

Ozempic Consideration of Upper Payment Limit

PDAB Meeting

May 18, 2026

PDAB Staff



UPL Chronology

- Preliminary Determination - Affordability Challenge
11/17/2025
- Policy Review Process and Preliminary Policy
Recommendations 02/23/2026
 - Public Information Hearings 12/16/25 at 1:00 & 6:00 pm
 - Stakeholder Council Input 12/15/25 PDASC Meeting
 - Staff research & analyses; Eligible gov't entity info



UPL Chronology

- Board provided guidance and direction to further develop UPLs for the Board's consideration 02/23/2025
- Staff recommended UPL Framework and Contextual Information – 02/23/2025
 - Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)
 - Contextual Information: COMAR 14.01.05.06C(1), (2), (4), (5), and (8)



UPL Chronology

- Calculations and Analyses Underpinning Potential UPL Values document posted 04/22/2026; public comment due 05/01/2026



Summary of Comments Received on Calculations and Analyses Underlying the UPL Amount - Ozempic

- Comments were received from the following:
 - AARP
 - PhRMA
 - Value of Care Coalition



Summary of Comments Received on Draft UPL Regulations - Ozempic

- Comments were received from the following:
 - AARP
 - EACH/PIC Coalition
 - Healthcare for All
 - PhRMA
 - Public Citizen
 - Value of Care Coalition



Support of UPL Regulations

- **Two 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



Summary of Comments Received on Draft UPL Regulations - COMAR 14.01.07.02

- **Multiple commenters noted concern with using the Medicare Maximum Fair Price as a benchmark for a state upper payment limit due to the unique dynamics of the Medicare market.**

Response: The Board received and considered this comment during approval of the Ozempic Framework document and the Calculations and Analyses Underpinning Potential Upper Payment Limits documents. The Board understands the input from the commenters, but disagrees that the analyses underpinning MFP are fundamentally different from considerations from the state and local government market. Additionally, COMAR 14.01.05.02D(1) sets the MFP as a UPL amount floor if it exists, which limits the Board from setting the UPL lower.

Proposed Updates: None.



Summary of Comments Received on Draft UPL Regulations - COMAR 14.01.07.02

- **Multiple commenters noted concern that the draft regulations do not contain mechanisms to reduce patient out-of-pocket cost.**

Response: The Board agrees with the priority of reducing patient out-of-pocket costs. As the Board has noted in deliberations, the prescription drug plans for Eligible Governmental Entities general use a copay structure (versus a co-insurance structure) that makes it difficult link an reductions in costs due to an upper payment limit to reducing patient out-of-pocket costs. The Board will continue explore opportunities to ensure that patients directly benefit from reductions in costs from upper payment limits.

Proposed Updates: None.



Summary of Comments Received on Draft UPL Regulations - COMAR 14.01.07.02

- **Multiple commenters noted concern about the operationalization of UPL, including reconsideration of MFP-Based UPLs, drugs in shortage, patient access, pharmacy reimbursement.**

Response: COMAR 14.01.07.02 sets a UPL, and provides for an inflation adjustment to the UPL. Reconsideration of a UPL and monitoring drugs in shortage are addressed in other regulations.

To the extent that these comments reflect a misunderstanding of how a UPL works, so as to impact patient access and pharmacy reimbursement, these UPLs apply to prescription drug products purchased or paid for by or on behalf of state and local governmental entities.

Proposed Updates: None.



Board UPL Decision Structure

- Guided by the following considerations and principles, and considering all the information presented, including public comments, the Board now:
 - **Determines whether, as a matter of public policy, to set a UPL for this drug and if so, the UPL value**
- This ultimately is done through notice and comment rulemaking under the Administrative Procedure Act - proposing and taking final action on a regulation



Board UPL Tasks

- **Review:** Public comments on draft UPL COMAR 14.01.07.02
- **Review:** Revisions to UPL COMAR 14.01.07.02
- **Consider:** UPL Criteria
- **Move:** To Set UPL and Adopt Proposed Regulation
- **Deliberate:** UPL Appropriate Policy; UPL Value
- **Vote:** Propose New Regulation



14.01.05.02 Criteria for Setting UPL Guiding Principles

B. The Board shall:

- (1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;
 - (2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;
 - (3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences;
- and
- (4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

C. The Board shall not set an upper payment limit if:

- (1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit; or
- (2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

D. The Board shall not set an upper payment limit at an amount that:

- (1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or
- (2) Is lower than the Medicare Maximum Fair Price.



UPL CRITERIA

COMAR 14.01.05.02B(1); Health-Gen. 21-2c-13(b)(1)-(2)

Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs

To establish the MFP, CMS evaluates the manufacturer's specific costs for production and distribution. By including data on specialized refrigeration and transport, CMS ensures that these logistical costs are recognized during price negotiations. Because the UPL is set above the MFP, it contemplates Ozempic's specialized storage and delivery needs.

Dispensing fees are not included in the UPL to ensure that pharmacies are reimbursed for their professional services.



