COMAR 14.01.06
Implementation and Monitoring of Upper Payment Limits

PDAB Meeting

November 16, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Register Comments Received on 14.01.06- Implementation and Monitoring of Upper Payment Limits

- The proposed regulations were published in the June 12, 2026 Maryland DSD Register
- Comments were due on July 13, 2026
- Comments were received from the following entities:
  - Aimed Alliance
  - Biotechnology Innovation Organization
  - Boehringer Ingelheim
  - Diabetes Patient Advocacy Coalition
  - EACH/PIC Coalition
  - Healthcare Distribution Alliance
  - National Association of Chain Drug Stores
  - Novo Nordisk
  - PhRMA
  - Value of Care Coalition

The written comment packet can be found on the website here.

Main Comment Themes

- Concern about Reduced Access, Need for Comprehensive Monitoring
- Adverse Financial Impact on Pharmacy and Provider Reimbursement
- Unclear Implementation Across the Supply Chain
- Ongoing legal uncertainty
- Protection of confidential information
- Implementation timelines

Comment Theme: Concern About Reduced Access, Need for Comprehensive Monitoring

- Commenters argued that Upper Payment Limits (UPLs) cap payer spending rather than direct patient out-of-pocket costs. They expressed concern that insurers and Pharmacy Benefit Managers (PBMs) might respond to UPLs by increasing utilization management (prior authorizations, step therapy), shifting drugs to higher formulary tiers, or initiating non-medical switching. Additionally, commenters urged the Board to expand monitoring beyond fiscal/contractual metrics to track clinical indicators, patient out-of-pocket expenses, treatment adherence, and prescription abandonment.

- PDAB Response: PDAB appreciates the recommendations from numerous commenters about the importance of focusing on patient experiences while setting policy, and about how to collect and interpret monitoring data regarding patient access. PDAB has statutory authority to set UPLs, but it also researches and considers non-UPL policies during the policy review process. The PDAB welcomes continued engagement from patients and stakeholders to ensure that its policies are effective and to identify any potential unintended consequences.

Comment Theme: Adverse Financial Impact on Pharmacy and Provider Reimbursement

- Commenters highlighted that UPLs could lead to reduced reimbursement that may fail to cover actual acquisition and dispensing costs, harming pharmacies and healthcare delivery. Insufficient reimbursement could reduce stocking of critical medications, discourage provider participation, or force pharmacies to close, particularly in underserved communities. PDAB should monitor and protect provider reimbursement.

- PDAB Response: UPLs are not intended to change reimbursement to providers or pharmacies. The PDAB suggests that the UPL be achieved through supplemental rebates. This should not impact pharmacy reimbursement. The PDAB appreciates the monitoring recommendations in these comments and will consider all available data to evaluate potential unintended policy consequences on pharmacies and other stakeholders. The PDAB welcomes these entities to submit data to PDAB if they detect that a UPL is adversely affecting their reimbursements.

Comment Theme: Unclear Implementation Across the Supply Chain

- Commenters noted that the proposed regulations lack detailed guidance on how UPLs will be operationalized across complex supply chain structures, including how UPL compliance, chargebacks, supplemental rebates, or price adjustments will be executed for third-party payor reimbursements versus direct government purchases. Commenters further argued that UPLs will require a highly complex and administratively burdensome payment system. Without a clear implementation framework, commenters argued, stakeholders will face significant uncertainty, increased administrative costs, and operational challenges that could disrupt the delivery of care.

- PDAB Response: PDAB intends for implementation mechanics to be established through standard contracting between Eligible Governmental Entities (EGEs) and their payors and suppliers. The Board recognizes that these logistics are complex, but the supply chain already successfully manages similarly complex tiered pricing programs today. Because EGE implementation is voluntary and will not begin until January 1, 2027, stakeholders should have ample time to align their administrative systems to implement the program to avoid potential unintended consequences.

Comment Theme: Ongoing Legal Uncertainty

- Recent litigation in Colorado underscores the legal and operational uncertainty associated with state UPL frameworks. PDAB needs to carefully assess whether a UPL could raise similar legal and operational challenges and, in turn, create risks to patient access.

- PDAB Response: The Maryland PDAB is closely monitoring UPL legal developments in Colorado, and throughout the country.

Comment Theme: Protection of Confidential Information

- The regulations require detailed disclosure of gross spending, net costs, utilization, and formulary placement. PDAB may also receive competitively sensitive pricing information that reveals effective rebate levels and proprietary contracting strategies. The Board has not addressed how it will implement statutory confidentiality protections.

- PDAB Response: PDAB is committed to ensuring the confidentiality of information it receives and has implemented rigorous procedures to maintain and protect confidential and proprietary information in compliance with COMAR 14.01.01.04.

Comment Theme: Implementation Timelines

- January 1, 2028, may not provide adequate time for manufacturers, eligible governmental entities, and other stakeholders to achieve compliance because there is still a significant lack of clarity over how stakeholders will implement the various operational, contractual, and system changes required for a UPL. The PDAB should address how the agency will monitor MFP changes and establish clear timelines for reconsidering UPLs and modifying or repealing accordingly.

- PDAB Response: Because mandatory UPL adoption does not occur until an EGE negotiates, renegotiates, or renews its health care contracts after January 1, 2028, entities will have ample time to manage this transition. The UPL is not linked to the MFP. The Board may use the MFP as a reference point or a benchmark. The Board may not set an Upper Payment Limit lower than the Medicare Maximum Fair Price (COMAR 14.01.05.02(D)(2). If CMS renegotiates an MFP that is higher than the UPL, then the Board has a process for reconsideration (COMAR 14.01.05.09).

MARYLAND
Prescription Drug Affordability Board

comments.pdab@maryland.gov
pdab.maryland.gov