COMAR 14.01.04
Cost Review Study Process

PDAB Meeting

November 16, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Register Comments Received

- Proposed amendments to repeal existing Regulation .01 and adopt new Regulation .01, amend Regulations .02—.05, and adopt new Regulation .06 under COMAR 14.01.04 Cost Review Study Process.
- Comments were due on October 5, 2026
- Comments were Received from the following entities (in combination with 14.01.01.05)
  - AbbVie
  - Boehringer Ingelheim USA Corporation
  - EACH/PIC Coalition
  - Healthcare Distribution Alliance
  - PhRMA
  - Regeneron Pharmaceuticals, Inc.
  - RxEconomics LLC
  - Value of Care Coalition

The written comment packet can be found here.

Main Comment Themes

- Standards and Definitions
- Patient Access, Affordability, and Safeguards
- Therapeutic Alternatives and "Any Comparator"
- Medicare Maximum Fair Price (MFP)
- Confidentiality

Comment Theme: Standards and Definitions

- Some commenters expressed significant concern that proposed COMAR 14.01.04.01 relies on broad, subjective, and undefined terms without objective thresholds, weighting rules, or evidentiary standards. Also, concerns about open ended “catch-all provisions,” such as "any other circumstance identified by the Board” were noted.
- Some commbers noted concerns about the transparency of the curated list in COMAR 14.01.04.03.
- PDAB Response: Board deliberations at open meetings will indicate how the Board prioritizes and evaluates information throughout Cost Reviews and Policy Reviews. The selection and Cost Review Study process allows for multiple opportunities for the public and stakeholders to provide comments, input, and feedback for the Board to consider in their deliberations and decisions.

Comment Theme: Patient Access, Affordability, and Safeguards

- Patient groups and manufacturers emphasized that aggregate healthcare spending metrics do not inherently correlate with individual patient affordability challenges. Commenters across sectors emphasized that patient affordability challenges are frequently driven by insurance benefit designs (e.g., high deductibles, coinsurance, formulary exclusions, and tier placement) and pharmacy benefit manager (PBM) and plan utilization management (UM) (e.g., prior authorization, step therapy) rather than manufacturer prices. They argued that UPLs would not resolve these root causes and could inadvertently harm patient access.
- One entity urged the Board to require that at least one direct patient affordability criterion be satisfied before an affordability challenge can be found or an Upper Payment Limit (UPL) pursued.

- PDAB Response: The statute authorizes the Board to consider setting UPLs or suggesting non-UPL policies for drugs that have system-level affordability challenges or patient level affordability challenges. PDAB considers system-level and patient-level affordability challenges throughout the cost review and policy review process.

Comment Theme: Therapeutic Alternatives and "Any Comparator"

- Objections to COMAR 14.01.04.05C(1)(e)(i) granting staff authority to use "any comparator" outside the formal therapeutic alternative process without clinical standards. The regulations lack standards for identifying appropriate comparators.

- PDAB Response: The Board appreciates the difficulty of analyzing therapeutic alternatives, including that each drug has a unique combination of therapeutic uses, benefits, and alternatives. The Cost Review Study Process relies on the Board's deliberation about data and testimony rather than on specific data thresholds or pre-established metrics due to the complex and diverse nature of the pharmaceutical supply chain, and a desire to avoid applying universal standards that might not be appropriate for all drugs.

Comment Theme: Medicare Maximum Fair Price

- Concerns about utilizing the Medicare Maximum Fair Price (MFP), arguing that federal statutory assumptions cannot be imported into Maryland reviews and that cross-referencing MFPs against different products is clinically and economically flawed.

- PDAB Response: The Board's Cost Review Study Process is uses Maryland-specific data whenever possible, and uses national data and information when it is the best available information. The Board uses the MFP and other national data points, with all of the relevant context, for consideration when selecting drugs, conducting Cost Review Studies, and, if applicable, setting UPLs.

Comment Theme: Confidentiality

- Commenters raised concerns regarding the nature and confidentiality of newly requested data.

- PDAB Response: PDAB remains committed to the confidentiality of data and records that the are submitted and designated as confidential, trade secret, or proprietary, as described in COMAR 14.01.01.04

Non-Substantive Changes at Final Action
COMAR 14.01.04

Summary of Non-substantive Changes at Final Action

- Standardizes language for how drugs are sorted during 14.01.04.02, Identifying Drugs Eligible for Cost Review
- Standardizes language for referring to the Medicare Maximum Fair Price ('MFP')
- Standardizes language for referring to the staff report to the Board during the "Preliminary Determination of Affordability Challenge" as the "preliminary determination cost review study report"
- Correct two citations to PDAB regulations
- Clarify that the Board makes a single preliminary determination of whether the use of a drug, consistent with FDA labelling or standard medical practice, "has led or will lead two (a) Affordability challenges to the State health care system; or (b) High out-of-pocket costs for patients."