COLORADO
Prescription Drug Affordability Board
Division of Insurance

2025 PDAB Stakeholder Workgroup Participant Guide

Purpose: This document is meant to provide the stakeholder workgroup with background information, research, and guidance for recommending best practices for patient engagement to the Prescription Drug Affordability Board (PDAB, the Board).

Background and Purpose

In 2023-2024, the Board completed its first round of affordability reviews on Cosentyx, Enbrel, Genvoya, Stelara, and Trikafta. Now that the first round of affordability reviews is complete, the Board will evaluate and refine the process of gathering patient information and identify more opportunities to leverage patient voice in their work. Section 10-16-1406(4)(h)(I)-(II), C.R.S., states that the Board must consider input from specified stakeholders during affordability review:

- Patients and caregivers affected by the condition or disease that is treated by the prescription drug under review by the Board, and
- Individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug under review by the Board.

Prior to the second round of affordability reviews, the Board asked staff to organize a stakeholder workgroup to provide suggestions for developing a framework for capturing patient data in a holistic, standardized manner.

Goals for stakeholder engagement during future affordability reviews are:

- **Trust** - Build trust and rapport with PDAB stakeholders and adopt a culture of process improvement.
- **Clarity** – Establish clarity for patients regarding what input the Board is seeking and how feedback will be used.
- **Analysis** – Ensure that patient feedback is considered and patients feel their input is heard by the Board.

Stakeholder Workgroup Details

Workgroup Responsibilities & Meeting Goals

This is a time-limited workgroup that will meet over two PDAAC meetings in a town hall-style session. Workgroup participants are asked to review meeting materials prior to each meeting and be prepared to discuss research, methods, and available evidence-based resources to recommend process improvements around each objective above. Workgroup materials will be emailed and published one week prior to each meeting.

Meeting 1

- **Date**: October 14, 2025 from 12-3 pm MT; register here.
- **Meeting goal**: Develop initial recommendations for actionable, feasible, and transparent practices that meet workgroup objectives.

Staff will prepare a draft report that includes workgroup recommendations and publish before meeting 2. Public comment is welcome on the draft report and will be shared with the stakeholder workgroup for further discussion.

Meeting 2 - Note: time/date are tentative.

- **Date**: December 11, 2025 from 9 am-12 pm MT
- **Meeting goal**: Review the draft report and identify if all objectives are met. Identify any voices that are not captured in the Board's current work and help formulate recommendations on how to include them.

Individuals who wish to provide feedback, but are unable to attend the meetings, may submit written comments to the workgroup. After the workgroup has concluded, staff will finalize the draft report and share with the Board at an upcoming PDAB meeting. All comments received will be collected and shared with the Board.

Final Work Product

The workgroup's final product will be a report to the Board outlining recommendations for best practices and process improvements for the PDAB's future affordability reviews. Staff will present the workgroup's report to the Board at a future PDAB meeting, and will work with the Board to identify applicable next steps for implementation.

Workgroup Objectives

The overall objective of the workgroup is to improve Board processes for capturing patient experience information during affordability reviews and identify best practices and recommendations regarding:

1. Tools for collecting patient experience information (e.g., surveys, meetings, etc.),
2. Timeline for collecting patient information,
3. Outreach & Communication for establishing clear communication channels with collaborators,
4. Assessing information received from stakeholders,
5. Conflicts of interest disclosure from stakeholders.

The following information is included with each workgroup objective:

A. **Round 1 Affordability Review Outcomes:** An overview of what the Board did during the first round of affordability reviews.

B. **Stakeholder Suggestions:** Improvements suggested by stakeholders.

C. **Research**: An overview of best practices about each objective, including methods used by other organizations, such as: CMS, HCPF, CDPHE, PhRMA, NASHP, other state PDABs, etc.

D. **Recommendations for Round 2**: Guiding discussion topics for the workgroup.

1. Tools to Collect Patient Experience Information

A. Affordability Review Round 1 Outcomes

The Board distributed two surveys for each drug under review: one for patient and caregivers; and one for individuals with scientific or medical training. Surveys were not drug-specific and intended to capture the health and financial impacts of a prescription drug on patients. Advocacy groups and researchers provided sample surveys and guidance that staff used in developing the surveys. Staff also held focus group and small group meetings for the drugs under review.

