

# UPL Regulations: Implementation and Monitoring of Upper Payment Limits

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PDAB Meeting

April 13, 2026

PDAB Staff



# Draft Upper Payment Limit Regulations

- **Overview of Upper Payment Limit Regulations:**
  - 14.01.06- Implementation and Monitoring of Upper Payment Limits
    - .01- Scope
    - .02- Contracting and Initial Reporting Requirements
    - .03- Application of Upper Payment Limits
    - .04- UPL Monitoring and Data Reporting
  - 14.01.07- Upper Payment Limit
    - .01- Upper Payment Limit for Farxiga (dapagliflozin).
    - .02- Upper Payment Limit for Jardiance (empagliflozin).
- **Draft Upper Payment Limit Regulations**
  - Draft regulations posted for public comment on March 16, 2026
  - Comments Due: March 30, 2026



# Summary of Comments on 14.01.06

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## 8 Comment Letters Received

- AARP
- AbbVie
- AstraZenca
- Boehringer Ingelheim
- Diabetes Patient Advocacy Coalition (DPAC)
- Frederick County Government
- PhRMA
- Value of Care Coalition



# Support of UPL Regulations

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- **One comment letter supported the structure and scope of setting upper payment limits**
- **One comment letter supported the general idea of upper payment limits, but identified concerns with adverse impacts on rural pharmacies and impacts on eligible governmental entity impacts**

**Response:** The PDAB thanks the commenters for their input. PDAB recommends that the payments to the pharmacies remain the same to minimize the impacts on pharmacies.

**Proposed Updates:** None



# Concern with the Burden and Information Included in Reporting Requirements

- **Multiple commenters noted concern that the reporting requirements may be difficult and resource intensive. One commenter also noted concern with the sensitivity some of the information requested.**

**Response:** The Board understands and appreciates the potential reporting burden for Eligible Governmental Entities, and worked to minimize the reporting requirements to the information that is necessary for the successful implementation of UPLs. The Board will protect any sensitive information per COMAR 14.01.01.04 Confidential, Trade-Secret, and Proprietary Information. Finally, the comments suggest the value of a “Submission Manual” to provide technical information for some requirements, such as reporting specifications and calculation methodologies to Eligible Governmental Entities.

**Proposed Updates:** Update regulations to reference a "Submission Manual" for technical information to Eligible Governmental Entities for successful submission of data .



# Request for Additional Operational Clarity and Guidance

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- **Multiple commenters noted that the regulations do not address all operational details for implementing upper payment limits (UPLs), specifically lacking explanation on the implementation mechanism and the roles of supply chain entities.**

**Response:** The comments made clear that there is confusion as to who and what transactions the regulations apply. These regulations govern Eligible Governmental Entities as purchasers and payors and apply to the governmental entities' ultimate payment to their contractors. The Board recommends supplemental rebates for payors to achieve the UPL amount (as discussed in open meetings) and will offer technical support and informal Q & A session to facilitate implementation. Eligible Governmental Entities retain flexibility in UPL implementation.

**Proposed Updates:** None



# Request for Standards for Compliance

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- **Some commenters noted that the regulations lack detail, especially on final net cost calculation/reporting, and that upper payment limit implies point-of-sale application**

**Response:** The regulations build on COMAR 14.01.05.08, which implement the UPL as the per unit final net cost paid by the Eligible Governmental Entity, and allows the implementation methodology to be entity-specific. The Board recognizes the value of agency support with technical questions related to implementation, such as through Q&A and support sessions.

**Proposed Updates:** No changes.



# Clarification on Implementation Date

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- **Some Commenters noted the implementation date differences. Contract provisions start after January 1, 2028, but some UPLs start as early as January 1, 2027.**

**Response:** January 1, 2028, is the date for new/renegotiated contracts to start to include the regulatory provisions, after which the UPL applies to all governmental entities. However, Eligible Governmental Entities may implement the UPL earlier if they renegotiate contracts before this date. The earliest effective date is January 1, 2027, for those with the regulatory provisions in their contract.

**Proposed Updates:** No changes.



# Automatic Reconsideration of Certain UPLs

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- **One commenter suggested that Medicare Maximum Fair Price (MFP)-based UPLs be automatically subject to reconsideration if the MFP is renegotiated.**
- **One commenter suggested developing regulations for monitoring for shortages.**

**Response:** The Board can currently reconsider a UPL for any reason, including if a benchmark price, such as an MFP, changes or is renegotiated. However, the Board generally supports an automatic reconsideration of a MFP-based UPL if the MFP is renegotiated. These changes would apply to a different Chapter of the regulations. The Board also intends to monitor for the impacts of UPLs, including shortages. These will be addressed in separate regulations.

**Proposed Updates:** No changes to these regulations. Include language in COMAR 14.01.05.09. for reconsideration of a UPL if a UPL is benchmarked off of the CMS Medicare Maximum Fair Price and CMS renegotiates the Maximum Fair Price.



# Suggestions for Monitoring the Impact of UPLs

- **Two commenters submitted language for monitoring the impact of UPLs patients and the health care system**

**Response:** The Board thanks the commenters for the helpful comments and suggested language. The Board agrees with the need to monitor the impact of UPLs on patients and the health care system, and the Board generally agrees with the suggested language provided by the commenters. However, the Board's monitoring activities will be addressed in a separate part of the regulations. These regulations articulate the reporting requirements for eligible governmental entities. The Board evaluated if the comments required additional reporting from Eligible Governmental Entities, but did not see any additional reporting requirements. The Board intends to address these comments in updates to other sections of the regulations.

**Proposed Updates:** No changes to these regulations. However, the Board intends to make changes based on these comments to other sections of the regulations.



# Proposed Changes UPL Regulations

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- **Update regulations to include definition of and reference to “Compliance and Implementation Manual”**
- **Future Action:**
  - Include language in COMAR 14.01.05.09. for Reconsideration of a UPL if a UPL is benchmarked off of the CMS Medicare Maximum Fair Price and CMS renegotiates the Maximum Fair Price
  - Include language in future chapter for monitoring the impact of UPLs





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