COMAR 14.01.07.02
Upper Payment Limit for Ozempic (semaglutide)

PDAB Meeting

November 16, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Comments Received on 14.01.07.02

- The proposed regulations for COMAR 14.01.07.02 were published in the June 26, 2026 Maryland DSD Register
- Comments were due on July 27, 2026
- Comments received from the following entities:
  - AARP
  - Aimed Alliance
  - Delaware-Maryland Synod
  - EACH/PIC Coalition
  - Maryland HealthCare for All
  - Novo Nordisk
  - PhRMA
  - Public Citizen
  - Value of Care Coalition

The written comment packet can be found here.

Non-substantive Changes at Final Action
COMAR 14.01.07.02

Summary of Non-substantive Changes at Final Action

- Clarifies that the UPL applies to purchases and payor reimbursements on behalf of an Eligible Governmental Entity in accordance with the implementation timelines established in COMAR 14.01.06, and may be applied voluntarily by an Eligible Governmental Entity beginning January 1, 2027.

Main Comment Themes

- Support for Upper Payment Limits
- Ongoing legal concerns
- Procedural Concerns
- Misapplication of Maximum Fair Price (MFP)
- Insufficient Timelines for Implementation
- Patient Access Risks
- Failure to Pursue Non-UPL Policies

Comment Theme: Support for Upper Payment Limits

- Four entities submitted comments supporting Upper Payment Limits with an emphasis on Statewide savings and contend that lower system acquisition costs will translate into improved patient adherence, expanded therapeutic access, and relief for taxpayer-funded health plans.
- PDAB Response: The PDAB appreciates the support.

Comment Theme: Ongoing Legal Concerns

- Highlighted federal court precedent in Colorado and that argue that state-level UPLs violate federal patent law.
- PDAB Response: The Maryland PDAB is monitoring developments in Colorado, and throughout the country.

Comment Theme: Procedural Deficiencies

- Concerns about how the Board failed to establish a legally sound finding of an "affordability challenge" under Md. Code Ann., Health-Gen. §§ 21-2C-13 to -14. They contend the Board improperly relied on a single 2023 gross spending statistic, without considering total budget impact, net pricing discounts, direct-to-patient assistance programs, or offsetting clinical cost-savings (e.g., reduced hospitalizations).
- PDAB Response: the Board has broad authority and explicit procedures under its statute and regulations to determine whether a drug has led “or will lead” to an affordability challenge, as described in § 21-2C-09.

Comment Theme: Misapplication of Maximum Fair Price (MFP)

- Industry and patient coalitions object to using Medicare's MFP as the state UPL benchmark. They argue MFP was designed strictly for the Medicare benefit structure and that adopting it without independent, state-tailored analysis violates statutory requirements.
- PDAB Response: The Cost Review Study and the Policy Review Process was based on Maryland-specific information. The Medicare Maximum Fair Price (MFP) serves as one of several reasonable, published benchmarks set forth in the PDAB's regulations for the Board to consider. Commenters are encouraged to provide additional information on why the MFP is inappropriate to consider for markets outside of Medicare.

Comment Theme: Insufficient Timelines for Implementation

- Concerns about a regulatory conflict between COMAR 14.01.07.02 (proposing an application date of January 1, 2027) and proposed COMAR 14.01.06 (setting a mandatory compliance date of January 1, 2028), arguing that a 2027 date fails to satisfy the statutory mandate to provide "sufficient time for implementation."
- PDAB Response: PDAB applied non-substantive changes to the most recent draft of the regulations to clarify that purchases and payor reimbursements on behalf of an Eligible Governmental Entity in accordance with the implementation timelines established in COMAR 14.01.06, and may be applied voluntarily by an Eligible Governmental Entity beginning January 1, 2027.

Comment Theme: Patient Access Risks

- Multiple groups caution that UPLs regulate payer/PBM reimbursement rather than patient copays. Unintended consequences could include increased utilization management (step therapy, prior authorization), tier shifts, pharmacy inventory cash-flow strain, and disruption of treatment continuity.
- PDAB Response: While UPLs govern reimbursement benchmarks, the Board's primary objective is expanding patient access. The implementation of the UPL in Maryland was specifically designed in to increase access and avoid unintended consequences in the supply chain.

  The Board takes concerns regarding increased utilization management and pharmacy friction seriously, and will evaluate post-implementation data to ensure cost containment does not come at the expense of patient care continuity.

Comment Theme: Failure to Pursue Non-UPL Policies

- Commenters expressed concern that the Board has prioritized UPLs over non-UPL policy solutions (e.g., regulating PBM spread pricing, copay accumulators, or benefit designs).

- PDAB Response: The Board evaluates a full spectrum of of non-UPL policy solutions alongside UPLs. At the May 18, 2026 meeting, the Board approved several specific policy recommendations for Ozempic to address broader affordability challenges, and will continue to identify and advance targeted, non-UPL solutions for Maryland patients. The Board continues to prioritize non-UPL policies with the same, if not higher, consideration as UPLs.