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Maryland Prescription Drug Affordability Board
Comments on Draft Cost-Review and UPL Documents for Ozempic
April 2026

AARP Maryland, which has about 850,000 members, congratulates the state's Prescription Drug Affordability Board (PDAB) on the three draft documents it released on April 22, 2026, regarding cost review and upper payment limits (UPLs) for Ozempic. They are thoroughly researched, balanced, clear, and justified in their conclusions and proposed actions.

Based on that and the very large and rapidly growing state and local government expenditures for Ozempic, AARP Maryland urges the prompt adoption of the draft Cost Review Study Report and draft UPL regulations for Ozempic. By doing that, the PDAB will position state and local governments to withstand the rapidly rising costs for this drug, which already accounts for 4.87 percent of their gross prescription drug spend in one instance. Moreover, the usage of this drug is likely to continue rising strongly since it is increasingly being prescribed "off label" by physicians for weight loss in addition to the FDA-approved uses for type 2 diabetes, cardiovascular disease (CVD) and chronic kidney disease (CKD).

The PDAB correctly made a unanimous prior preliminary determination that Ozempic has created an affordability challenge for the state health care system. The cost to the state and local government in Maryland, the PDAB found, is "disproportionate to the net cost paid by payors." And these costs also hit individual state and local government beneficiaries hard, with the impact likely to expand in the future, since the drug is considered the preferred GLP-1 option not only for type 2 diabetes but also for CVD and CKD.

The case for taking prompt action is strengthened further by FDA findings that Ozempic is no longer in a shortage situation. Moreover, the last of the drug's patents don't expire until December 2031 and June 2033, the PDAB noted. Therefore, no generic drugs that might exert downward pressure on Ozempic's price are on the near-term horizon.

Given this situation, the PDAB's draft UPL regulation on Ozempic is needed and appropriate. Under this draft, the UPL starting January 1, 2027, would be $274 for a 30-day supply. This cost is the same as the negotiated Medicare Fair Price, lending added credence to the suitability of the figure Maryland would use as its base when the UPL starts. And there would be annual inflation adjustments starting January 1, 2028, with the new rate then tied to the federal Consumer Price Index for 18 months before the UPL took effect.

For all these reasons, AARP Maryland praises the PDAB for the Draft Cost Review Study Report, the Calculations and Analyses Underpinning Potential UPL Values, and the draft UPL

regulations for Ozempic. AARP urges the prompt adoption of all these documents so that state and local governments in Maryland — and especially their beneficiaries — can begin receiving much-needed relief from the costs of this important drug.

EACH PIC COALITION

May 1, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on COMAR 14.01.07.02 Upper Payment Limit for Ozempic

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We appreciate the opportunity to comment on the board's proposed upper payment limit (UPL) rulemaking for Ozempic. We urge the board not to move forward with the proposed UPL since it does not directly address patient needs and alternative policy solutions have not yet been fully considered or evaluated by the board.

UPLs Do Not Guarantee Savings for Patients

We continue to underscore the limitations of a UPL in addressing patient affordability. UPLs may change what insurers or the state pay for a medication, but they do not cap or guarantee reductions in patient out-of-pocket costs. As our coalition has cautioned before, these policies can introduce new incentives for insurers and pharmacy benefit managers (PBMs) that may ultimately restrict access to needed treatments through greater utilization management, formulary reshuffling, or adverse tiering. These shifts risk delaying or disrupting care, and as our Patient Experience Study has demonstrated, insurance barriers, not price alone, are often the real drivers of patient hardship and perceived "unaffordability."

Furthermore, patients reported that treatments are not interchangeable and that accessing the correct medication is critically important for patients with chronic conditions. Therefore, while intended to reduce costs, implementing a UPL without complementary patient protections could worsen the very challenges patients already face.

We urge the board to establish clear safeguards before advancing any UPL frameworks and to continue exploring its policy alternatives, including reforms that directly address PBM and insurance practices that most influence patient costs.

Limitations of Applying Medicare MFP

Maryland's proposal to apply the "maximum fair price" (MFP) established by the Medicare Drug Price Negotiation Program (MDPNP) to state programs is concerning because those prices were negotiated specifically for the Medicare population and benefit design. Those rates reflect the structure and cost-sharing rules of Medicare, which are not the same as those that apply in state-regulated coverage. Applying those prices outside of Medicare assumes the markets function the same way, and they do not.

