

# Proposed Regulations- Review of Comments Part I

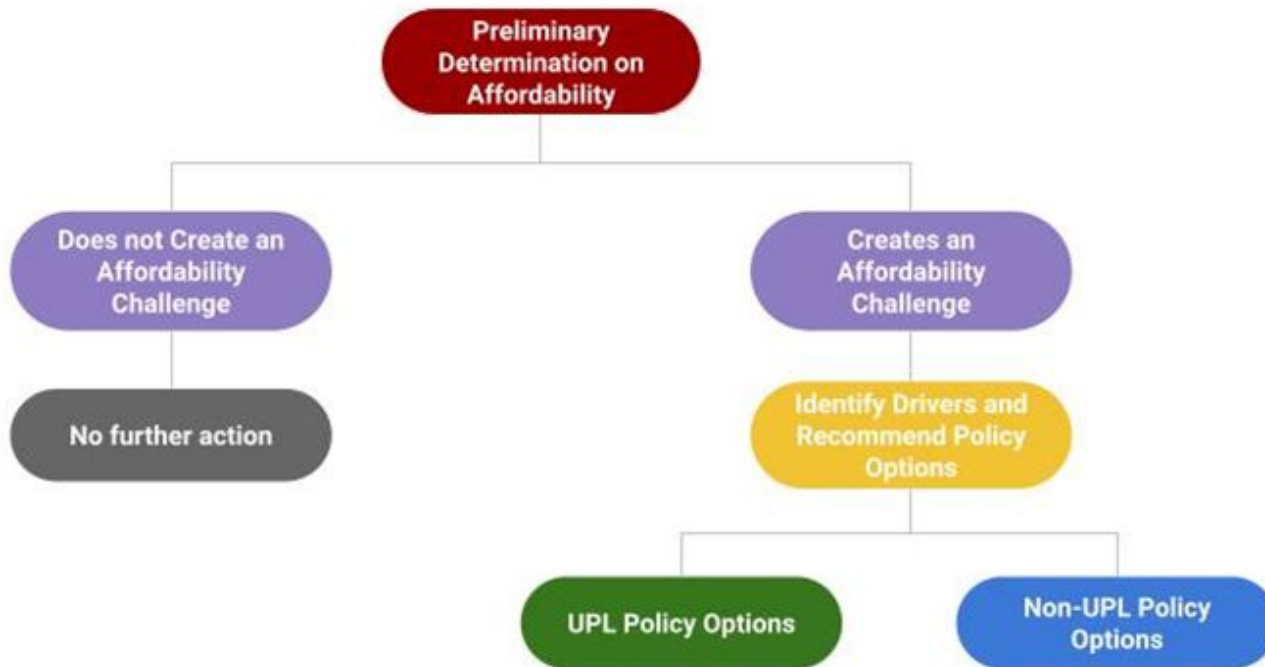
Amend COMAR 14.01.01.01 (definitions);  
Add COMAR 14.01.01.06 (hearing procedures);  
Add COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

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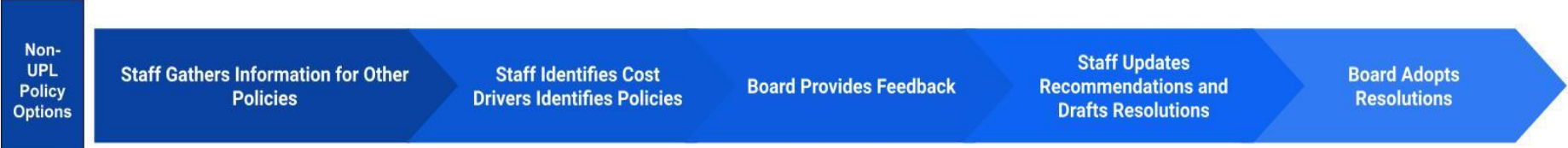
PDAB Meeting  
Work Session  
February 26, 2025  
PDAB Staff



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



# Upper Payment Limit and Policy Review Process



# Regulations

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The following proposed regulations were posted in the January 10, 2025 Maryland DSD Register:

- 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 proposed regulations were due February 10, 2025.

Thirteen organizations submitted comments. These comments were shared with the Board and posted on the website.



