PDAB Regulations
COMAR 14.01

April 18, 2023

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

Overview of Regulation Structure

Title 14	Independent Agencies
Subtitle .01	Prescription Drug Affordability Board
Chapter .01	General Provisions
Regulation .01	Definitions

Subtitle .01 and Chapters .01-.03

- COMAR 14.01.01 General Provisions
- COMAR 14.01.02 Prescription Drug Affordability Fund
- COMAR 14.01.03 Cost Review Process

.01 General Provisions

- .01 Definitions
  - Rescind existing; All new definitions

Sample:
(3) "Active moiety" means the molecule or ion responsible for the physiological or pharmacological action of the drug substance, excluding those appended portions of the molecule that cause the drug to be an ester, salt, or other noncovalent derivative of the molecule, as defined in 21 CFR §314.3.

.01 General Provisions in Development*

.02 Rules of Construction.

.03 Open Meetings.

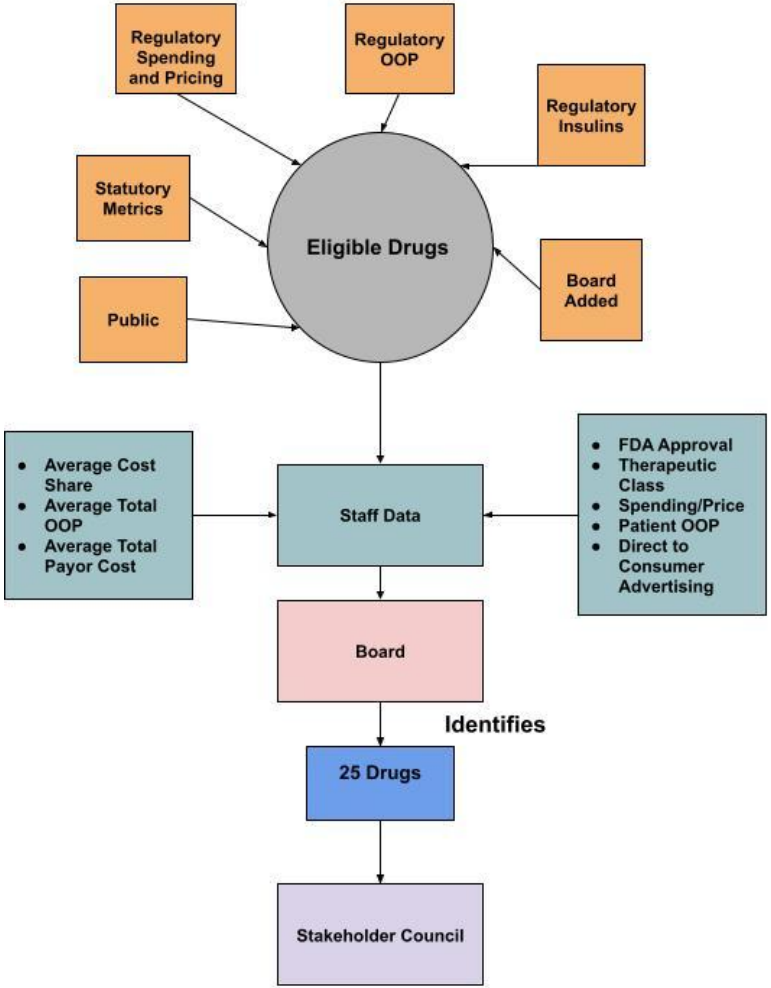
.04 Confidential, Proprietary and Trade-Secret Information.

.02 Prescription Drug Affordability Fund

- Amendments to existing regulations
  - Clarifies payment by ACH
  - Specifies documentation for exemption (business records certificate, affidavit, certain documents)
  - Removes waiver process
  - Codifies reconsideration of denial of exemption process
  - Provides for maintenance of list of assessed entities

.03 Cost Review Process

- .01 Public Reporting of Drug Affordability Issues
- .02 Identifying Drugs Eligible for Cost Review
- .03 Selecting Drugs for Cost Review
- .04 Request for Information for Cost Review
- .05 Cost Review



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.01 Public Reporting of Drug Affordability Issues

- Public input
- Individual members of the public may report their personal experience
- Use a Board form

