

Updates to Cost Review Study Process and Policy Review Process

PDAB Meeting

March 23, 2026

PDAB Staff



Purpose

Improve depth and efficiency of PDAB analysis:

- (1) Enable input from government entities
- (2) Investigate therapeutic class information during selection, cost review, and policy review
- (3) Broaden consideration of drugs subject to Medicare Maximum Fair Price
- (4) Consider certain measures of cost-effectiveness
- (5) Supplement public comment procedures



Overview - Cost Review Study Process- Current Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results



Current Cost Review Study Process



PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
<p>Public Reporting of Drug Affordability Issues</p> <p>Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review</p>	<p>Identifying prescription drug products to consider for cost review- this is a subset from eligibility list</p> <p>Refer prescription drug products to the Stakeholder Council for input</p>	<p>PDASC will review and discuss the referred prescription drug products at an open meeting</p>	<p>Public comment</p>	<p>Board selects prescription drug product(s) for cost review</p> <p>Next Steps:</p> <ul style="list-style-type: none">→ Collect→ Analyze→ Results

Current Cost and Policy Review Process



Drug(s) in Cost Review	Data Collection	Analyze	Preliminary Determination	Policy Review Process	Final Results
<p>Drug(s) selected for Cost Review Study will be posted on the Board's Website.</p> <ul style="list-style-type: none"> - 60 day written comment period begins with posting 	<p>PDAB may request information from, and post request:</p> <ul style="list-style-type: none"> - Manufacturers - Carrier, HMO and MCO - Pharmacy Benefits Managers - Wholesale Distributor 	<p>Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.</p>	<p>Board may preliminarily determine whether the prescription drug has led or will lead to:</p> <ul style="list-style-type: none"> - Affordability challenges to the State health care system or - High out of pocket costs for patients 	<p>Board may perform the policy review process to identify and recommend policies to address affordability challenges:</p> <ul style="list-style-type: none"> - Process for setting upper payment limits - Process for all other policies that are not upper payment limits 	<p>Board takes final action:</p> <ul style="list-style-type: none"> - Board Finalizes Determination and Adopts Final Cost Review Study Report - Board Adopts Policy Recommendations - Board Adopts Proposed UPL Regulation

Public Comments about Cost Reviews

Thank you to all who have submitted comments or spoken at meetings - we value your feedback and encourage continued public engagement.

Notable themes from public comments:

- Lack of Maryland-specific data
- Drug selection methodology and use of MFP to help select drugs
- Requested focus on patient costs and barriers to access
- Uncertainty regarding selection of drugs, policy prioritization, impact of UPLs
- Need for fast action to bring relief to patients



Summary of Feedback through Informational Hearing and Stakeholder Council

- Informational Hearing- Held on February 10, 2026 at 1:00 PM and 6:00 PM
- Stakeholder Council Meeting- February 23, 2026 at 2:00 PM



Informational Hearing

- The Maryland Prescription Drug Affordability Board is evaluating its cost review study process (COMAR 14.01.04.01, et seq.) and policy review procedures (COMAR 14.01.05.01, et seq.), and welcomed public comment on these procedures.
- The PDAB hosted two informational hearings to obtain input on February 10, 2026.
 - 1:00 PM Session: 3 Speakers
 - 6:00 PM Session: 3 Speakers
 - Exhibits: 10 Written Comments Submitted



Summary of Feedback from Informational Hearing

Feedback for Better Stakeholder Engagement and Input

- **Low Public Awareness and Participation Barriers**
 - Public awareness of PDAB activities is limited overall, making it difficult to reach patients directly.
 - In-person testimony is a barrier, and public hearings are mostly held during the daytime.
 - Verbal public comment time limits are too short to provide meaningful input, and there is a lack of in-person engagement opportunities
 - Participation may require motivation, and the lack of a clearly identified, visible, and structured testimony process is a problem.
- **Communication and Accessibility**
 - The PDAB website relies heavily on technical language
 - Patients require clearer informational output, accessible meeting recaps, and ongoing input opportunities for selected and reviewed drugs
 - There is a lack of clear communication regarding the process and timing of the Board's activities
- **Outreach Gaps**
 - Patients are not receiving PDAB materials in healthcare settings
 - Physicians are not sufficiently looped into awareness efforts
 - Community resources, such as high-traffic public spaces and the faith community, are not being sufficiently leveraged



Summary of Feedback from Informational Hearing Oral and Written Comments

- Feedback for Additional Data and Considerations
 - Prioritize and focus on Patient Out-of-Pocket Costs
 - Ensure documentation and consideration of patient benefits of the therapy
 - Ensure documentation, analysis, and consideration of impacts of plan design and utilization management
 - Prioritize non-UPL policies
 - Ensure consideration of economic impacts of policies and impact on supply chain and access



Stakeholder Council Feedback

Patient Advocacy & Economic Impact

- Prioritize drugs with a high out-of-pocket (OOP) cost relative to the drug's net cost.
- Emphasis on the socioeconomic sacrifices patients make (e.g., household upkeep vs. medication) and noted that the current engagement process (confusing sign-ups, meetings during work hours) creates a barrier for real-world storytelling.

