

Cost Review: Additional Metrics for Identifying Potential Drugs

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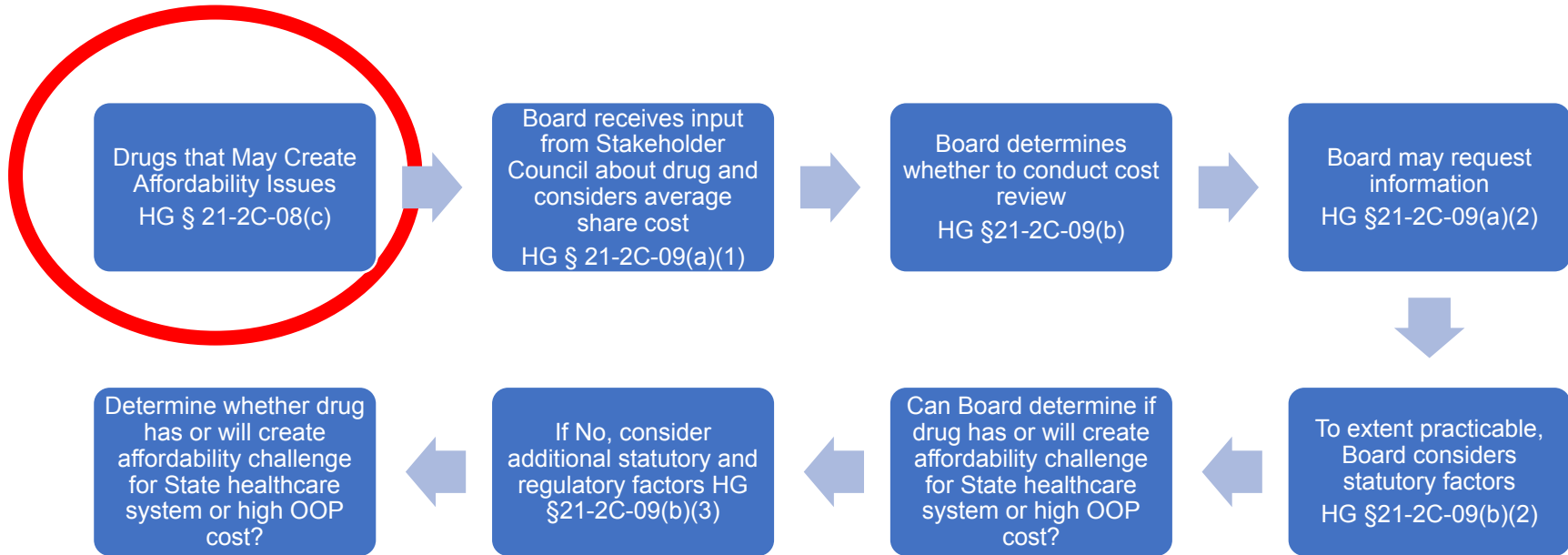
MARYLAND
Prescription Drug Affordability Board

Agenda

- Review of Identifying Drugs that are Eligible for the Cost Review
- Summary of Potential Metrics
- Public Comment and Feedback
- Staff Recommendations



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



Identifying Drugs Eligible for Cost Review

- The first step of our process is to identify the universe of drugs that are eligible to be selected for the cost review
- 2 Sources:
 - Legislative metrics defined in HG § 21-2C-08
 - Additional metrics selected by the Board HG § 21-2C-08(c)(4)
 - “Other prescription drug products that may create affordability challenges for the State health care system and patients, in consultation with the Stakeholder Council”



Identifying Drugs Eligible for Cost Review: Legislative Metrics

- Brand name drugs with launch WAC of \$30,000 or more per year OR increase of \$3,000 or more in 12 month period
- Biosimilar drugs with WAC that is not at least 15% lower than reference biologic
- Generic drugs with WAC of \$100 for 30 days AND increase by 200% or more during immediately preceding 12-month period



Identifying Drugs Eligible for Cost Review: Additional Metrics

- The Board may select additional metrics to identify drugs eligible for cost review—an additional screening tool.
- These metrics supplement the legislative metrics to ensure that all drugs that may be causing affordability issues are eligible for cost reviews



Suggested Options for Additional Metrics

- Drugs with the highest overall spend
- Drugs with the highest per-patient spend
- Drugs with the highest patient out-of-pocket cost
- Drugs with the highest price increases (% and gross)
- Drugs that are reported to cause affordability issues for Marylanders



Additional Metrics from Public Comment

- Drugs that are Approved through an FDA Accelerated Approval Pathway
- Drugs that are the Only Drug in Class
- Drugs with the Highest Advertising Spend
- Drugs with the Longest Patent Extensions
- Insulins