Further, the establishment of UPLs at MFP rates does not guarantee any savings for patients. Patients could instead face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug, which results in higher profits for their PBM. Recent research from the Pioneer Institute has shown that patient out-of-pocket costs have increased by an average of 32 percent under the MDPNP even before the maximum fair price caps for the first round of drugs went into effect on January 1st.

Simply importing Medicare pricing may create disruption without meaningfully improving what patients actually pay or experience.

Consider More Effective, Patient-Centered Reforms

We have long cautioned that UPLs are not a patient-centered solution and have urged the board to seek the authority to implement alternative reforms that will better address patient problems. We urge once again that the board ensures non-UPL policy alternatives are given equal weight alongside UPL proposals.

In the February 2025 comment letter on the rules and regulations concerning the UPL process submitted by the EACH Coalition and signed by more than 25 organizations, we raised this issue:

"[W]e continue to urge the board to seek authority to implement policy alternatives before proceeding with the UPL process. The board currently has no authority to implement alternative policies nor has it outlined any alternatives under consideration. Proceeding with the UPL process without taking these important steps increases the likelihood that the board will resort to implementing UPLs simply because other policy solutions have not been explored and are therefore not available to implement."

Unfortunately, the scenario we outlined has now come to fruition. The board is moving forward with establishing UPLs. Meanwhile, alternative policy options that may better address the needs of Maryland patients are advancing more slowly because the board lacks the authority to pursue them directly. Whether by design or simply ease of authority, the board has now demonstrated that UPLs are its preferred mechanism for intervention.

Moving forward with implementing UPLs will place more value on lowering system costs than on addressing real patient needs. We therefore urge the board not to move forward with approval of the UPL for Ozempic until the alternative policy recommendations under consideration also move forward.

We thank the board for its consideration of our comments.

Sincerely,

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Ensuring Access through Collaborative Health (EACH) Coalition Lead

EACH PIC COALITION

Vanessa Lathan
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Patient Inclusion Council (PIC) Coalition Lead

May 1, 2026

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

The Maryland Health Care for All! Coalition appreciates the opportunity to provide comment on the Draft Proposed Regulations – COMAR 14.01.07.02 – Upper Payment Limit for Ozempic. We applaud the dedicated work that the Board and its Staff has done to reach this point and are pleased to see a proposed number for an upper payment limit that is based on the CMS negotiated Medicare Maximum Fair Price. We encourage the Board and Staff to consider if additional action should be taken to modify a state-level UPL, should the MFP negotiated number for Ozempic be superseded by the lower Most Favored Nation pricing, if implemented.

We have seen the considerable impacts that the cost of Ozempic has had on patients, our health care system, and our State and local governments. 2024 KFF Health Tracking Polling shows that over half of those who had previously taken a GLP-1 found it hard to afford.[i] Many patients are finding that Ozempic is no longer covered by insurance, or that their premiums have gone up. Blue Cross Blue Shield estimated that employer-provided coverage could increase by nearly 15% as GLP-1 coverage costs rise in concert with the demand.[ii] These costs have also burdened our government budgets. In Howard County, the cost to the public school system for GLP-1 coverage increased from $485,000 to $3.6M, threatening other essential services provided by the county and forcing reductions in coverage.[iii]

We urge the swift adoption of the proposed regulations to establish an upper payment limit on Ozempic, as this action would bring real relief to State and local government entities struggling to afford coverage of this medication. Additionally, should the upper payment limit be applied to the State's private payer market, Marylanders are estimated to see a savings of between $113-165M/year for on-label uses of Ozempic.[iv]

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[i] https://www.kff.org/health-costs/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs/

[ii] https://www.bcbs.com/news-and-insights/article/glp-1-could-increase-employer-premiums

[iii] https://staff.hcpss.org/news/hcpss-ending-coverage-glp-1-drugs-weight-management

[iv] https://healthcareforall.com/uplestimates/

PhRMA
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By Electronic Submission

May 1, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

RE: Draft Regulation – New Regulation COMAR 14.01.07.02 (Upper Payment Limit); Ozempic: Calculations and Analyses Underpinning Potential UPL Values

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Maryland Prescription Drug Affordability Board's (the "PDAB's" or "Board's") request for written comments on its draft regulation regarding an Upper Payment Limit for Ozempic (COMAR § 14.01.07.02) ("Draft Regulation") and its Calculations and Analyses Underpinning Potential UPL Values for Ozempic ("Calculations and Analyses Document"").[1] PhRMA represents the country's leading innovative

