Health General Article § 21-2C-13(d)- Prescription Drug Affordability Board- Upper Payment Limit Action Plan

Maryland Prescription Drug Affordability Board

MARYLAND
Prescription Drug Affordability Board

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Prescription Drug Affordability Board

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INTRODUCTION

Established in 2019, the Maryland Prescription Drug Affordability Board ("Board") is an independent agency charged with "protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drugs." Md. Code Ann., Health-Gen. ("HG") § 21-2C-02(b). The five-member Board is supported by four staff members and an assistant attorney general. The Board confers with, and receives input from, a 26-member appointed advisory Stakeholder Council composed of experts across the supply chain and stakeholder representatives.

Under HG § 21-2C-09, the Board may conduct a cost review study to determine whether use of a 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 ("affordability challenges")." *See also* COMAR 14.01.04.05 (establishing Cost Review Study Process). This study informs policy decisions and actions by the Board.

If the Board determines that a prescription drug product has led or will lead to affordability challenges, the Board may consider, recommend, and implement policies to address those affordability challenges, including establishing an upper payment limit ("UPL") that applies to state and local governments and units. Pursuant to HG § 21-2C-07, the Board issued a draft report finding that "it is in the best interest of the state to establish a process for setting upper payment limits." However, because a UPL may not be the preferred policy solution for every affordability challenge, the Board may recommend other policy actions. Board policy actions may include seeking additional legislative authority to implement a policy solution and providing policy recommendations to the legislature, state and local government partners, and others to address the affordability challenges identified in the cost review study.

In compliance with HG § 21-2C-13, and in conjunction with the Stakeholder Council, the Board drafted this "plan of action for implementing the process that includes the criteria the Board shall use to set upper payment limits ("UPL Action Plan")." The criteria for setting a UPL shall include consideration of the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs. HG § 21-2C-13(b).

A UPL may not be applied to a prescription drug product that is on the federal Food and Drug Administration prescription drug shortage list. HG § 21-2C-13(c)(1). The Board shall also "[m]onitor the availability of any prescription drug product for which it sets an upper payment limit," and "[i]f there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit."

The Board shall submit the UPL Action Plan to the Legislative Policy Committee ("LPC"), in accordance with § 2-1257 of the State Government Article, for approval. If the LPC does not approve the plan within 45 days, the Board shall submit the plan to the Governor and the Attorney General for approval.

When the UPL Action Plan is approved, the Board may set UPLs for prescription drug products that are "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including: State or county correctional facilities; State hospitals; and health clinics at State institutions of higher education." The Board may also set UPLs for prescription drug products that are "[p]aid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan," or "[p]urchased for or paid for by the Maryland State Medical Assistance Program." HG § 21-2C-14(a). Thus, the authority to establish UPLs applies only to purchases and payments made by state and local governments and their units ("Eligible Governmental Entities").

UPPER PAYMENT LIMIT ACTION PLAN AND PROCESS

I. Overview of Upper Payment Limits

A UPL is a policy tool that may be used to redress the factors that cause (hereinafter "drivers") the phenomenon of an affordability challenge. Because setting a prospective UPL is a quasi-legislative action, the procedures in this action plan provide for setting a UPL by adopting a regulation through the notice and comment rulemaking provisions of the Maryland Administrative Procedure Act. The UPL process is transparent and offers multiple opportunities for public engagement and input. Both the cost review study and the policy review process are part of the quasi-legislative process that enables the Board to acquire relevant data and information to inform the development and promulgation of public policy and to leverage its technical expertise for the benefit of the public and the State in crafting that policy.

Through the process, the Board assesses whether a UPL is an appropriate policy solution to redress the driver(s) of the affordability challenge; that assessment includes consideration of certain regulatory criteria. Staff then recommends methodologies and contextual information to consider and use in setting a UPL by regulation. These recommendations are posted on the Board's website for public comment. The Board directs staff to perform analyses and make calculations using specified methodologies to develop a collection of potential UPL amounts consistent with certain regulatory criteria. A public version of the collected potential UPL values, and staff's recommendations are posted on the Board's website for public comment. If needed, the Board may convene a technical hearing to receive additional technical input and information. If Board staff modifies or amends the collected UPL values or staff's recommendations, staff posts the amendments to the Board's website, and requests additional public written comment.

