# Updates to Cost Review Study Process and Policy Review Process

PDAB Meeting

May 18, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

# 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. |
| **Timeline** | 60-day comment period triggers upon posting the drug selection. | 60-day comment period triggers upon staff posting the request for comments. |

# Public Engagement with Cost Review Study Process

**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:

- 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

# 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

# Informational Hearing Feedback

The Maryland Prescription Drug Affordability Board invited public feedback in 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

# Summary of Informational Hearing Oral and Written Comments

- Feedback for Additional Data and Considerations
  - Focus on Patient Out-of-Pocket Costs
  - Consider and document the patient benefits of the therapy
  - Analyze 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

# Updates to Cost Review Regulations

Overall Goal: streamline cost review studies and enable Board Staff recommendations to the Board

1. Authorize Board staff to provide a “curated list” of drugs that are organized according to Board instructions
2. Expand Board’s ability to consider information about therapeutic alternatives, therapeutic equivalents, and therapeutic classes
3. Broaden consideration of drugs subject to Medicare Maximum Fair Price
4. Enable consideration of qualitative research and certain measures of cost-effectiveness, including information from health and outcomes research
5. Supplement public comment procedures and enable additional input from eligible government entities, patients, and stakeholders

# Draft Cost Review Regulation Updates

## Identification of Eligible Prescription Drug Products (14.01.04.02)

- Clarify that prescription drug products are organized and selected by NDC.
- Delete selection metrics and criteria that are unlikely to be useful (for example, the 100 prescription drug products with the highest percent change increase in WAC over the most recent available 5-year period).
- Authorize the Board to consider any drug subject to the Medicare Drug Price Negotiation Program as eligible for selection for cost review.

# Draft Cost Review Regulation Updates

## Selection (14.01.04.03)

- Board provides priorities to staff;  staff creates a “curated list” of eligible drugs by organizing, comparing, and prioritizing the list of eligible drugs in the dashboard.
- Board considers recommendations from staff.
- Board staff applies Board priorities to recommend drugs for referral to the stakeholder council.
- Board shares the curated and redacted dashboard with the Stakeholder Council.
- Board considers a drug’s estimated net price, and its involvement in the Medicare Drug Price Negotiation Program, including the published MFP and the estimated net cost of the drug.

# Draft Cost Review Regulation Updates

## Request for Information (14.01.04.04)

- Board may request additional data, including
  - Net drug price
  - Gross and net sales
  - Drug-specific patient-assistance-programs and costs of marketing the drug to patients and physicians.
  - Therapeutic alternatives identified by the PBM
  - Price concessions and revenues for wholesale distributors

# Draft Cost Review Regulation Updates

## Cost Review Study (14.01.04.05)

- Reorganization of “Additional Board Factors” that may be considered during cost review
  - Approximately 1-page deletion and reinsertion to avoid confusing markup
  - Clarify and organize the additional non-statutory factors that the Board may consider
  - Enable Board to consider information about the relationship between drug price, cost of development, and therapeutic benefit, and other pertinent pricing information from any source (not just from a manufacturer)
- Reorganization of considered information into categories:
  - (a) Prescription drug under study
  - (b) Regulatory Approval and Market Context
  - (c) Utilization of the drug
  - (d) pricing information and rebates
  - (e) Therapeutic classes, equivalents, and alternatives
  - (f) Cost-sharing
  - (g) Other information (state and federal compliance, input from government entities, Board staff research and analysis, public input, CMS reports)

# Procedural Updates to Draft Regulations

- Board sets priorities to inform drug selection
- Staff organizes dashboard and provides curated list
- Staff may provide recommendations concerning drugs for referral to the Stakeholder Council
- Staff may provide the Board with recommendations concerning the preliminary determination

# Content Updates to Draft Regulations

**Eligibility and Selection for referral to Stakeholder Council:**

- Delete four unnecessary eligibility categories
- Enable Board consideration of all drugs in the Medicare Drug Price Negotiation Program, the Maximum Fair Price and estimated net price
- Expand the dashboard to include information regarding drugs that are approved for indications treating rare diseases
- Staff may provide: (1) data summaries and analyses; (2) reports of affordability issues by the public and by eligible government entities; and (3) recommendations concerning drugs for referral to the Stakeholder Council.

# Content Updates to Draft Regulations

**Request for Information for Cost Review:**

- Request price and utilization data in aggregate, separated by payor type, and separated by market segment
- Clarify that sales calculations should be reported in gross and net
- Delete three categories of requests for information
- Request information concerning patient assistance programs and direct-to-consumer and direct-to-physician marketing
- Request information about units paid for by insurance, health plan
- Request information about total discounts and rebates
- Request information about therapeutic alternatives identified by a PBM

# Content Updates to Draft Regulations

**Cost Review Study:**

- Clarify that Staff may report data and analyses from source documents in addition to conducting their own analysis
- Illustrate types of qualitative and quantitative data that Staff may collect
- Include Board consideration of price data from National VA Contract Price, Big 4 Price, and MFP
- Categorize the additional data the Board consider during cost reviews, broaden consideration of clinical information, utilization, therapeutic class information, health outcomes research, and cost sharing
- Staff may provide the Board with recommendations concerning the preliminary determination

# Comments on Draft Regulations

In response to requests for additional time from the pharmaceutical industry, the Board is extending the comment period to Monday, June 1, 2026. All comments will now be due Monday, June 1, 2026.

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