Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .05 Policy Review, Final Action, Upper Payment Limits

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

.01 Definitions.

A. In this Chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Driver" means a factor that causes a particular phenomenon to happen or develop.

(2) "Eligible governmental entity" means a unit of State or local government, an organization on behalf of a unit of State or local government, or the Maryland State Medical Assistance Program, as identified in Health-General Article, §21-2C-14(a), Annotated Code of Maryland, that pays for or purchases prescription drug products.

(3) "FDA prescription drug shortage list" means the U.S. Food and Drug Administration's Drug Shortage Database.

(4) "Medicaid Best Price" has the meaning stated in 42 CFR §447.505.

(5) "Medicare Maximum Fair Price" has the meaning stated in 42 USC §1320f(c)(3).

(6) "Upper payment limit" or "UPL" means the amount established by the Board that an eligible governmental entity may not exceed when purchasing or paying for the ingredient cost for a prescription drug product after all price concessions, discounts, and rebates.

C. For the purpose of this Regulation, "affordability challenge" refers to either (a) high out-of-pocket costs for patients or (b) an affordability challenge for the State health care system.

.02 Criteria for Setting an Upper Payment Limit.

A. When determining whether to set an upper payment limit and when setting an upper payment limit amount, the Board shall apply the criteria set forth in this Regulation.

B. The Board shall:

(1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;

(2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;
(3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences; and
(4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug.

C. The Board shall not set an upper payment limit if:
(1) Utilization of the prescription drug product by Eligible Governmental Entities is minimal; or
(2) The prescription drug product is a generic and there are nine (9) or more marketed therapeutic equivalents for the product.

D. The Board shall not set an upper payment limit at an amount that:
(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or
(2) Is lower than the Medicare Maximum Fair Price.

.03 Policy Review and Final Action Process Overview.

A. If the Board makes a preliminary determination that use of the prescription drug product has led or will lead to an affordability challenge, the Board shall commence the policy review process.

B. The purpose of the policy review process is to:
(1) Based on the best available information, confirm the drivers and market conditions causing the affordability challenge phenomena; and
(2) Identify the policies that may address those drivers and redress the affordability challenges.

C. The policy review process includes:
(1) Information gathering:
(a) Informational hearings;
(b) Stakeholder Council input;
(c) Expert testimony hearings;
(d) Board staff research and analysis; and
(e) Eligible governmental entities' information;
(2) Preliminary policy recommendations:
(a) Policy actions other than UPLs; and
(b) Policy action in the form of a UPL and the process for setting upper payment limits; and
(3) Final actions:
(a) Adoption of the final cost review report;
(b) Adoption of non-UPL policy recommendations; and
(c) Adoption of proposed regulations setting a UPL amount.

.04 Policy Review—Information Gathering.

A. In studying the drivers, market conditions and policy options, the Board and staff may consider the information collected through the cost review study process pursuant to Health-General Article, § 21-2C-09, Annotated Code of Maryland and COMAR 14.01.04.05, including all information, analyses, and public input collected and considered during the selection of drug for the cost review study and the cost review study process.

B. If additional information is needed, the Board and staff may gather additional information through the tools outlined in §D of this Regulation.

C. If additional information is needed, the Board may utilize the information-gathering tools outlined in §D of this Regulation at any point in the policy review process, including the consideration and setting of a UPL.

D. Information Gathering Tools.

(1) Public Informational Hearings.

(a) The Board may, through Board staff, convene a hearing to receive input, information, and opinions from the public and stakeholders to inform the consideration and development of policy options including upper payment limits to redress an affordability challenge.

(b) The public informational hearing shall be conducted in accordance with COMAR 14.01.01.01.06.

(2) Stakeholder Council Input.

(a) The Board may request input from the Stakeholder Council. This input can be a request for general input and ideas on policies or more specific requests for specific information.

(b) Board staff may provide the Board with summaries of input from the Stakeholder Council.

(3) Technical Hearings.

(a) The Board may convene a hearing for the purpose of receiving technical input, technical information or expert testimony.

(b) The technical hearing shall be conducted in accordance with COMAR 14.01.01.06.

(4) Board Staff Research and Analysis.

(a) Board staff may provide the Board with policy research and analyses related to the drivers of the potential affordability and potential options.

(b) Research may include a literature review of available literature and original quantitative or qualitative research conducted by staff.

(5) Eligible Governmental Entities' Information.

(a) Board staff may collect information concerning the prescription drug product and therapeutic alternatives from eligible governmental entities.
(b) The information collected may include utilization, spending, costs, benefit design, formulary placement, rebates, discounts, price concessions and other relevant information.

