Overview of Prescription Drug Affordability Boards

National Council of Insurance Legislators

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Agenda

- PDAB Overview
- MD PDAB Overview
- Comparison of PDABs

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PDAB Overview

- Entities created to make prescription drugs more affordable for the state
- Structure:
  - Board- Most states have a Board of subject matter experts that that set policy
  - Advisory Council- Most Boards are supported by an advisory council with representatives from throughout the pharmaceutical supply chain and reimbursement system
- Functions:
  - Cost/Affordability Review- Study specific prescription drugs to understand if they cause affordability challenges for the state
  - Policy Recommendations- Implement policies, such as setting upper payment limits, to make prescription drugs more affordable for states
  - Subject Matter Expertice- Serve as a resource for state policy makers on issues related to prescription drug affordability

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MD PDAB Overview

- During the 2019 Session, the General Assembly enacted HB768/SB759 creating the Maryland Prescription Drug Affordability Board as an independent agency

- 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."

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PDAB Overview

Priority Projects:

- Cost Review Study Process
  - 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

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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."**

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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

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results

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Cost Review Study Process Timeline

Identify → **Select**

PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
Public Reporting of Drug Affordability Issues Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review	Identifying prescription drug products to consider for cost review- this is a subset from eligibility list Refer prescription drug products to the Stakeholder Council for input	PDASC will review and discuss the referred prescription drug products at an open meeting	Public comment Listening sessions	Board selects prescription drug product(s) for cost review Next Steps: → Collect → Analyze → Results

Timeline

Collect → **Results**

Drug(s) in Cost Review	Data Collection	Analyze	PDAB Preliminary Determination of Affordability	Cost Review Study Report
Drug(s) selected for Cost Review Study will be posted on the Board's Website. - 60 day written comment period begins with posting	PDAB may request information from, and post request: 1. Manufacturers 2. Carrier, HMO and MCO 3. Pharmacy Benefits Managers 4. Wholesale Distributor	Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.	Board may determine whether the prescription drug has led or will lead to: - Affordability challenges to the State health care system or - High out of pocket costs for patients	Board creates and adopts a report of the cost review study that summarizes the information considered by the Board in conducting the cost review study, and the Board's determination.

Overview-
Policy Review Process and UPL Development

1. Optional Information Gathering

2. Staff Recommends Policy Options

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

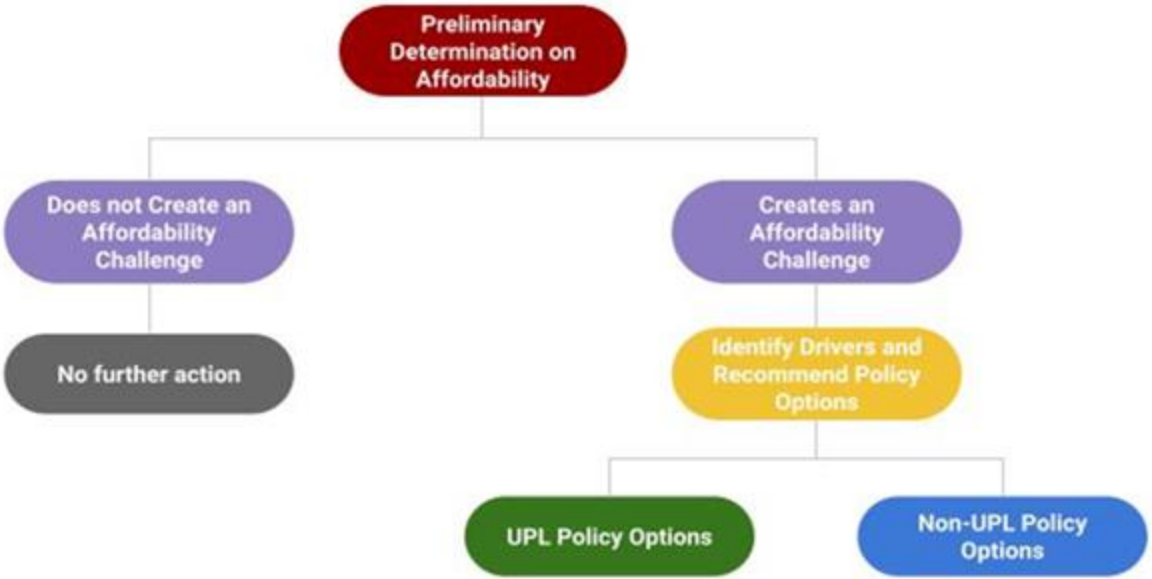
3. Final Actions

- 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.

Cost and Policy Review Process

Drug(s) in Cost Review	Data Collection	Analyze	Preliminary Determination	Policy Review Process	Final Results
Drug(s) selected for Cost Review Study will be posted on the Board's Website. - 60 day written comment period begins with posting	PDAB may request information from, and post request: - Manufacturers - Carrier, HMO and MCO - Pharmacy Benefits Managers - Wholesale Distributor	Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.	Board may preliminarily determine whether the prescription drug has led or will lead to: - Affordability challenges to the State health care system or - High out of pocket costs for patients	Board may perform the policy review process to identify and recommend policies to address affordability challenges: - Process for setting upper payment limits - Process for all other policies that are not upper payment limits	Board takes final action: - Board Finalizes Determination and Adopts Final Cost Review Study Report - Board Adopts Policy Recommendations - Board Adopts Proposed UPL Regulation

Process after Board Makes Preliminary Determination on Affordability



Policy Options- Drug Deemed to Create Affordability Challenges

MD 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)**

Prescription Drug Affordability Board- Comparison

- States with PDABs
  - Colorado (CO), Maryland (MD), Minnesota (MN), and Washington (WA) have created Prescription Drug Affordability Boards with comparable authority
  - Maine, New Hampshire, New Jersey, and Oregon also have Prescription Drug Affordability Boards with varying levels of authority, primarily related to Cost Reviews
- UPL Authority-
  - Full State- CO, MN
  - Full state with process- MD, WA
- Example Organization- CO- Division of Insurance; MD- Independent Agency; MN- Commerce Department; OR- Division of Financial Regulation; WA- Washington State Health Care Authority

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