Following multiple opportunities for public comment on the methodologies, contextual information and calculations, the Board may propose the adoption of a regulation setting the UPL at a specified amount.

Some processes may require consideration and discussion of proprietary, confidential, and trade secret information. When such information is discussed, the Board will go into closed session. The Board may pause the policy review process at any time. The Board may also discontinue the development of a UPL.

II. Criteria for Setting an Upper Payment Limit

The Board shall apply the following criteria when determining whether to set an upper payment limit and when setting an upper payment limit amount:

- The Board shall consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;
- The Board shall determine that an upper payment limit is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product;
- The Board shall not set an upper payment limit for the prescription drug product if utilization of the product by Eligible Governmental Entities is minimal;
- The Board shall set an upper payment limit in a way to minimize adverse outcomes and the risk of unintended consequences;
- The Board shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug;
- The Board shall not set an upper payment limit for generic prescription drug products that have nine (9) or more marketed therapeutic equivalents;
- The Board shall not set an upper payment limit amount that impacts statutory or regulatory amounts, such as Medicaid Best Price;
- The Board shall not set an upper payment limit that is lower than the Medicare Maximum Fair Price.

III. Cost Review Study Process

Pursuant to HG § 21-2C-09 and COMAR 14.01.04.05, the Board conducts a cost review study of a prescription drug product to determine whether use of the drug "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." This study involves Board staff compiling and analyzing quantitative data, qualitative data, and public input for the Board to consider and determine whether use of the drug has led or will lead to affordability challenges. This study process informs subsequent policy action.

As part of the cost review study process, the Board may collect additional prescription drug data requested from manufacturers, health insurance carriers, HMOs, MCOs, pharmacy benefit managers, and wholesale distributors. COMAR 14.01.04.04B. For example, among many other information requests, the Board may request that manufacturers submit documents explaining the relationship between the price of a prescription drug product and the cost of development and therapeutic benefit, the total amount of price concessions, discounts, and rebates provided to different payor types in Maryland, and net manufacturer revenue for the prescription drug product. COMAR 14.01.04.04B(1).

In the cost review study, the Board may consider many different factors, including but not limited to the following: various drug prices at different points in the supply chain; price concessions, discounts, and rebates; therapeutic alternatives; patient access; cost and comparative effectiveness analyses; cost sharing; clinical information; disease burden; gross spending and utilization data; shortage status; industry entity responses to requests for information; and public input. COMAR 14.01.04.05B.

A. Preliminary Determination Concerning Affordability Challenge

After reviewing data, analyses, and public input from the cost review study process, the Board makes 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."

The Board makes this preliminary determination at an open Board meeting. The Board shall make public materials, including the preliminary public dossier of summarized data, analyses, and public input from the cost review study and supporting materials, available before the Board meeting for review and comment.

A preliminary determination is non-final and subject to revision and modification.

1. Board Does Not Make a Preliminary Determination That Prescription Drug Product Has Led or Will Lead to an Affordability Challenge

If the Board does not make a preliminary determination that use of the prescription drug product has led or will lead to affordability challenges, then no further policy action is needed.

Board staff prepares a draft of the preliminary determination cost review report that summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, and the Board's preliminary determination.

The public may comment on the draft of the preliminary determination cost review report.

2. Board Makes a Preliminary Determination That Prescription Drug Product Has Led or Will Lead to an Affordability Challenge

If the Board makes a preliminary determination that use of the prescription drug product has led or will lead to affordability challenges, the Board commences the policy review process. The policy review process, which includes the procedures for setting a UPL, runs parallel to the process for reviewing and adopting a final determination and cost review study report.

Board staff prepares a draft of the preliminary determination cost review report that summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, and the Board's preliminary determination.

The public may comment on the draft of the preliminary determination cost review report.

B. Final Determination Concerning Affordability Challenge

After considering public comments, the Board may vote to finalize the preliminary determination and approve the draft cost review report as final. The Board's determination of whether use of a prescription drug has or will create an affordability challenge is not final until the final cost review report is adopted by the Board.

