

# **Cost Review Study Process and Policy Review Process: Feedback from the PDASC**

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PDASC Meeting

February 23, 2026

PDAB Staff



# Purpose

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**Gather input from the Stakeholder Council regarding the cost review study process (COMAR 14.01.04.01, et seq.) and policy review procedures (COMAR 14.01.05.01, et seq.)**



# Overview - Cost Review Study Process- Current Process

COMAR 14.01.04

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**Identify**

**Select**

**Collect**

**Analyze**

**Results**



# Cost Review Study Process



PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
<p>Public Reporting of Drug Affordability Issues</p> <p>Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review</p>	<p>Identifying prescription drug products to consider for cost review- this is a subset from eligibility list</p> <p>Refer prescription drug products to the Stakeholder Council for input</p>	<p>PDASC will review and discuss the referred prescription drug products at an open meeting</p>	<p>Public comment</p>	<p>Board selects prescription drug product(s) for cost review</p> <p>Next Steps:</p> <ul style="list-style-type: none"><li>→ Collect</li><li>→ Analyze</li><li>→ Results</li></ul>

# Cost and Policy Review Process



Drug(s) in Cost Review	Data Collection	Analyze	Preliminary Determination	Policy Review Process	Final Results
<p>Drug(s) selected for Cost Review Study will be posted on the Board's Website.</p> <ul style="list-style-type: none"> <li>- 60 day written comment period begins with posting</li> </ul>	<p>PDAB may request information from, and post request:</p> <ul style="list-style-type: none"> <li>- Manufacturers</li> <li>- Carrier, HMO and MCO</li> <li>- Pharmacy Benefits Managers</li> <li>- Wholesale Distributor</li> </ul>	<p>Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.</p>	<p>Board may preliminarily determine whether the prescription drug has led or will lead to:</p> <ul style="list-style-type: none"> <li>- Affordability challenges to the State health care system or</li> <li>- High out of pocket costs for patients</li> </ul>	<p>Board may perform the policy review process to identify and recommend policies to address affordability challenges:</p> <ul style="list-style-type: none"> <li>- Process for setting upper payment limits</li> <li>- Process for all other policies that are not upper payment limits</li> </ul>	<p>Board takes final action:</p> <ul style="list-style-type: none"> <li>- Board Finalizes Determination and Adopts Final Cost Review Study Report</li> <li>- Board Adopts Policy Recommendations</li> <li>- Board Adopts Proposed UPL Regulation</li> </ul>

# Cost Review Study Process

## COMAR 14.01.04

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### 04- Cost Review Study Process

- .01 Public Reporting of Drug Affordability Issues
- .02 Identifying Drugs Eligible for Cost Review
- .03 Selecting Drugs for Cost Review
- .04 Request for Information for Cost Review
- .05 Cost Review Study



# Overview-

## Policy Review Process and UPL Development

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### 1. Optional Information Gathering

### 2. Staff Recommends Policy Options

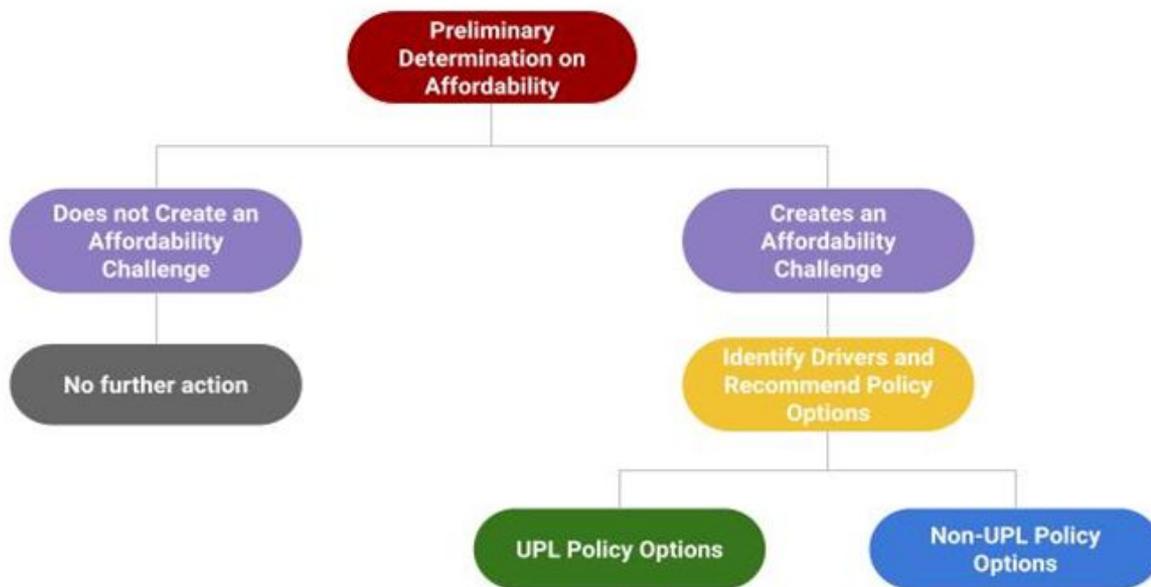
- Drivers of Affordability Challenges
- Policy Options to Address Identified Drivers
  - Non-UPL Policy
  - UPL Policy

### 3. Final Actions

- Adopt Final Determination Concerning Affordability Challenge
- Adopt (a) other (non-UPL) policy recommendations; (b) proposed regulations setting the UPL at the specified amount; or (c) both.



# Process after Board Makes Preliminary Determination on Affordability



# Policy Options- Drug Deemed to Create Affordability Challenges



# Regulations Pertaining to the Policy Review Process- COMAR 14.01.05

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## 05- Policy Review, Final Action, Upper Payment Limits Authority

- .01 Definitions
- .02 Criteria for Setting and Upper Payment Limit
- .03 Policy Review and Final Action Process Overview
- .04 Policy Review–Information Gathering
- .05 Policy Review–Preliminary Policy Recommendations
- .06 Policy Review–Process for Establishing a UPL
- .07 Policy Review–Final Policy Action
- .08 Establishing and Monitoring a UPL
- .09 Reconsideration





**MARYLAND**

Prescription Drug Affordability Board

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