# 14 INDEPENDENT AGENCIES

## Subtitle 01 PRESCRIPTION DRUG AFFORDABILITY BOARD

**Notice of Final Action**

[24-221-F]

On March 24, 2025, the Maryland Prescription Drug Affordability Board adopted:

(1) Amendments to Regulation **.01** under **COMAR 14.01.01 General Provisions**;

(2) New Regulation **.06** under **COMAR 14.01.01 General Provisions**; and

(3) New Regulations **.01—.09** under a new chapter, **COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits**.

This action, which was proposed for adoption in 52:1 Md. R. 33—40 (January 10, 2025), has been adopted with the nonsubstantive changes shown below.

**Effective Date: April 28, 2025.**

**Attorney General's Certification**

In accordance with State Government Article, §10-113, Annotated Code of Maryland, the Attorney General certifies that the following changes do not differ substantively from the proposed text. The nature of the changes and the basis for this conclusion are as follows:

COMAR 14.01.01.06B(2), C(2), and F: This change removes the descriptor "staff" in front of "designee" to clarify the broad scope and replaces "staff member designated by the Chair" with "designee" for consistency. This change is clarifying and does not significantly alter any benefit or burden under the regulation as initially proposed.

COMAR 14.01.05.05B(2)(d): This change clarifies that "[w]hen recommending [non-UPL] policy options, Board staff may analyze the" "possible implementation of the [non-UPL] policy option" "through legislation, regulation or enforcement." As the comments observed, the Board's primary authority to address affordability challenges is limited to upper payment limits (UPL). This change clarifies that, consistent with that authority, when assessing a non-UPL policy option, how such an option could be implemented may include any necessary legislation, regulatory or enforcement considerations. This change is clarifying and does not significantly alter any benefit or burden under the regulation as initially proposed but COMAR 14.01.05.05B(2)—(4): This change corrects the misnumbered sections.

COMAR 14.01.05.05C(2)(c)—(e): In consideration of several comments, and in the interest of clarity and symmetry, this change adds three provisions already contained in COMAR 14.01.05.05B(2) (describing items staff may analyze in recommending a non-UPL policy) to COMAR 14.01.05.05C(2) (describing items staff may analyze in recommending UPL policy). Specifically, this change adds the strengths and weaknesses and potential impacts of the UPL policy (items already discussed in the supply chain report) and the possible implementation of the UPL policy through legislation, regulation or enforcement as considerations that may be analyzed in recommending a UPL policy option. Under these regulatory procedures a UPL may be established through notice and comment rulemaking. This change does not significantly alter any benefit or burden under the regulation as initially proposed but provides symmetry between the non-UPL policy options and UPL policy option responsive to the comments.

COMAR 14.01.05.05C(2)(c)—(d): This change renumbers these sections to (f)—(g) to accommodate the additions above.

COMAR 14.01.05.06A, B and D: This change replaces the term "methodology" and "methodologies" with "framework" and "frameworks." This neutral language clarifies that a "framework" reflects a broad analytical approach to analyzing and calculating an upper payment limit amount rather than a prescribed rigid method for performing the analysis. This change in terminology is for clarity and does not significantly alter any benefit or burden under the regulation as initially proposed.

## 14.01.01 General Provisions

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

***.06 Hearing Procedures.***

*A.* (proposed text unchanged)

*B. General Hearing Provisions.*

*(1)* (proposed text unchanged)

*(2) Conducting a Quasi-Legislative Hearing*.

*(a) A hearing held under this regulation is quasi-legislative and may be conducted or presided over by:*

*(i)* (proposed text unchanged)

*(ii)* **[[***A staff member designated by the Chair***]]** *Designee.*

*(b) The Chair or* **[[***staff***]]** *designee shall determine the conduct of the hearing, including:*

*(i)—(ii)* (proposed text unchanged)

*(c) The Chair or* **[[***staff***]]** *designee may:*

*(i)—(iii)* (proposed text unchanged)

*(d)* (proposed text unchanged)

*(e) If an exhibit is offered and is relevant to the hearing, the Chair or* **[[***staff***]]** *designee shall receive and mark the exhibit offered in testimony.*

*(f) Unless the Chair or* **[[***staff***]]** *designee believes that an oath provides some assurance of veracity, formality, or decorum to the hearing, the Chair or* **[[***staff***]]** *designee may dispense with the formality of an oath.*

*(g) The Chair or* **[[***staff***]]** *designee has discretion to:*

*(i)—(ii)* (proposed text unchanged)

*C. Informational Hearings.*

*(1)* (proposed text unchanged)

*(2) Conducting an Informational Hearing.*

*(a)* (proposed text unchanged)

*(b) The Chair or* **[[***staff***]]** *designee shall give all persons who register to speak an opportunity to do so but may limit repetitious testimony.*

*(c) The Chair or* **[[***staff***]]** *designee may:*

*(i)—(iv)* (proposed text unchanged)

