Title 14
INDEPENDENT AGENCIES
Subtitle 01 PRESCRIPTION DRUG AFFORDABILITY BOARD
14.01.04 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

.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.

.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 with the highest total gross spending in the most recent available calendar year;

(b) The 100 prescription drug products with the highest total gross spending per patient in the most recent available calendar year;

(c) The 100 prescription drug products with the highest percent change increase in WAC over the most recent available calendar year;

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

(e) 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;

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

(g) 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 patient total out-of-pocket costs in the most recent available calendar year;

(b) The 100 prescription drug products with the highest average patient total out-of-pocket costs in the most recent available calendar year;

(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.

.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.

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 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 by the Secretary of the FDA, under 21 U.S.C. §360bb, as a drug for a 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-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-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 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).

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.

(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) Notwithstanding the pre-meeting identification of drugs for consideration, the Board may consider any drug identified in Regulation .02 of this chapter for referral to the Stakeholder Council.

(6) At an open meeting, the Board may:

(a) Consider the prescription drug products identified on the Board's agenda 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;

(2) The information provided under §B 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.

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:

(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. 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;

(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 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 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.

.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 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 for the drug product in the State accounting for all price concessions, discounts, and rebates;

(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 sales of the prescription drug product into the State;

(h) The total dollar amount of sales of the prescription drug product nationally;

(i) The invoice 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-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 concerning all authorized generics as defined by 42 CFR §447.502 for the prescription drug product;

(n) Information 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.

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

(a) The total amount of the price concessions, discounts, and rebates the manufacturer provides to each health plan operating in the State, expressed as a percent of the WAC;

(b) The average price concession, discount, and rebate provided in the State for therapeutic alternatives;

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

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

(e) The net cost incurred by the insurance carrier for the prescription drug product in the State; and

(f) 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 total amount of the price concessions, discounts, and rebates the manufacturer provides to each PBM operating in the State, expressed as a percent of the WAC;

(c) The average price concession, discount, and rebate provided in the State for therapeutic alternatives;

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

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

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

(g) 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;

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

(d) 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.

.05 Cost Review Study.

A. The Board may 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 consistent with:

(a) The labeling approved by the FDA; or

(b) Standard medical practice.

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 from published peer-reviewed literature;

(b) 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 other databases; or

(g) Derived from reports generated by U.S. governmental entities, foreign governmental and quasi-governmental agencies, and U.S. and foreign non-profit organizations.

C. Factors Considered in Cost Review Study.

(1) To the extent practicable, the Board may consider the following 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, 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; and

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

(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;

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

(ii) 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 prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product copying;

(xii) Input from the public; and

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

(2) 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 on the Board's website; and

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

D. 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) Close the session to discuss confidential, trade-secret, and proprietary information; and

(5) Determine whether:

(a) Use of the prescription drug product, identified by NDC, has led or will lead to:

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

(ii) 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. 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. Cost Review Study Report. The Board shall create and adopt a 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.