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UPL CRITERIA

Md. Code Ann., Health-Gen. 21-2c-13(b)(3)

Consider the effect the UPL will have on providers of 340B drugs

Because the implementation of UPLs for state and local government should not impact payment amounts to pharmacies and hospitals, the Board does not foresee any impact on providers of 340B drugs.



UPL CRITERIA

COMAR 14.01.05.02B(4)

Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

In closed session, the Board considered the patient out-of-pocket (OOP) costs of Ozempic compared to the net cost paid by payors and did not find a circumstances that indicated an affordability challenge related to this issue. However, the Board continues to prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.



UPL CRITERIA COMAR 14.01.05.02B(2)

Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product.



Earlier Staff Identified Six Drivers for Ozempic

Two Drivers were mapped to the One Circumstance

1. Gross Spending - driver 3.1, 3.2



UPL May Address Drivers

- **UPLs address drivers 3.1 (high gross spend from high utilization) and 3.2 (high gross spend from off-label use)**
- Due to these drivers, State and local governmental entities have employed certain utilization management tools for Ozempic (e.g., prior authorization, quantity limitations).
- A UPL reduces the amount paid by state and local government payers for these drugs, which allows the allocation of those resources to other needs and uses.



Driver 3.1: Gross Spending is High Because these Drugs have High Price and High Utilization

- These drugs have a special place in therapy for treating patients with comorbidities, which represents a large portion of patients with diabetes
- Gross spend is high in part because there are a large number of users (*i.e.*, high utilization) and the drug has a high price (*i.e.*, high cost)
- In the case of these drugs, the price is high on both a list and net basis, so high gross spend is associated with a high net spend



Driver 3.2: Gross Spending May be Impacted By Off-label Use

- Information was developed through the Information Gathering process suggesting widespread off-label use of semaglutide for weight loss.
- Nationally, the number of Ozempic users with a documented diabetes diagnosis fell from 91% in 2019 to 63% in 2022.¹
- However, staff confirmed that Ozempic utilization through the state employee benefit plan and some local government employee benefit plans is consistent with FDA label indications (e.g., diabetes) rather than off-label uses.

1. Gordon AC. Off-label use of Semaglutides Continued to Grow in 2022 for those with Employer-Sponsored Insurance. Health Care Cost Institute. April 1, 2025.
<https://healthcostinstitute.org/all-hcci-reports/off-label-use-of-semaglutides-continued-to-grow-in-2022-for-those-with-employer-sponsored-insurance/>



Additional Information from Policy Review Process on Appropriateness of UPL to Address Affordability Challenge

- **Savings Estimates for UPL-** The Ozempic Framework document (02/02/2026, at p.5) estimated savings of \$5.8 million for state and local governments. The Medicare MFP is estimated to represent savings compared to the average commercial net price.



UPL CRITERIA

Md. Code Ann., Health-Gen. 21-2c-13(b)(3)

For a UPL on a drug that is designated as a drug for a rare disease or condition, consider the impact of the upper payment limit on patients with rare diseases.

Not applicable. Ozempic has not been so designated.

COMAR 14.01.04.03B(1)(d) (“Whether the prescription drug product is designated by the Secretary of the FDA, under 21 U.S.C. §360bb, as a drug for a rare disease or condition”).



UPL CRITERIA

COMAR 14.01.05.02B(3)

Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences

The Boards proposed method of UPL implementation through supplemental rebates is designed to minimize unintended consequences, such as impacts on supply chain entities or impacts of access to the drug for patients.

Leverage state and local government contracts for implementation; ongoing feedback.



COMAR 14.01.05.02C

The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit;

The Board's review of state and local government spending, and determinations based on the gross spend of state and local government confirm that spending on Ozempic is more than the cost to implement a UPL.

(2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

Not applicable.



COMAR 14.01.05.02D - The Board shall not set an upper payment limit at an amount that:

(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price;

Best price is at least MFP, if not lower. Benchmarking on the MFP ensures that no statutory or regulatory amounts are impacted.

(2) Is lower than the Medicare Maximum Fair Price.

The Staff recommended UPL value is not lower than MFP.



Updates to the Draft Regulations

C. Automatic Suspension.

- (1) By operation of law, the UPL established in §§A and B of this Regulation shall be automatically suspended for the time that the prescription drug product is identified by the federal Food and Drug Administration as “currently in shortage” on the prescription drug shortage list.
- (2) Board staff shall post notice of the automatic suspension on the Board website.
- (3) The suspension shall be automatically lifted when the prescription drug product is identified as “resolved” by the federal Food and Drug Administration on the prescription drug shortage list.
- (4) Board staff shall post notice of the lifting of the automatic suspension on the Board website.
- (5) The automatic suspension and lifting of the suspension provided for in §§C(1) and (3) of this Regulation are self-executing.



Board UPL Tasks

Having Reviewed the Public Comments and Draft Regulation, and Having Considered the UPL Criteria, the Board may now:

- **Move to Set UPL by Proposing New Regulation**
- **Deliberate:** UPL Appropriate Policy; UPL Value
- **Vote:** Propose New Regulation





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