.05 Policy Review—Preliminary Policy Recommendations.

A. When developing preliminary policy recommendations for the Board, Board staff may use information gathered or obtained through the:
(1) Cost review study process under COMAR 14.01.04; and
(2) Information gathering process under Regulation .04 of this Chapter.

B. Policy Action Other than UPL.
(1) Board staff may recommend policy options to redress the affordability challenge.
(2) When recommending policy options, Board staff may analyze the:
(a) Drivers of the affordability challenge;
(b) How the policy addresses a driver;
(c) Strengths and weaknesses of the policy;
(d) Possible implementation of the policy; and
(e) Potential impacts of the policy.
(2) The Board may:
(a) Adopt none of the non-UPL policy recommendations;
(b) Adopt one or more policy recommendations; or
(c) Adopt and modify one or more policy recommendations.
(3) The Board may adopt a final policy recommendation only after the Board has:
(a) Made a final affordability challenge determination; and
(b) Adopted the final cost review study report under COMAR 14.01.04.05G.
(4) The public may provide oral and written comments concerning any agenda item of the Board or any decision pending before the Board in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).

C. Policy Action in the Form of an Upper Payment Limit.
(1) Board staff may recommend a UPL as a policy option to redress an affordability challenge.
(2) When recommending a UPL as a policy option, Board staff may analyze the:

(a) The drivers and market conditions causing the affordability challenge phenomena;
(b) Ability of a UPL to address these issues;
(c) Relevant regulatory criteria under Regulation .02 of this Chapter; and
(d) Use of the drug by eligible governmental entities.

(3) Board staff may provide recommendations related to establishing a UPL including:
(a) An assessment of the drivers of the affordability challenge; and
(b) The extent to which a UPL may address the drivers.

(4) The Board may pursue development of a UPL as a policy option and direct Board staff to provide recommendations concerning the methodologies and contextual information that may be used to set a UPL in accordance with the UPL process set forth in Regulation .06 of this Chapter.

(5) The public may provide oral and written comments concerning any agenda item of the Board or any decision pending before the Board in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).

.06 Policy Review—Process for Establishing a UPL.

A. Staff Recommends Methodologies and Contextual Information.

(1) Board staff shall recommend at least one methodology, identified in §B of this Regulation, for use in developing a UPL for the subject prescription drug product.

(2) Board staff may recommend certain contextual information identified in §C of this Regulation for use in developing a UPL for the subject prescription drug product.

(3) Board staff shall:
(a) Post staff's recommendations on the Board's website in advance of the Board meeting; and
(b) Request public comment.

(4) The public may submit written comments by the date specified in the posting in accordance with COMAR 14.01.01.05B(4).

(5) Board staff shall present the recommendations to the Board.

B. Methodologies.

(1) Cost Effectiveness Analysis.
(a) Under this methodology, a maximum UPL value may be set by:
(i) using a cost-effectiveness analysis to model how much additional health outcome is gained per dollar of additional spending when using a drug product compared to an alternative;

(ii) comparing this number to a threshold to determine if a product is "cost-effective"; and

(iii) then, if the product is not already cost-effective, given the specified threshold in (ii) and the model in (i), calculating the maximum UPL for which it would be "cost-effective."

(b) When providing a UPL amount developed using this methodology, Board staff shall identify the health outcome, threshold, and relevant underlying assumptions used in the analysis.

(2) Therapeutic Class Reference Upper Payment Limit.

(a) Under this methodology, a UPL value may be set as the lowest net price or net cost among competitor products in the same therapeutic class.

(b) The Board may limit the prescription drug products used for analysis to a subset of drugs in the same therapeutic class.

(c) When determining whether to use a product in the same therapeutic class as a reference product, the Board may consider:

(i) A difference in indication including a difference in the patient population and disease severity; and

(ii) Comparative effectiveness research.

(3) Launch Price-Based Upper Payment Limit.

(a) Under this methodology, a UPL value may be set as the initial price at which the drug was first marketed (launch price) adjusted for inflation.

(b) The Board shall adjust the launch price using the CPI-U.

(4) Same Molecule Reference Upper Payment Limit.

(a) Under the same molecule reference UPL methodology, a UPL value may be set by comparing prices of certain reference drugs:

(i) A generic drug product that is therapeutically equivalent to the product under the review;

(ii) An authorized generic of the product under review;

(iii) A drug product licensed under a BLA that has the same active ingredient and is approved for one or more of the same or similar indications as the product under review;

(iv) A biosimilar for the product under review;

(v) The reference product for the product under review; and

(vi) A drug product approved under an NDA or ANDA that has the same active ingredient and is approved for one or more of the same or similar indications as the product under review.

