Draft Regulations- Presentation

Amend COMAR 14.01.01.01 (definitions);
Add COMAR 14.01.01.06 (hearing procedures);
Add COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

PDAB Meeting

November 25, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Discussion Items

- Upper Payment Limit and Policy Review Process
- UPL Status
- Draft Regulations

UPL Status and Next Steps

Status:

- Board approved UPL Action Plan on 9/10/2024
- Legislative Policy Committee Approved UPL Action Plan on 10/22/2024

Next Steps :

- Adopt regulations establishing Policy Review Process

Regulations

The following draft regulations were posted on October 28, 2024.

- Amendments to COMAR 14.01.01.01 (Definitions)
- New Regulation 14.01.01.06 (Hearing Procedures)
- New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Comments on the draft regulations were due November 8, 2024

16 comment letters were received, shared with the Board and posted on the website.

Addressing Specific Comments

Overall Feedback

- Concerns with UPL as a policy tool
- Concerns with impact of UPL on access, patient cost sharing, and supply chain
- Concerns with Board process in developing UPL policies
- Concerns with specificity of certain definitions, criteria, and steps

Specific Feedback

- Definition clarifications
  - Utilization
  - Definition of Term Affordability Challenge
  - Net ingredient Costs
- Hearing regulations
- APA process clarification
- Timelines for Specific Steps and Opportunities for Comment

PDASC Feedback

- The PDASC provided feedback on the regulations at the November 4, 2024 meeting.
- The PDASC asked some excellent questions and provided feedback around the regulations.

The main discussion themes included:

- Definition suggestions and clarifications
- Hearing logistics and procedures
- Short and long term timelines for UPLs
- Consumer expectations
- Monitoring and enforcement
- Consistency
- UPL suspension clarification

Updates to Regulations

- Clarification on definition of upper payment limit, including adding “eligible governmental entities upper payment limit” (GovUPL) and clarifying definition of “system net ingredient cost”
- Clarification on UPL criteria, including clarifying “minimal” use

Overview of Regulation Structure

Title 14	Independent Agencies
Subtitle .01	Prescription Drug Affordability Board
Chapter .01	General Provisions
Regulation .01	Definitions

Subtitle .01

- COMAR 14.01.01 General Provisions
- COMAR 14.01.02 Prescription Drug Affordability Fund
- COMAR 14.01.03 Public Information Act
- COMAR 14.01.04 Cost Review Process
- COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits (New)

Amendments to COMAR 14.01.01.01 (Definitions)

.01 Definitions

- Add and update definitions

For example:

(56) “Purchaser” means an entity that purchases prescription drug products that is not a payor or a patient.

(62) “System net cost” means the sum of the net cost as defined above and the per unit patient out-of-pocket cost.

(71) “Utilization” means information about the use of a drug including the number of units, the number of patients and number of prescriptions or claims.

New Regulation 14.01.01.06 (Hearing Procedures)

