PDAB Emergency Regulations COMAR 14.01.04.05 Cost Review Study

September 10, 2024

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

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.

.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;

.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.

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