Title 14
INDEPENDENT AGENCIES

Subtitle 01 – Prescription Drug Affordability Board

Chapter .04 Cost Review Study Process

Authority: Health-General Article, §§ 21-2C-03(f)(1), 21-2C-08(b), and 21-2C-09, Annotated Code of Maryland

[14.01.04.01 Public Reporting of Drug Affordability Issues.
A. Individual members of the public may report their personal experience with a drug or drugs that have caused or are causing an affordability issue for the individual.
B. Individuals may report a drug:
(1) By completing the form available on the Board's website electronically; or
(2) By downloading or obtaining the form from the Board, completing the form, and submitting it to the Board.
C. Blank forms may be requested by contacting the Board by email or phone.**]**

14.01.04.01 *Circumstances Under Which Use of a Drug May Create an Affordability Challenge.*
A. The Board may determine that use of a prescription drug product has led or will lead to an affordability challenge for the State health care system.
B. The circumstances under which use of a prescription drug product has led or will lead to an affordability challenge for the State health care system include, but are not limited to:

(1) High spending by entities that pay for the prescription drug product, as may be indicated by:

(a) Spending on the drug is disproportionate to spending on other drugs in the impacted budget;

(b) Gross spending on the drug increased significantly over the most recent available calendar year or over the most recently available five-year period; or

(c) Large price increases, such as the wholesale acquisition cost (WAC) increasing significantly faster than inflation over the most recently available calendar year, over the most recently available five-year period, or from launch date to the most recently available year.

(2) At its current net or gross price, a drug does not provide sufficient value to the State health care system, as may be indicated by:

(a) The average net price of the drug exceeds the average net price for therapeutic alternatives that provide similar clinical outcomes; or

(b) Compared to therapeutic alternatives, the drug was approved with limited evidence of improvement in clinical outcomes and has substantial spending.

(3) Patients encounter barriers to affordable access for the prescription drug product, as may be indicated by:

(a) Insurance plans cover fewer uses or conditions for this drug than what the FDA has approved or what clinical guidelines recommend; or

(b) High occurrence of required prior authorization or high claims rejection rate.

(4) Any other circumstance identified by the Board through the cost review study under which use of a drug has or will lead to an affordability challenge for the State health care system.
C. The Board may determine that use of a prescription drug product has led or will lead to high out-of-pocket costs for patients.

D. The circumstances under which use of a drug has or will lead to high out-of-pocket costs for patients may be indicated by, but not limited to:

(1) The average total out-of-pocket costs for a drug are disproportionate to the average State household income;

(2) At the 90th percentile, patient out-of-pocket costs in certain markets are disproportionate to the average net cost paid by payors;

(3) A significant proportion of patients do not take the drug as prescribed;

(4) Observed disparities in patient out-of-pocket costs or utilization of the drug in priority populations; or

(5) Any other circumstance identified by the Board through the cost review study under which use of a drug has or will lead to high out-of-pocket costs for patients.

14.01.04.02 Identifying Drugs Eligible for Cost Review.

A. The Board shall apply the metrics specified in Health-General Article, §21-2C-08(c), Annotated Code of Maryland, and this regulation to the following data sets to identify drugs eligible for selection for a cost review study:

(1) The claims data in the MCDB;

(2) Available subsets of claims data in the MCDB, such as the commercial market, Medicaid, and Medicare; and

(3) The data obtained from governmental and commercial databases, other databases, and other data sets as available.

B. The Board may identify the prescription drug products that meet these statutory metrics and regulatory criteria on at least an annual basis.

C. Data Management

(1) For any metric requiring adjustment for inflation, the adjustment for inflation shall be based on the Consumer Price Index for All Urban Consumers (CPI-U) as reported by the U.S. Bureau of Labor Statistics.

(2) For any data-based metric, the Board may account for data errors and outliers.

