

Prescription Drug Affordability Board

Briefing for the House Health & Government Operations
Committee

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MARYLAND
Prescription Drug Affordability Board

Agenda

- **PDAB Overview**
- **Cost Review Study Process**
- **Upper Payment Limit Action Plan**



PDAB Overview

- **Independent Agency Created in 2019**
- **Structure:**
 - **5 Member Board**
 - **26 Member Stakeholder Council**
- **Purpose:**
 - **“...protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products.”**



PDAB Overview

- **Cost Reviews**
 - **In-depth review of select drugs to determine if they cause affordability challenges**
- **Upper Payment Limits**
 - **Policy tool to address drugs that cause affordability challenges**
- **Recommend Additional Policies**
 - **Annual report that summarizes price trends and recommends policies**



Cost Review Study Process

- **Board can Select Drugs to Undergo a Cost Review**
 - **Must select from a list of eligible drugs based on statutory metrics**
 - **Name Brand Drugs over \$30,000 per year**
 - **Name Brand Drugs increase by \$3,000 over a year**
 - **Biosimilars that are not at least 15% less than the reference biologic**
 - **Generic drugs that are more than \$100 per month AND go up in price by 200% or more in a year**
 - **Other metrics as added by the Board**
- **Must select during an open meeting**



Cost Review Study Process

- Cost Review allows for an in-depth analysis based on additional collected data
- Board uses Cost Review to determine “...whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients.”



Cost Review Study Process

Approved Final Regulations (effective December 25, 2023)

- COMAR 14.01.01 – General Provisions
- COMAR 14.01.04 – Cost Review Study Process



Cost Review Study Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results



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Cost Review Study Process Timeline



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>Listening sessions</p>	<p>Board selects prescription drug product(s) for cost review</p> <p>Next Steps:</p> <ul style="list-style-type: none">→ Collect→ Analyze→ Results

Cost Review Study Process- Opportunity for Public Comment and Engagement

- **Public Reporting of Drug Affordability Issues (COMAR 14.01.04.01)**
- **Public Comment in Selection Process**
 - Oral and written comments concerning the drugs proposed for referral to the Stakeholder Council (COMAR 14.01.04.03C(4))
 - Written comments concerning the list of prescription drug products referred to the Stakeholder Council (30 days) (COMAR 14.01.04.03F)
 - Written comments concerning list of therapeutic alternatives (30 days) (COMAR 14.01.04.03H)
 - Oral and written comments concerning Board selection of prescription drug product for cost review (COMAR 14.01.04.03I(2))
- **Public Facing Information to Understand the Process**
- **Series of Listening Sessions**



Upper Payment Limits

- **Maryland PDAB may set Upper Payment Limits for state and local government**
 - **State, county, and local employees**
 - **State direct purchases**
 - **Maryland State Medical Assistance Program (i.e., Medicaid)**



Upper Payment Limits

- **PDAB must draft Upper Payment Limit Action Plan to be approved by the General Assembly Legislative Policy Committee**
 - **What drugs would be subject to Upper Payment Limits?**
 - **How would the PDAB set the Upper Payment Limits?**
 - **How would the Upper Payment Limits be implemented (i.e., how with the UPLs flow through the supply chain)**
- **PDAB will also draft a report on whether or not to expand the scope of Upper Payment Limits to the entire state**



PDAB Support

- **Resource and Subject Matter Experts (SME) for Legislators**
- **Additional research and analysis to identify affordability issues**
- **Patient Resources**



Recommended Additional Policies

- **Insulin Affordability Program**
 - **Patient Navigator Program**
- **Transparency Program**
- **Annual Report that summarizes prices trends and recommends policies**

