PDAB Regulations

COMAR 14.01.01.01-.05
COMAR 14.01.04.01-.05

August 28, 2023

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

Overview of Regulation Structure

Title 14	Independent Agencies
Subtitle .01	Prescription Drug Affordability Board
Chapter .01	General Provisions
Regulation .01	Definitions

COMAR 14.01.01
General Provisions

14.01.01.01 — Definitions
14.01.01.02 — Rules of Construction
14.01.01.03 — Open Meetings
14.01.01.04 — Confidential, Trade-Secret and Proprietary Information
14.01.01.05 — Public Comment Procedures

COMAR 14.01.04
Cost Review Study Process

14.01.04.01 — Public Reporting of Drug Affordability Issues
14.01.04.02 — Identifying Drugs Eligible for Cost Review
14.01.04.03 — Selecting Drugs for Cost Review
14.01.04.04 — Request for Information for Cost Review
14.01.04.05 — Cost Review Study

Summary of Comment Process

- Two Rounds of Written Comments
  - 1st Draft Comments Received by May 2, 2023 and May 5, 2023
  - 2nd Draft Comments Received by June 30, 2023
  - 3rd Draft Posted on July 17, 2023

First Draft Comments Received

12 comment letters on the cost review and fee assessment regulations received by May 2, 2023:

- Three letters from manufacturers and the pharmaceutical industry (PhRMA, BIO, and Boehringer Ingelheim)
- Three letters from payers (Carefirst, Kaiser Permanente, and ACLI/LLHIM)
- One letter from wholesalers (HDA)
- Two letters from health policy experts (Jane Horvath and Jim Gutman)
- Two letters from advocates and the public (Maryland Health Care for All and Partnership to Improve Patient Care)
- One letter from the technology sector (Maryland Tech Council).

Comments are posted on the PDAB website.

Summary of Comment on Second Draft

8 comment letters on the cost review regulations received by June 30, 2023

- Two letters from manufacturers and the pharmaceutical industry (PhRMA, Biotechnology Innovation Organization (BIO))
- One letters from payers (Kaiser Permanente)
- One letter from wholesalers (Healthcare Distribution Alliance)
- Two letters from health policy experts (Jane Horvath, Jim Gutman
- One letter from advocates (Arthritis Foundation and Attachment (Value in the States Principles)
- One letter from the tech sectors (Maryland Tech Council)

Comments are posted on the PDAB website.

Summary of Key Themes in Comments on Second Draft

- Multiple Comments Provided Feedback on Definitions
- Multiple Comments Requested Opportunities for Public Feedback throughout the Selection Process
- Multiple Comments Recommended Clarification on the Selection Process and Timelines
- Multiple Comments Recommended Removal of Eligibility Criteria around Public Added Prescription Drugs
- One Comment Recommended Additional Criteria of Consideration in Selection Process, Especially If Drug Treats Rare Disease
- Multiple Comments Provided Feedback on Protection of Confidential and Proprietary Information

Definitions

- Multiple Comments Provided Feedback on Definitions
  - Updated 8 definitions based on comments

Opportunities for Public Comments

- Multiple Comments Requested Opportunities for Public Feedback throughout the Selection Process
  - Added 30 day comment period for drugs referred to SC and therapeutic alternatives
  - Added 60 day comment period for drug under cost review study
  - Comments on decisions pending before the Board at meetings
  - Created Public Comment Procedures Regulation at 14.01.01.05 General Provisions and procedure for providing confidential information

Clarification of Selection Process

- Multiple Comments Recommended Clarification of the Selection Process and Timelines
  - Updated and clarified selection process with opportunities for Stakeholder Feedback

Public Feedback as Eligibility Criteria

- Multiple Comments Recommended Eliminating Public Reporting of Drug Affordability Issues
  - Public reporting of drug affordability issue no longer qualifies drug for eligibility list but public report may be considered as a data element when selecting drug
  - Still have a mechanism for the public to report affordability challenges to the Board

Consideration of Treatment of Rare Disease

- One Comment Recommended Additional Factors for Consideration
  - ADDED: whether a drug is designated as treating a rare disease may be considered as an additional data point

Protection of Confidential and Proprietary Information

- Multiple Comments Provided Feedback on Protection of Confidential and Proprietary Information
  - Agree confidential, trade secret and proprietary information must be protected but internal training and procedures not established by regulation

OVERVIEW OF SELECTION PROCESS

Create Eligible List

COMAR 14.01.01.02

- Apply statutory and regulatory metrics to create list of drugs eligible for selection for a cost review study.
- At public meeting, Board may add drug(s) to eligible list by vote - identify how drug may create affordability challenge

Select Drug(s) to Refer to SC

COMAR 14.01.01.03

- Staff provides data to Board in dashboard.
- Board identifies drugs to consider referring to SC on its agenda.
- Public comment on identified drugs at Board meeting
- Board votes on drugs to refer to SC

Drugs Referred to SC

COMAR 14.01.01.03E, F. H

- Board posts list of drugs referred to SC
- Board posts list of therapeutic alternatives
- Public may submit comments on referred drugs and therapeutic alternatives for 30 days.

Select Drug for Cost Review Study

COMAR 14.01.01.03I

- Board considers public comment, SC input, data points, average patient total out-of-pocket cost, the average total payor cost, and publicly available data on direct-to-consumer advertising spending
- At public meeting, Board selects drug or drugs for cost review study

Request Information for Cost Review Study

COMAR 14.01.01.04

- Board may request information from manufacturer, PBMs, health insurance carriers, wholesale distributors, HMOs, and MCOs
- Entities submit information within 30 days request in compliance with COMAR 14.01.01.04
    - An entity may request one 30-day extension of time

Cost Review Study - Public Comment

COMAR 14.01.01.05

- Within 60 days of the date the drug's selection for cost review study is posted on the Board's website, public may provide comments on the selected drug under study.

Cost Review Study

COMAR 14.01.01.05

- At meeting Board considers public comments, specified factors (data) to evaluate whether use of the prescription drug product has led or will lead to:
    - Affordability challenges to the State health care system; or
    - High out-of-pocket costs for patients;
- In closed session, discuss confidential, trade secret and proprietary information.

Cost Review Study - Report

COMAR 14.01.01.05

- Board creates and adopts a report of the cost review study.

Board Amendments

COMAR 14.01.01.04

- The Board amended the timelines for data submission for Request Information for Cost Review Study
  - Updated the 60 day deadline for entities to submit data to a 30 day deadline with the option to request a 30 day extension

Board Approval

- With no opposition, the Board unanimously approved COMAR 14.01.01.01-.05 General Provisions Chapter Fee as submitted.

- With no opposition, the Board unanimously approved COMAR 14.01.04.01-.05 Cost Review Chapter, as redlined, submitted, and amended.

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