# Comments Received

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The Board received from 13 commenters totaling 135 pages of comments

- All commenters submitted new comments (Approximately 70 pages)
  - 3 commenters resubmitted previous comments (Approximately 60 pages)
- 4 letters representing pharmaceutical industry and manufacturers
- 7 letters representing patients and patient advocacy groups
- 1 letter representing payors
- 1 letter representing pharmacies and wholesalers



# **General Comments: Definitions, Lack of Procedures on Certain Topics, Lack of Response to Comments under APA, Interpretation of Statute, Hearing Procedures, and Economic Impact Statement**

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# Comment: Maryland APA Requires Board to Respond to Comments

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- Commenter states that the Maryland APA requires the Board to explain its reasoning for declining to make recommended changes.
- Staff recommendation: No action.
  - Disagree with commenter's statement/interpretation of Maryland APA rulemaking requirements.



# Comment: Definition Affordability Challenge

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- Commenter urges the Board to revise its proposed definition of “affordability challenge.”
  - COMAR 14.01.05.01C – For the purpose of this chapter, “affordability challenge” refers to either (a) high out-of-pocket costs for patients or (b) an affordability challenge for the State health care system.
- Staff recommendation: No action. Not definition but shorthand reference for referring to two statutory assessments.





## Comment: Definition “System Net Cost”

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- Commenter urges the Board to clarify “system net cost” alleging the term relies on the definition of “net cost.” Commenter “asks the Board to provide additional transparency regarding how it intends to calculate this metric.”
  - Proposed COMAR 14.01.01.01B(62) “System net cost” means the sum of the net cost as defined above and the per unit patient out-of-pocket cost.
  - (44) “Net cost” means the per-unit cost paid by payors of a drug after accounting for all price concessions, discounts, and rebates.
- Staff recommendation: No action.



# Comment: Confidential, Trade-Secret and Proprietary Information

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- Commenter alleges the “Board has not addressed how it will implement statutory confidentiality protections and protect that confidential, trade secret, and propriety [sic] information against public disclosure.”
- Staff recommendation: No action.
  - See COMAR 14.01.01.04 (Confidential, Trade-Secret, and Proprietary Information) effective December 25, 2023.



# Comment: Specific Timelines for Providing Notice of Board Information Gathering Hearings

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- Commenter requests that the Board specify in regulation the advance notice it will provide of a Board hearing (informational hearing, or technical hearing) and specify the time by which an agenda or materials related to those hearings will be provided to stakeholders.
- Staff recommendation: No action.
  - Regulations include advance notice of information gathering hearings but allow for flexibility in scheduling. Proposed COMAR 14.01.01.06B.



# Comment: Recording and Posting Board meetings

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- Commenter requests that regulations be adopted requiring that all Board meetings (commentor seems to include public informational hearings and technical hearings in this charge) be recorded and made accessible on the Board's website within forty-eight hours thereafter.
- Staff Recommendation: No action.
  - Presently, Board meetings are recorded and promptly posted. Proposed regulations for informal public information hearings and technical hearings provide for the recording of hearings.



# Comment: Limit Repetitious Testimony

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- Commenters request that the Board strike the provision giving the Board Chair or staff designee the power to “limit repetitious testimony” in a quasi-legislative hearing.
- Staff Recommendation: No action.
  - Proposed COMAR 14.01.01.06C(2)(b) provides “The Chair or staff designee shall give all persons who register to speak an opportunity to do so but may limit repetitious testimony”; this provides an appropriate time management tool rather than imposing a specified time limit.



# Comment: Commenter's Interpretation of "State health care system"

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- Commenter interprets "State health care system" to mean the specific State entities that could be subject to a UPL, i.e., state or county correctional facilities and their patients, state hospitals and their patients, health clinics at state institutions of higher education and their patients, health benefit plans making payments on behalf of a unit of State or local government and enrollees thereof, and (to the extent legally permissible) the Maryland State Medical Assistance Program and Medicaid enrollees." Commenter requests that "affordability challenge" include "consideration of both the net price at which state health care system entities currently access the drug and the level of purchases and utilization by those entities."
- Staff recommendation: No action. Disagree with commenter's interpretation.



# Comment: Concerns with Assumptions in Economic Impacts

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- Commenters express concerns that the economic impacts does not adequately consider the impacts on different members of the supply chain, such as impacts on pharmacies, providers, and patients.
- Staff recommendation: No action.

The Board's discussed implementation of UPLs for state and local government addresses the risks identified by the commenters to stakeholders in the supply chain or risk access for patients.



