AARP Maryland

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The Maryland Prescription Drug Affordability Board's (PDAB) Upper Payment Limit (UPL) Framework documents published on November 4 are well done and point out the importance of moving ahead quickly with these initial cost-saving measures on Jardiance and Farxiga. AARP Maryland, which has approximately 850,000 members in the state, finds this new research to be objective, appropriately focused, and clear in its implications for what needs to be done regarding UPLs.

If anything, the PDAB's research understates — for good reasons — the potential savings to state and local government entities and their beneficiaries in Maryland. The board used list-price data for 2023 as its base for determining the savings to Maryland entities from adopting the Maximum Fair Price (MFP) negotiated by Medicare for 2026 as the maximum price that government bodies in the state would pay. These were the latest complete figures available from the federal government at the time. Those list prices have since risen substantially. While the list price for Jardiance in 2023 was $573, the 2023 data show, the list price now is well over $600. Similarly, the Farxiga list price in 2023 of $556 is now approximately $600.

Marylanders suffering from these excessively high prices need appropriate relief now. The Medicare MFPs, as the PDAB research points out, may be just the starting point on price relief for patients covered by Medicare, since drug plans may negotiate additional discounts. With this in mind, the use of the new Medicare-negotiated maximum prices for Jardiance and Farxiga is a very justifiable action that would rapidly help state and local governmental entities in Maryland — and the people they employ and serve.

Another major reason for promptly adopting the PDAB's UPL framework for Jardiance and Farxiga is that the law enacted by the Maryland General Assembly this year allows

the PDAB's UPL framework for the affected prescription drugs to be extended to all citizens of the state beginning one year after they are applied to the governmental entities. The sooner the clock starts on this timeline, the better the outcome for all Marylanders.

For all these reasons, AARP Maryland recommends the prompt adoption of the PDAB staff's UPL framework for Jardiance and Farxiga.

November 12, 2025

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on FARXIGA® Upper Payment Limit Framework

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca appreciates the opportunity to provide comment on the proposed Upper Payment Limit (UPL) framework for FARXIGA® (dapagliflozin) (the "Draft UPL Framework").[1] We share the Board's goal of supporting Maryland patients while ensuring responsible stewardship of public resources and offer the following observations and recommendations to help ensure any final approach is Maryland specific, consistent with statutory and regulatory requirements, and focused on measurable benefits for patients and programs.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines, primarily for the treatment of diseases in four therapy areas: Oncology, Cardiovascular, Renal and Metabolism, Respiratory, and Rare Diseases. Based in Cambridge, UK, AstraZeneca is committed to developing innovative, lifesaving medicines and making these medicines accessible to patients. FARXIGA® is a first-in-class, oral, once-daily sodium-glucose cotransporter 2 ("SGLT2") inhibitor indicated: (1) to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression; (2) to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure; (3) to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors; and (4) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

EXECUTIVE SUMMARY

[1] Maryland PDAB, Draft Farxiga Upper Payment Limit Framework (Version 1.0) (Nov. 4, 2025), at https://pdab.maryland.gov/Documents/Cost%20Review/2025/Farxiga.Upper%20Payment%20Limit%20Framework.2025.11.04.1630.v.1.0.pdf.

- As we have relayed in prior comment submissions,[2] the Board inappropriately selected FARXIGA® for cost review and has failed to appropriately demonstrate "affordability challenges" for state and local government payors or high out-of-pocket costs for patients. Proceeding further with this cost review and implementing policy options would be arbitrary and capricious under the Board's statutory and regulatory authority. The Draft UPL Framework only amplifies our concerns as it contains significant flaws.
- Given imminent generic entry, the Draft UPL Framework's indication of limited incremental savings, existing Medicaid protections, and the statutory best interest requirement, the Board may wish to prioritize other products.
- The Board's own framework indicates that FARXIGA® is already affordable under current conditions for Maryland's state and local programs and patients, considering net cost realities and near-term market changes.
- The Board should establish a Maryland-specific UPL methodology for future determinations. The methodology should include clear criteria, factor weighting, and documentation suitable for policy and legal review.
- The Board should also conduct an independent, Maryland-focused financial analysis that incorporates net acquisition costs, patient out of pocket impacts, and clinical cost offsets tied to outcomes.
- The Board should prioritize policy changes likely to deliver greater impact on affordability, including pharmacy benefit design and PBM practices, that directly influence patient costs.

