

Proposed Regulations- Review of Comments Part 2

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

March 24, 2025

PDAB Staff



General Comments: Definitions, Lack of Procedures on Certain Topics, and Economic Impact Statement



Comment: Therapeutic Alternatives Definition Too Broad

- Commenter states definition of therapeutic alternative is too broad and does not consider for differences between drugs and different populations.
- Staff recommendation: No action recommended. The definition is designed to allow consideration of all factors in comparing prescription drugs including the differences cited by commenter.



Comment: Definition “System Net Ingredient”

- Commenter requests Board limit definition of “system net ingredient cost” to utilization of the prescription drug product **by eligible government entities** after accounting for all discounts and price concessions applicable to such utilization.
- Staff recommendation: No action recommended.



Comment: Economic Impact Statement Individuals with Disabilities

- Commenter objects to statement that “proposed action has no impact on individuals with disabilities.” Disruptions in the marketplace could have devastating consequences for these patients.
- Staff recommendation: No action recommended. No change in access to drugs, for individuals with disabilities or any patient, is anticipated.



Comment: Economic Impact Statement Small Businesses

- Commenter objects to statement that “proposed action has minimal or no economic impact on small businesses” citing letters submitted in November 2024 by coalitions and associations contending that UPL methodology may result in adequate or below-cost reimbursement to community pharmacies, does not account for the acquisition costs of independent medical practices, will impose “a large financial burden”, and will likely lead to consolidation or closures within the pharmacy community.
- Staff recommendation: No action recommended.



UPL Procedures and UPL Policy Options



Comment: Lack of Detail Regarding Enforcement of UPL

- Commenter requests “additional clarity on how the Board will hold the eligible governmental entities accountable for the UPL.”
- Staff recommendation: No action recommended.



Comment: Ordering of Policy Options

- Commenter requests Board consider UPLs only after determining that non-UPL policy options could not address an affordability challenge, and only after evaluating and mitigating potential obstacles for patients to access their medicine.
- Staff recommendation: No action recommended. Implementation.



Comment: Lack of Detail Regarding How Information is Used and Weighed

- Commenter states the regulations lack specific, concrete, and meaningful procedures and standards that explain how the Board intends to use and weigh information.
- Staff recommendation: No action recommended.



Comment: Fails to Adopt a Specific Methodology

- Commenter states regulations fail to establish a specific methodology for setting a UPL.
- Staff recommendation: No action recommended.



Comment: Caution Using Reference Pricing

- Commenter advises caution when considering implementing reference prices within a therapeutic class of drugs and expressed concern that payers could be incentivized to implement utilization management or adverse tiering which could result in non-medical switching of their medications, increased costs, or decreased access to their preferred medication.
- Staff recommendation: No action recommended.



Comment: UPL Unintended Consequences Pharmacies May Refuse to Carry Drugs

- Commenter states broadly that UPLs may have unintended consequences such as “pharmacies, who purchase the drugs at wholesale acquisition cost, refuse to sell the drug at a loss.”
- Staff recommendation: No action recommended.



Legal Concerns



Comment: Complaint Concerning Already Adopted Procedures and Assorted Legal Claims

- Referencing prior comments submitted concerning aspects of the cost review study process, the commenter broadly states "the statute and the Board's implementation and administration of the law is unconstitutional and inconsistent with Maryland's APA, implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause."
- Staff recommendation: No action recommended. The pending regulation concerns the UPL procedures. Disagree with broad assertion.



Comment: UPL Action is Quasi-Judicial

- Commenter states that “[i]n authorizing the Board to evaluate the necessity of UPLs, the General Assembly plainly envisioned that the Board would act in a quasi-judicial, not a quasi-legislative, capacity.”
- Staff recommendation: No action.



Compare Comment: Policy Review and UPL Development Subject to Agency Rulemaking

- Commenter states that “the predicate processes that lead to the setting of that UPL amount (*i.e.*, the policy review and UPL development) are” subject to rulemaking process as policies of general application.
- Staff recommendation: No action.



Comment: Proposed Rules Inconsistent with Contested Case Hearing Procedures under APA

- Incorporating comments from a prior letter, Commenter alleges that the draft regulations do not contain procedural protections afforded to participants in contested case hearings under the APA.
- Staff recommendation: No action recommended. UPL procedure is structured through APA rulemaking procedures, with multiple opportunities for public input and comment, not APA contested case hearing procedures.



Comment: Various commenters support the regulations proposed by Prescription Drug Affordability Board

- Commenters state their support of the Prescription Drug Affordability Board and the process to consider policies to make prescription drugs affordable.
- Staff recommendation: No action recommended.



Recommended Revisions



Changes to Proposed Text

- For clarity, replace term “methodology” with “framework” throughout.
- Clarify broad scope of designee by removing term “staff” in COMAR 14.01.01.06 hearing provisions.
- As discussed at last meeting, for purpose of clarity, staff recommends amending COMAR 14.01.05.05B(2)(d) (non-UPL) “possible implementation of the policy through legislation, regulation or enforcement”. And for the purpose of clarity and completeness, adding to COMAR 14.01.05.05C(2) (UPL) “strengths and weaknesses of the policy”, “potential impacts of the policy” and “possible implementation of the policy through legislation, regulation or enforcement”