# Lack of Specificity Regarding Comment Opportunities

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# Comment: Comment Opportunities in UPL process

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- “The Proposed Regulations explicitly provide for comment opportunities at certain steps of the UPL-setting process but not for others,” and they generally provide for public comment on “any decision pending before the Board” but fail to set forth any specific procedures or standards for such comment.
- Staff recommendation: No action.
  - See COMAR 14.01.01.05A and B (establishing public comment procedures)



# Comment: Comment Opportunities in UPL process

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- Commenter asserts that the regulations must “provide a meaningful opportunity for public comment at every such step.”
- Staff recommendation: No action.
  - See COMAR 14.01.01.05A and B (establishing public comment procedures); Proposed COMAR 14.01.05.06A (staff posts methodology recommends and seek public comment); COMAR 14.01.05.06 (staff posts UPL values developed, staff’s recommendation for a proposed UPL amount with a description of the calculation and analyses and relevant underlying assumptions, and requests comment)



# Comment: No Minimum Comment Period

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- Multiple commenters state “there is no minimum comment period” or no standard comment period.
- Staff recommendation: No action.
  - See COMAR 14.01.01.05A and B (establishing public comment procedures); other comment periods are driven by when certain materials/analyses are posted and comments requested; in conjunction with Board meetings and meeting procedures.



# Comment: Mandate Board Disclose Data Where There is Public Comment Opportunity

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- Multiple commenters assert that the Board should “revise its Proposed Regulations to make clear that, where opportunities for public comment are provided, the Board will disclose the underlying data and information relied on to reach its preliminary conclusions, to the extent such data are not confidential.”
- Staff recommendation: No action.
  - See Proposed COMAR 14.01.05.06A (staff posts methodology recommends and seek public comment); COMAR 14.01.05.06 (staff posts UPL values developed, staff’s recommendation for a proposed UPL amount with a description of the calculation and analyses and relevant underlying assumptions, and requests comment)



# Comment: Specify Opportunities for Patient Input

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- Multiple commenters recommend providing specific opportunities for patient input, including through tools such as meetings and focus groups, and prioritizing patient input and experience.
- Staff recommendation: No action recommended at this time.

See COMAR 14.01.01.05A and B (establishing public comment procedures). COMAR 14.01.01.06.C(1) also provides opportunities to engage patients (public) through an informational hearing.



# UPL Procedures and UPL Policy Options

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# Comment: Board seek Authority for Non-UPL Policies

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- Commenters noted that the Board does not have the authority to implement policies other than upper payment limits, and one commenter recommended that the Board seek the authority to implement other policies.
- Staff recommendation: No action.



# Comment: Adopt UPL Policy Option at Beginning of Process

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- “[T]he Proposed Regulations should be revised to require the Board to formally adopt a recommendation of a UPL as the appropriate policy solution for a particular affordability challenge before selecting a methodology and developing a UPL amount for a particular medicine.”
- Staff recommendation: No action.





# Comment: Combined Decision Making

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- Commenter requests that regulations be revised so no combined decision making in a single meeting. Commenter states that Board must render “decisions” at each stage at separate meetings with separate opportunities for public comment.
- Staff recommendation: No action. Disagree with commenter’s interpretation.



# Comment: Factors in Staff Analysis of UPL policy option

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- Multiple commenters propose that when staff recommend a UPL policy option, the factors that staff may analyze be the same as the factors that may be analyzed when staff recommends a non-UPL policy option, including the strengths and weaknesses of the UPL option (parallel). See Proposed COMAR 14.01.05.05B(2) and C(2). Some commenters recommend the same timelines for non-UPL policies and UPL policy.
- Staff recommendation: The Supply Chain Report already reflects an assessment of UPL as a policy solution. For purpose of clarity, however, staff recommends revising to include certain language for non-UPL policy actions in UPL section under proposed COMAR 14.01.05.05C to include “Strengths and weaknesses of the policy” and “Potential impacts of the policy.”



# Comment: Mandate that All Factors be Considered when Evaluating Policy Options

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- Commenter recommends “that the Board be required, by express regulation, to consider all relevant factors when evaluating policy options.” Objects to use of “may.”
- Staff recommendation: No action. The Board has identified factors that may be considered when recommending a policy option. This approach ensures necessary flexibility.