IMMINENT LOSS OF FARXIGA® PATENT EXCLUSIVITY

Before commenting on the Board's UPL recommendations, it should be noted that FARXIGA®'s primary patent exclusivity is expected to expire in April 2026.[3] Further, as of June

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[2] AstraZeneca's prior submissions to the Board, the PDASC, and to the Maryland Legislative Policy Committee regarding the Board's activities are incorporated herein by reference herein and include, but are not limited to, the following: AstraZeneca's Comments on the Board's FARXIGA® Dossier (July 3, 2025), 9-11, at https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf; AstraZeneca's Comments on FARXIGA®'s Referral to the Stakeholder Council (May 15, 2024), 9-11, at https://pdab.maryland.gov/Documents/comments/May%2020th%20Board%20Meeting%20Written%20Comment%20Pack.pdf; AstraZeneca's Comments on the Board's Draft UPL Regulations (Nov. 8, 2024), 34-36, at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf; AstraZeneca's Written Testimony to the Maryland Legislative Policy Committee Regarding the Board's Draft UPL Action Plan (Oct. 18, 2024),51-53, at https://mgaleg.maryland.gov/meeting_material/2024/lpc%20-%20133746007389905217%20-%20All%20Meeting%20Materials.pdf.

[3] AstraZeneca 2024 Annual Report. https://www.astrazeneca.com/investor-relations/annual-reports/annual-report-2024.html). Page 40.

2025, the FDA has tentatively approved 18 Abbreviated New Drug Applications (ANDAs) for generic dapagliflozin. While final approvals and launch timing depend on several factors, the significant number of tentative FDA approvals and historical record suggests rapid post-Loss of Exclusivity (LOE) competition.

In light of imminent generic entry and expected competitive pricing, the Board should discontinue any potential UPL for FARXIGA®. If uncertainty remains, the Board should defer until post-LOE to assess actual market outcomes, protect taxpayer funds and avoid unnecessary administrative burden.

A MARYLAND-SPECIFIC ANALYSIS WILL LIKELY DEMONSTRATE LIMITED SAVINGS FOR MARYLAND

The Draft UPL Framework notes that a UPL set at the Medicare Maximum Fair Price (MFP) "may not result in additional discounts" and "may not yield significant savings for State and local government health plans." This admission undermines the rationale for including FARXIGA® in the Board's cost review, preliminary determination of unaffordability, and implementation of a UPL. If the Board still wishes to pursue this process, we note that given the Draft UPL Framework's acknowledgment of potentially minimal savings, the Board should conduct additional, Maryland-specific analysis to substantiate that a FARXIGA® UPL meets this standard before any final action is taken.

A sound UPL determination should be supported by an independent analysis of Maryland-specific utilization and patient mix; net acquisition costs paid by Maryland government entities; budget impacts on state and local programs; and patient out-of-pocket effects at the pharmacy counter. This should be in addition to the proprietary data already submitted to the PDAB by AstraZeneca. Reliance on Medicare's national list prices or the Medicare Drug Price Negotiation Program (DPNP) does not meet this standard and can overstate potential savings for the State.

The draft framework's stated savings of $4.9 million dollars may be overstated because the comparison uses the Medicare MFP and the 2023 CMS list price of $556 dollars, rather than the actual net acquisition costs paid by Maryland government entities, as referenced in COMAR 14.01.05.06C. Using list price as the baseline, rather than net costs, could lead to an inaccurate savings estimate. In particular, the current approach:

- May not fully reflect existing rebates and discounts that government entities already receive.
- May not account for discounts provided to wholesalers and other participants in the supply chain.
- Relies on list price as a proxy for payment, which is uncommon in practice.

UPL DETERMINATIONS SHOULD FACTOR IN CLINICAL VALUE TO PATIENTS

The Draft UPL Framework does not address the significant clinical benefits and cost-effectiveness of FARXIGA®. FARXIGA® is an SGLT2 inhibitor with four distinct FDA-approved indications providing substantial medical cost savings through prevention of costly complications and hospitalizations.

The interconnectivity between metabolic risk factors, chronic kidney disease (CKD), and cardiovascular health plays a pivotal role in shaping overall morbidity and mortality. This complex interplay, known as cardiovascular-kidney-metabolic (CKM) syndrome, has far-reaching multisystem consequences, with the most significant clinical impact on cardiovascular disease (CVD) and mortality.

