

Upper Payment Limit- Update

PDASC Meeting

December 16, 2024

PDAB Staff



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Prescription Drug Affordability Board

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
- Draft regulations establishing the Policy Review Process were posted and open for public comment until 11/8/2024 (see next slide)
- Draft Proposed Regulations were approved by the Board on 11/25/2024

Next Steps :

- Draft Proposed Regulations will be submitted through the standard APA 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

- PDASC provided feedback on the regulations at the November 4, 2024 meeting.
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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
- UPL suspension clarification



Updates to Regulations

- Technical changes from the first to second iterations of the regulations are described in subsequent slides
- Changes were made to incorporate specific feedback and comments



Amendments to COMAR 14.01.01.01 (Definitions)

.01 Definitions

- Add and update definitions

(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.



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New Regulation- COMAR 14.01.01.06 (Hearing Procedures)

- Minor technical changes



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

- 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
- Clarifying UPL value calculations





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