[1] *See* Draft New Regulation – COMAR 14.01.07.02 (Upper Payment Limit), *available at* https://pdab.maryland.gov/Documents/regulations/2026/14.01.07.02.Propsed%20Ozmepic%20UPL%20Regs%204.22.26.pdf**;** Ozempic: Calculations and Analyses Underpinning Potential UPL Values, *available at* https://pdab.maryland.gov/Documents/Cost%20Review/2026/4.22.26%20OZEMPIC.Upper%20Payment%20Limit.Calculations%20and%20Analyses%20%281%29%20%281%29.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the constitutionality of Md. Code, Health Gen. §§ 21-2C-01–16 (the "PDAB Statute"). PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute. *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations – New Regulation COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits); New Regulation – COMAR 14.01.07 (Upper Payment Limit) (Mar. 30, 2026); Letter from PhRMA to Board Regarding Draft Cost Review Study Reports for Comment (Mar. 30, 2026); Letter from PhRMA to Board Regarding UPL Amount and Methodology Documents (Mar. 4, 2026); Letter from PhRMA to Board Regarding Cost Review Study Process and Policy Review Process (Feb. 10, 2026); Letter from PhRMA to Board Regarding Proposed Rules – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Feb. 10, 2025); Letter from PhRMA to Board Regarding Proposed Regulation – Amendments to COMAR § 14.01.04.05 (Cost Review Study Process) (Dec. 2, 2024); Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 12, 2022).

biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA has previously commented on various aspects of the Board's work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] We have expressed our concerns in detail regarding the Board's process for setting upper payment limits ("UPLs") and its activities more broadly, and we encourage the Board to consider these previously submitted comments.[3] In addition, we provide below select comments and concerns with respect to the Draft Regulation and the Board's UPL-setting process in general.

I. Lack of Clear and Meaningful Standards for the UPL-Setting Process

PhRMA continues to have concerns regarding the lack of clear and meaningful standards governing the Board's UPL-setting process, including its process for reconsidering a UPL after it is set.[4]

A. Reconsideration of UPLs

- **Reconsideration of Maximum Fair Price ("MFP")-Based UPLs.** PhRMA remains concerned that the Board has proposed using the Medicare MFP as the UPL benchmark. A drug subject to an MFP may be subject to renegotiation under the Medicare Drug Negotiation Program ("MDPNP") or may cease to be subject to an MFP altogether, but the Board has not established clear and meaningful standards and processes for reconsideration of an MFP-based UPL in such circumstances. The Board has recently indicated that it intends to amend the regulations to allow for reconsideration of MFP-based UPLs if the MFP is renegotiated.[5] PhRMA urges the Board to provide for automatic UPL reconsideration if the corresponding MFP is renegotiated or the drug is no longer subject to an MFP.[6] PhRMA also urges the Board to address how it will monitor MFP changes and establish clear timelines for reconsidering UPLs and modifying or repealing accordingly.

- **Reconsideration of UPLs for Drugs in Shortage.** The PDAB Statute specifically authorizes the Board to "reconsider" a UPL if there is a shortage and prohibits it from applying a new UPL to a drug in "current shortage."[7] The Board's regulations also provide that "the Board shall reconsider" a UPL if it "becomes aware of a shortage . . . in the State."[8] However, as discussed

[2] *See* Md. Code, Health Gen. §§ 21-2C-01–16.
[3] *See* comments cited *supra* note 1.
[4] *See* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-4; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 1 at 1-7.
[5] UPL Regulations: Implementation and Monitoring of Upper Payment Limits, PDAB Meeting Materials, Apr. 13, 2026 ("April 13 Meeting Materials") at 9, *available at* https://pdab.maryland.gov/Documents/meetings/2026/April%2013%2c%202026/2026.04.13.UPL%20Regulations-%20General%20Provisions.pdf.
[6] *See* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2.
[7] *See* Md. Code, Health Gen. § 21-2C-13(c)(1)-(2); *see also* COMAR § 14.01.05.09(A)(2); Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-3.
[8] COMAR § 14.01.05.09(A)(2); *see* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-3.

in our previous comment letters, the regulations do not explain how the Board will monitor for shortages.[9] While the Board's regulations require it to "develop a program for monitoring the availability of any prescription drug product for which it sets a UPL," the Board has not yet developed such a program.[10] The Board should revise its regulations to specifically address how the Board will monitor for shortages and ensure timely UPL reconsideration if shortages arise.

