

Cost Review Study Process and Policy Review Process- Circumstances and Input

PDASC Meeting

April 27, 2026

PDAB Staff



Updates and Purpose

- The PDAB received feedback from the Stakeholder Council at the February 23, 2026 meeting on updates to the Cost Review Study Process and Policy Review Process regulations.
- This feedback was presented to the Board at the March 23, 2026 PDAB meeting.
- The purpose of today's meeting is to gather input on "Defining Circumstances that Indicate and Affordability Challenge"



Identification of Circumstances

- 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).
- Given its recent experience in reviewing drug data and public feedback, the Board is evaluating whether categories of circumstances can be identified prospectively.



PDASC Input

- The PDAB wants to incorporate Stakeholder feedback and publish circumstances prospectively.
- Staff would like the PDASC to help identify circumstances under which the use of a prescription drug product may create or has created affordability challenges for the State health care system or high out-of-pocket costs to patients.



Overview - Cost Review Study Process- Current Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results



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Potential Circumstance Themes

- High Spending by Payors
- High Patient Out of Pocket Spending
- Patient Burden Compared to Insurer Burden
- Cost Effectiveness
- Market Distortions Caused by Drug Pricing
- Exclusion Criteria
- Other Themes or Categories



Previous Identified Circumstances

- the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation)
- at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors
- total gross spending for state and local governments exceeds X% of gross prescription drug spend for state and local governments



Themes and Circumstance Examples

High Spending by Payors

Example: For entities that pay for the prescription drug product, the drug makes up a large proportion of the impacted budget.

High Patient Out of Pocket Spending

Example: Patients report or public data indicate high Out of Pocket costs or high cost-sharing burden for patients.

Patient Burden vs. Insurer Burden

Example: Patient reports or public data indicate an affordability challenge or access barriers for patients in Maryland.

Cost Effectiveness

Example: The drug is not cost-effective at the current average net price.

Market Distortions Caused by Drug Pricing

Example: Board staff has identified the drug as a cost driver and has provided appropriate data to justify its nomination.

Exclusion Criteria

Example: The drug is in shortage according to the FDA shortage database.

Other Themes or Categories

Other circumstances that may be introduced and prioritized by the Board at an open meeting.



Examples and Evaluation



What are some circumstances within these main themes that the PDAB could consider?



Can those circumstances be effectively evaluated? If so, how? What data sources are available?



Are there other themes missing from this list?





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