(b) When using this methodology Board staff may consider:

(i) Any differences between the product under review and the same molecule reference products; and

(ii) The utilization of the same molecule reference products.

(5) Domestic Reference Upper Payment Limit.

(a) Under the domestic reference UPL methodology, a UPL value may be set based on the estimated net cost of a prescription drug product to other purchasers and payors for the same prescription drug product within the United States or the net price received by the manufacturer.

(b) Under this methodology, the UPL may be set to the cost of the lowest estimated net-cost purchaser or payor, excluding Medicaid.

(c) The Board may consider information for all other payors, including information on the Medicare Maximum Fair Price.

(6) International Reference Upper Payment Limit.

(a) Under the international reference UPL methodology, a UPL value may be set by comparing drug prices in other countries.

(b) Under this methodology, the Board may consider the lowest price received by manufacturers for sales in the United Kingdom, Germany, France, and Canada, converted to U.S. dollars.

(7) Budget Impact-Based Upper Payment Limits.

(a) Under the budget impact-based UPL methodology, a UPL value may be set so that spending on the drug does not exceed a certain percentage of a budget as specified by the Board or have a disproportionate impact on that budget.

(b) The Board may consider current spending, projected spending, and potential offsets in developing a UPL value.

(c) When setting the percentage, the Board may consider the number of patients impacted, the disease burden, the current and projected future spending on other treatments and management of the disease.

(8) Blend of Multiple Methodologies.

(a) Under this methodology, Board staff may recommend potential UPL values derived from:

(i) A blend of methodologies; and

(ii) A variation in implementing a methodology.

(b) When providing a blended UPL amount developed using this methodology, Board staff shall identify how the potential blended UPL value was generated.

C. Contextual Information for the Prescription Drug Product:

(1) Information gathered during the cost review study process or the policy review process;

(2) Net costs for:
(a) State health plan;
(b) County, bicounty, and municipal health plans;
(c) Direct government purchases; and
(d) Medicaid;
(3) Total out-of-pocket costs in:
(a) State health plan;
(b) County, bicounty, and municipal health plans; and
(c) Medicaid;
(4) Current coverage status of the drug in:
(a) State health plan;
(b) County, bicounty, and municipal health plans; and
(c) Medicaid;
(5) Utilization in the following program by patients and prescriptions:
(a) State health plan;
(b) County, bicounty, and municipal health plans; and
(c) Medicaid;
(6) Amount of direct government purchases by units and patients served;
(7) For the Maryland State Medical Assistance Program:
(a) Number of prescriptions paid;
(b) Number of patients who received the prescription drug product; and
(c) Total amount paid for the prescription drug product;
(10) Budget impact analysis;
(11) Comparisons of health system costs to research and development costs;
(12) Life cycle revenue analysis; and
(13) Information that can be derived from the aggregation, calculation, and comparison of available information.

D. UPL Values.
(1) The Board may:
(a) Select one or more of the methodologies and contextual information identified in §§B and C of this Regulation;
(b) Identify another methodology;
(c) Prioritize the selected and identified methodologies and contextual information; and
(d) Direct staff to use the selected and identified methodologies and contextual information to perform analyses and calculations to obtain UPL values.

(2) Based on guidance from the Board and the regulatory criteria under Regulation .02 of this Chapter, Board staff shall perform calculations and analyses to develop a collection of potential UPL values.
(3) Board staff shall post a public version of:
(a) The UPL values developed through analysis;
(b) Staff's recommendation for a proposed UPL amount with a description of the calculation and analyses and relevant underlying assumptions used in the analysis such as health outcome or threshold; and
(c) A request for public written comment on the Board's website.
(4) Board staff may also request public written comment addressing specific questions or proposing alternative analyses.
(5) The public may submit written comments by the date specified in the posting in accordance with COMAR 14.01.01.05B(4).

E. Technical Hearing.
(1) The Board may convene a hearing for the purpose of receiving technical input, technical information or expert testimony.
(2) The technical hearing shall be conducted in accordance with COMAR 14.01.01.01.06.
F. Amendment of Recommendations and UPL Values.
(1) Board staff may modify or amend the public version of the developed UPL values, and staff's recommendations for a proposed UPL amount.
(2) If Board staff modifies or amends the developed UPL values and staff's recommendations, staff shall post the amendments to the Board's website, and request public written comment by a specified date.
(3) The public may submit written comments by the date specified in the posting in accordance with COMAR 14.01.01.05B(4).

