**.05 Cost Review Study.**

A. The Board may determine:

(1) Whether use of the prescription drug product has led or will lead to:

(a) Affordability challenges to the State health care system; or

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

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

(a) The labeling approved by the FDA; or

(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) To the extent practicable, Board staff may assemble the data and analyses specified by Health-General Article §21-2C-09(b), Annotated Code of Maryland, and this regulation for consideration by the Board, including the data elements and information provided to the Board under Regulation .03A and B of this chapter.

(2) These data and analyses may be:

(a) Derived from published peer-reviewed literature;

(b) Derived from published public sources such as the FDA Orange Book, the FDA Purple Book, and other sources;

(c) Reported by or derived from manufacturers, health insurance plans, HMOs, MCOs, PBMs, and wholesale distributors;

(d) Produced by Board staff through analysis;

(e) Derived from external analyses and modeling studies;

(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) Drug Pricing for Drug Product Under Review:

(i) The WAC, AWP, NADAC, SAAC, ASP, and FSS; and

(ii) Information estimating manufacturer net price and net sales amounts of the prescription drug product under review;

(b) Price Concessions, Discounts, and Rebates:

(i) The average price concession, discount, and rebate provided by the manufacturer or expected to be provided to each payor class in the State for the drug under review, expressed as a number and as a percent of the WAC; and

(ii) The average price concession, discount, and rebate the manufacturer provided or is expected to provide for the prescription drug product under review to each PBM operating in the State, expressed as a number and as a percent of the WAC;

(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) The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice;

(ii) The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design; and

(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) Cost and Comparative Effectiveness Analyses:

(i) The incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives; and

(ii) Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

(f) Cost Sharing:

(i) The average patient copay and other cost-sharing data for the prescription drug in the State; and

(ii) The average cost share; and

(g) Additional Board Factors:

(i) Clinical information, including FDA indications and doses and information concerning standard medical practice;

(ii) The disease burden of the condition that is treated by the prescription drug product;

(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;

(iv) The total gross spending in the State for the prescription drug product under review, the total number of patients in the State using the prescription drug product, and the percentage of overall total prescription drug product spending that the product's spending represents;

(v) The change in total gross spending and utilization for a prescription drug product in the State between the two most recent available calendar years and the percent change in total gross spending for a prescription drug product in the State between the two most recent available calendar years;

(vi) The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes;

(vii) An assessment of the impact of the prescription drug product's cost to access by priority populations and the impact on equity;

(viii) Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the prescription drug product and (a) the cost of development and (b) the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer's pricing decision;

(ix) Analysis of the prescription drug product's approval process;

(x) Analysis of the prescription drug product's shortage status;

(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) The public may provide written comments concerning the prescription drug product:

(a) Within 60 days of the date the drug's selection for cost review study is posted on the Board's website; and

(b) In accordance with the procedures in COMAR 14.01.01.05B(3).

D. At an open meeting, the Board may:

(1) Hear oral public comments concerning the prescription drug product in accordance with the procedures in COMAR 14.01.01.05A;

(2) To the extent permitted by Health-General Article, §§21-2C-03 and 21-2C-10, Annotated Code of Maryland, consider written comments submitted in accordance with the procedures in COMAR 14.01.01.05;

(3) To the extent practicable, and in compliance with Health-General Article, §21-2C-03(e)(1)(iv), Annotated Code of Maryland, consider the data and analyses specified by §C of this regulation, including the data elements and information provided to the Board under Regulation .03 of this chapter;

(4) Close the session to discuss confidential, trade-secret, and proprietary information; and

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

(a) Use of the prescription drug product, identified by NDC, has led or will lead to:

(i) Affordability challenges to the State health care system; or

(ii) High out-of-pocket costs for patients; and

(b) Whether the use that has led to affordability challenges or high out-of-pocket costs is consistent with:

(i) The labeling approved by the FDA; or

(ii) Standard medical practice.

E. If the Board is unable to determine whether a prescription drug product will produce or has produced challenges to the affordability of the prescription drug product for the State health care system, the Board may consider:

(1) The additional factors identified in Health-General Article, §21-2C-09(b)(3)(i)—(iv), Annotated Code of Maryland; and

(2) The following additional factors:

(a) Federal support for the research and development of the prescription drug product; and

(b) Pricing data from other countries for the prescription drug product.

*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 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.*

[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.*

*(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.