The presence of one or more CKM comorbidities increases a patient's risk of hospitalization, kidney failure, and mortality, substantially increasing healthcare costs. FARXIGA® provides a particular advance in treating CKD, HF, and T2DM because it, uniquely alongside certain other SGLT2i, can lower blood glucose while also providing cardiorenal benefits, such as reducing the progression of CKD and lowering the rate of cardiovascular (CV) death and hospitalization for heart failure (hHF).

Given that CKD, HF, and T2DM combine to place substantial clinical burden and costs to patients, a cost offset analysis should account for the clinical value and the cost avoidance associated with treatment.

A comprehensive cost offset analysis should include reductions in healthcare resource utilization associated with:

- Hospitalization for Heart Failure
- Urgent HF visits
- Cardiovascular death
- Declining Renal function
- Kidney failure
- Death from renal causes
- Dialysis avoidance

MEDICARE MFP IS INAPPROPRIATE FOR STATE UPL DETERMINATIONS

Fundamentally Different Patient Populations

Finally, Medicare's MDPNP prices are inappropriate as the basis for state UPLs because Medicare serves different patient populations than those affected by state UPLs, including Medicaid beneficiaries and state employee plan members. In addition, there would be a significant administrative burden of operationalizing MFP at a state level. The federal MFP effectuation plan involves a Medicare Transaction Facilitator (MTF) and complex claims and

payment flows between manufacturers and retailers, mechanisms that are not currently contemplated at a state level.

Medicare MFPs reflect:

- **Medicare-specific utilization patterns** in elderly and disabled populations
- **Federal program assumptions** about cost-effectiveness within Medicare's unique benefit structure
- **Medicare Part D formulary dynamics** specific to that program
- **Federal negotiation parameters** established under the Inflation Reduction Act for Medicare's distinct patient population

These factors are not applicable to state employee health plans, Medicaid programs serving diverse age groups, or the commercial insurance markets that would be affected by state UPLs.

The arbitrary decision to rely on MFP as the sole basis for establishing a UPL, without Maryland-specific analysis, appears insufficiently supported. This approach could allow the Board to reach conclusions first and then seek justification after the fact, and it does not appear to meet the legal obligations set forth in the Maryland Code.

CONCLUSION

AstraZeneca values the Board's mission and the opportunity to contribute Maryland-relevant information. Given the Draft UPL Framework's indication of limited savings from an MFP-based UPL, the imminent availability of generics, existing Medicaid protections, and the importance of a Maryland- specific methodology and net-cost analysis, we respectfully urge the Board to discontinue the UPL process for FARXIGA® and focus efforts on addressing systemic issues in the pharmaceutical supply chain that impact patient affordability.

Sincerely,

Geoffrey A. Gallo
Head of Corporate & State Government Affairs

Written Comment
Maryland PDAB Board Meeting
November 17, 2025

Robert Anderson
VP, Corporate Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.

Re: Policy review process: Upper Payment Limit Framework- Jardiance ®

At Boehringer Ingelheim, we recognize the challenges within the U.S. healthcare system—particularly the burden patients face when confronted with high out-of-pocket costs at the pharmacy counter. While we agree that action is needed to make medicines more affordable, *we believe that government-imposed price controls are not the most effective path forward.* Instead, we advocate for solutions that improve patient access while preserving innovation.

During its July 28, 2025, meeting, the Maryland Prescription Drug Affordability Board (PDAB) issued a preliminary determination that Jardiance® creates an "affordability challenge" for the state health care system. The Board subsequently began a review process intended to identify the policies that may address the "drivers" of the purported affordability challenge. As characterized by the Board and staff, a "toolbox" of polices is available to the board during this process, and one potential policy option is to impose an upper payment limit (UPL). The purpose of the November 17th Board Meeting is, in part, to select a framework for setting the Jardiance® UPL.

Boehringer disagrees with the Maryland PDAB's proposed framework for setting a potential UPL using COMAR 14.01.05.06B(5) National Domestic Reference Pricing - Medicare Maximum Fair Price (MFP). We are committed to ensuring that Jardiance® is affordable for all patients in Maryland, but the use of Medicare MFP as the benchmark for setting a potential UPL may inadvertently restrict access for patients. The MFP for Jardiance® was designed for the federal Medicare program; it was never intended to serve and is unsuitable as a benchmark for a state-specific payment limit. MFP does not account for Maryland-specific factors such as local plan design and reimbursement

structures, state economics, or specific patient populations. Applying this proposed framework without taking these local factors into consideration may risk creating misaligned policies negatively impacting patient coverage, affordability, and access.

