

# Upper Payment Limit Action Plan

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PDAB Meeting

September 10, 2024

PDAB Staff



# 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 part of this quasi-legislative process that enables the Board to acquire relevant data and information to inform the development and promulgation of public policy



# 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.**



# 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



# 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 Regulation</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.**



# Criteria for Setting an Upper Payment Limit

The Board shall apply the following criteria (as applicable) when determining whether to set a UPL and when setting a UPL 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 a UPL is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product
- The Board shall not set a UPL for the prescription drug product if utilization of the product by Eligible Governmental Entities is minimal
- The Board shall set a UPL 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 a UPL for generic prescription drug products that have nine (9) or more marketed therapeutic equivalents
- The Board shall not set a UPL amount that impacts statutory or regulatory amounts, such as Medicaid Best Price
- The Board shall not set a UPL that is lower than the Medicare Maximum Fair Prices



# 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 needed, 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 10)**
  - **UPL (go to slide 11)**



# 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 Contextual Information to Establish a UPL (opportunity for public comment)
- B. Staff Performs Calculations and Analyses to Develop a Collection of Potential 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 & Contextual Information to Establish a UPL**

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## **Preliminary Recommendations for UPL Methodologies and Contextual Information**

- **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(s)**



# 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**



# Contextual Information for Setting UPL

## The Board may consider the following contextual information when setting a UPL 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 Collection of Potential UPL Values**

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

- **The collected potential UPL values**
- **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 collection of potential UPL values, and staff's recommendations for a proposed UPL amount**
- **If Board staff modifies or amends the collection of potential UPL values 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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**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.**



# Establishing and Implementing a UPL

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- **The UPL is the maximum final net ingredient cost paid by Eligible Governmental Entities**
- **Each UPL will be established by a regulation that specifies:**
  - **UPL amount**
  - **Specified Eligible Governmental Entities**
  - **Prospective effective date that provides sufficient time for implementation**
- **The Board and staff shall work with Eligible Governmental Entities to develop the best method for implementing the UPL for the entity**



# Monitoring, Suspending, and Rescinding a UPL

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- **The Board shall develop a program for monitoring the availability of any prescription drug product for which it sets a UPL**
- **The Board shall adopt regulations providing for the suspension, modification, and rescission of a UPL**
  - **If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL**
  - **The Board shall provide for the automatic suspension of the UPL for the time that the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list**



# Summary of Comments Received

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- **Feedback from the PDASC**
  - **Questions clarifying the process**
  - **General feedback and concerns on timeline and process**
- **22 Written Comments Received on Draft UPL Action Plan**
  - **Feedback on Process for Developing the UPL Action Plan and Opportunities for Input**
  - **Feedback on the level of detail of how the UPL will be set**
  - **Feedback on potential adverse consequences of setting Upper Payment Limit**



# Changes in the August 30, 2024 Draft

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- **Technical corrections**
- **Updated and clarified terminology**
- **Added section to address implementation**
  - **The final net ingredient cost paid by the Eligible Governmental Entities shall not exceed the UPL established by the Board.**
- **Added section to address monitoring, suspending and rescinding a UPL**



# UPL Status

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## Previous Actions:

- Stakeholder Council reviewed UPL draft and provided feedback at 8/26/24 meeting
- Public comments were accepted on the UPL draft until 8/26/24
  - 22 Comment Letters Received, posted on the website and shared with the Board
- Comments were reviewed by staff and changes were made in current draft

## Prior UPL work:

- Board meeting July 24, 2023
- PDASC meeting August 28, 2023
- Board meeting September 18, 2023
- PDASC meeting October 23, 2023
- Supply Chain Report January 29, 2024
- Board meeting July 22, 2024







**MARYLAND**

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