

# Upper Payment Limit Action Plan

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PDASC Meeting

August 26, 2024

PDAB Staff



# Upper Payment Limit Action Plan

## Background

- Under HG § 21-2C-09, the Board may conduct a cost review study to determine whether use of a prescription drug product “has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients (“affordability challenges”).”
- This study informs policy decisions and actions by the Board.
- If the Board determines that a prescription drug product has led or will lead to affordability challenges, the Board may consider, recommend, and implement policies to address those affordability challenges, including establishing an upper payment limit (“UPL”) that applies to state and local governments and units.



# Upper Payment Limit Action Plan

## Background

- **When the UPL Action Plan is approved by the Legislative Policy Committee, the Board may set UPLs for prescription drug products that are:**
  - **[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including: State or county correctional facilities; State hospitals; and health clinics at State institutions of higher education;**
  - **prescription drug products that are “[p]aid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan,” or “[p]urchased for or paid for by the Maryland State Medical Assistance Program.” HG § 21-2C-14(a);**
  - **the authority to establish UPLs applies only to purchases and payments made by state and local governments and their units (Eligible Governmental Entities)**



# Overview- UPL Action Plan

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- Board develops “plan of action for implementing the process that includes the criteria the Board shall use to set upper payment limits (“UPL Action Plan”)”
- Because setting a UPL is a quasi-legislative action, the procedures in this action plan provide for the setting of a UPL by adopting a regulation through the notice and comment rulemaking provisions of the Maryland Administrative Procedure Act
- The cost review study and the policy review process are both part of the quasi-legislative process that enables the Board to acquire relevant data and information to inform the development and promulgation of public policy



# Criteria for Setting an Upper Payment Limit

The Board shall apply the following criteria (as applicable) when determining whether to set an upper payment limit and when setting an upper payment limit amount:

- The Board shall consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs
- The Board shall determine that an upper payment limit is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product
- The Board shall not set an upper payment limit for the prescription drug product if utilization of the product by Eligible Governmental Entities is minimal
- The Board shall set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences
- The Board shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug
- The Board shall not set an upper payment limit for generic prescription drug products that have nine (9) or more marketed therapeutic equivalents
- The Board shall not set an upper payment limit amount that impacts statutory or regulatory amounts, such as Medicaid Best Price
- The Board shall not set an upper payment limit that is lower than the Medicare Maximum Fair Prices



# Cost and Policy Review Process



PDAB Meeting	<u>PDAB Meeting</u>	Stakeholder Council Meeting	Interim	<u>PDAB Meeting</u>
<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> <ol style="list-style-type: none"> <li>1. Manufacturers</li> <li>2. Carrier, HMO and MCO</li> <li>3. Pharmacy Benefits Managers</li> <li>4. Wholesale Distributor</li> </ol>	<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 Regulations</li> </ul>

# Updates to Cost Review Study Process

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**After Collecting and Analyzing Data in the Cost Review Study Process:**

- 1. Board makes Preliminary Determination whether use of a prescription drug product “has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients (“affordability challenges”).” A preliminary determination is non-final and subject to revision and modification.**
- 2. Board Staff Drafts Preliminary Determination Report**
  - Public Comment on the Draft Preliminary Determination Report**
- 3. Board Finally Determines Whether Drug has or will create an affordability challenge. Board Adopts Final Cost Review Study Report.**