B. Other Concerns with the UPL-Setting Process

The Board continues to lack clear and meaningful standards for other aspects of the UPL-setting process. PhRMA reintroduces the following, non-exhaustive examples and encourages the Board to review its previously submitted comments for further discussion.[11]

- **UPL Development.**[12] PhRMA remains concerned by the lack of clear standards and processes governing the development of proposed UPLs, including with respect to selecting information to consider, choosing UPL framework parameters and amounts, and determining the appropriateness of a UPL.[13] We urge the Board to establish meaningful standards to guide its actions and limit the risk of arbitrary decision-making.

- **Patient Access and Affordability.**[14] PhRMA is concerned that the Draft Regulation does not provide an adequate process for monitoring the impact of the proposed UPL on patient access and affordability. We request that the Board establish robust measures to monitor access and affordability factors, including benefit design.

- **Confidentiality.**[15] In its response to public comments on government entity reporting requirements, the Board indicated that it intends to "protect any sensitive information per COMAR 14.01.01.04 Confidential, Trade-Secret, and Proprietary Information."[16] PhRMA again asks the Board to address how it will safeguard confidential, proprietary, and trade secret information (as statutorily required) and amend its regulations to expressly protect such information disclosed to the Board.[17]

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[9] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 3.

[10] COMAR § 14.01.05.08(B)(1); *see* COMAR § 14.01.05.08(B)(2) ("If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL"); Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

[11] *See, e.g.*, *See* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1.

[12] *See, e.g.*, Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 2-4.

[13] *See* COMAR § 14.01.05.02(B)(2); *see, e.g.*, Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 2-4.

[14] *See* Draft COMAR § 14.01.07.02; *see also, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

[15] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3-4.

[16] *See* April 13 Meeting Materials at 5.

[17] *See* Md. Code, Health Gen. § 21-2C-10(a)–(b) ("Only Board members and staff may access trade secrets and confidential and proprietary data and information ... that is not otherwise publicly available"; "all information and data" shall be "considered to be a trade secret and confidential and proprietary information" and "is not subject to disclosure under the Public Information Act" if it is obtained by the Board "and is not otherwise publicly available.").

- **Stakeholder Comment.**[18] To allow for meaningful feedback and participation, PhRMA again asks the Board to both post all documents subject to public comment on its website and distribute the same to stakeholders and distribution lists at least 14 days before the comment deadline.[19] The Board should explain how it will incorporate and address all feedback.[20]

II. Improper Characterization of Medicare Maximum Fair Prices ("MFPs") as "Negotiated"

The Calculations and Analyses Document misrepresents the MFP-setting process by describing MFPs as "negotiated."[21] Under the Inflation Reduction Act ("IRA") and Centers for Medicare & Medicaid Services ("CMS") implementing guidance, the process for establishing an MFP is far from a "negotiation," as that word is customarily used.[22] CMS has unilateral and virtually unconstrained discretion to set any price it wishes (below a statutory ceiling) and impose severe penalties on manufacturers that do not agree to CMS's prices or refuse to engage in the process. A manufacturer that does not agree to "negotiate" or does not agree to the MFP that CMS sets must withdraw *all* of its products from Medicare and Medicaid—which account for approximately 45 percent of nationwide retail prescription drug spending.[23] Manufacturers' only alternative is to accept an excise tax of up to 1,900 percent and, in some circumstances, civil monetary penalties. These penalties and taxes command acquiescence, not true negotiation.[24] Furthermore, CMS dictates MFP terms through a rigid, non-negotiable framework. Manufacturers must sign the agreement with CMS before knowing the final price, they cannot revise the terms, and they are denied legal recourse or transparency into CMS's decision-making process.[25]

III. MFP Is an Inherently Flawed Metric for State Use and Could Create Access Challenges for Patients

PhRMA remains concerned about the Board's use of MFPs as benchmarks for setting Maryland UPLs.[26] MFPs are specifically developed for the Medicare program and patient population under the statutory framework of the Inflation Reduction Act, but the Draft Regulation would apply these prices to an entirely different market and patient population. In doing so, the Board would be disregarding the unique market dynamics and affordability challenges that patients in Maryland may be facing.[27] As PhRMA has previously

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[18] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 5-6.

[19] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4.

[20] *See, e.g.*, *id.*

[21] Calculations and Analyses Document at 1.

[22] *See, e.g.*, Decl. of P. Costello, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-00707-DII (W.D. Tex. Aug. 10, 2023), ECF No. 35-6 at ¶¶ 12-14, 20 (describing the MFP-setting process and indicating that, "[a]bsent a legal compulsion to do so, Amgen would not agree to these prices").