Survey Responses		
Drug Name	**Patients & Caregivers**	**Individuals with Scientific or Medical Training**
Cosentyx	15 (5 CO)	3
Enbrel	276 (38 CO)	3
Genvoya	22 (all CO)	1
Stelara	15 (5 CO)	10
Trikafta	47 (2 CO)	8

Focus Group Attendance		
Drug Name	**Patients & Caregivers**	**Individuals with Scientific or Medical Training**
Cosentyx	2	1
Enbrel	3	2
Genvoya	3	2
Stelara	3	8
Trikafta	32	8

Small Groups Attendance		
Drug Name	**Patients & Caregivers**	**Individuals with Scientific or Medical Training**
Cosentyx	NA	1
Enbrel	NA	5 across 3 meetings
Genvoya	3	NA
Stelara	NA	4 across 2 meetings

B. Stakeholder Suggestions

- Improve survey questions about utilization management practices to get to "why" patients report unaffordability issues.
- Include patient advocacy groups in the development of survey questions.
- Improve patient engagement throughout the affordability review process.

C. Research

Surveys

- Patients need to have the opportunity to explain how insurance, health status, and financial strain impact "affordability."[1]
- Additional patient insights should be collected from direct conversations through roundtables, listening sessions, or moderated discussions.[2]
- Survey questions should be well-aligned with the research objective(s) and specific to the targeted concept for the research question (e.g., disease/condition symptoms and impacts, current treatment, past treatments, treatment side effects) with minimal redundancies across questions.[3]
- The questions should also be formatted in a simple manner to maximize the ease of use for respondents, in addition to being assessed for potential response bias.[4]
- Oregon PDAB's patient and caregiver survey, which is available in both English and Spanish, requests patient's personal information but caveats by stating individual data will not be disclosed to the public and will be used at a de-identified level for analysis purposes. The survey also asks if the patient filling out the form is an Oregon resident.[5]
- Oregon PDAB also has a separate survey for safety net providers and does not combine surveys for individuals with scientific or medical training.[6]

Focus Groups

- Conduct separate focus groups for different types of participants to ensure everyone's openness and comfortability in sharing their perspectives without the influence of hierarchical dynamics.[7]
- Consider accessibility features during a virtual setting (e.g., closed captioning).[8]
- Introductions should help participants and facilitators develop rapport and mutual trust.[9]
- Exclude tangential questions and focus on questions directly related to the objectives.[10]
- The moderator of a focus group can explore issues at the individual level, as well as encourage discussions among participants at the group level, eliciting a range of experiences.[11]

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[1] PIC Patient Experience Survey (pg 8)
[2] PIC Patient Experience Survey (pg 8)
[3] Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (pg 10)
[4] Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (pg 10)
[5] Oregon PDAB Patients, Caregivers, and Advocacy Groups survey
[6] Oregon PDAB Patients, Caregivers, and Advocacy Groups survey
[7] IES Considerations & Best Practices for Focus Group Collection (pg 1)
[8] IES Considerations & Best Practices for Focus Group Collection (pg 1)
[9] IES Considerations & Best Practices for Focus Group Collection (pg 4)
[10] IES Considerations & Best Practices for Focus Group Collection (pg 2)
[11] Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (pg 5)

One-on-One Interviews

- One-on-one interviews offer opportunities to explore topics in-depth at an individual level using probing questions.[12]
- One-on-one interviews can also be used to address sensitive topics and explore diseases or conditions with many different symptoms that vary from patient to patient.[13]

D. Workgroup Recommendations for Round 2

Workgroup members are encouraged to discuss:

- Other tools the Board should consider when collecting patient experience information during affordability reviews.
- Tips for improving survey design (examples are encouraged).
- Tips for improving survey response rate.
- Strategies to promote and publicize surveys to target populations.

2. Timeline for Collecting Patient Information

A. Affordability Review Round 1 Outcomes

Round 1 Timeline

- **Selection:** The Board selected five drugs for review on August 4, 2023.
- **Voluntarily Submitted Information:** Manufacturers, carriers, PBMs, and other entities have 60 days from the last day of selection (October 3, 2023) to provide voluntarily submitted information to the Board.
- **Surveys**: Surveys were published on September 12, 2023 (a little less than 6 weeks after selection) and stakeholders had until October 12, 2023, to complete the survey. To offer stakeholders more time to respond, the Board voted to re-open the surveys for another month for four out of the five selected drugs.
- **Office Hours:** Staff held weekly one-hour meetings in August and September, 2023, where stakeholders could ask any questions about the affordability review process and how to provide input to the Board.
- **Focus Groups & Stakeholder Meetings:** Staff facilitated two focus group meetings per selected drug, and held small group meetings as requested.
- **First Affordability Review:** The first affordability review, which was for Trikafta, was completed on December 8, 2023.

