Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .03 Cost Review Process

.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 by mail.

C. Blank forms may be requested by contacting the Board by email or phone.

Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .03 Cost Review Process

.02 Identifying Drugs Eligible for Cost Review

A. The Board may 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:

(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 shall identify the prescription drug products that meet these statutory metrics and regulatory criteria by NDC 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 extreme outliers.

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

(1) Aggregated Spending and Pricing Data:

(a) The 100 prescription drug products with the highest total spending in the most recently available calendar year;

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

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

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

(e) The 100 prescription drug products with the highest dollar increase in price per year or course of treatment over the most recently available calendar year;

(f) The 100 prescription drug products with the highest dollar increase in price over the most recently available five-year period; and

(g) The 100 prescription drug products with the highest percent change increase in total 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 recently available calendar year;

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

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

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

(3) The prescription drug products reported by individual members of the public under Regulation .02 of this chapter;

(4) All insulins marketed in the State in the most recently available calendar year; and

(5) 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(s) be added to the eligible list; and
(2) Identifying the reasons why the prescription drug product(s) should be added.

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 cost review.

Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .03 Cost Review Process

.03 Selecting Drugs for Cost Review

A. Board staff shall 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 shall 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; and

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

(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) Spending and Price Data:

(a) The overall total spending for the prescription drug product in the most recently available calendar year;

(b) The overall total spending per patient for the prescription drug product in the most recently available calendar year;

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

(d) The percent increase in WAC of the prescription drug product over the most recently available five-year period;

(e) The dollar increase in WAC over the most recently available calendar year;

(f) The dollar increase in WAC over the most recently available five-year period;

(g) The dollar increase in price per year or course of treatment over the most recently available calendar year;

(h) The percent increase in overall total spending for the prescription drug product in the most recently available calendar year;

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

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

(k) 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 recently available calendar year;

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

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

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

(5) The publicly available data on direct-to-consumer advertising spending for the prescription drug product.

C. At an open meeting, the Board shall:

(1) Consider the prescription drug products identified by NDC in Regulation .02 of this chapter as eligible for cost review; and

(2) Identify at least 25 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 a prescription drug product to refer to the Stakeholder Council, the Board shall 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; and

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

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

F. Stakeholder Council Input.

(1) To the extent practicable, the Board shall provide the Stakeholder Council with:

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

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

(iii) 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 will present the Stakeholder Council input discussed at the open meeting to the Board.

G. Board Selection of Drugs for Cost Review.

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

(2) The public may provide oral comments concerning the selection of a prescription drug product for cost review in accordance with the procedures under Regulation XX of Chapter XX at the open meeting, and written comments submitted in accordance with the procedures under Regulation XX of Chapter XX.

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

(a) The prescription drug products referred to the Stakeholder Counsel 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, average patient total out-of-pocket cost and the average total payor cost;

(c) Input from the Stakeholder Council provided under § D of this Regulation; and

(d) Input from the public provided under Regulation XX of Chapter XX.

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

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

(a) NDC; and

(b) active moiety or active ingredient.

(6) If the Board selects a prescription drug product for cost review, the Board will identify and approve all NDCs with the same moiety or active ingredient to be included in the cost review.

(7) If the Board selects a prescription drug product for cost review, the Board will identify and approve the therapeutic alternatives to be used in conducting the cost review.

Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .03 Cost Review Process

.04 Request for Information for Cost Review

A. Request for Information

(1) Within three business days of selecting a prescription drug product for cost review, the Board shall post notice of the selected NDCs and active moieties or active ingredients 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 from the manufacturer, PBMs, and health insurance carriers under Health General Article, §21-2C-09(a)(2), Annotated Code of Maryland, and this regulation.

(3) The Board may request information by:

(a) Posting notice of the request on its website;

(b) Sending email or postal mail to the entity; or

(c) Any combination of these methods.

(4) The Board may also request data and information from wholesale distributors, HMOs, and MCOs.

(5) Entities may submit the information requested by the Board, and any other relevant information, for 60 days from the date the request for information is posted to the website or transmitted to the entity.

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 pricing and the therapeutic benefit of the prescription drug product, 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 average price concession, discount and rebate provided in the State per payor type;

(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 subject prescription drug product into the State;

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

(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.

(2) 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.

(3) Pharmacy Benefits Managers:

(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.

(4) 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.

C. Submission of Information.

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

(i) completing the form provided by the Board; and

(ii) providing supporting documentation.

(2) A person submitting information for the Board's consideration under this regulation shall clearly designate the specific information the person considers to be confidential, trade-secret or proprietary.

(3) Information may be submitted to the Board:

(i) in paper form using a common carrier; or

(ii) electronically using secure file transfer.

(4) The 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 Health General Article, §§21-2C-03 and 21-2C-10, Annotated Code of Maryland.

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

Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .03 Cost Review Process

.05 Cost Review

A. 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.

B. Analyses and Data Compilation.

(1) To the extent practicable, Board staff shall 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 .03 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 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, peer-reviewed journal articles, foreign governmental and quasi-governmental agencies, and U.S and foreign non-profit organizations.

(3) Board staff shall include the data elements and information provided to the Board under §§A and B of Regulation .03.

C. Factors Considered in Cost Review.

(1) To the extent practicable, the Board may 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-cost and net-sale amounts of the subject prescription drug product;

(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;

(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;

(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;

(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.

(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;

(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;

(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 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 of the prescription drug product, or that is otherwise pertinent to the manufacturer's pricing decision;

(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.

D. At an open meeting, the Board may:

(1) Hear public comments concerning the prescription drug product in accordance with the procedures under Regulation XX of Chapter XX at the open meeting, if any;

(2) Consider written comments submitted in accordance with the procedures under Regulation XX of Chapter XX, if any;

(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 consider proprietary, confidential and trademark information; and

(5) Determine whether:

(a) Use of the prescription drug product 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:

(i) Consistent with 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. 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.