.07 Policy Review—Final Policy Action.
A. Final Determination Concerning Affordability Challenge.
(1) Prior to taking an action with respect to policy, the Board shall:
(a) Make a final determination of whether the prescription drug has or will create an affordability challenge;
(b) Adopt as final a cost review study report under COMAR 14.01.04.05G.
(2) The Board's determination of whether a prescription drug has or will create an affordability challenge is not final until the final cost review study report is adopted by the Board.

(3) The public may provide oral and written comments concerning any agenda item of the Board or any decision pending before the Board in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).

B. Final Policy Action: Policy Recommendations and Proposed Regulations.

(1) If the Board makes a final determination that the prescription drug has or will create an affordability challenge, the Board may adopt:

(a) Non-UPL policy recommendations in accordance with Regulation .05 of this Chapter;

(b) Proposed regulations setting the UPL at the specified amount in accordance with Regulation .08 of this Chapter; or

(c) Both.

(2) The public may provide oral and written comments concerning any agenda item of the Board or any decision pending before the Board in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2).

(3) Where applicable, the adoption of the final cost review study report, non-UPL policy recommendations, and proposed regulations setting a UPL amount:

(a) Shall be performed sequentially; and

(b) May be taken at the same Board meeting.

.08 Establishing and Monitoring a UPL.

A. Adopting a Proposed Regulation Setting a UPL.

(1) The proposed regulation shall set a specified UPL amount for specified eligible governmental entities.

(2) The Board and staff shall work with eligible governmental entities to develop the best method for implementing the UPL for the entity and a prospective effective date that provides sufficient time for implementation.

(3) The final net ingredient cost paid by the eligible governmental entities shall not exceed the UPL amount established by the Board.

(4) The Board shall provide for the automatic suspension of the UPL for the time that the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list by regulation.

B. Monitoring a UPL.

(1) The Board shall develop a program for monitoring the availability of any prescription drug product for which it sets a UPL.

(2) If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL.

.09 Reconsideration.

A. Authority to Reconsider UPL.

(1) The Board may reconsider a UPL for any reason.

(2) If the Board becomes aware of a shortage of a prescription drug product in the State, for a drug that is subject to a UPL, the Board shall reconsider the UPL.

(3) The Board may suspend a UPL at any time and may suspend the UPL for the duration of the reconsideration process by proposing an amended regulation.

(4) Following completion of the reconsideration process the Board may:

(a) Take no action and allow the UPL to stand;

(b) Modify the UPL amount and propose amendment of the UPL regulation setting the new modified UPL amount;

(c) Suspend the UPL for a specified period and propose amendment of the regulation to proscribe the suspension; and

(d) Repeal the UPL and propose repealing the regulation setting the UPL amount.

B. Reconsideration Process.

(1) General Procedures.

(a) Board staff shall post notice of the reconsideration of the UPL on the Board's website.

(b) The Board may solicit patient and stakeholder feedback through written comments submitted in accordance with COMAR 14.01.01.05B(4) and informational hearings held under COMAR 14.01.01.06C.

(c) The Board may use the information gathering process under Regulation .04 of this Chapter to obtain information for the reconsideration process.

(d) Board staff shall present to the Board:

(i) The basis for reconsideration;

(ii) A summary of the feedback obtained through written comments, informational hearings and the information gathering process, as applicable;

(iii) A summary of the information generated through the UPL monitoring program, as applicable;

(iv) Estimated impact of the UPL to date such as savings estimates, and estimated impact on access to the drug; and

(v) Staff recommendations for Board action.

(e) The Board may take any action specified under § A(4) of this regulation.

(2) Modifying a UPL.

(a) If Board staff recommends further study to support modification of the UPL, the Board shall use the procedures in Regulations .06D-F and .07B(1)(b) of this Chapter to develop a new UPL amount and receive public comment.

(b) The Board may modify the UPL amount and propose amendment of the UPL regulation setting the modified UPL amount under § A(4)(b) of this Regulation.

C. Action on Drug where UPL was Repealed.

(1) For any prescription drug product previously subject to a UPL that was later repealed, the Board may:

(a) Select the prescription drug product for cost review study if the drug product meets the eligibility requirements set forth in COMAR 14.01.04.02;

(b) Conduct a cost review study in accordance with COMAR 14.01.04.05; and

(c) Make a preliminary determination in accordance with COMAR 14.01.04.05.

(2) If the Board makes a preliminary determination that the prescription drug product has or will create an affordability challenge the Board may:

(a) Consider any element or analysis from the original cost review study report;

(b) If available, consider information from the UPL monitoring program;

(c) Consider information obtained through the reconsideration process under of this Regulation; and

(d) Set a UPL or make other policy recommendations in accordance with Regulations .07-.08 of this Chapter.