D. To the extent practicable, and in addition to the statutory metrics set forth in Health-General Article, §21-2C-08(c), Annotated Code of Maryland, the Board may consider the following additional metrics and criteria to identify prescription drug products eligible for selection for a cost review study:

(1) Aggregated Spending and Pricing Data:

(a) The 100 prescription drug products~~,~~ [[*by NDC,*]] with the highest total gross spending in the most recent available calendar year *by prescription drug product, with a breakdown by NDC*;

(b) The 100 prescription drug products with the highest total gross spending per patient in the most recent available calendar year *by prescription drug product, with a breakdown by NDC*;

(c) The 100 prescription drug products with the highest percent change increase in WAC over the most recent available calendar year *by prescription drug product, with a breakdown by NDC*;

[(d) The 100 prescription drug products with the highest percent change increase in WAC over the most recent available 5-year period;**]**

[e**]***(d)* The 100 prescription drug products with the highest dollar increase in WAC per year or course of treatment over the most recent available calendar year; *and*

[(f) The 100 prescription drug products with the highest dollar increase in WAC over the most recent available 5-year period; and**]**

[(g)**]** *(e)*The 100 prescription drug products with the highest percent change increase in total gross spending;

(2) Patient Out-of-Pocket Costs:

(a) The 100 prescription drug products with the highest total patient out-of-pocket costs in the most recent available calendar year *by prescription drug product, with a breakdown by NDC*; *and*

(b) The 100 prescription drug products with the highest average patient total out-of-pocket costs in the most recent available calendar year *by prescription drug product, with a breakdown by NDC*;

[(c) The 100 prescription drug products ranked at the 50th percentile for patient total out-of-pocket costs in the most recent available calendar year; and

(d) The 100 prescription drug products ranked at the 90th percentile for patient total out-of-pocket costs; and**]**

(3) Any prescription drug product added by the Board to the list of prescription drug products eligible for cost review under this regulation.

E. At an open meeting, a Board member may propose one or more additional prescription drug products for inclusion on the list of drugs eligible for cost review by:

(1) Moving that the prescription drug product or products be added to the eligible list; and

(2) Identifying how the prescription drug product or products may create affordability challenges for the State health care system or patients.

F. After discussion at an open meeting, the Board may vote to add one or more prescription drug products to the list of drugs eligible for selection for a cost review study.

14.01.04.03 Selecting Drugs for Cost Review.

A. **[**Board staff may provide the Board with a dashboard containing the prescription drug products identified under the statutory metrics and regulatory criteria in Regulation .02 of this chapter.**]** *Priority Setting and Development of Curated Eligible List.*

(1) The Board may prioritize the information and comparisons of information in §B of this regulation, and direct Board staff to develop a curated list of drugs eligible for selection consistent with these priorities.

(2) Board staff may provide the Board with a dashboard containing the prescription drug products identified in the curated list of eligible drugs for selection developed [[*in §A(1) of this regulation*]] *under Regulation .01 of this chapter, including all NDCs for the prescription drug product.*

(3) Board staff may provide the Board with a dashboard containing the full list of prescription drug products identified in Regulation .02 of this chapter.

B. To the extent practicable, Board staff may provide the following information for each prescription drug product in the dashboard:

(1) FDA Approval:

(a) The date the FDA first approved the prescription drug product;

(b) If applicable, the date the *initial primary patent and* last patent expired or will expire;

(c) Whether the prescription drug product was approved through an FDA accelerated approval pathway; and

(d) Whether the prescription drug product is designated *for a rare disease or condition* by the Secretary of the **[**FDA**]** *U.S. Department of Health and Human Services*, under 21 U.S.C. §360bb, **[**as a drug for a rare disease or condition**]** *and if the prescription drug product is approved for an indication treating that rare disease or condition*;

(2) Therapeutic Class:

(a) The class of the prescription drug product as identified in a recognized classification system;

(b) Whether the prescription drug product is the only prescription drug product in its class;

(c) Any therapeutic equivalent prescription drug product identified by examination of the FDA Orange Book, FDA Purple Book, or other therapeutic equivalence databases; and

(d) The availability and number of therapeutic equivalents for sale in the State;

(3) Utilization, Spending and Price Data:

(a) The patient count for the prescription drug product in the most recent available calendar year;

(b) The total gross spending for the prescription drug product in the most recent available calendar year;

(c) The total gross spending per patient for the prescription drug product in the most recent available calendar year;

