Colorado**
- **Average price per unit charged to purchasers in Colorado:** *Information should include minimum, maximum, median, and mean.*

Units and Utilization

- **Total units sold in Colorado**
- **Total units purchased in Colorado:** *The total number of units purchased directly from the manufacturer for each payer type.*

Rebates & Discounts

- **Net prices in Colorado:** *The net price of the drug after discounts and rebates. Information should include minimum, maximum, median, and mean across contracts in Colorado, not including 340B estimates.*
- **Average rebates or discounts received from a manufacturer for business in Colorado**

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Carrier Submissions

Transactions

Sales, Purchases, and Reimbursements
- **Total reimbursement amount**
- **Patient cost-sharing:** *The drug's average out-of-pocket amount, and the change in patient cost-sharing over time.*

Units and Utilization
- **Total units:** *The total number of units for which a carrier reimbursed for the drug.*
- **Utilization:** *The number of covered patients using the drug.*

Rebates & Discounts

- **Net price in Colorado:** *The net price for the drug after discounts and rebates. Information should include minimum, maximum, median, and mean.*
- **Average revenues from rebates for the drug:** *Provide an explanation for how you use the revenue (e.g., to reduce premiums, reduce general out-of-pocket costs, reduce out-of-pocket costs for specific drugs, administration, profits, etc)*
- **Other retail discounts and fees:** *Any additional discounts, concessions, and fees received for the drug.*

Plan Design

- **Describe any utilization management practices for the drug** (e.g., prior authorization, step therapy, etc.)
- **Describe how a UPL might impact** *formulary placement, cost-sharing, benefit design, and/or copayment and coinsurance amounts.*

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PBM Submissions

Transactions

Sales, Purchases, and Reimbursements
- **Total reimbursement amount**
- **Gross and net revenues for the drug**
- **Patient cost-sharing:** *The drug's average out-of-pocket amount, and the change in patient cost-sharing over time.*

Units and Utilization
- **Total units:** *The total number of units for which a carrier reimbursed for the drug.*
- **Utilization:** *The number of covered patients using the drug.*

Rebates & Discounts

- **Net price in Colorado:** *The net price for the drug after discounts and rebates. Information should include minimum, maximum, median, and mean.*
- **Average revenues from rebates for the drug:** *and provide an explanation for how you use the revenue (e.g., to reduce premiums, reduce general out-of-pocket costs, reduce out-of-pocket costs for specific drugs, administration, profits, etc)*
- **Total discounts and other fees paid to pharmacies, prescription drug networks, or pharmacy services administrative organizations in Colorado:**

Plan Design

- **Describe any utilization management practices for the drug** (e.g., prior authorization, step therapy, etc.)
- **Describe how a UPL might impact** *formulary placement, cost-sharing, benefit design, and/or copayment and coinsurance amounts.*

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Draft UPL Data Submission Guide

Pharmacy/Provider Submissions

Transactions

Sales, Purchases, and Reimbursements

- **Average purchase price:** *The average price the pharmacy purchased the drug.*
- **Total sales price of the drug:** *The total price and/or reimbursement for the drug (i.e., the average dollars recouped from carrier reimbursement and patient payments). Information should include minimum, maximum, median, and mean.*

Units and Utilization

- **Total unit dispensed:** *The total number of prescriptions for the drug that were filled.*
- **Utilization:** *The total number of patients that filled the prescriptions for the drug.*

Rebates & Discounts

- **Cards, coupons, manufacturer discounts, or other discounts:** *A description of, and the total dollar amount or any percentage of any cards, coupons, manufacturer discounts, or other discounts patients may receive for the drug.*

Director Updates & Board Business

Draft UPL Data Submission Guide

Confidentiality

Information containing confidential, proprietary, or trade secret information must be submitted through a secure File Transfer Protocol (FTP).

- Request access by emailing staff at dora_ins_pdab@state.co.us.
- Staff will respond within two weeks with full instructions on how to access the FTP and upload confidential data.

Please be aware:

- FTP has a size limit of 1 GB, so larger amounts of data may need to be sent in multiple messages.
- Access to the FTP can only be granted for a 14 day time period, so please do not start this process until ready to submit data.

The submitted information will be transmitted to the Board confidentially and will not be available to the public.

- The Board will deliberate the confidential information in executive session and will invite the stakeholder into executive session as necessary to ask questions exclusively about the confidential information.

Public Comment

Please sign up via the link in the chat. Comments will be limited to two minutes.

Upcoming Meetings

PDAAC Meeting: January 23 at 9 am MT
PDAB Meeting: March 7 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*.