.02 Identifying Drugs Eligible for Cost Review (statutory metrics)

- Apply metrics HG § 21-2C-08(c) and this regulation to MCDB or other available databases to identify drugs
- Use CPI-U to adjust for inflation
- May account for data errors and extreme outliers

.02 Identifying Drugs Eligible for Cost Review (regulatory metric 100 prescription drug products)

- highest total spending;
- highest spending per patient;
- highest percent change increase in WAC;
- highest percent change increase in WAC over the most recently available five-year period;
- highest dollar increase in price per year or course of treatment;
- highest dollar increase in price over the most recently available five-year period;
- highest percent change increase in total spending

.02 Identifying Drugs Eligible for Cost Review (regulatory metric 100 prescription drug products)

- highest patient total out-of-pocket costs;
- highest average patient total out-of-pocket costs;
- ranked at the 50th percentile for patient total out-of-pocket costs;
- ranked at the 90th percentile for patient total out of pocket costs;

And,

- drugs reported by public under .02;
- all insulins;
- any prescription drug product added by Board after identifying reason to add and Board vote

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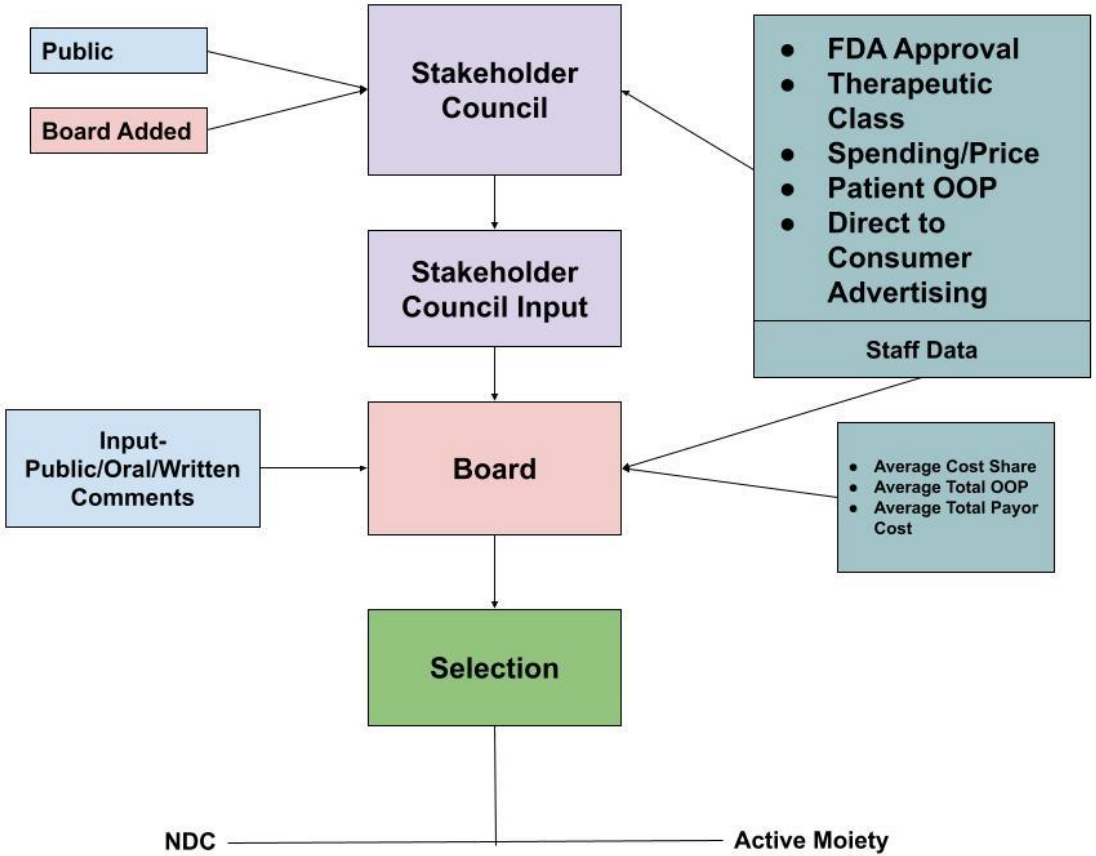
.03A-B Selecting Drugs for Cost Review

Staff collect data and information for Board about drugs:

(1) FDA Approval;
(2) Therapeutic Class;
(3) Spending and Price Data;
(4) Patient Out-of-Pocket;
(5) Publicly available data on direct-to-consumer advertising spending.