(d) The WAC on January 1 of the current calendar year, on January 1 of the previous calendar year, and at launch of the product;

(e) The percent increase in WAC of the prescription drug product over the most recent available calendar year;

(f) The percent increase in WAC of the prescription drug product over the most recent available **[**5**]***five*-year period;

(g) The dollar increase in WAC over the most recent available calendar year;

(h) The dollar increase in WAC over the most recent available **[**5**]***five*-year period;

(i) The dollar increase in WAC per year or course of treatment over the most recent available calendar year;

(j) The percent increase in overall total gross spending for the prescription drug product in the most recent available calendar year;

(k) The estimated percentage of manufacturer national net sales to gross sales of a prescription drug product for the most recently reported year;

(l) The average payor cost per patient for the prescription drug product in the most recent available calendar year; and

(m) The average cost share for the prescription drug product;

(4) Patient Out-of-Pocket:

(a) The total patient out-of-pocket cost for the prescription drug product in the most recent available calendar year;

(b) The average total out-of-pocket costs in the most recent available calendar year;

(c) Patient total out-of-pocket costs ranked at the 50th percentile in the most recent available calendar year; and

(d) Patient total out-of-pocket costs ranked at the 90th percentile in the most recent available calendar year;

(5) Whether the prescription drug product is currently in active shortage status; **[**and**]**

(6) **[**Whether the**]** *For a* prescription drug product **[**is currently subject to or has been**]** subject to the Medicare Drug Price Negotiation Program, under the Inflation Reduction Act (IRA) (Public Law 117-169)*, the published Medicare Maximum Fair Price and the estimated net cost; and*

(7) Data summaries, rankings, comparisons, and analyses prepared by Board Staff of the information in §B of this regulation.

C. Selecting Drugs for Referral to Stakeholder Council.

(1) The Board may select one or more prescription drug products identified in Regulation .02 of this chapter as eligible for cost review to refer to the Stakeholder Council.

(2) **[**Prior to a Board meeting, a Board member may request that a prescription drug product or products be placed on the Board's meeting agenda for consideration for referral to the Stakeholder Council by submitting the proprietary drug name or nonproprietary name, as applicable, and NDC to the Board Chair in writing.**]** *Prior to a Board meeting, Board staff may provide the Board with staff's recommendations concerning prescription drug products for referral to the Stakeholder Council.*

[(3) The Board Chair may include the prescription drug product name and dose on the Board's agenda.

(4) The public may provide oral and written comments concerning the drugs proposed for referral to the Stakeholder Council and identified on the meeting agenda in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).**]**

[(5)**]***(3)* Notwithstanding **[**the pre-meeting identification**]** *staff's recommendations* of drugs for **[**consideration**]** *referral*, the Board may consider any drug identified in Regulation .02 of this chapter *and any drug added to the eligible list* for referral to the Stakeholder Council.

[(6)**]***(4)* At an open meeting, the Board may:

(a) Consider the prescription drug products **[**identified on the Board's agenda**]** *recommended by Board staff* and any eligible drug proposed for consideration by a Board member at the meeting; and

(b) Select one or more prescription drug products **[**by NDC**]** to refer to the Stakeholder Council to receive input from the Stakeholder Council on the selection of prescription drug products for cost review.

D. In selecting one or more prescription drug products to refer to the Stakeholder Council, the Board may consider:

(1) The prescription drug products identified under the statutory metrics and regulatory criteria in Regulation .02 of this chapter *and in the curated list of drugs eligible for selection;*

(2) The information *and comparisons of information* provided under §B *of* this regulation;

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

(4) Any written or oral public **[**comment.**]** *comment;*

(5) Public reporting of prescription drug product affordability issue by an individual under COMAR 14.01.04.06; and

(6) Reporting of prescription drug product affordability issues by an eligible governmental entity.

E. The Board shall post notice of the prescription drug products referred to the Stakeholder Council on its website.

F. The public may provide written comments concerning the list of prescription drug products referred to the Stakeholder Council by:

(1) Complying with the procedures in COMAR 14.01.01.05B(3); and

(2) Submitting the written comments to the Board within 30 calendar days of the date the list is posted on the Board's website.

