Updates to Cost Review Study Process COMAR 14.01.04

PDAB Meeting

July 27, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Cost Review Study Regulations Timeline

- Informational Hearing- Held on February 10, 2026 at 1:00 PM and 6:00 PM.
- The PDASC provided initial feedback on COMAR 14.01.04- Cost Review Study Process, at the February 23, 2026 PDASC Meeting.
    - Summary of feedback and staff recommendations for draft proposed changes were presented at the March 23, 2026 PDAB Meeting.
- The PDASC provided initial feedback on the circumstances, at the April 27, 2026 PDASC Meeting.
    - Summary of feedback and staff recommendations for draft proposed changes were presented at the May 18, 2026 PDAB Meeting
- The PDASC provided final feedback on the regulations at the June 22, 2026 PDASC meeting.

Cost Review Study Regulations- Timeline

- 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 were due June 26, 2026.
- 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.

Comments Received :
Draft proposed revisions on COMAR 14.01.04.01 Cost Review Study Process- Circumstances

- AARP Maryland
- AbbVie
- Arthritis and Rheumatism Associates (ARA)
- Biotechnology Innovation Organization (BIO)
- Boehringer Ingelheim Pharmaceuticals
- Diabetes Patient Advocacy Coalition (DPAC)
- Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) Coalition
- Healthcare Distribution Alliance (HDA)
- Infusion Access Foundation Patient Advocacy Organization
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Value of Care Coalition

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters expressed confusion with the “removal” of Public Reporting from COMAR 14.01.04.01

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters alleged that the draft regulations do not specify any standard of proof, or evidentiary threshold

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters requested numeric thresholds for each circumstance

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters opined that each circumstance should be measurable and observable in the available data

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters noted the challenges associated with assessing the cost effectiveness of certain drugs

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters expressed concern with using behaviors that prevent or delay market competition as a circumstance

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters noted the importance of considering context and nuance when comparing therapeutic alternatives (TAs)

Overarching Comment Themes: COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Commenters expressed concerns with “catch-all” provisions that allow the Board to identify circumstances disclosed through the cost review study

Key Changes:
COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge

1. Clarified language to provide specific time-periods and percentiles where possible

   Amendment COMAR 14.01.01.05B(4) (at least 15 days comment period when comment posted and requested by Board); Revisions COMAR 14.01.01.01B

2. Removed circumstance based on cost-effectiveness

   Revision COMAR 14.01.01.01B

3. Removed circumstances based on conduct to prevent or delay market competition

   Revision COMAR 14.01.01.01B

Comments Received : Draft proposed revisions on COMAR 14.01.04 Cost Review Study Process

- AbbVie
- Biotechnology Innovation Organization (BIO)
- Community Access National Network (CANN)
- Diabetes Patient Advocacy Coalition (DPAC)
- Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) Coalition
- HealthHIV
- Maryland Tech Council (MTC)
- National Association of Chain Drug Stores(NACDS)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Value of Care Coalition (VCC)

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters noted concerns regarding delegation of authority for staff curated eligible drug list and staff drug selection recommendations

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters expressed concern with using any federal federal benchmark, especially the Medicare Maximum Fair Price. Commenters also objected to the use of the MFP as a stand-alone criterion for the list of drugs eligible for selection

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters expressed concern that therapeutic alternatives not be treated as interchangeable and that the selection of therapeutic alternatives lacked specified standards

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters remarked that some information sought through the Request for Information process is logistically burdensome, highly confidential, and may not indicate affordability challenges

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenter noted concern with tighter regulatory provision that narrowed consideration of orphan drug designation

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters recommended additional information and analysis of supply chain dynamics and insurance coverage features that impact patient access and affordability

Comment Themes:
COMAR 14.01.04 Cost Review Study Process

Commenters requested consistent timelines for public comment and input

Key Changes:
COMAR 14.01.04 Cost Review Study Process

1. Removed Medicare Drug Price Negotiation Drugs as an eligibility criteria

   Removed Draft Proposed COMAR 14.01.04.02D(4)

2. Allows Board to consider if drug is designated for a rare disease or condition AND if if the drug is approved for an indication treating that rare disease or condition

   Revision COMAR 14.01.04.03B(1)(d)

3. Revised proposed regulations to maintain Board approval of list of therapeutic alternatives

   Revision COMAR 14.01.04.03H

Key Changes:
COMAR 14.01.04 Cost Review Study Process

1. Updated Request for Information to collect information on formulary changes

   Revision COMAR 14.01.04.04B(3)(g)

2. Moved Reporting of Drug Affordability Issues to 14.01.04.06 and Updated reporting for Drug Affordability Issues, including a process for Eligible Governmental Entities to provide information to the Board
3. Updated COMAR 14.01.01.05B(4) Public Comments to provide for a comment period of at least 15 days when the Board requests comment by posting notice on its website (and no other regulatory provision applies)

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