Jardiance® is already accessible, affordable, and a highly efficacious treatment option for a wide range of patients. The proposed framework fails to recognize Jardiance® is more affordable for Maryland patients than the national average. Maryland has a lower-than-average commercial OOP cost of Jardiance®, which is $44.13, while the national commercial average OOP cost of Jardiance® is $44.41[1]. It also does not take into consideration copay assistance available to patients in the state. There is a 47% commercial utilization rate of Boehringer's copay assistance program for Jardiance®[2], providing reduced copays for Maryland state employees and commercial patients. In these circumstances, instead of improving access to Jardiance®, a UPL could jeopardize that access, discourage life-changing innovation, and cause harmful, unintended consequences.

In seeking to identify the drivers of affordability challenges, the Board should recognize that the current system allows middlemen to demand increasingly large rebates from manufacturers—rebates that most times do not reach patients. These entities prioritize formulary access over patient outcomes, creating access barriers even for proven therapies like Jardiance®. If the potential state-level UPL makes coverage or dispensing financially unsustainable to plans, it may lead to formulary restrictions of Jardiance®, including potential addition of burdensome prior authorization requirements, medically unnecessary utilization management, and unfavorable changes to formulary placement Ultimately, a choice by the Board to follow the suggested framework may result in reduced access for patients or failure of patients benefiting from the framework at the pharmacy counter.

Boehringer stands ready to collaborate with policymakers to bring greater transparency and affordability to the U.S. drug pricing system. We share the goal of ensuring that the value of innovative medicines is consistently recognized, not only for those medicines' impact on individual lives, but for their broader societal benefit. We

[1] IQVIA Longitudinal Access and Adjudication Data (LAAD). Data run September 2024.

[2] MedImpact Healthcare Systems, Inc. MedImpact Prescription Handbook. Maryland Department of Budget and Management. 2023. Accessed July 1, 2025.

urge the Maryland PDAB to consider non-UPL policy options that address affordability while supporting continued medical innovations and sustainability of patient care. Together, we can build a system that works better for patients and transforms lives—one that balances affordability, access, and innovation for generations to come.

Sincerely,

VP, Corporate Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.

1720 W. Division Street
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info@committeetoprotect.org

COMMITTEE TO PROTECT
HEALTH CARE

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

November 12, 2025

Dear Members of the Maryland Prescription Drug Affordability Board,

The Committee to Protect Health Care writes to express our strong support for your continued work on making Jardiance and Farxiga more affordable for local governments and the state government of Maryland. As physicians committed to expanding access to affordable health care, we appreciate your ongoing work to make high-cost drugs more affordable for patients like ours and all Marylanders.

Most recently, the frameworks you have put together on upper payment limits (UPLs) for Jardiance and Farxiga support what doctors witness everyday and know to be true: The climbing costs of these drugs are pricing more and more patients out, putting their health and well-being at risk. As you know, these medications are lifelines for patients dealing with Type 2 diabetes and kidney disease, helping prevent some of the most painful and costly complications such as heart disease and even amputations.

When patients can't afford the drugs they need, such as Farxiga and Jardiance, their manageable conditions can become unmanageable — and quickly. Time often isn't on our side.

Marylanders who can't afford these drugs need relief as soon as possible. Taking swift action to make Jardiance and Farxiga affordable will help state and local government entities, and then our entire communities, have better health outcomes and quality of life. Just as in medicine, the earlier the intervention, the better.

The Committee to Protect Health Care looks forward to continuing to support your work to hold pharmaceutical corporations accountable for their price-gouging, and to set upper payment limits on life-saving drugs so that patients can actually afford them. You have an opportunity to improve the health of countless people in Maryland so that they can access the drugs they need to live, work, learn, and thrive.

Thank you.

