Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

.04 Cost Review Study Process

Authority: Health-General Article, §§ 21-2C-03(f)(1), 21-2C-08(b), 21-2C-09, Annotated Code of Maryland

.05 Cost Review Study.

A. The Board may [determine]:

(1) **[**Whether**]** *Determine whether* use of the prescription drug product has led or will lead to:

(a) (text unchanged)

(b) High out-of-pocket costs for patients; [and]

(2) **[**Whether**]** *Determine whether* the use that has led to affordability challenges or high out-of-pocket costs is consistent with:

(a) (text unchanged)

(b) Standard medical practice[.]*; and*

(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.

B. Analyses and Data Compilation.

(1) (text unchanged)

(2) These data and analyses may be:

(a)—(e) (text unchanged)

(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.

C. Factors Considered in Cost Review Study.

(1) To the extent practicable, the Board may consider the following data, information, and analyses in conducting a cost review study:

(a)—(b) (text unchanged)

(c) Therapeutic Alternatives:

(i) The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives; [and]

(ii) The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State; *and*

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

(d) Patient Access:

(i) —(ii) (text unchanged)

(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*;

(e)—(f) (text unchanged)

(g) Additional Board Factors:

(i)—(x) (text unchanged)

(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*;

(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;

(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;

[(xii)] *(xvii)* Input from the public; and

[(xiii)] *(xviii)* Information and analyses submitted by an entity under Regulation .04 of this chapter.

(2) (text unchanged)

D. At an open meeting, the Board may:

(1)—(4) (text unchanged)

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

(a)—(b) (text unchanged)

E. (text unchanged)

F. 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.

(3) Preliminary Determination of Affordability Challenge.

(a) Board staff shall prepare a draft of the preliminary determination cost review study 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 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 study 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 study report is adopted by the Board.

(3) The Board shall create and adopt a final report of the cost review study that, to the extent permitted by Health-General Article, §§21-2C-03 and 21-2C-10, Annotated Code of Maryland, summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, and the Board's determination.