[23] Congressional Budget Office ("CBO"), Prescription Drugs: Spending, Use, and Prices (Jan. 2022), *available at* https://www.cbo.gov/publication/57050.

[24] In fact, the CBO score for the IRA presumes that the excise tax will not generate any revenue independent of its effects on drug pricing through imposition of the government's MFP. *See* CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 at 5 (Sept. 7, 2022), *available at* https://www.cbo.gov/publication/58455.

[25] *See* Inflation Reduction Act of 2022, Pub. L. 117-168, §§ 11001(c), 11002(c) (lack of notice-and-comment rulemaking); 42 U.S.C. § 1320f–7, Social Security Act § 1198 (lack of judicial review).

[26] *See* Calculations and Analyses Document at 1-2; *see also e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 10.

[27] *See* Calculations and Analyses Document at 1-2.

expressed, MFP-based UPLs raise serious concerns for patient access, particularly if expanded to the commercial market.[28]

CMS sets its MFPs through the Medicare Drug Negotiation Program ("MDPNP"), but because the program is still at an early stage, many operational and legal issues remain unresolved. The MFPs for the initial set of drugs only recently went into effect. Although it will be years before the effects of MFPs on patient affordability and access are fully understood, recent evidence shows that out-of-pocket costs for Medicare patients have significantly increased and the number of patients benefiting from MFPs has remained relatively small. Avalere Health's analyses of 2025 and 2026 Part D plan formularies found Part D plans were tightening access to branded medicines, changes that could translate into fewer therapeutic alternatives within classes that contain drugs with an MFP.[29] Further, analyses of 2025 and 2026 Part D plan formularies found that Part D plans have increased utilization management, shifted tier placement, and limited access to drugs subject to an MFP.[30]

The downstream effects of the UPL on patient access are likely to be exacerbated by the use of MFPs in state populations. Using MFP as a benchmark is therefore premature, and PhRMA is concerned with the Board moving forward with an MFP-based UPL without fully understanding the patient impact from the MDPNP.[31]

Finally, the Draft Regulation is silent on the fundamental question of how UPLs will be effectuated. At the federal level, even CMS's complicated process has outstanding key issues not yet resolved, and the MFP applies only to Medicare—raising serious doubts about how Maryland will effectuate a UPL given that the U.S. pharmaceutical market and distribution strategies function nationally. In the case of the MFP, the federal government has designed a specific process for implementing the price for patients insured by Medicare—this system does not apply to other markets. This is a significant shortcoming that Maryland cannot disregard, because an unworkable approach could lead to access challenges for patients. Without understanding how UPLs will work in practice, the Board will not be able to meaningfully assess the impact on the supply chain and patients.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA remains concerned about the Draft Regulation and the Calculations and Analyses Document, we continue to stand ready to be a constructive partner in this dialogue. Please contact Kristin Parde at Kparde@phrma.org with any questions.

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[28] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 10.

[29] Avalere Health, 2025 Part D Formularies Shift to More Coinsurance and UM (Oct. 2024); Avalere Health, Part D Formulary Management Tightens in 2026 (Nov. 2025).

[30] Avalere Health, 2025 Part D Formularies Shift to More Coinsurance and UM (Oct. 2024; Avalere Health, Part D Formulary Management Tightens in 2026 (Nov. 2025). In addition, a 2025 physician survey by Avalere found that nearly all providers (92%) would be somewhat or very likely to stop stocking Part B drugs subject to an MFP. *See* Avalere Health, White Paper: Provider Survey on Part B Negotiation (Sept. 2025).

[31] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 10.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director – Law

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Comments on the Draft Proposed Regulations on an Upper Payment Limit for Ozempic

Maryland is working to support affordability through its Prescription Drug Affordability Board (PDAB). On April 22, 2026, the PDAB released draft proposed regulations for an Upper Payment Limit for Ozempic.

Ozempic (semaglutide) is manufactured by Novo Nordisk and approved by the FDA to help control blood sugar levels, reduce the risk of cardiovascular disease, and reduce the risk of worsening kidney disease in patients with type 2 diabetes.

The pharmaceutical industry often fights efforts to rein in prescription drug costs by claiming that attempts to make drugs more affordable will harm the ability to invest in research and development for new medicines. In reality, pharmaceutical companies do not set prices based on a drug's research and development cost. Rather, insulated from competition by monopoly protections, companies set prices based on what the market will bear and reap large profits in the process.