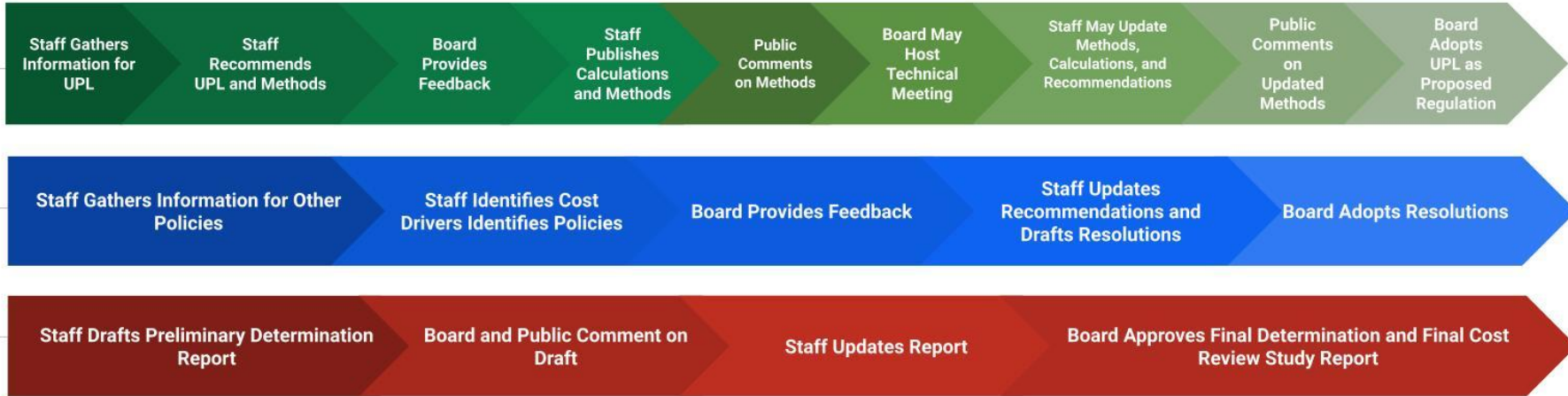




# Policy Review Process and Upper Payment Limit (UPL) Development

## Policy Review Process

Board Makes Preliminary Determination



**Green**= Upper Payment Limit Policy Review Process  
**Blue**= Non-UPL Policy Review Process  
**Red**= Cost Review Study Process



# 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 (go to slide 13)
  - UPL (go to slide 14)

### 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.**



# 1. Optional Information Gathering- Policy Review Process and UPL Development

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## 1. Optional Information Gathering

- **Staff assesses if additional information is needed.**
- **If additional information is necessary, the Board may use the following tools:**
  - **Informational Hearings**
  - **Stakeholder Council Input**
  - **Expert Testimony Hearings**
  - **Board Staff Research and Analysis**
  - **Input from Eligible Governmental Entities**



## 2. Staff Recommends Policy Options

### Policy Review Process and UPL Development

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#### 2. Staff Recommends Policy Options

- **Drivers of Affordability Challenges**– the factors which cause the phenomenon of an affordability challenge
- **Policy Options to Address Identified Drivers**
  - **Non-UPL Policy (go to slide 13)**
  - **UPL (go to slide 14)**



# Staff Recommends Policy Options

## Non- UPL Policy Review Process

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### Preliminary Policy Recommendations

- **Staff identifies drivers of affordability challenges**
- **Staff proposes policy options to address identified drivers which may include:**
  - **how a particular policy addresses a driver**
  - **the strengths and weaknesses of such a policy**
  - **information regarding possible implementation of such a policy**
  - **the potential impacts of the policy option.**



# Staff Recommends Policy Options

## UPL Development Process

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### Preliminary Policy Recommendations

- **Staff identifies drivers of affordability challenges**
- **Staff proposes UPL option which may include analysis of:**
  - **contextual issues related to the driver(s) of the affordability challenge**
  - **the ability of a UPL to address these issues**
  - **the relevant regulatory criteria**
  - **the use of the drugs by Eligible Governmental Entities**



# Overview-

## Upper Payment Limit (UPL) Development

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**After staff recommends a UPL as a policy option:**

- A. Staff Recommends Methodologies and Factors to Establish a UPL (opportunity for public comment)**
- B. Staff Performs Calculations and Analyses to Develop a Market Basket of UPL Values (opportunity for public comment)**
- C. Board May Convene Technical Hearing**
- D. Staff May Update Calculation of UPL Amount (opportunity for public comment)**



## **A. Staff Recommends Methodologies & Factors to Establish a UPL**

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### **Preliminary Recommendations for Upper Payment Limit Methodologies and Factors**

- **Staff recommends methodologies and contextual information to establish a UPL**
- **Staff posts the recommendations on the Board's website prior to the Board meeting and requests public comment**
- **Staff presents recommendations to the Board**
- **Board directs staff to calculate preliminary UPL amount**