*(d)* (proposed text unchanged)

*D.—E.* (proposed text unchanged)

*F. Hearing Record.*

*(1) The Chair or* **[[***staff***]]** *designee controls the record.*

*(2) The Chair or* **[[***staff***]]** *designee shall assemble a record that may include the following:*

*(a)—(f)* (proposed text unchanged)

*(3)* (proposed text unchanged)

## *14.01.05 Policy Review, Final Action, Upper Payment Limits*

*Authority: Health-General Article, §§21-2C-03(f)(1), 21-2C-09, 21-2C-13, 21-2C-14, Annotated Code of Maryland*

***.05 Policy Review—Preliminary Policy Recommendations.***

*A.* (proposed text unchanged)

*B. Policy Action Other than UPL.*

*(1)* (proposed text unchanged)

*(2) When recommending policy options, Board staff may analyze the:*

*(a)—(c)* (proposed text unchanged)

*(d) Possible implementation of the policy <u>through legislation, regulation or enforcement</u>; and*

*(e)* (proposed text unchanged)

**[[***(2)***]]** *<u>(3)</u>*—**[[***(4)***]]** *<u>(5)</u>* (proposed text unchanged)

*C. Policy Action in the Form of an Upper Payment Limit.*

*(1)* (proposed text unchanged)

*(2) When recommending a UPL as a policy option, Board staff may analyze the:*

*(a)—(b)* (proposed text unchanged)

*<u>(c) Strengths and weaknesses of the UPL policy;</u>*

*<u>(d) Potential impacts of the UPL policy;</u>*

*<u>(e) Possible implementation of the policy through legislation, regulation or enforcement</u>;*

**[[***(c)***]]***(f)*—[[*(d)***]]***<u>(g)</u>* (proposed text unchanged)

*(3)* (proposed text unchanged)

*(4) The Board may pursue development of a UPL as a policy option and direct Board staff to provide recommendations concerning the* **[[***methodologies***]]** *<u>frameworks</u> 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)* (proposed text unchanged)

***.06 Policy Review—Process for Establishing a UPL.***

*A. Staff Recommends* **[[***Methodologies***]]** *<u>Frameworks</u> and Contextual Information.*

*(1) Board staff shall recommend at least one* **[[***methodology***]]** *<u>framework</u>, identified in §B of this regulation, for use in developing a UPL for the subject prescription drug product.*

*(2)—(5)* (proposed text unchanged)

*B.* **[[***Methodologies***]]** *<u>Frameworks</u>.*

*(1) Cost Effectiveness Analysis.*

*(a) Under this* **[[***methodology***]]** *<u>framework</u>, a maximum UPL value may be set by:*

*(i)—(iii)* (proposed text unchanged)

*(b) When providing a UPL amount developed using this* **[[***methodology***]]** *<u>framework</u>, 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***]]** *framework, a UPL value may be set using the lowest net price or net cost among competitor products in the same therapeutic class.*

*(b)—(c)* (proposed text unchanged)

*(3) Launch Price-Based Upper Payment Limit.*

*(a) Under this* **[[***methodology***]]** *framework, a UPL value may be set based on the initial price at which the drug was first marketed (launch price) adjusted for inflation.*

*(b)* (proposed text unchanged)

*(4) Same Molecule Reference Upper Payment Limit.*

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

*(i)—(vi)* (proposed text unchanged)

*(b) When using this* **[[***methodology***]]** *framework Board staff may consider:*

*(i)—(ii)* (proposed text unchanged)

*(5) Domestic Reference Upper Payment Limit.*

*(a) Under the domestic reference UPL* **[[***methodology***]]** *framework, a UPL value may be set using 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***]]** *framework, the UPL may be set using the cost of the lowest estimated net-cost purchaser or payor, excluding Medicaid.*

*(c)* (proposed text unchanged)

*(6) International Reference Upper Payment Limit.*

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

*(b) Under this* **[[***methodology***]]** *framework, 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***]]** *framework, 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)—(c)* (proposed text unchanged)

*(8) Blend of Multiple* **[[***Methodologies***]]** *Frameworks.*

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

*(i) A blend of* **[[***methodologies***]]** *frameworks; and*

*(ii) A variation in implementing a* **[[***methodology***]]** *framework.*

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

*C.* (proposed text unchanged)

*D. UPL Values.*

*(1) The Board may:*

*(a) Select one or more of the* **[[***methodologies***]]** *frameworks and contextual information identified in §§B and C of this regulation;*

*(b) Identify another* **[[***methodology***]]** *framework;*

*(c) Prioritize the selected and identified* **[[***methodologies***]]** *frameworks and contextual information; and*

*(d) Direct staff to use the selected and identified* **[[***methodologies***]]** *frameworks and contextual information to perform analyses and calculations to obtain UPL values.*

*(2)—(6)* (proposed text unchanged)

*E.—F.* (proposed text unchanged)

ANDREW W. YORK
Executive Director