The adoption of the final cost review report, adoption of policy recommendations by resolution and the adoption of proposed regulations setting a UPL amount shall be performed sequentially, where applicable. These actions may be taken at the same Board meeting.

IV. Policy Review Process and Upper Payment Limit (UPL) Development

The preliminary determination that use of a drug has led or will lead to an affordability challenge is a predicate for the Board to start the policy review process to study and assess what, if any, policy tools are best suited to redress the identified affordability challenges, including whether a UPL is an appropriate policy solution. Because a UPL may not be the preferred policy solution to every affordability challenge, the Board may recommend other policy actions, which may include seeking additional legislative authority to implement a policy solution and providing policy recommendations to the legislature, state and local government partners, and others.

Policy Review Process

The policy review process commences with a preliminary determination that the prescription drug product has or will create an affordability challenge to the State health care system or high out of pocket costs for patients. The following phases make up the policy review process: information

gathering, preliminary policy recommendations, and policy approval.

A. Information Gathering

One goal of the information gathering phase is to confirm, based on the best available information, the drivers and market failures causing the affordability challenge phenomena. The second goal is to identify the policies that have the highest likelihood of addressing those drivers and resolving the affordability challenges.

When studying policy options, the Board and staff may consider the information collected through the cost review study process pursuant to HG § 21-2C-09 and COMAR 14.01.04.05. This includes all information, analyses, and public input collected and considered during the selection of drug for the cost review study process and the cost review study process itself, including data collected during the Request for Information.

If additional information is needed, the Board and staff may gather additional information from informational hearings, Stakeholder Council input, expert hearings, eligible governmental entities and policy research and analyses conducted by Board staff.

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

1. Informational Hearings

The Board may, through Board staff, convene informational hearings to receive input and information from the public and stakeholders to inform the consideration and development of policy options including upper payment limits. The Board may publish specific questions or topics in advance of a hearing identifying matters upon which the Board would like to receive testimony and information. Board staff may provide the Board with summaries of the testimony and staff's recommendations. The Board shall adopt regulations governing these quasi- legislative hearings.

2. Stakeholder Council Input

The Board may request input from the Stakeholder Council. This input can be a request for general input and ideas on policies or requests for specific information. Board staff may provide the Board with summaries of the Stakeholder Council's input.

3. Expert Testimony Hearings

The Board may convene a hearing for the purpose of receiving expert testimony and soliciting testimony from persons with specific knowledge, skills or expertise. The Board shall adopt

regulations governing these quasi-legislative hearings.

4. Board Staff Research and Analysis

Board staff may provide the Board with policy research and analyses related to the drivers of the potential affordability and potential options. Board staff research may include a literature review and original quantitative or qualitative research conducted by staff.

5. Eligible Governmental Entities

Board staff may collect from Eligible Governmental Entities relevant information concerning the prescription drug product and therapeutic alternatives such as utilization, costs, benefit design, formulary placement, rebates, discounts and price concessions.

B. Preliminary Policy Recommendations

Board staff may use the information gathered through the cost review study process and the information gathering phase to develop preliminary policy recommendations. Board staff may synthesize the information and draft preliminary recommendations.

1. Preliminary Recommendations for Policy Action (Other than UPLs)

Board staff may recommend policy options to redress thse affordability challenge. These recommendations may include an assessment of the drivers of the affordability challenge, how a particular policy addresses a driver, the strengths and weaknesses of such a policy, information regarding possible implementation of such a policy, and the potential impacts of the policy option.

The Board may adopt, or adopt and modify, one or more policy recommendation(s) as Board resolutions at a subsequent Board meeting. The adoption of a final policy recommendation shall occur after the final determination and adoption of the final cost review study report.

2. Preliminary Recommendation for Policy Action and Process for Upper Payment Limits

Board staff may also recommend a UPL as an appropriate policy option to redress an affordability challenge. In understanding if a UPL is an appropriate policy option, Board staff may analyze the contextual issues related to the driver(s) of the affordability challenge, the ability of a UPL to address these issues, the relevant regulatory criteria, and the use of the drugs by Eligible Governmental Entities. Board staff may also provide recommendations related to establishing a UPL, which may include an assessment of the driver(s) of the affordability challenge and the extent to which a UPL may address the driver(s).