Sincerely,

Rob Davidson, MD MPH
Executive Director

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

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Email: jen@tiicann.org

November 11, 2025

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

RE: Policy Proposals/Framework Development

Dear Honorable Members of the Maryland Prescription Drug Affordability Board,

The **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

Preliminary Policy Recommendations are Encouraging

During the last meeting, it was encouraging to see discussion on non-UPL policy recommendations. One of the recommendations the Board suggested for staff to move forward with doing more research on was the WAC Inflation Penalty. In theory, it was presented as manufacturers paying a penalty based on Maryland expenditures resulting from WAC increases that exceed inflation rates. Dependent upon how it is implemented, a WAC inflation penalty could be a back-door mechanism to counteract PBM rebate manipulation by creating an additional disincentive to WAC increases. It is presented as being similar to the Medicaid drug rebate inflation penalty. Thus, it is crucial to ascertain detailed quantitative information and a benefit analysis of how it would affect Maryland's expenditures and translate into savings for patients and benefits for other entities, such as community health centers. Given that this recommendation requires legislation, a very detailed analysis is also necessary to give legislators the tools and incentives to devote resources to drafting legislation.

The patient navigator program was also a promising option for recommendation. Due to insurance plan design, deductibles and coinsurance are financially burdensome for patients in addition to co-pays. Low-income residents would benefit from support in identifying and navigating patient assistance resources, whether manufacturer- or charity-based. It is worth noting that many Federally Qualified Health Centers and pharmacies, when not barred from doing so by their

contracts with Pharmacy Benefit Managers, already offer these types of services for some patients. Implementation of a UPL risks reducing these entities' sustaining revenues and thus threatens their ability to offer non-core services on which their vulnerable populations rely. The staff presentation highlighted savings seen in the Kentucky prescription assistance program; thus, an inquiry into potential Maryland-specific benefits is essential.

Strengthening existing programming, which is already well-positioned to reach vulnerable patient populations, better aligns with the Board's stated priorities regarding this issue.

We also encourage further exploration of the recommendation to delink PBM compensation from rebates, using a flat fee or another mechanism.

Upper Payment Limit Framework Is Concerning

Prior to additional UPL discussion below, the Board must consider that since this Board's last meeting, AstraZeneca has announced a reduced price for Farxiga, set to be implemented beginning January 1. CANN understands the language of the announcement to imply the price reduction as expected to be similar to the announced negotiated price for Medicare, otherwise known as the "maximum fair price" (MFP). The impact this will have on patient access is not yet known. Similarly, the impact on 340B ceiling price or covered entity revenue generation is also not yet known.

For both Farxiga and Jardiance, staff have posted in the meeting materials information regarding the potential rationale for setting UPLs. It is encouraging that staff interpreted options such as therapeutic class reference pricing and international reference pricing as unfavorable, since they are inherently problematic for reasons beyond the resulting estimate being lower than MFP.

However, we are concerned with the way staff have interpreted utilizing a National Domestic Reference Pricing framework to workshop potential UPLs. In terms of national domestic reference pricing, using MFP as a reference does not reflect the specifics of Maryland's patient population and the financial realities of institutions such as community hospitals or safety-net providers. If national domestic reference pricing were to be used as a framework, it would seem more beneficial and accurate to research pricing in a state with structural and patient demographics more aligned with Maryland's status quo, rather than the MFP, which is a view from a national perspective.

Additionally, using MFP for potential UPL settings does not account for providers and pharmacies that would have to acquire medicines at a higher cost, with no remedy for full reimbursement. Under the Medicare MFP program, manufacturers are responsible for making up the difference between the MFP and acquisition costs so that providers and pharmacies are made whole. The state does not have that capability and would require appropriations to provide that support.

Moreover, Maryland does not have the same level of negotiating leverage as CMS, particularly regarding volume. Manufacturers must already contend with losses related to MFP. However, a UPL based on MFP would be a different level of challenge in terms of its effects on insurer activity and PBM-influenced plan design. Additionally, it remains unclear how staff proposes that a UPL will directly lower patients' out-of-pocket costs, as a UPL could restrict negotiations, especially in light of a proposed further supplemental rebate requirement.

We are encouraged that more energy is being directed toward considering non-UPL solutions to improve patient affordability. However, we are concerned with the idea of using MFP as a marker for UPL consideration, as well as advancing UPL as a tool, given the lack of analysis demonstrating that it would be beneficial and not cause harm.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Respectfully submitted,

Ranier Simons
Director of State Policy, PDABs
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

DIABETES PATIENT ADVOCACY COALITION

November 12, 2025

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

RE: PDAB November 17, 2025 Meeting

Dear Members of the Maryland Prescription Drug Affordability Board,

On behalf of the **Diabetes Patient Advocacy Coalition (DPAC),** and the thousands of Marylanders living with diabetes, we are deeply concerned that the Board's upcoming meeting appears focused primarily on reviewing the framework for setting Upper Payment Limits (UPLs), rather than maintaining a balanced approach by also continuing to evaluate non-UPL policy solutions for Farxiga and Jardiance.