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.03C-E Selecting Drugs for Cost Review -Referral to Stakeholder Council

- Board consider: (1) information from statutory and regulatory metrics; (2) information collected (prior slide); and (3) average cost share of the prescription drug product, average patient total out-of-pocket cost and the average total payor cost.
- Board selects at least 25 drugs to refer to SC to receive input from SC on the selection of prescription drug products for cost review.

.03F Selecting Drugs for Cost Review -Stakeholder Council Input

- To the extent practicable, the Board provides the collected information to SC along with: whether the drug was reported by an individual member of the public, and whether the drug was added by the Board.
- SC reviews information and discusses drug.
- Board staff presents SC input to Board.

.03G Selecting Drugs for Cost Review -Selection of Drugs at Open Meeting

- Board considers:

  (a) The prescription drug products referred to SC from the products identified under the statutory metrics and regulatory criteria in Regulation .02 and the information provided under § B of this Regulation;

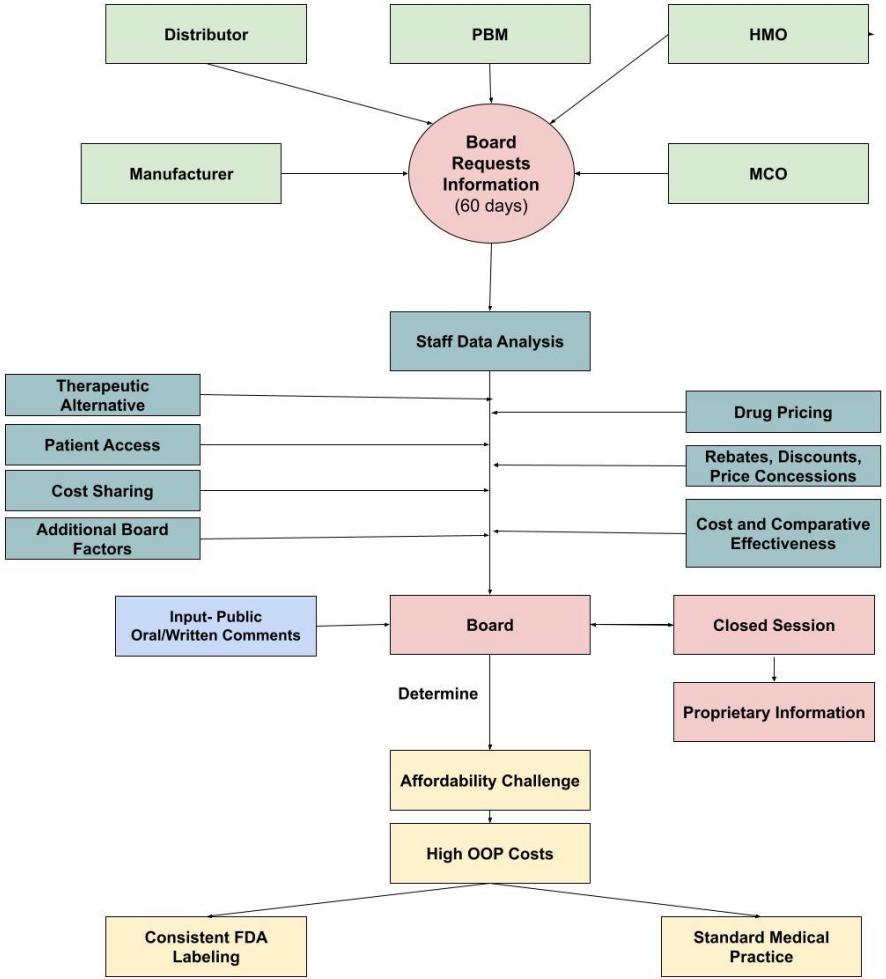
  (b) The average cost share of the prescription drug product, average patient total out-of-pocket cost and the average total payor cost;

  (c) Input from the Stakeholder Council; and

  (d) Input from the public (oral and written comments).