# UPL Methodologies

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# Comment: More Details for UPL Methodologies

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- Commenter asks the Board to provide further details regarding each contemplated UPL methodology so that stakeholders can meaningfully comment.
- Staff recommendation: No action.
  - Staff posts its methodology recommendations on the Board's website in advance of the Board meeting, and requests public comment. Proposed COMAR 14.01.05.06A. The public may also comment at the Board meeting and has an opportunity to comment on the calculations and analyses performed by staff under the methodologies, including any assumptions. COMAR 14.01.05.06D.



# Comment: UPL Methodologies Must Account for Complex Supply Chain

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- Commenter asks the Board to ensure its “methodologies adequately account for relevant supply chain complexities that impact both the implementation of the methodologies and their suitability.”
- Staff recommendation: No action.
  - The Board is aware of the supply chain complexities. The Board is also cognizant of the scope of a UPL – state and local government entities.



# Comment: Guardrails Against Inconsistent Application of UPL Methodologies for Different Drugs

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- Commenter “urges the Board to incorporate explicit guardrails against inconsistent application of analytical methods and considerations across different drugs.”
- Staff recommendation: No action.



# Comment: Oppose UPL Methodologies and Consideration of CEA that Use QALYS

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- Commenters object to proposed methodologies that use “cost effectiveness analysis and international prices from countries known to use quality-adjusted life years (QALYs)”. Contends that the “Board has failed to include any safeguards in the proposed rulemaking that would protect people with disabilities and serious chronic conditions from decisions made in reliance on discriminatory value assessments.”
- Staff recommendation: No action.





## Comment: Oppose International Reference Pricing

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- Commenters suggest that it is inappropriate to consider international prices when setting a UPL because there are substantive differences in different international markets.
- Staff recommendation: No action.



# Comment: Use of Comparative Effectiveness Research in Relation to Therapeutic Alternatives

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- Commenter asserts that “the Board does not describe how comparative effectiveness research (CER) may be used in decisions related to therapeutic alternatives, where treatments often impact patients very differently.”
- Staff recommendation: No action.



# **Additional Considerations: Impact on Medicaid Best Price, Patient Access, Benefit Design and Provider Behavior, and Out-of-Pocket Costs**

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# Comment: Include Explanation How Board Would Ensure that UPL Not Impact Metrics, such as Medicaid Best Price

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- Several commenters direct the Board to explain in regulation how it would ensure that a UPL would not “impact[] statutory or regulatory amounts, such as Medicaid Best Price.”
- Staff recommendation: No action.



## Comment: Add Impact on Patient Access

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- Commenters urge the Board carefully consider if setting a UPL could adversely impact access to the therapy, including pushing patients towards therapeutic alternatives. One commenter suggested adopting additional criterion that would consider the potential impact on patient access of a UPL.
- Staff recommendation: No action.



# Comment: UPL Could Impact Benefit Design and Prescriber Behavior

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- Commenter alleges that UPLs could impact benefit design which “could prompt providers to adjust referral, prescribing, and acquisition patterns for UPL-selected drugs. This could lead to provider pressure to choose specific low-cost medications, not necessarily the product deemed most clinically appropriate for the patient.
- Staff recommendation: No action. Disagree with commenter’s interpretation.



# Comment: Consider out-of-pocket costs for patients

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- Commenter urges the Board consider direct patient costs as part of their analyses when determining a UPL. Additionally, one commenter recommended considering and weighing the cost relative to patients higher than other considerations.
- Staff recommendation: No action.
  - The Board may consider patient out-of-pocket costs as part of the contextual information in Proposed COMAR 14.01.05.06.C.1 and 3. The Board may consider out-of-pocket costs when setting a UPL in Proposed COMAR 14.01.05.06.D.3.



# Monitoring UPLS: UPL Suspension, FDA Shortage List, and Patient Feedback

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## Comment: UPL Suspension

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- Commenter urges the Board to establish standards and processes for determining the circumstances under which a UPL suspension could appropriately be lifted or the length of the suspension.
- Staff recommendation: No action.



# Comment: FDA Shortage List

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- Commenter urges the Board to revise the Proposed Regulations to require at least monthly checks of the FDA website concerning the FDA shortage list.
- Staff recommendation: No action.



# Comment: Use an active monitoring approach for patient feedback

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- Commenter urges use an active monitoring program for patient feedback through working with patient advocacy groups
- Staff recommendation: No action.
  - The Board shall develop a monitoring plan to monitor the impact of the UPL. This will include passive monitoring allowing patients and stakeholders to report any adverse impacts of an upper payment limit, and active monitoring through tools, such as surveys.





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