The Board may pursue the 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. *See* Section IV.B.2.a.

a. Staff Recommends Methodologies and Contextual Information to Establish a UPL

Board staff shall develop and present to the Board recommendations concerning the methodologies used to set a UPL for the prescription drug product. *See* Section IV.B.2.a.i (identifying methodologies). Staff may also recommend that the Board consider certain contextual information. This may include information in the cost review study process dossier, new information that may become available during the policy review process, and information related to the Eligible Governmental Entities. *See* Section IV.B.2.a.ii (identifying contextual information).

Staff shall post the recommendations on the Board's website prior to the Board meeting and request public comment. Written comments may be submitted by the date specified in the notice in accordance with COMAR 14.01.01.05B(4).

The Board may select or prioritize one or more of the methodologies and factors, and direct staff to use those methodologies and any other methodology identified by the Board, to conduct analyses and calculations to obtain upper payment limit amounts.

i. Methodologies

Staff may recommend one or more of the following methodologies:

Cost Effectiveness Analysis

According to the Centers for Disease Control and Prevention (CDC), "[c]ost-effectiveness analysis is a way to examine both the costs and health outcomes of one or more interventions. It compares an intervention to another intervention (or the status quo) by estimating how much it costs to gain a unit of a health outcome, like a life year gained or a death prevented."[1]

Cost-effectiveness Analysis ("CEA") is traditionally used to determine how much additional health outcome is gained per dollar of additional spending when using a drug product. Researchers then compare this number to a threshold to determine if a product is "cost-effective." This process can be reversed so that given a threshold, the UPL for which it is "cost-effective" can be

[1] Cost-Effectiveness Analysis | POLARIS | Policy, Performance, and Evaluation | CDC (last checked August 30, 2024).

calculated.

The policy review process will guide the determination of the appropriate health outcome for the drug and the appropriate threshold.

CEA often relies on various assumptions that may result in different calculations. The policy review process will help the Board determine which assumptions are the most appropriate.

Therapeutic Class Reference Upper Payment Limit

Many drugs are not the only products in their therapeutic class. As a result, many drugs have competitor products that have similar chemical structures and act through similar pathways to treat the same conditions. A therapeutic class reference UPL sets the UPL to the lowest net price among the competitor products.

When using a therapeutic class reference UPL, the Board may limit the products under consideration to a subset of drugs in the same class. This includes information on comparative effectiveness research. The Board may not consider the information on products that are proven less effective for all indications than the product under review. The Board may also consider differences in indications (including differences in the patient population and disease severity) when determining if a product in the same class should be considered a potential reference product.

Launch Price-Based Upper Payment Limit

Some drugs have been on the market for years. Often the price of these drugs increases much faster than the overall rate of inflation. When a drug enters the market, the manufacturer begins marketing with an initial price. This initial price is often referred to as a "launch price." If using the launch price-based UPL, the Board may set the UPL as the launch price adjusted for inflation.

Same Molecule Reference Upper Payment Limit

"Same molecule" reference UPL refers to setting a UPL based on the prices of: (1) generic drug products referencing the product under the review; (2) authorized generics of the product under review; (3) biosimilars referencing the product under review; (4) drug products approved under a New Drug Applications ("NDAs") that have the same active ingredient and are approved in the same or similar indication(s) as the product under review; and (5) drug products licensed under a Biologics License Application ("BLA") that have the same active ingredient and are approved in the same or similar indication(s) as the product under review.

Domestic Reference Upper Payment Limit

Domestic reference UPL refers to setting a UPL based on the net prices paid by other purchasers and payors for the same product within the United States. Under such an approach, the UPL may be set to be the price of the lowest net-price purchaser or payor. In doing so, the Board may consider information for all other payors, including information on the Medicare Maximum Fair Price.

International Reference Upper Payment Limit

Drug manufacturers sell their products throughout the world. This methodology utilizes drug prices in other countries in setting a UPL. If the Board uses the international reference UPL as the method for setting the UPL, the Board may consider the lowest price paid in the United Kingdom, Germany, France, and Canada, converted to U.S. dollars.

Budget Impact-Based Upper Payment Limits

Budget impact-based UPL reflects the process of setting a UPL so that spending on the drug does not exceed a certain percentage of a specified budget or have a disproportionate impact on that budget.