Comments Applicable to All Metrics

- One commenter supported the use of all listed metrics
- One commenter requested clarification on how the compiled list will be shared, and sought assurance that the process would comply with applicable confidentiality and trade secret protections



Highest Overall Spend

- Use the All Payer Claims Database (APCD) to identify the drugs with the highest overall spend in the state
 - Likely identifies high-volume and high-cost drugs
- Example metric:
 - Top 100 NDCs by Gross Spend for Total APCD, Medicare, Medicaid, and Commercial
- No Submitted Comments



Highest Per-Patient Spend

- We can use the APCD to identify the drugs with the highest per-patient spend in the state
 - Likely identifies high-cost drugs
- Example metric:
 - Top 100 NDCs for per-patient spend for the APCD, Medicaid, Medicare, and Commercial
- No Submitted Comments



Highest Out-Of-Pocket Cost

- Use the APCD to identify the drugs with the highest patient OOP spend in the state
 - Likely identifies drugs with the highest patient burden
- Example metric:
 - Top 100 NDCs by total OOP costs
 - Top 100 NDCs by 90th percentile patient-level OOP spending per year



Highest Out-Of-Pocket Cost- Comments

- One commenter flagged that it is important to apply the nuance of overall OOP costs vs high individual OOP costs
- One commenter noted that any OOP cost metric should account for all elements that affect OOP costs. Namely, OOP cost is a plan design issue that is not directly tied to drug costs.
 - OOP metrics should account for benefit design, high OOP costs, and analysis of how rebates are shared with the patient at point of sale



Highest Price Increases

- Use the Wholesale Acquisition Cost (WAC) to identify drugs with the highest price increases over time
- Example metric:
 - Top 100 NDCs by highest annual % increase; 5 year % increase
 - Top 100 NDCs by highest annual price increase; 5 year price increase
- No Submitted Comments



Patient Reporting

- Develop a process for Marylanders to report drugs that are causing affordability challenges
- Example metric:
 - NDCs of drugs that are reported by Marylanders to cause affordability issues ranked by the number of complaints



Patient Reporting- Comments

- One commenter noted that we must include multiple methods for patients to report drugs
- One commenter noted that this metric is vague and would require specification of the information to be submitted, how the information will be validated and reviewed, and how it will be considered



Accelerated Approval

- Use the list of drugs approved under FDA accelerated approval pathways
- Example metric:
 - NDCs of drugs approved under FDA accelerated approval pathways based on surrogate endpoints



Accelerated Approval- Comments

- One commenter noted that this metric should account for what the pathway is, what it entails, and how the pathway affects patients



Drugs that are the Only Drug in Class

- Identify drugs that are the only drug in their class
- Example Metric:
 - NDCs of drugs approved under FDA accelerated approval pathways based on surrogate endpoints



Drugs that are the Only Drug in Class- Comments

- One commenter expressed support of including a metric for drugs that are the only drug in class
- One commenter noted that very few drugs are the only drug in class, and drugs that are the only drug in class are often subject to market competition in different ways, such as drugs in other classes



Drugs with the Highest Advertising Spend

- We can use publicly advertising data to identify drugs that have the highest spending on advertising
- Example metric:
 - Top 25 drugs by publicly available advertising spend



Drugs with the Highest Advertising Spend- Comments

- One commenter noted that it is not clear that advertising spend is related to drug costs



Drugs with the Most Patent Extensions

- Review patents listed in the Orange Book and the Purple Book to identify drugs with the most patent extensions
- Example metric:
 - Top 25 with the most patent extensions



Drugs with the Most Patent Extensions- Comments

- One commenter noted that patent extensions can be an important tool to drive post-approval advances and innovation



Insulins

- Include all insulin drugs
- Example metric:
 - All insulin drugs



Insulins- Comments

- One commenter noted that this metric lacks clarity or detail on how and why it would be included as a criteria
- The commenter noted that it is important to account for the net, post-rebate price for all drugs, but especially insulins



Additional Metrics Suggested for Consideration

- Drugs with the most “evergreening”
 - Drugs with the most patents
 - Drugs with product line extensions
 - Drugs with patent settlements
 - Drugs approved under the Unapproved Drug Initiative
- Drugs with high coupon usage
- Drugs with high non-fill rates



Staff Recommendations

- Staff recommends continuing to work on developing the specifics of these metrics
 - Metrics may have different purposes/functions
 - Data-based metrics can be used to make drugs eligible
 - Manual metrics can provide additional information on eligible drugs



Next Steps - Agency Rulemaking

- Staff will prepare draft regulations of these metrics
- Staff will present draft regulations for comment, consideration, revision, and ultimately adoption by the Board as proposed regulations
- Proposed Regulations then submitted for publication and public comment for 30 days





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