

Updates to Cost Review Study Process

PDASC Meeting

June 22, 2026

PDAB Staff



Purpose

Gather input from the Stakeholder Council regarding the cost review study process (COMAR 14.01.04.01, et seq.)



PDASC Involvement

- The PDASC provided initial feedback on COMAR 14.01.04- Cost Review Study Process, at the February 23, 2026 PDASC Meeting
- Further feedback on the circumstances were provided at the April 27, 2026 PDASC Meeting
- Draft proposed revisions on COMAR 14.01.04 Cost Review Study Process, were posted for public comment on May 1, 2026. Comments were due June 1, 2026.
- Draft proposed revisions on COMAR 14.01.04.01 Cost Review Study Process-Circumstances Under Which Use of a Drug May Create an Affordability Challenge, were posted for public comment on May 27, 2026. Comments are due June 26, 2026.



Comparison of Cost Review Study Process-

COMAR 14.01.04

Key Changes At A Glance

Feature	Current Process	New Proposed Process
Priorities/Initial Curation	Board receives every eligible drug.	Staff creates a curated list based on Board priorities.
Technical Lists	Board formally approves NDCs and Therapeutic Alternatives.	Staff publishes these lists.
Staff Role	Staff provides all data with no recommendations.	Staff provides a Recommendation Memo for Board consideration.
Data	Existing data elements captured through RFI and allowed for consideration.	Added and removed data elements to allow the Board to consider all necessary factors.
Timeline	60-day comment period triggers upon posting the drug selection.	60-day comment period triggers upon staff posting the request for comments.

Informational Hearing Feedback

The Maryland Prescription Drug Affordability Board invited public feedback from informational hearings on the cost review study process (COMAR 14.01.04.01, et seq.) on February 10, 2026 at 1pm and 6pm (three speakers provided comments at each session).

Comments Received:

- Document and consider patient benefits of the therapy
- Consider impacts of plan design and utilization management
- Consider policy impacts on supply chain and patient access
- Prioritize patient Out-of-Pocket costs
- Prioritize non-UPL policies



Public Engagement with Cost Review Study Process

Notable themes from public comments:

- Emphasized need for fast action to bring relief to patients
- Requested focus on patient costs and barriers to access
- Criticized procedures and unpredictable outcomes for selection and cost reviews
- Requested greater reliance on Maryland-specific data



Circumstances

- COMAR 14.01.04.01 Cost Review Study Process-Circumstances Under Which Use of a Drug May Create an Affordability Challenge (revision)
- Purpose of this addition is: The identification of the circumstances under which use of the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients is data driven. COMAR 14.01.04.05A(3).
- When making a preliminary affordability challenge determination the Board reviews the data in the dossier and identifies “the circumstances or indicia reflecting the affordability challenge.” COMAR 14.01.04.05F(3)(a).



Feedback from April 27 Stakeholder Council Meeting

Recommendation to Consider Barriers to Affordable Access for Insured Patients

- Investigate indicators of patient burden such as patient abandonment of prescriptions
- Focus on indicators of high drug costs for payors and patients
 - Shifting out-of-pocket costs towards individuals
 - Insurers with coverage requirements that are narrower than FDA indications
 - High rates of prior authorization rejections
- 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)
- Consider challenges with obtaining data, evidence of utilization beyond clinical need, utilization of brand vs. generic medications, and continued high utilization of brand drugs despite available generics

Information was presented at the May 18, 2026 PDAB meeting.



Questions for the Stakeholder Council

- Are there additional changes to the draft regulations that should be considered?
- Beyond the current draft, are there specific items that remain unclear?
- Any additional questions or considerations?





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