.03G Selecting Drugs for Cost Review -Selected Drugs

- Board post notice of selection of prescription drug product(s) for cost review on website.
- Prescription Drug Products shall be identified by: (a) NDC; and (b) active moiety or active ingredient.
- Board will identify and approve all NDCs with the same moiety or active ingredient to be included in the cost review.
- Board will identify and approve the therapeutic alternatives to be used in conducting the cost review.



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.04A Request for Information for Cost Review

- In compliance with HG §21-2C-09(a)(2), Board may request information to conduct a cost review from manufacturer, PBMs, health insurance carriers, wholesale distributors, HMOs, and MCOs.
- Email and/or Post Notice of Request
- Entities have 60 days to submit requested information

.04B Request for Information From Manufacturer

(a) Documents and research about pricing and (1) the cost of development, (2) the therapeutic benefit, and (3) other information relevant to pricing decision such as: (i) life cycle management; (ii) net average price in the State; and (iii) the estimated value or cost-effectiveness of the prescription drug product.
(b) Price concessions, discounts, and rebates provided to each payor type operating in the State;
(c) Price concessions, discounts, and rebates the manufacturer is expected to provide to each payor type;
(d) The average price concession, discount and rebate provided in the State per payor type;

.04B Request for Information From Manufacturer

(e) The units of the prescription drug product sold in the State;
(f) Units of the drug sold nationally;
(g) Total dollar amount of sales of the drug into the State;
(h) Total dollar amount of sales of the drug nationally;
(i) Prices for the prescription drug product that are charged to purchasers outside the United States reported in U.S. dollars;
(j) Prices charged to typical purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;

.04B Request for Information From Manufacturer

(k) The average profit margin of the prescription drug product over the prior five-year period and the projected profit margin anticipated for the prescription drug product;
(l) Gross and net manufacturer revenues for the prescription drug product under review for the most recent tax year; and
(m) Any additional factors or information the manufacturer proposes that the Board consider.

.04B Request for Information from Health Insurance Carrier, HMO and MCO

(a) The total amount of the price concession, discount, or rebate the manufacturer provides to each health plan operating in the State, expressed as a percent of the WAC;
(b) The average price concession, discount, or rebate provided in the State for therapeutic alternatives;
(c) Formulary placement and benefit design around the prescription drug product, including copay and coinsurance amounts; and
(d) Any additional factors the health insurance carrier, HMO or MCO proposes that the Board consider.

.04B Request for Information from PBMs

(a) The therapeutic alternatives for the prescription drug product(s) under review based on the PBM's formulary;
(b) The total amount of the price concession, discount, or rebate the manufacturer provides to each PBM operating in the State, expressed as a percent of the WAC;
(c) The average price concession, discount, or rebate provided in the State for therapeutic alternatives;
(d) Formulary placement and benefit design around the prescription drug product, including copay and coinsurance amounts;
(e) Gross and net PBM revenues for the prescription drug product under review for the most recent tax year; and
(f) Any additional factors or information the PBM proposes that the Board consider.

.04B Request for Information from Wholesale Distributors

(a) Prices charged to typical purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;
(b) The total amount of price concession and discounts provided by the wholesale distributor to typical purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;
(c) Units of the prescription drug product sold in the State; and
(d) Any additional factors or information the whole distributor proposes that the Board consider.

.04C Submission of Information

- Entity may submit the requested information by:
  (i) completing the form provided by the Board; and
  (ii) providing supporting documentation.
- A person submitting information shall clearly designate the specific information the person considers to be confidential, trade-secret or proprietary.
- Information may be submitted
  (i) in paper form using a common carrier; or
  (ii) electronically using secure file transfer.

.04C Submission of Information

- Board and Board staff shall use, protect, and manage records containing confidential, trade-secret and proprietary information in compliance with COMAR 14.01.01.0X and HG §§21-2C-03 and 21-2C-10.

- Board may consider confidential, trade-secret and proprietary information in a closed session.

.05A Cost Review

The Board shall 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:

(a) Consistent with the labeling approved by the FDA; or

(b) Standard medical practice.

