# Final Action- Amendments to COMAR 14.01.04.05 Cost Review Study

January 27, 2025

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

# Regulations Process

- Board approved proposed amended regulations at the September 10, 2024 Board meeting
- Proposed Regulations published in the November 1, 2024 Maryland Register
- Comments accepted through December 2, 2024
- 3 Comment letters were received
- These regulations were also approved as Emergency Regulations with an effective date of November 14, 2024

# Overview

Three primary categories of amendments:

(1) Clarify Analyses and Data Sources

(2) Include Additional Factors Considered in the Cost Review Study

(3) NEW – Track UPL Action Plan –Preliminary Determination that Drug Has or Will Lead to Affordability Challenge and Identify Circumstances of Affordability Challenge

# .05B(2) Analyses and Data Compilation.

(2) These data and analyses may be: . . .

(f) Derived from the MCDB, any claims set of the MCDB, and *any* other databases *containing relevant information*; [or]

(g) Derived from reports generated by U.S. governmental entities, *state governmental entities,* foreign governmental and quasi-governmental agencies, and U.S. and foreign non-profit organizations*; or*

*(h) Derived from quantitative and qualitative data collected by Board staff.*

# Summary of Comments on Proposed Amendments Analyses and Data Sources (COMAR 14.01.04.05B(2))

- Two commenters stated that the amendments *"any* other database *containing relevant information*" and "quantitative and qualitative data collected by Board staff" failed to identify the specific databases and data to be used
- Two commenters objected to "reports generated by . . . State governmental entities" to allow other States' reports

# .05C(1) Factors Considered in Cost Review Study

(c) Therapeutic Alternatives:

*(iii) The utilization, costs, and out-of-pocket costs for therapeutic alternatives;*

(d) Patient Access:

(iii) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer *for the drug product under review and the policies surrounding and implementing such programs*;

# .05C(1) Factors Considered in Cost Review Study

(g) Additional Board Factors:

(iii) [In the case of generic prescription drug products, the] *The* number of pharmaceutical manufacturers that produce [the] prescription drug [product] products that are therapeutically equivalent to the drug product under study;

(xi) Analysis of the *market context of the prescription drug product including the* prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product [copying] *hopping*;

# .05C(1) Factors Considered in Cost Review Study

(g) Additional Board Factors:

*(xii) The utilization and pricing of therapeutically equivalent drug products;*

*(xiii) Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product;*

*(xiv) Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators;*

# .05C(1) Factors Considered in Cost Review Study

(g) Additional Board Factors:

*(xv) Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks;*

*(xvi) Analyses and research including literature review by Board staff in response to information submitted by an entity under Regulation .04 of this chapter, or through any public comment or public input procedure;*

# Summary of Comments on Proposed Amendments–Additional Factors in Cost Review Study (COMAR 14.01.04.05C(1))

- Overall: Commenters noted the level of detail used to describe the different factors that the Board may consider in determining an affordability challenge, and the level of detail regarding how different factors may be weighed (*e.g.*, patient access programs, impact on public budgets, impact of state/federal regulatory/compliance issues, market context, and literature review).
- Therapeutic Alternatives: Commenters identified a lack of clarity regarding how therapeutic alternatives are considered and related data; one commenter stated that consideration of therapeutic alternatives should be based on clinical appropriateness and should not include consideration of the costs of therapy of other drugs.

# Summary of Comments on Proposed Amendments–Additional Factors in Cost Review Study (COMAR 14.01.04.05C(1))

- Market context: One commenter requested removal of "product hopping."
- Analysis of the impact of state and federal regulatory and compliance issues on drug: One commenter perceived this to expand the Board's role to cover compliance with all federal and state laws relating to prescription drugs.
- Commenters recommended that the Board consider out-of-pocket costs for patients and the patient experience, and emphasized considering the value of manufacturer discount programs, cost offsets, and the impact of benefit design on out-of-pocket costs.

# .05D Board Action

D. At an open meeting, the Board may:

(5) *Preliminarily* [Determine] *determine* whether:

# .05F Preliminary Determination

*(1) In accordance with §C of this regulation, the Board may make a preliminary determination of whether use of the 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.*

*(2) A preliminary determination is non-final and subject to revision and modification.*

# .05F Preliminary Determination (cont.)

*(3) Preliminary Determination of Affordability Challenge.*

*(a) Board staff shall prepare a draft of the preliminary determination cost review report that summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, the circumstances or indicia reflecting the affordability challenge, and the Board's preliminary determination.*

*(b) The public may comment on the draft of the preliminary determination cost review report.*

# Cross-Reference
# .05A Cost Review Study - Board Action.

(3) Identify the circumstances under which the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients under §A(1) of this regulation.

# .05G Final Determination Concerning Affordability Challenge and Final Cost Review Study Report

[F.] *G. Final Determination Concerning Affordability Challenge and Final* Cost Review Study Report.

*(1) The Board may vote to finalize the preliminary determination and approve the draft cost review report as final.*

*(2) The Board's determination of whether a prescription drug has or will lead to an affordability challenge is not final until the final cost review report is adopted by the Board.*

# Summary of Comments on Proposed Amendments - Preliminary and Final Determination (COMAR 14.01.04.05F and G)

- One commenter expressed the view that the Board is not authorized by statute to make bifurcated affordability determinations–one for eligible State government entity utilization and a separate one for all other utilization.
- One commenter requested a fixed 60-day period to comment on the draft cost review study report and more specificity regarding how the preliminary determination is made.

# Recommendations

- Adopt Amendments to COMAR 14.01.04.05- Cost Review Study as FINAL

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