G. Stakeholder Council Input.

(1) To the extent practicable, the Board may provide the Stakeholder Council **[**with:**]** *with a selected dashboard for the referred prescription drug products that contains the public information set forth in §B of this regulation.*

[(a) The information set forth in §B of this regulation;

(b) Whether the prescription drug product was reported by an individual member of the public; and

(c) Whether the prescription drug product was added by the Board for consideration under Regulation .02 of this chapter.**]**

(2) To the extent practicable, the Stakeholder Council shall:

(a) Review the information provided for each referred prescription drug product; and

(b) Discuss the referred prescription drug products at an open meeting.

(3) Board staff may present the Stakeholder Council input discussed at the open meeting to the Board.

H. *Identifying* Therapeutic Alternatives.

(1) Board staff may develop a list of therapeutic alternatives for each prescription drug product referred to the Stakeholder Council.

(2) Board staff shall post a list of therapeutic alternatives developed by staff on the Board's website for comment.

(3) The public may provide written comments concerning the list of therapeutic alternatives by:

(a) Complying with the procedures in COMAR 14.01.01.05B(3); and

(b) Submitting the written comments to the Board within 30 calendar days of the date the list is posted on the Board's website.

(4) Board staff may modify the list of therapeutic alternatives for consideration by the Board.

[(5) The Board shall determine the therapeutic alternatives for each prescription drug product selected for a cost review study.**]**

I. Board Selection of Drugs for Cost Review.

(1) At an open meeting, the Board may select one or more prescription drug products for a cost review study.

(2) The public may provide oral and written comments concerning the selection of a prescription drug product for cost review in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).

(3) In selecting a prescription drug product for cost review, the Board shall consider:

(a) The prescription drug products referred to the Stakeholder Council **[**from the prescription drug products identified under the statutory metrics and regulatory criteria in Regulation .02 of this chapter**]** and the information provided under §B of this regulation;

(b) The average cost share of the prescription drug product, the average patient total out-of-pocket cost, the average total payor **[**cost, and publicly available data on direct-to-consumer advertising spending for the prescription drug product;**]** *cost;*

(c) Input from the Stakeholder Council provided under §G of this regulation; and

(d) Input from the public provided under COMAR 14.01.01.05.

(4) During an open meeting, the Board may select one or more prescription drug products for cost review *study* under Regulation .05 of this chapter and provide notice of the selection on its website within 3 work days of the meeting.

(5) The prescription drug product shall be identified by:

(a) NDC;

(b) ANDA, NDA, or BLA, as applicable; and

(c) Active moiety or active ingredient.

(6) If the Board selects a prescription drug product for cost review, **[**the Board may identify and approve**]** *Board staff shall include* all NDCs marketed under the same ANDA, NDA, or BLA **[**to be included**]** in the cost review.

(7) If the Board selects a prescription drug product for cost review that is an unapproved generic within the meaning of Health-General Article, §21-2C-01(f), Annotated Code of Maryland, the Board may identify and approve all NDCs with the same active moiety and manufacturer to be included in the cost review study.

(8) If the Board selects a prescription drug product for cost review, the Board shall approve the therapeutic alternatives to be used in conducting the cost review study.

14.01.04.04 Request for Information for Cost Review.

A. Request for Information.

(1) The Board shall post notice of the prescription drug product or products selected for cost review *study* through the process outlined in Regulation .03I of this chapter on the Board's website.

(2) To the extent there is no publicly available information to conduct an aspect of the statutory cost review, the Board may request information to conduct a cost review study under Health-General Article, §21-2C-09(a)(2), Annotated Code of Maryland, and this regulation.

(3) The Board may request information by sending an email or postal mail to the manufacturer, PBMs, health insurance carriers, wholesale distributors, HMOs, and MCOs.

(4) The Board shall post notice of the request for information on its website.

(5) An entity that has not received a request for information from the Board may submit relevant information in accordance with this regulation.

(6) Within 30 days of the date the request for information is posted to the website or transmitted to the entity, an entity may submit the information requested by the Board, and any other relevant information, in accordance with §C of this regulation.