B. Stakeholder Suggestions from Affordability Review Round 1

- More time is needed to complete the surveys and participate in group meetings.
- A wider dissemination of surveys would help with reaching more respondents.

[12] Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (pg 4)
[13] Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (pg 6)

C. Research

- The ideal timeframe to gather patient input is three to four weeks, as it allows staff to establish and coordinate relationships with patient advocacy groups, in addition to recruiting and engaging participants.[14]
- This three to four week timeline also depends on the resources required to support patient engagement activities.[15]
- Transparency with stakeholders regarding timeline is important because it facilitates reaching an agreement on timescales that suit everyone involved.[16]
- Provide a clear and thorough visual of the timeline for collecting information so stakeholders are able to participate at the right time.[17]

D. Workgroup Recommendations for Round 2

Workgroup members are encouraged to discuss:

- Strategies the Board can use to keep stakeholders informed and engaged during affordability reviews.
- The best time to distribute surveys and facilitate meetings to maximize stakeholder awareness and participation.
- The amount of time needed to collect information.

3. Outreach and Communication

A. Affordability Review Round 1 Outcomes

Outreach and Recruiting

- Stakeholders were recruited primarily through the PDAB listserv and outreach via the PDAB website.
- Staff discussed recruitment with patient advocacy organizations.
- Staff offered to meet directly with interested organizations and established collaborative communication channels.

Communication

- Office Hours: Staff held weekly one-hour open meetings in August and September 2023 to answer stakeholder questions about the affordability review process.
    - Office hours were not a public comment forum, but an informal space for stakeholders to ask for clarification on the Board's work and provide insight into participation opportunities.
    - Staff authored a stakeholder engagement guide and updated it regularly based on stakeholder suggestions.

B. Stakeholder Suggestions from Affordability Review Round 1

- Better explain the process of the Board's work.

[14] Insights & Best Practices for Planning & Implementing Patient Advisory Boards (pg 3)
[15] PFMD: How-To Guide for Patient Engagement in Early Discovery & Preclinical Phases (pg 15)
[16] PFMD: How-To Guide for Patient Engagement in Early Discovery & Preclinical Phases (pg 16)
[17] PFMD: How-To Guide for Patient Engagement in Early Discovery & Preclinical Phases (pg 16)

- Better explain the purpose of stakeholder input.
- What will the Board do with the stakeholder input?
- How will it guide the Board's decision making?

C. Research

- Comprehensive recruitment plans describe who and how stakeholders will be recruited, and what recruitment materials they will use.[18]
- One-on-one outreach is a key strategy for recruiting patient stakeholders.[19]
- Identify trusted community partners to assist with recruitment.[20]
- Patients need readable, comprehensible, and consistent materials disseminated in order to stimulate their interest. [21]
- Information should be provided in payment terms utilizing visual aid as often as possible.[22]

D. Workgroup Recommendations for Round 2

Workgroup members are encouraged to discuss how the Board can:

- Reach a wider population of Coloradans, particularly priority populations[23] and uninsured Coloradans.
- Leverage its current stakeholder network to identify other relevant and impacted stakeholders.
- Educate patients/providers about the Board's work.
- Explain to patients what they will do with their input.

4. Assessment

A. Affordability Review Round 1 Outcomes

- Board staff performed a thematic analysis of the qualitative data from the surveys and meetings.
  - Appendix H on page 117 of the Affordability Review Summary Report for Enbrel details the assessment and results of the surveys and meetings.
- The Board included all surveys received in the results, which included responses from individuals in other states and patients covered by plans that will not be subject to an upper payment limit (Medicare).

B. Stakeholder Suggestions from Affordability Review Round 1

- If the Board accepts out-of-state input, should it be weighted differently than information from CO residents? How so?

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[18] HARPS Toolkit (pg 8)
[19] HARPS Toolkit(pg 8)
[20] HARPS Toolkit (pg 8)
[21] Strategies for Disseminating Recommendations or Guidelines to Patients
[22] Five Strategies for Providing Effective Patient Education
[23] The Board's adopted definition of priority populations is: people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board. 3 CCR 702-9, 1.1.C.

- Patient and caregiver input should not be considered as speaking for all Coloradans.