Operational Urgency & "Immediate Relief" Strategies

- Some members of the PDASC challenged the Board to move beyond long-term studies and implement non-UPL (Upper Payment Limit) policies that can provide immediate financial breathing room for working families while the deliberative UPL process continues.
- Feedback to prioritize drugs with high non-adherence rates, those prevalent in underprivileged communities, and those already flagged as unaffordable by CMS.



Stakeholder Council Feedback

Engagement & Accessibility Overhaul

- Marketing campaign using QR codes to drive awareness of PDAB surveys to obtain information on drug affordability issues.
- Multi-language support.
- Some members expressed a desire for the Stakeholder Council to be more deeply embedded in the process. They requested more time for testimony, a formal "feedback loop" where the Board responds to their comments, and more granular newsletter outlines so members can navigate specific topics of interest.

Regulatory & Policy Considerations

- Address how the Board will handle fluctuations in the WAC (Wholesale Acquisition Cost) if it changes during the UPL determination process.



Staff Recommended Changes to the Cost Review Study Process

Identify

Select

Collect

Analyze

Results



Overall

1. **Streamline Process-** Streamline the the process wherever possible to target an annual cycle
 - a. Clear Timelines and Milestones for Posting Documents and Receiving Public Comment
2. **Clear and Structured Process for Stakeholder Input-**
 - a. Create clear and understandable opportunities for stakeholder input
 - b. Show how stakeholder input is considered and used
3. **Clear Communication and Organization on the Process and Status**
 - a. Greater clarity (website, timeline for accepting comments, use of comments)
 - b. More opportunities for comment, sustained consideration of comments
 - c. Deeper engagement (more time, back-and-forth interactions)
 - d. Consideration of comments at Board meetings
 - e. Longer comment periods
 - f. More accessible participation opportunities for patients



Identify

Additional Inputs for Eligible Drugs

1. **Input from Government Entities** - Create direct lines of communication that eligible governmental entities may use to contact and share information with the Board.
 - a. This can include making certain drugs eligible for consideration, and provides additional information for selection.
2. **Therapeutic Class** - Make entire therapeutic classes eligible for consideration for the Cost Review Study Process



Select

Updates to Data that the Board can consider in the Selection Process

1. **Input from Government Entities** - Allow Board to consider input from Eligible Governmental Entities when selecting a drug
2. **Maximum Fair Price Amount and Estimated Savings**- For drugs that have a CMS Maximum Fair Price, allow the Board to consider the Maximum Fair Price amount and estimated savings compared the current estimated net price
3. **Cost Effectiveness Data**- Where possible, allow the Board to consider cost and comparative effectiveness during the selection process
4. **Remove Unnecessary Data**- Streamline the data that is available to prioritize highest impact data



Select

Updates to Process for Selecting Drugs

1. **Board Set Annual Priorities for Selection of Drugs-** At the start of the year, the Board can indicate priorities or guidance to staff on the types of drugs that it wants to consider
2. **Staff Develop Recommendations to Board based on Board Priorities-** Allow staff to process data based on Board guidance and priorities to identify potential drugs for selection



Collect

Prioritize Collection of High-Impact Data for Cost Review Study

- 1. Update Data Elements in the Request for Information (RFI) to Collect Actionable Data-**
The staff will update data elements to capture the most essential and actionable data
- 2. Prioritize Reporting Rates and Data Quality-** Staff may develop incentives to submit high-quality data, and look for additional data sources.
- 3. Allow for Staff to Meet with Submitters for Technical Discussion-** Similar to the CMS Negotiation process, set up a forum for staff and stakeholders to work through technical issues



Analyze

Update the Criteria for the Cost Review Study

- 1. Create mechanism to collect and consider updated data-** Allow Board members to consider and take action on new data the becomes available during the Cost Review Study Process
- 2. Remove unnecessary Factors from Consideration from Cost Review Study Process-** Remove unnecessary or duplicative factors
- 3. Allow for Staff Driven Analysis of Data to Curate Data for the Board**



Results

Streamline Affordability Determination

1. **Allow for Staff Recommendation for Affordability Determination-** Allow staff to conduct analyses and make recommendations that the Board can consider when making determinations of affordability challenges
2. **Publish Exemplary Circumstances for Affordability Determination-** Publish a list of examples of circumstances that can indicate an affordability challenge





MARYLAND

Prescription Drug Affordability Board

comments.pdab@maryland.gov

pdab.maryland.gov