(7) An entity may request one 30-day extension of time to submit information under §A(6) of this regulation.

(8) An entity shall submit the request for a 30-day extension to the Board in writing on or before the expiration of the initial submission period.

B. For each prescription drug product under review, the Board may request the following information from:

(1) Manufacturer:

(a) Documents and research explaining the relationship between the pricing of the prescription drug product and the cost of development, the relationship between the pricing of the prescription drug product and the therapeutic benefit, and information that is otherwise pertinent to the manufacturer's 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) The total amount of the price concessions, discounts, and rebates provided to each payor type operating in the State.

(c) The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to each payor type;

(d) The net price received by **[**manufacturers**]** *the manufacturer* for the drug product in the State accounting for all price concessions, discounts, and rebates*, reported by payor type and in aggregate*;

(e) The units of the prescription drug product sold in the State;

(f) The units of the prescription drug product sold nationally;

(g) The total dollar amount of *gross and net* sales of the prescription drug product into the State;

(h) The total dollar amount of *gross and net* sales of the prescription drug product nationally;

(i) The invoice *and net* price per unit for the prescription drug product charged to purchasers in the United Kingdom, Germany, France, and Canada, reported in U.S. dollars;

(j) Prices charged to purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, and other direct purchasers;

(k) The average profit margin of the prescription drug product over the prior **[**5**]** *five*-year period and the projected profit margin anticipated for the current year for the prescription drug product;

(l) Maryland and national gross and net manufacturer revenues for the prescription drug product under review for the most recent tax year;

(m) Information*, including utilization, net prices, and gross and net revenue by payor type,* concerning all authorized generics as defined by 42 CFR §447.502 for the prescription drug product;

(n) Information*, including utilization, net prices, and gross and net revenue by payor type,* concerning all other ANDAs, BLAs, and NDAs that pertain to the same active moiety and the same manufacturer;

(o) 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;

[(p) 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

(q) Any additional factors or information the manufacturer proposes that the Board consider.**]**

(p) Information concerning the manufacturer's drug-specific patient access programs, including:

(i) The identity of all patient assistance programs or charities providing medications to patients that are operated or supported by the manufacturer;

(ii) The value of all coupons, free samples, and drug donations to charities provided by the manufacturer;

(iii) The number of people served by the manufacturer's patient assistance programs, coupons, or free samples;

(iv) Information on the policies, limitations, enrollment processes, and patient eligibility requirements for each program; and

(v) The total dollar value of the tax benefits realized as a result of the patient assistance programs for the product under review in the most recent year.

(q) The total amount of direct-to-physician marketing costs for the product under review in the most recent year;

(r) 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

(s) Any additional factors or information the manufacturer proposes that the Board consider.

(2) Health Insurance Carrier, HMO, and MCO:

(a) **[**The**]** *For each market segment, the* total amount of the price concessions, discounts, and rebates the manufacturer provides to **[**each**]** health **[**plan**]** *plans* operating in the State, expressed *in dollars per-unit and* as a percent of the WAC;

(b) **[**The**]** *For each market segment, the* average price concession, discount, and **[**rebate**]** *rebates the manufacturer* **[**provided**]** *provides* in the State for therapeutic alternatives*, expressed in dollars per unit and as a percent of the WAC*;

(c) For each market segment, the total number of units of the prescription drug product paid for by the health plan or insurance carrier.

[(c)**]** *(d)* Placement in each formulary offered or administered in the State and the number of covered lives for each formulary;

[(d)**]** *(e)* Benefit design around the prescription drug product, including copayment and coinsurance amounts in the State;

[(e)**]** *(f)* The net cost *per-unit* incurred by the insurance carrier *or health plan* for the prescription drug product in the State*, separated by market segment*; and

[(f)**]** *(g)* Any additional factors or information the health insurance carrier, HMO, or MCO proposes that the Board consider.