Novo Nordisk's pricing and revenues for Ozempic cannot be explained by research and development (R&D) spending. The company has made over $69.5 billion in sales revenue from Ozempic since the drug's launch in 2018. These revenues are an order of magnitude higher than even the most generous estimates of research and development costs that take into account failed candidates and a reasonable return on investment. Since Novo Nordisk launched Ozempic, the company has spent over $56.3 billion on share repurchases and shareholder dividends—1.7 times as much as it spent on R&D across its entire portfolio ($32.6 billion).[1]

Novo Nordisk sells the same drug at much lower prices in comparable countries and still makes a profit at those prices. Based on net price estimates, Ozempic is as much as five times as expensive in the U.S as in peer countries. Meanwhile, researchers estimate that the drug could be profitably manufactured for as little as around $3 for a monthly supply.

Novo Nordisk's patenting tactics could stave off generic competition — a proven way to lower prices — keeping prices higher for longer. Follow-on patents for semaglutide, many of which cover minor modifications, provide patent protections until 2042, ten years after the patent covering the drug substance expires.

We encourage the PDAB to act to reduce Ozempic costs and ensure Novo Nordisk cannot put profits over the needs of everyday Americans.

[1] Public Citizen analysis of company financial reports 2018–2025.

Value of Care Coalition

May 1, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Comments on Proposed COMAR 14.01.07.02 — Upper Payment Limit for Ozempic (Semaglutide)

The Value of Care Coalition (VCC) appreciates the opportunity to comment on proposed COMAR 14.01.07.02, which would establish an upper payment limit (UPL) of $274.00 per 30-day supply for Ozempic (semaglutide), effective January 1, 2027. We share the Board's goal of improving drug affordability for Marylanders but have concerns with the proposed regulation. These comments identify three analytic gaps that we believe should be addressed before the regulation is finalized.

I. Medicare MFP Is Not an Appropriate Benchmark for Maryland

The proposed $274 UPL is calibrated to the Medicare Maximum Fair Price (MFP) negotiated under the Inflation Reduction Act. That price was established within a defined statutory framework applicable to Medicare — a specific payer with specific market conditions, infrastructure, formulary structures, patient protections and volume commitments. COMAR 14.01.07.02 would apply that benchmark to eligible governmental entities, and eventually to commercial insurers, operating outside that framework. We encourage the Board to document the basis for concluding that the Medicare MFP appropriately reflects acquisition costs and payer dynamics for the non-Medicare entities subject to this regulation.

II. The Regulation Does Not Contain a Mechanism to Reduce Patient Out-of-Pocket Costs

The proposed regulation caps what eligible governmental entities pay and will be the basis for future UPL expansion into commercial markets; however, it does not require that savings be passed through to patients at the point of sale. For most Marylanders, out-of-pocket costs are determined by deductibles, coinsurance, and formulary tier placement — factors the UPL does not directly affect. To the extent the Board's objective will ever be patient affordability, we encourage the Board to consider whether additional provisions are needed to ensure that the savings generated by the UPL translate into meaningful reductions in what patients pay for Ozempic.

III. The Board Should Assess the Regulation’s Effect on Patient Access Before Implementation

If the UPL is set below what pharmacies and providers pay to acquire Ozempic, they may face difficulty sustaining access to the drug. This risk is most acute for independent and community

pharmacies serving rural and underserved populations, which often operate on thin margins. We encourage the Board to conduct and publish a reimbursement adequacy assessment using current acquisition cost data prior to adopting the UPL. Understanding where the $274 limit sits relative to actual acquisition costs would help the Board assess whether implementation adjustments are necessary to preserve patient access. Additional information should be provided regarding the operationalization of the UPL and how supply chain entities that do continue to purchase, stock, deliver or administer the drug will be made whole if necessary.

IV. Requested Action

VCC respectfully urges the Board to supplement the proposed regulation with: (1) an analysis establishing that $274 per 30-day supply is appropriate for the non-Medicare entities subject to this regulation; (2) a supply chain analysis using current acquisition cost data that provides detail on operationalization of the UPL; and (3) an assessment of whether the regulation as drafted will produce measurable reductions in patient out-of-pocket costs now and in the future, and if not, what additional mechanisms might achieve that outcome.

Leaving these questions unaddressed only furthers concern amongst the stakeholder community and allows doubt that the Board will achieve its affordability goals to linger.

We appreciate the Board's attention to these comments.

Sincerely,

Derek Flowers
Value of Care Coalition