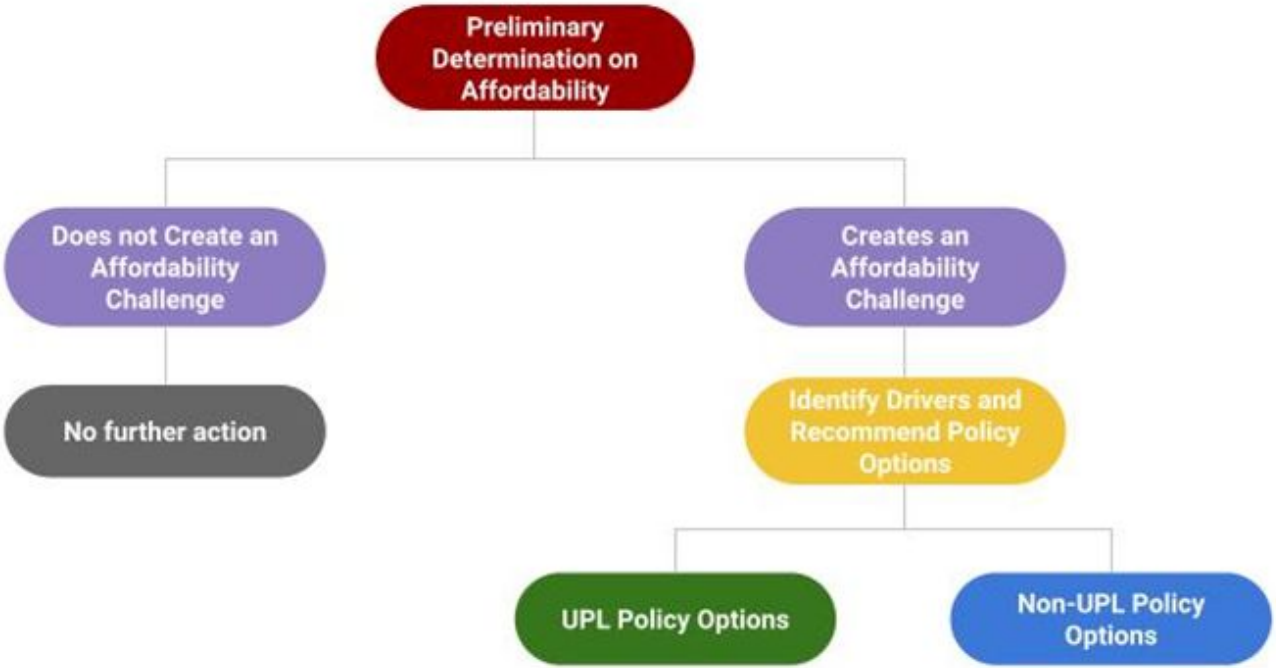
.06 Hearing Procedures

A. Scope
B. General Hearing Provisions
C. Informational Hearings
D. Technical Hearings
E. Recordings of Quasi- Legislative Hearings
F. Hearing Record

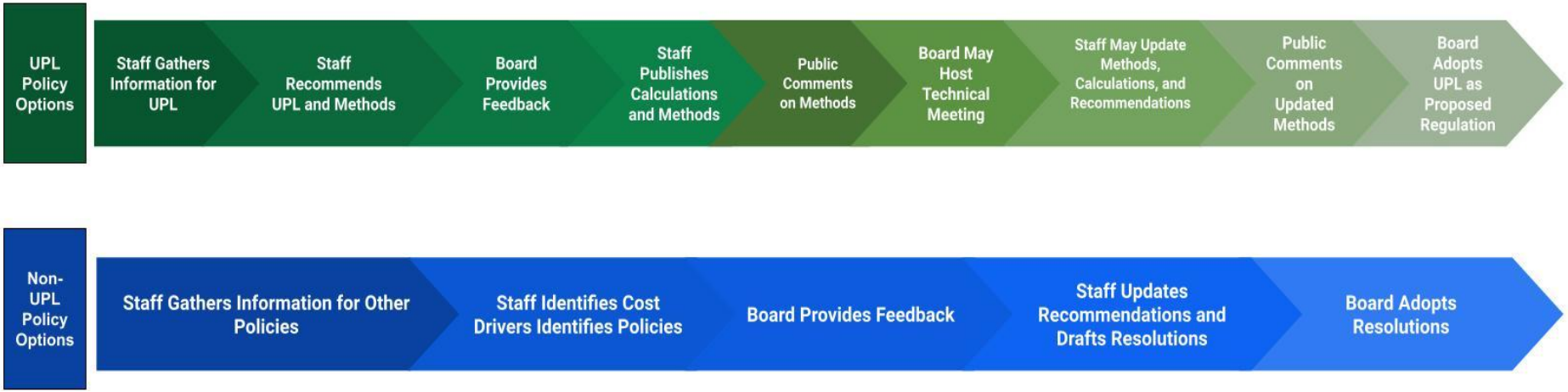
New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.01	Definitions
.02	Criteria for Setting Upper Payment Limits
.03	Policy Review and Final Action Process Overview
.04	Policy Review- Information Gathering
.05	Policy Review- Preliminary Policy Recommendations
.06	Policy Review- Process for Establishing a UPL
.07	Policy Review- Final Policy Action
.08	Establishing and Monitoring a UPL
.09	Reconsideration

Upper Payment Limit and Policy Review Process
Process after Board Makes Preliminary Determination on Affordability