(3) Pharmacy Benefits Managers:

[(a) The therapeutic alternatives for the prescription drug product(s) under review identified by each formulary administered by the PBM;**]**

[(b) The**]** *(a) For each market segment, the* total amount of the price concessions, discounts, and rebates the manufacturer provides to each PBM operating in the State, expressed *in dollars per-unit and* as a percent of the WAC;

(b) The total amount of price concessions, discounts, and rebates aggregated across all health plans;

(c) For each market segment, the total number of units of the prescription drug product paid for by the PBM;

[c**]** *(d)* The average price concession, discount, and **[**rebate**]** *rebates the manufacturer* **[**provided**]** *provides* in the State for therapeutic alternatives*, expressed in dollars per-unit and as a percent of the WAC*;

[d**]** *(e)* Placement in each formulary offered or administered in the State and the number of covered lives for each formulary;

[e**]** *(f)* Benefit design around the prescription drug product, including copayment and coinsurance amounts;

(g) The frequency of mid-year formulary or coverage changes and the policies regarding patient notification, exceptions, and transition procedures for patients taking the medication;

(h) The therapeutic alternatives for the prescription drug product(s) under review identified by each formulary administered by the PBM;

[(f)**]** *(i)* Maryland and national gross and net PBM revenues for the prescription drug product under review for the most recent tax year; and

[(g)**]** *(j)* Any additional factors or information the PBM proposes that the Board consider.

(4) Wholesale Distributors:

(a) Prices charged to purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, and other direct purchasers;

(b) The total amount of price concessions and discounts provided by the wholesale distributor to purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, and other direct purchasers*, expressed in dollars per-unit and as a percent of the WAC*;

(c) Units of the prescription drug product sold in the State; **[**and**]**

(d) *Gross and net wholesale distributor revenues for the prescription drug product under review for the most recent tax year; and*

(e) Any additional factors or information the wholesale distributor proposes that the Board consider.

C. Submission of Information.

(1) An entity may submit the information requested in §A of this regulation by:

(a) Completing the data form developed by the Board; and

(b) Providing supporting documentation.

(2) A person submitting information, including data and records, for the Board's consideration shall comply with the procedures for designating confidential, trade-secret, and proprietary information set forth in COMAR 14.01.01.04.

(3) Information may be submitted to the Board:

(a) In paper form using a tracked common carrier, courier, or postal service; or

(b) Electronically using secure file transfer.

14.01.04.05 Cost Review Study.

A. The Board may determine:

(1) Whether use of the prescription drug product, *consistent with the labeling approved by the FDA or standard medical practice,* 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)**]** The circumstances under which *use of* 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]] *Regulation .01 of this chapter*.

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**]** *Reported in or derived* from published peer-reviewed literature*, including the original source documents*;

(b) **[**Derived**]** *Reported in or 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;

(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.**]** *staff, which may include structured interviews, focus groups, field observations, surveys, ethnographic studies, and patient feedback that may be gathered or requested*.

C. Factors Considered in Cost Review Study.

(1) To the extent practicable, the Board may consider the following *historic and current* 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, *National VA Contract Price, Big 4 Price,* [[*MFP*]] *Medicare Maximum Fair Price ('MFP')*, 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;

(ii) The WAC, AWP, NADAC, SAAC, ASP, *National VA Contract, Big 4 Price,* [[*MFP*]] *Medicare Maximum Fair Price ('MFP'),* 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) *Board staff may utilize any comparator including, but not limited to, therapeutic alternatives identified under* [[*COMAR 14.01.04.03C(1)(e),*]] *14.01.04.03 H. in performing analyses under this section.*

[i**]** *(ii)* 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)**]** *(iii)* 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 number of pharmaceutical manufacturers that produce the prescription drug product;

(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 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
(xvii) Input from the public; and
(xviii) Information and analyses submitted by an entity under Regulation .04 of this chapter.
(2)**]**

(2) *To the extent practicable, the Board may also consider the following data, information, and analyses as Board factors in conducting a cost review study:*

(a) Prescription Drug Product Under Study.

(i) Clinical information, including FDA indications and doses, evidence of therapeutic costs and benefits, mechanism of action, therapeutic class, and information concerning standard medical practice;

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

(b) Regulatory Approval and Market Context.

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

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

(iii) Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping;

(c) Utilization of Drug Product Under Review.

(i) 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;

(ii) 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;

(iii) 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;

(d) Pricing Information and Rebates.