## Sample Methodologies

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- **Cost Effectiveness Analysis**
- **Therapeutic Class Reference Upper Payment Limit**
- **Launch Price-Based Upper Payment Limit**
- **Same Molecule Reference Upper Payment Limit**
- **Domestic Reference Upper Payment Limit**
- **International Reference Upper Payment Limit**
- **Budget Impact-Based Upper Payment Limits**
- **Blend of Multiple Methodologies**



# Factors – Contextual Information for Setting UPL

**The Board may consider the following contextual information when setting the upper payment limit amount:**

- Any information contained in the Cost Review dossier
- Utilization in the state health plan in terms of patients and prescriptions
- Utilization in county, bicounty, and municipal health plans in terms of patients and prescriptions
- Amount of direct government purchases in terms of units and patients served
- Utilization in Medicaid in terms of patients and prescriptions
- Net prices for the state health plan
- Net prices for county, bicounty, and municipal health plans
- Net prices for direct government purchases
- Net prices for Medicaid
- Total out-of-pocket costs in the state health plan
- Total out-of-pocket costs in county, bicounty, and municipal health plans
- Total out-of-pocket costs in Medicaid
- Current coverage status of the drug in the state health plan
- Current coverage status in Medicaid
- Current coverage status in the county, bicounty, and municipal health plans
- The number of prescriptions paid through the Maryland State Medical Assistance Program
- The number of patients for the drug helped through the Maryland State Medical Assistance Program
- The total amount paid for the drug through the Maryland State Medical Assistance Program
- Information submitted as part of a request for information
- Information provided based on public testimony
- Information derived from listening sessions hosted by board staff
- Any information provided by entities potentially subject to UPLs
- Information derived from feedback from the stakeholder council
- Information derived from public comments on board meetings
- Any information that can be derived from the manipulation, aggregation, calculation, and comparison of the information listed above
- Information on the potential impact setting a UPL (e.g., savings, impacts on access, behavioral changes)



## **B. Staff Performs Calculations and Analyses to Develop a “Market Basket” of UPL Values**

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**Board staff shall post a public version of:**

- **The “market basket”**
- **Staff’s recommendation for a proposed UPL amount**
- **A description of the calculation and analyses**
- **A request for public written comment**



## C. Board May Convene Technical Hearing

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- **The Board may convene a technical hearing to receive additional technical input and information**
- **The Board may request that persons who submitted technical written comments, or comments that raised additional issues the Board wishes to explore, attend the hearing and provide testimony**
- **The Board shall adopt regulations governing these quasi-legislative hearings**



## D. Staff May Update Calculation of UPL Amount

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- **Board staff may modify or amend the public version of the market basket, and staff's recommendations for a proposed UPL amount**
- **If Board staff modifies or amends the market basket and staff's recommendations, staff shall post the amendments to the Board's website, and request public written comment by a specified date**



## 3. Final Policy Action and Final Cost Review

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### 3. Final Action:

The adoption of a final policy recommendation shall occur after the final determination and adoption of the final cost review study report.

The policy review process culminates in the adoption of: (1) other (non-UPL) policy recommendation(s) as Board resolutions; (2) proposed regulations setting the UPL at the specified amount; or (3) both.

The adoption of the final cost review report, adoption of policy recommendations (non-UPL) by resolution and the adoption of proposed regulations setting a UPL amount shall be performed sequentially, where applicable. These actions may be taken at the same Board meeting.



# Next Steps

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- **Draft of Upper Payment Limit Action Plan Published for Public Comment and Stakeholder Council Input**
- **Stakeholder Council Meeting to Provide Input**
- **Publish Final Upper Payment Limit Action Plan for Board Meeting**
- **Board approves Upper Payment Limit Action Plan**
- **Legislative Policy Committee (LPC) reviews and may approve the Upper Payment Limit Action Plan**
- **If the LPC does not approve the Upper Payment Limit Action Plan, the Governor and the Attorney General may approve the Upper Payment Limit**





**MARYLAND**

Prescription Drug Affordability Board

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