Blend of Multiple Methodologies

Board staff may recommend potential values for a UPL derived from a blend of methodologies or variations in implementing the methodologies.

ii. Contextual Information

Staff may recommend that the Board consider certain contextual information in setting a UPL:

- Any information gathered during the cost review study process or the policy review process
- Utilization, in terms of patients and prescriptions, in
    - the state health plan
    - county, bicounty, and municipal health plans
    - Medicaid
- Amount of direct government purchases in terms of units and patients served
- Net prices for
    - state health plan
    - county, bicounty, and municipal health plans
    - direct government purchases
    - Medicaid

- Total out-of-pocket costs in the
    - state health plan
    - county, bicounty, and municipal health plans
    - Medicaid
- Current coverage status of the drug in
    - the state health plan
    - county, bicounty, and municipal health plans
    - Medicaid
- The number of prescriptions paid through the Maryland State Medical Assistance Program
- The number of patients for the drug received through the Maryland State Medical Assistance Program
- The total amount paid for the drug through the Maryland State Medical Assistance Program
- Any budget impact analysis
- Comparisons of health system costs to research and develop cost
- Life cycle revenue analysis
- The Maximum Fair Price, as negotiated under the Medicare Price Negotiation Program
- Any information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information

b. Staff Calculation of Potential UPL Values and Staff-Proposed UPL Amount

Based on guidance from the Board and guided by the regulatory criteria for setting a UPL, Board staff shall perform calculations and analyses to develop a collection of potential UPL values.

Board staff shall post a public version of the collected potential UPL values, staff's recommendation for a proposed UPL amount with a description of the calculation and analyses, and a request for public written comment on the Board's website. Board staff may also request public written comment in the form of answers to specific questions or alternative analyses. Written comments may be submitted by the date specified in the notice in accordance with COMAR 14.01.01.05B(4).

c. Board Technical Hearing

The Board may convene a technical hearing to receive additional technical input and information. The Board may request that persons who submitted technical written comments, or comments that raised additional issues the Board wishes to explore, attend the hearing and provide testimony. The Board shall adopt regulations governing these quasi-legislative hearings.

Board staff may modify or amend the public version of the collected potential UPL values, and staff's recommendations for a proposed UPL amount. If Board staff modifies or amends the collected 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.

C. Final Policy Action

1. Final Determination Concerning Affordability Challenge

Prior to taking any action with respect to policy, the Board shall finally determine whether a prescription drug has or will create an affordability challenge.

After considering public comments, the Board may vote to finalize the preliminary determination and approve the draft cost review report as final. The Board's determination of whether a prescription drug has or will create an affordability challenge is not final until the final cost review report is adopted by the Board. *See* Cost Review Study Process, III at page 4.

2. Final Policy Action: Policy Recommendations and Proposed Regulations

The policy review process culminates in the adoption of: (1) other (non-UPL) policy recommendations; (2) proposed regulations setting the UPL at the specified amount; or (3) both.

The adoption of the final cost review report, adoption of policy recommendations (non-UPL) by resolution and the adoption of proposed regulations setting a UPL amount shall be performed sequentially, where applicable. These actions may be taken at the same Board meeting.

V. Establishing a UPL.

When enacting a UPL by regulation, the regulation shall set a specified UPL for specified Eligible Governmental Entities[2] and a prospective effective date that provides sufficient time for implementation. HG § 21-2C-14(a). The Board and staff shall work with Eligible Governmental Entities to develop the best method for implementing the UPL for the entity. The final net ingredient cost paid by the Eligible Governmental Entities shall not exceed the UPL established by the Board.

VI. Monitoring, Suspending and Rescinding a UPL.

The Board shall develop a program for monitoring the availability of any prescription drug

[2] The authority to establish UPLs applies to purchases and payments made by state and local governments and their units ("Eligible Governmental Entities").

product for which it sets a UPL. If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL. *See* HG § 21-2C-13(c)(2); § 21-2C-14(c)(1). The Board shall adopt regulations providing for the suspension, modification and recission of UPLs.

When enacting a UPL by regulation, 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. *See* HG § 21-2C-13(c)(1); § 21-2C-14(c)(2).