Maryland Prescription Drug Affordability Board

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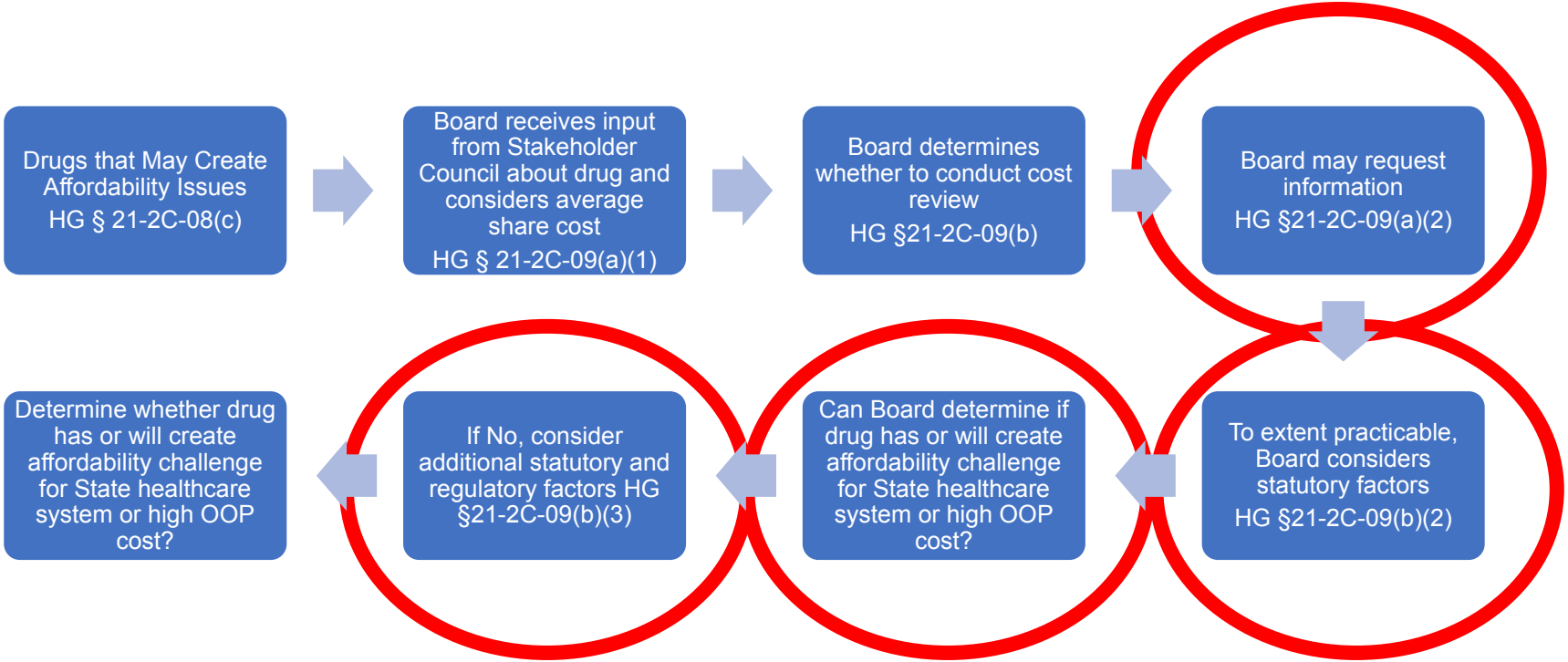
Agenda

- Cost Review Process
  - Definition of Cost Share
  - Factors for Consideration

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



Cost Review Process

- HG § 21-2C-09(a)(1)
- After identifying prescription drug products as required by § 21-2C-08 of this subtitle, the Board shall determine whether to conduct a cost review as described in subsection (b) of this section for each identified prescription drug product by:
    - Seeking Stakeholder Council input about the prescription drug product; and
    - Considering the average cost share of the prescription drug product.

Average Cost Share of the Prescription Drug Product

- Average cost share represents the patient liability is the amount that the insurer says that the patient is supposed to pay
- Average cost share represents the patient out-of-pocket costs (i.e., is the amount after manufacturer coupons and other tools to reduce patient liability)
- Average cost share can represent the patient liability and/or the insurer liability

Average Cost Share of the Prescription Drug Product Feedback

Comments from the Board

- The 3rd definition makes the most sense because even if there is not OOP cost, you need to pay through premiums or the state manages the cost through taxation, state or insurer liability is an important factor to consider
- Each insurer may be unique based on the insured circumstances
- Initially we should look at what the state and its' employees are required to pay

- Question: To what extent are we trying to choose appropriate definitions and to what extent does that need to map to what we can realistically estimate given the data sources?

- OOP costs are at the discretion of the PBM and manufacturer

Conducting the Cost Review

- HG § 21-2C-09(b)(1)

- 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.