(i) Generally available public prices such as GoodRx or direct-to-consumer prices; and

(ii) Information explaining the relationship between the pricing of the prescription drug product, the cost of development, the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer's pricing decision.

(e) Therapeutic Equivalents, Therapeutic Classes, and Therapeutic Alternatives.

(i) The WAC, AWP, NADAC, SAAC, ASP, National VA Contract, Big 4 Price, and FSS at which each therapeutic alternative and drugs in the same therapeutic class has been sold in the State;

(ii) 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 drugs in the same therapeutic class;

(iii) 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 the standard of care, and drugs in the same therapeutic class;

(iv) 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, the standard of care, drugs in the same therapeutic class, or no treatment;

(v) Clinical information, including FDA indications and doses, evidence of therapeutic costs and benefits, mechanism of action, therapeutic class, and information concerning standard medical practice; and

(vi) The number of pharmaceutical manufacturers that produce therapeutically equivalent, biosimilar, or interchangeable prescription drug products.

(f) Cost-Sharing and Insurance Benefit Design.

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

(ii) Information about patient access and medication adherence, including the use and impact of utilization management tools;

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

(iv) Information concerning the manufacturer's drug-specific patient access programs, including the information requested in 14.01.04.04 B(1)(p).

(g) Other Information.

(i) Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product;

(ii) Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators;

(iii) 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;

(iv) Input from the public;

(v) Information and analyses submitted by an entity under Regulation .04 of this chapter.

(vi) Information and analyses submitted by an eligible government entity; and

(vii) Information, analyses, and data published by the Centers for Medicare and Medicaid Services underpinning the [[*MFP*]] *Medicare Maximum Fair Price ('MFP') produced through the Medicare Drug Price Negotiation program.*

(3) 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**]** *when the Board posts a request for public comment about the drug* on the Board's website; and

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

D. Board Staff Recommendations.

(1) Board staff shall:

(a) Prepare a memorandum that contains staff's recommendations; and

(b) Redact any confidential, trade secret and proprietary information.

(2) As an addendum to the memorandum, Board staff may provide the Board with recently available information that updates the data and information in either the dossier or dashboard.

[D.**]** *E.* 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) Consider Board staff recommendations and any addendum;

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

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

[[(a)]] *whether* [[-Use]] *use* of the prescription drug product, *consistent with the labeling approved by the FDA or standard medical practice, and* identified by NDC, has led or will lead to:

[[(i)]] *(a)* Affordability challenges to the State health care system; or

[[(ii)]] *(b)* 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.**]** *F.* 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.**]** *G.* 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 *study* report that summarizes **[**the information considered by the Board in conducting the cost review study,**]** the Board's deliberations, *and preliminary determination* **[**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 *study* report.

[G.**]** *H.* 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**]** *adopt* a cost review *study* 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 *study* 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.

14.01.04.06 *Reporting of Drug Affordability Issues.*

A. Public Reporting.

(1) Individual members of the public may report their personal experience with a drug or drugs that have caused or are causing an affordability issue for the individual.

(2) An individual may report a drug:

(a) By completing the form available on the Board's website electronically; or

(b) By downloading or obtaining the form from the Board, completing the form, and submitting it to the Board.

(3) Blank forms may be requested by contacting the Board by email or phone.

B. Reporting by Eligible Governmental Entities.

(1) An Eligible Governmental Entity may:

(a) Refer a prescription drug product to the Board for possible study, along with drug purchasing data, and other relevant information about the prescription drug product; or

(b) Report to the Board their experiences, drug purchasing data, and other relevant information about a prescription drug product during the cost review study and policy review processes.

(2) An Eligible Governmental Entity may submit the information identified in §B(1) of this regulation by:

(a) Completing the data form developed by the Board; and

(b) Providing supporting documentation.

(3) An Eligible Governmental entity submitting information, including data and records, for the Board's consideration shall comply with the procedures for designating confidential, trade-secret, and proprietary information set forth in COMAR 14.01.01.04.

(4) Information may be submitted to the Board:

(a) In paper form using a tracked common carrier, courier, or postal service; or

(b) Electronically using secure file transfer.