

Cost Review Process: Determination of Affordability

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Andrew York, Executive Director

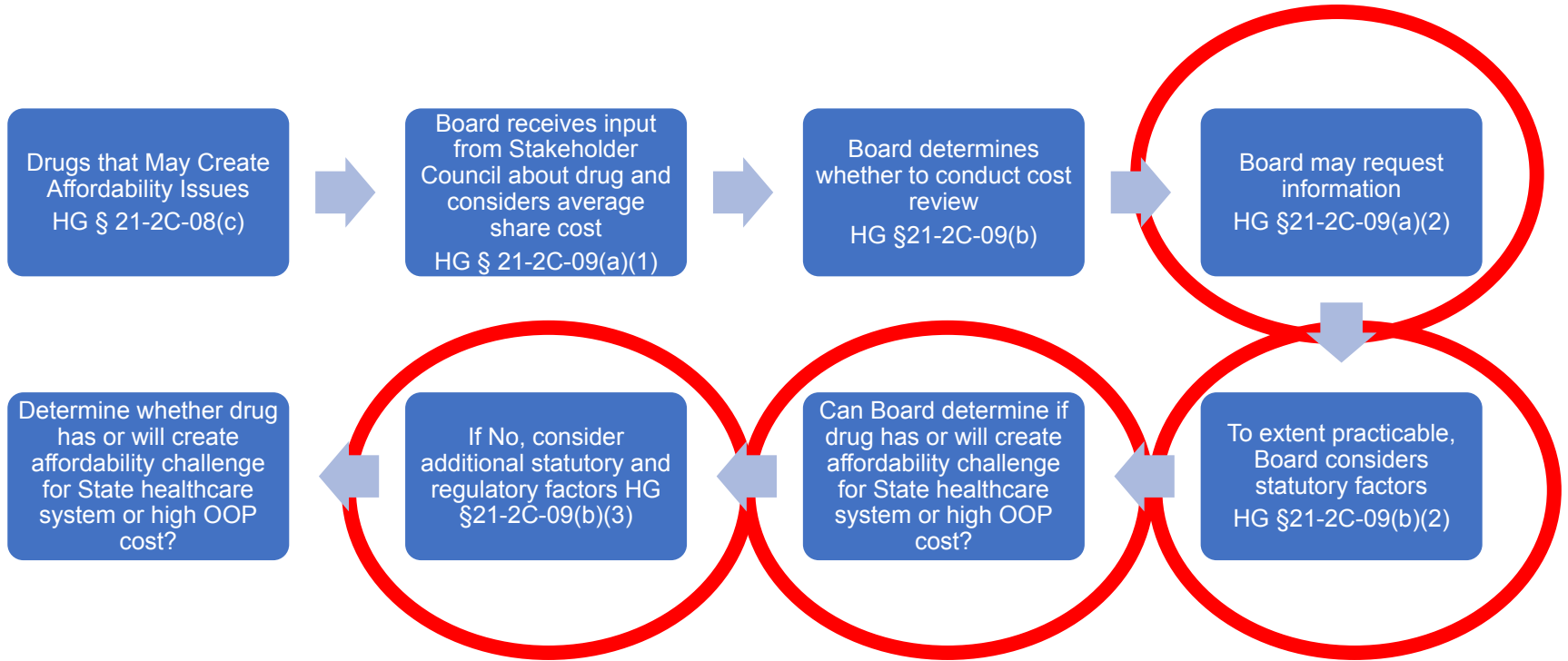
Maryland Prescription Drug Affordability Board

Agenda

- ✚ Additional Factors for Cost Review
- ✚ Process for Determination of Affordability




Overview of Statutory Cost Review Process Under HG § 21-2C-09



Statutory Factors to Consider in Cost Review

HG § 21-2C-09(b)(2)

 To the extent practicable, in determining whether a prescription drug product identified under § 21-2C-08 of this subtitle has led or will lead to an affordability challenge, the Board shall consider the following factors:

- There are **ten** (10) statutory factors



Factors to Consider under HG § 21-2C-09(b)(2)

1. List Price and Other Price Indices
2. Price Concessions, Discounts, or Rebates to Health Plans
3. Price Concessions, Discounts, or Rebates to PBMs
4. Therapeutic Alternatives: Price
5. Therapeutic Alternatives: Price Concessions, Discounts, or Rebates
6. Cost to Health Plans
7. Patient Access
8. Patient Access Programs
9. Relative Costs Compared to Baseline Therapeutic Alternatives
10. Average Patient Cost Sharing
11. **Other Factors as Determined by the Board**





Explore Other Factors to Consider in Initial Effort to Determine Affordability

- 🇲🇩 Overall spend in the state (gross and % of total drug spend)
- 🇲🇩 Rank based on overall spend in the state
- 🇲🇩 Rank of spend per patient
- 🇲🇩 Changes drug spend (gross and %) year over year
- 🇲🇩 Cost-effectiveness metrics
- 🇲🇩 Representative (mean, median, percentile) per patient OOP and representative state incomes
- 🇲🇩 Impact on Equity
- 🇲🇩 Accelerated Approval
- 🇲🇩 Longest patent extension (evergreening)
- 🇲🇩 Feedback from stakeholders (payers, patients)




Explore Other Factors to Consider in Determining Affordability (cont.)

-  Whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations
-  Patient Non-adherence and Utilization Management Information



Initial Determination of Affordability Process

 If the Board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice **has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients.**

- The Board shall, to the extent practicable, consider the 10 statutory factors, and any regulatory factors.
- If the Board is able to determine that the use of a 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, the Board will create and adopt a report summarizing the information considered and the Board's findings.



Second Determination of Affordability Process

- ❏ If the Board is **unable to determine** whether the 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, the Board considers four additional statutory factors/information and any additional factors specified in regulation.



Additional Factors for Consideration

1. Research and Development Costs
2. Direct to Consumer Marketing Costs
3. Gross and Net Revenues for Manufacturers, Wholesalers, and PBMs Most Recent Tax Year
4. Additional factors proposed by the manufacturer, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers
5. **Other Factors as Determined by the Board**



Input for Additional Factors 4 and 5

- 🇺🇸 Seek input for additional factors from the manufacturer, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers
- 🇺🇸 Other Factors as Determined by the Board
 - What other information would assist the Board in assessing affordability?



Second Determination

- ✠ The Board shall, to the extent practicable, consider the 4 additional statutory factors, and any regulatory factors.
- ✠ If the Board is able to determine that the use of a 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, the Board will create and adopt a report summarizing the information considered and the Board's findings.





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Prescription Drug Affordability Board

support.pdab@maryland.gov

pdab.maryland.gov