Cost Review Process Study Process- Timeline

Board Meeting

January 29, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Final Regulations

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

Identify

Public Reporting of Drug Affordability Issues

- **Individual member of the public may report their personal experience with a drug or drugs that have caused or are causing an affordability issue for the individual**

COMAR 14.01.04.01

Identifying Drugs Eligible for Cost Review

- **Utilize data (statutory and regulatory metrics) to identify drugs eligible for selection for a cost review study**
- **At meeting, Board member may move to add one or more additional prescription drug products for consideration**

COMAR.14.01.04.02

Selection Process

Selecting Drugs Eligible for Cost Review: COMAR 14.01.04.03

DASHBOARD

SELECTING DRUG(S) FOR REFERRAL TO STAKEHOLDER COUNCIL

STAKEHOLDER COUNCIL INPUT

THERAPEUTIC ALTERNATIVES

BOARD SELECTS DRUG(S) FOR COST REVIEW

Select:
Dashboard

- Staff may provide Board with a dashboard containing the prescription drug products identified under the statutory metrics and regulatory criteria
- Dashboard data elements may include:
  - FDA approval
  - Therapeutic Class
  - Utilization, Spending and Price Data
  - Patient Out-of-Pocket
  - Prescription Drug Product currently in active Shortage Status
  - Prescription Drug Subject to the Medicare Drug Price Negotiation

Select:
Dashboard

- **Dashboard Development**
  - **Staff will develop a dashboard based on the regulatory metrics for all eligible drugs based on the most recent year of All Payer Claims Database data.**
  - **The eligibility list and dashboard will remain static all calendar year, except for drugs that are added to the eligibility list by board members.**
  - **Board members will receive a draft of the dashboard every December with new data, and a final version of the dashboard in January that is updated based on any changes in January 1 WAC.**

Select:
Selecting Drug(s) for Referral to Stakeholder Council

- Board may select one or more prescription drug products identified under 14.01.04.02 as eligible for cost review to the Stakeholder Council
- Board Member may request that a prescription drug product(s) be placed on the Board's meeting agenda for consideration for referral to the Stakeholder Council
- Board Chair may include the prescription drug product name and dose on the Board's agenda
- <u>Public may provide oral and written comments concerning proposed drugs on Board agenda</u>

Select:
Selecting Drug(s) for Referral to Stakeholder Council

At an open meeting, the Board may:

- **Consider the prescription drug products identified on the Board's agenda and any eligible drug proposed for consideration by a Board member at the meeting; and**
- **Select one or more prescription drug products to refer to Stakeholder Council to receive input from the Stakeholder Council**

Select:
Selecting Drug(s) for Referral to Stakeholder Council

Board may consider:

- **The prescription drug products identified under the statutory metrics and regulatory criteria in COMAR 14.01.04.02**
- **Information provided under COMAR 14.01.04.03B**
- **The average cost share of the prescription drug product, the average patient total out-of-pocket cost, and the average total payor cost**
- **Any written or oral public comment**

Board posts notice of referred drugs on website and public may provide written comments concerning prescription drug products referred to the Stakeholder Council

Select:
Stakeholder Council Input

The Stakeholder Council:

- **Reviews the information provided for each referred prescription drug product**
- **Discusses the referred prescription drug products at an open meeting**
- **Board staff presents the Stakeholder Council input discussed at the open meeting to the Board**

Select:
Therapeutic Alternatives

- Board staff may develop and post therapeutic alternatives for each drug referred to Stakeholder Council
- Public may provide written comments regarding therapeutic alternatives
- Staff may modify the list of therapeutic alternatives for consideration by Board
- Board shall determine the therapeutic alternatives for each prescription drug product selected for cost review study

Select:
Board Selects Drugs for Cost Review

- Public may provide oral and written comments concerning the selection of a prescription drug product for cost review
- In selecting a prescription drug product for cost review Board considers:
  - The prescription drug products referred to the Stakeholder Council
  - Average cost share, average patient total out of pocket, average total payor cost, and direct to consumer advertising spending
  - Input from the Stakeholder Council
  - Input from the public
- During open meeting, Board may select one or more prescription drug products for cost review study and provide notice of the selection on its website within 3 working days of the meeting

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

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

Questions/Feedback

- Comments may always be submitted to comments.pdab@maryland.gov

2024 is going to be a very busy and exciting year!

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