Upper Payment Limit and Policy Review Process



New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.01 Definitions

- Adds definitions specific to the Policy Review Process
    - “Eligible governmental entities upper payment limit” or “GovUPL” means the per unit final net cost paid by the eligible governmental entity, which is the upper payment limit established by the Board minus applicable patient out-of-pocket costs.
    - "System net ingredient cost” means the final system cost attributable to or related to the prescription drug product after accounting for all discounts and price concessions, excluding dispensing, administration and direct and indirect remuneration to pharmacies, including patient out-of-pocket cost
    - “Upper payment limit” or “UPL” means the amount established by the Board and represents the system net ingredient cost.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.02 Criteria for Setting Upper Payment Limits

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 system net cost of the drug.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.02 Criteria for Setting Upper Payment Limits (continued)

The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the Eligible Governmental Entities is less than the administrative cost to implement an upper payment limit; or

(2) The prescription drug product is a generic and there are nine (9) or more marketed therapeutic equivalents for the product.

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.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.03 Policy Review and Final Action Process

(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 UPL amount.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.04 Policy Review- Information Gathering

D. Information Gathering Tools.

(1) Public Informational Hearings.

(2) Stakeholder Council Input.

(3) Technical Hearings.

(4) Board Staff Research and Analysis.

(5) Eligible Governmental Entities' Information.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.05 Policy Review- Preliminary Policy Recommendations

A. Information that can be used for the preliminary policy recommendation.

B. Policy Action Other than UPL.

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

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.05 Policy Review- Preliminary Policy Recommendations (continued)

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 adopt or modify one or more policy recommendations

(3) The Board may adopt a final policy recommendation only after the Board has made a final affordability challenge determination and adopted the final cost review study report.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.05 Policy Review- Preliminary Policy Recommendations

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; 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

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL

A. Staff Recommends Methodologies and Contextual Information.

B. Methodologies.

C. Contextual Information for the Prescription Drug Product.

D. UPL Values.

E. Technical Hearing.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL (continued)

B. Methodologies.

(1) Cost Effectiveness Analysis.

(2) Therapeutic Class Reference Upper Payment Limit.

(3) Launch Price-Based Upper Payment Limit.

(4) Same Molecule Reference Upper Payment Limit.

(5) Domestic Reference Upper Payment Limit.

(6) International Reference Upper Payment Limit.

(7) Budget Impact-Based Upper Payment Limits.

(8) Blend of Multiple Methodologies.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL (continued)

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 State health plan; County, bicounty, and municipal health plans, direct government purchases, and Medicaid;
(3) Total out-of-pocket costs in State health plan; County, bicounty, and municipal health plans; and Medicaid,
(4) Current coverage status of the drug in State health plan; County, bicounty, and municipal health plans; and Medicaid;
(5) Utilization in the following program by patients and prescriptions state health plan, county, bicounty, and municipal health plans; and medicaid;
(6) Amount of direct government purchases by units and patients served;
(7) For the Maryland State Medical Assistance Program, the number of prescriptions paid, number of patients who received the prescription drug product; and 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.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL (Continued)

D. UPL Values.

(1) The Board may:

(a) Select one or more of the methodologies and contextual information.
(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.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL (continued)

E. Technical Hearing.

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

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.06 Policy Review- Process for Establishing a UPL (continued)

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.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.07 Policy Review- Final Policy Action

A. Final Determination Concerning Affordability Challenge.

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

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.08 Establishing and Monitoring a UPL

A. Adopting a Proposed Regulation Setting a UPL.

B. Monitoring a UPL.

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

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.09 Reconsideration

A. Authority to Reconsider UPL.

B. Reconsideration Process.

C. Action on Drug where UPL was Repealed.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.09A Authority to Reconsider UPL.

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.

New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

.09 B(1) Reconsideration Process General Procedures

- Notice
- Solicit Patient and Stakeholder Feedback
    - Written Comment
    - Informational Hearings
- Information Gathering Process
- Staff Presents to the Board Basis for Reconsideration, Summary of Feedback, Summary of Information through UPL Monitoring Program, Estimated Impact of the UPL to Date, Staff Recommendations
- Board may take Action

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.09 B(2) Reconsideration Process 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.

New Chapter - COMAR 14.01.05
(Policy Review, Final Action, Upper Payment Limits)

.09 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.

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