.05B Cost Review

To the extent practicable, Board staff shall assemble the data and analyses specified by HG §21-2C-09(b), and this regulation. The data and analysis may be derived or produced from a variety of sources:

(a) Published peer reviewed literature;
(b) Published public sources;
(c) Reports by entities (e.g., manufacturers, health insurance plans, PBMs, etc);
(d) Produced by Board staff through analysis;
(e) External analyses and modeling studies;
(f) MCDB, any claims set of the MCDB, and other databases; or
(g) Reports generated by U.S. governmental entities, peer-reviewed journal articles, etc.

05C Factors Considered in Cost Review Drug Pricing for Subject Drug

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

(a) Drug Pricing for Subject Drug:

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

(ii) Information estimating manufacturer net-costs and net-sales of the subject prescription drug product;

05C(1) Factors Considered in Cost Review Rebates, Discounts, and Price Concessions

(b) Rebates, Discounts, and Price Concessions:

(i) The average monetary 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;

(ii) The average monetary 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;

05C(1) Factors Considered in Cost Review Therapeutic Alternatives

(c) Therapeutic Alternatives:

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

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

05C(1) Factors Considered in Cost Review
Patient Access

(d) Patient Access:

(i) The costs to health plans based on patient access consistent with FDA labeled indications;

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

(iii) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;

05C(1) Factors Considered in Cost Review
Cost and Comparative Effectiveness Analyses

(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 costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(ii) Information derived from health economics and outcomes research that may address the effectiveness of the drug 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.

05C(1) Factors Considered in Cost Review
Cost Sharing

(f) Cost Sharing:

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

(ii) The average cost share;

05C(1) Factors Considered in Cost Review Additional Board Factors

(g) Additional Board Factors:

(i) the epidemiology, prevalence, and seriousness of the disease or condition that is treated by the prescription drug product;

(ii) In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product;

(iii) The total gross spending in the State for the subject prescription drug product, the total number of patients using the prescription drug product in the state, and the percentage of overall total prescription drug product spending that spending represents;

05C(1) Factors Considered in Cost Review Additional Board Factors (cont.)

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

(v) The representative out-of-pocket costs (mean, median, percentile) per patient compared to representative state incomes;

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

(vii) 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, or that is otherwise pertinent to the manufacturer's pricing decision;

05C(1) Factors Considered in Cost Review Additional Board Factors (cont.)

(viii) Analysis of the prescription drug product approval process;

(ix) Analysis of prescription drug product shortage status;

(x) Analysis of the prescription drug product lifecycle management, patent management, market exclusivities, and product copying;

(xi) Input from the public; and

(xii) Information and analyses submitted by any entity under Regulation .04.

05D At Open Meeting, Board may

(1) Hear public comments concerning the prescription drug product;

(2) Consider written comments;

(3) To the extent practicable, and in compliance with HG §21-2C-03(e)(1)(iv), consider the data and analyses specified in the regulation;

(4) Close the session to consider proprietary, confidential and trademark information; and

(5) Determine whether the prescription drug product has or will lead to:

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

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

.05E If unable to determine affordability, try again with additional factors

E. If the Board is unable to determine whether a prescription drug product will produce or has produced an affordability challenge, the Board may consider:

(1) the additional factors identified in HG §21-2C-09(b)(3)(i)—(iv); and

(2) The following additional factors:

- Federal support for the research and development of the prescription drug product; and
- Pricing data from other countries for the prescription drug product.

.05F. Report and Determination.

(1) The Board will create and adopt a report:

(a) outlining the information considered by the Board in conducting the affordability review;

(b) summarizing the Board's deliberations; and

(c) stating its determination.

Comment Process

- Post April 11, 2023
  COMAR 14.01.01.01 (Definitions) NEW
  COMAR 14.01.02.02 (Fee Assessment, Exemption, Waiver, and Collection) Amendments
  COMAR 14.01.03.01-05 (Cost Review Process) NEW
- Written Comments Due May 2, 2023

Comment Process Part II

- Post April 21, 2023
  COMAR 14.01.01.02-.04 ALL NEW
  COMAR 14.01.04 ALL NEW
- Written Comments Due May 5, 2023

Proposed Comment Schedule

- Based on comments make revisions to drafts
- Post ASAP but no later than May 15, 2023
- Any additional written comments for Board meeting received by May 18
- Consider draft regulations at May 22 Board meeting

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