Conducting the Cost Review

Comments from the Board

- We need to consider that labelling can be used on the on-label use and also some off-label indications
- FDA can do provisional approval or accelerated approval decision
  - Evidence may not directly demonstrate effectiveness of the drug

Factors to Consider

- HG § 21-2C-09(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

Factor 1: List Price and Other Price Indexes

- Legislative Language: The wholesale acquisition cost and any other relevant prescription drug cost index for the prescription drug product sold in the State;

- Potential Data Sources:
  - Literature Review
  - WAC Data
  - Price Paid in the Market (All Payer Claims Database)
  - Other Price Indexes: National Average Drug Acquisition Cost; State Actual Acquisition Cost (SAAC)

Factor 1: List Price and Other Price Indexes

- Comments from the Board:
  - Request data from private insurers on actual prices paid
  - Removed SSR data because not relevant for a pricing index

Factor 2: Price Concessions, Discounts, or Rebates

- Legislative Language: The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the State for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percent of the wholesale acquisition costs;

- Potential Data Sources:
  - Literature Review
  - Manufacturer Reported Data
  - PBM Reported Data

Factor 2: Price Concessions, Discounts, or Rebates

Comments from the Board

- Look at physician, hospital, and 340B administered drug discounts in the near future
- When looking at datasets among the insured, keep in mind that affordability extends out of pocket

Factor 3: Therapeutic Alternatives: Price

- The price at which therapeutic alternatives have been sold in the State;

- Potential Data Sources:
  - Literature Review
  - Comparative Effectiveness Research and Clinical Effectiveness Reviews
  - All Payer Claims Database (APCD) and other claims data
  - NIH for clinical areas

Factor 3: Therapeutic Alternatives: Price

Comments from the Board

- Consider prior authorization as a proxy for therapeutic alternatives
- Look at studies that the NIH on clinical areas

Factor 4: Therapeutic Alternatives: Price Concessions, Discounts, or Rebates

- Legislative Language: The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the State for therapeutic alternatives;

- Potential Data Sources:
  - Literature Review
  - Manufacturer Reported Data
  - PBM Reported Data

Factor 4: Therapeutic Alternatives: Price Concessions, Discounts, or Rebates

- Comments from the Board
  - Try to obtain this information from the state first

Factor 5: Cost to Health Plans

- Legislative Language: The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications;

- Potential Data Sources:
  - Literature Review
  - Plan reported data
  - All payer claims database (APCD)
  - PBM Reported Data
  - Insurers

Factor 5: Cost to Health Plans

- Comments from the Board
  - Consider insurer data

Factor 6: Patient Access

- Legislative Language: The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

- Potential Data Sources:
  - Literature Review
  - All Payer Claims Database (APCD) and other claims data
  - Patient Reported Data
  - Surveys

Factor 6: Patient Access

Comments from the Board

- Add enhanced listening sessions
  - Are there drugs that are consistently showing up on these lists?
- Public outreach should begin with state employee survey
  - Survey to include: which drugs are most concerned with?

Factor 7: Patient Access Programs

- Legislative Language: The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

- Potential Data Sources:
  - Literature Review
  - Manufacturer Reported Data
  - Patient Reported Data

Factor 7: Patient Access Programs

Comments from the Board

Things to consider:

- Patient access programs
- Brand named drugs
- Look at the coupons being handed out by PBMs, which often promote generic drugs
- Consider public programs, patient assistance programs, and charities

Factor 8: Relative Costs Compared to Baseline Therapeutic Alternatives

- Legislative Language: The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

- Potential Data Sources:
  - Literature Review
  - Comparative Effectiveness Research and Clinical Effectiveness Reviews

Factor 8: Relative Costs Compared to Baseline Therapeutic Alternatives

Comments from the Board

- This information may be outdated, so recommend against using a precise formula
- Weight of criteria can be based on data availability

Factor 9: Average Patient Cost-Sharing

- The average patient copay or other cost-sharing for the prescription drug product in the State; and

- Potential Data Sources:
  - Literature Review
  - All Payer Claims Database (APCD) and other claims data
  - Payer-reported data and PBM reported data

Factor 9: Average Patient Cost-Sharing

- Comments from the Board
- It's important to consider patient cost share

Factor 10: Other Factors As Determined By the Board

- Legislative Language: Any other factors as determined by the Board in regulations adopted by the Board.

Factor 10: Other Factors As Determined By the Board

Comments from the Board

- Has the drug ever received prior federal support?
- How long has the drug received patent protection?
- What is the unit cost of production?
- What are the research & development costs for developing the new drug
- Look at clinical effectiveness/comparative effectiveness research relative to alternatives

Unable to Determine Affordability Challenges

- HG § 21-2C-09(3)

- If the Board is unable to determine whether a prescription drug product will produce or has produced challenges to the affordability of the drug for the State health care system, using the factors listed in paragraph (2) of this subsection, the Board may consider the following factors:

    - Five (5) additional factors

Factor 1: Research and Development Costs

- Legislative Language: The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal Securities and Exchange Commission for the most recent tax year in proportion to the manufacturer's sales in the State;

- Potential Data Sources:
  - Literature Review
  - Manufacturer federal tax filing and information filed with the SEC

Factor 1: Research and Development Costs

Comments from the Board

- SEC data may not be useful; will have aggregate numbers, but won't be drug specific
- We should look at acquisition costs for the drugs as a factor
  - Hep C- research and development was $200-$300M, and acquisition cost was $2-3B
- Appears like Factor 1 and 2 are state-specific; may be worth staying consider

Factor 2: Direct to Consumer Marketing Costs

- Legislative Language: The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in-State sales to total manufacturer sales in the United States for the product under review;

- Potential Data Sources:
  - Literature Review
  - Manufacturer reported data

Factor 2: Direct to Consumer Marketing Costs

Comments from the Board

- Consider data from IQVIA

Factor 3: Gross and Net Sales

- Legislative Language: Gross and net manufacturer, pharmacy benefits manager, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;

- Potential Data Sources:
  - Literature Review
  - Manufacturer reported data
  - PBM Reported Data
  - Wholesaler Reported Data

Factor 4: Additional Factors from Stakeholders

- Any additional factors proposed by the manufacturer and appropriate health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers that the Board considers relevant; and

- Potential Data Sources:
  - Manufacturer reported data
  - Payer reported Data
  - PBM Reported Data
  - Wholesaler Reported Data

Factor 5: Additional Factors from Board

- Any additional factors as established by the Board in regulations.

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