C. Research

- Using surveys to collect qualitative data may not allow for structured and in-depth exploration of a given topic but offers a feasible way to collect information from a broad range of individuals.[24]
- For in-depth exploration, focus groups and interviews are the preferred methods, as they can effectively explore collective perspectives on a topic.[25]
- It is critical to thoroughly describe the data collection method used and justify its use in relation to its ability to support the research aims.[26]
- Include members of the target population (for example, patients or clinicians) and subject matter experts in the design of interview questions, focus group guide or survey.[27]
- Develop code lists and perform thematic analysis of the surveys and focus groups.[28]
- Substantiate reported themes with the data collected by using verbatim extracts or text excerpts. Triangulate findings with other data sources as well.[29]
- Transcribe and code interviews and focus groups to be able to conduct synthesis and abstraction to group the codes.[30]
- Qualitative data or research should be assessed in an adaptive and refinement manner based on lessons learned from earlier steps in the process.[31]
- The assessment process for evidence from identified patient experience outcomes will likely need to rely largely on expert opinions of participants and stakeholders.[32]

D. Workgroup Recommendations for Round 2

Workgroup members are encouraged to discuss:

- If the Board should limit input to those residing within Colorado or also consider perspectives from outside stakeholders.
- If the Board should limit input from patients covered by plans that will not be subject to a UPL.
- Tips for analyzing stakeholder input.

5. Conflict of Interest (COI) Disclosure

A. Affordability Review Round 1 Outcomes

- The Board did not have a COI disclosure policy for stakeholders during the first round of affordability reviews.

[24] Quality in Qualitative Evidence: New Best Practices from NICE
[25] Quality in Qualitative Evidence: New Best Practices from NICE
[26] Quality in Qualitative Evidence: New Best Practices from NICE
[27] Quality in Qualitative Evidence: New Best Practices from NICE
[28] Quality in Qualitative Evidence: New Best Practices from NICE
[29] Quality in Qualitative Evidence: New Best Practices from NICE
[30] Quality in Qualitative Evidence: New Best Practices from NICE
[31] How to Use and Assess Qualitative Research Methods
[32] Assessing Clinical Benefit in Medicare Drug Price Negotiation

B. Stakeholder Suggestions from Affordability Review Round 1

- Individuals with scientific and medical training should provide disclosures about funding, industry involvement, and other relevant activities across any part of the supply chain that could be considered a conflict of interest.
- How can a COI disclosure policy be established for stakeholders?

C. Research

- Outline precisely what the organization views to be a conflict of interest: financial, non-financial, institutional.[33]
- Transparency allows stakeholders to evaluate decisions critically and ensures that professionals act in the best interest of their organization or the public.[34]
- Develop a robust COI disclosure policy to maintain ethical standards and transparency.[35]
- Clearly define the purpose of the COI, why it exists, and who it applies to. Outline when and how conflicts are to be disclosed.[36]
- A diverse committee free from significant conflict of interest is important and must be taken into consideration.[37]
- Linked below are examples for conflict of interest disclosure languages to utilize.[38, 39]

D. Workgroup Recommendations for Round 2

Workgroup members are encouraged to discuss:

- When and how should COIs be disclosed (e.g., focus group meetings, written comments, public comment sessions, etc.).
- Disclosure format (e.g. verbal, written, both).
- What the disclosure should include (e.g., name of the prescription drugs, manufacturing company, any financial benefit/funding from the prescription drug or its manufacturer).

Next Steps

Between Meetings 1 & 2: October 14 - December 10, 2025

- Staff, along with the PDAAC chair, will draft a recommendations report based on the discussion from the first workgroup meeting.
- Staff will publish the draft report on the PDAB website and through the listserv at least two weeks prior to the second workgroup meeting.
- Stakeholders may provide written feedback on the draft report and are asked to submit comments at least two business days prior to the second workgroup meeting.

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[33] Disclosure-Conflict of Interest Expert Guide for 2024
[34] Disclosure-Conflict of Interest Expert Guide for 2024
[35] Disclosure-Conflict of Interest Expert Guide for 2024
[36] Disclosure-Conflict of Interest Expert Guide for 2024
[37] Disclosure-Conflict of Interest Expert Guide for 2024
[38] HRSA Example COI Form
[39] COI Example Language

Meeting 2: December 11, 2025 (tentative)

- Workgroup members will receive a copy of the draft report and an overview of comments and suggestions received from written feedback.
- The workgroup will discuss the report and include any final changes before members of the PDAAC vote on the report.

After Meeting 2

- After the PDAAC votes to approve the report, it will be shared with Board members at a future meeting.