While the Board has not yet moved forward with setting UPLs for Farxiga and Jardiance, this meeting was expected to include both a review of the UPL framework and continued evaluation of the non-UPL policy options previously identified by the Board, along with a broader discussion of national models and responses to outstanding questions raised in earlier meetings. However, based on the published agenda, it appears that only the UPL framework will be discussed, without comparable attention to the identified non-UPL policy solutions. This narrowed focus risks missing an important opportunity to meaningfully address patient affordability through **non-UPL policy approaches** that directly reduce out-of-pocket costs and preserve access to life-saving therapies without the risks and disruptions associated with implementing UPLs. As DPAC has emphasized in our previous comments, affordability measures such as UPLs disrupt existing rebate and formulary structures without ensuring patient protections and risk producing the opposite of their intended effect: higher out-of-pocket costs, reduced access, and treatment disruptions.

We again urge the Board to center its actions on patient affordability. UPLs, even when well-intentioned, may lead Pharmacy Benefit Managers (PBMs) and insurers to exclude these drugs from formularies, move them to higher cost-sharing tiers, or impose new prior authorization hurdles, all of which undermine continuity of care and threaten patient health. Farxiga and Jardiance are not optional therapies; they are clinically proven, guideline-recommended treatments that prevent heart failure, kidney disease, and other life-threatening complications for people with type 2 diabetes.

Instead of UPLs, we again call on the Board to prioritize **direct, patient-facing reforms**:

- Require that **rebates and price concessions be passed through at the point of sale**, so patients pay based on the true net price of their medications.
- **De-link PBM compensation** from list prices to remove incentives that drive up costs.
- Adopt **out-of-pocket caps and deductible smoothing** to stabilize patient costs and support adherence.

Every affordability action the Board takes should ensure that Marylanders living with diabetes pay less *at the pharmacy counter* and not through a complex rebate system that benefits intermediaries. While the Board has not yet decided whether to set UPLs for Farxiga and Jardiance, we urge it to proceed with great caution and to prioritize advancing non-UPL policies that directly reduce patient costs while preserving access to these life-saving therapies. At the very least, we respectfully ask that the Board give **equal weight and attention** to evaluating non-UPL policy solutions as it continues consideration of the UPL framework.

DPAC urges the Board to keep patients' voices central in its deliberations. Jardiance and Farxiga are lifesaving therapies, and affordability solutions must protect uninterrupted access for Maryland patients.

Sincerely,

George Huntley

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

EACH PIC COALITION

November 12, 2025

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

RE: Public Comments on Drug Reviews and UPL Framework

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 upcoming review of the proposed upper payment limit (UPL) frameworks for Jardiance and Farxiga and the cost reviews of Ozempic and Trulicity.

Transparency on Supplemental Rebate Structures

As the board begins its discussion of the proposed UPL frameworks for Jardiance and Farxiga, we encourage greater transparency regarding the supplemental rebate component referenced in prior discussions. Although stakeholders were advised that details would be included in the UPL Action Plan, that document does not currently describe how these rebates would operate or what their intended purpose may be. We respectfully ask the board to clarify how such rebates would be designed, administered, and evaluated. Providing this information in advance will allow patients and other stakeholders to offer informed feedback on the potential impact of these mechanisms.

UPLs Do Not Guarantee Savings for Patients

We also 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 Survey shows, insurance barriers, not price alone, are often the real drivers of patient hardship and perceived "unaffordability."

While intended to reduce costs, implementing a UPL without complementary patient protections could worsen the very challenges patients already face. We therefore 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.

Resubmission of Comments on Ozempic and Trulicity

As the board reviews materials on Ozempic and Trulicity, we are resubmitting comments previously sent in September and appreciate the opportunity for those comments to be considered in your review process.

Conclusion

We thank the board for its continued attention to these complex issues and urge a cautious, transparent, and patient-centered approach that safeguards access to care. Our coalition remains available as a resource and partner to ensure that patients' lived experiences meaningfully inform Maryland's affordability work.

Thank you for your consideration and for your commitment to ensuring patients' needs remain at the center of this process.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

EACH PIC COALITION

September 4, 2025

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

RE: Public Comments on Ozempic Dossier

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.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Ozempic. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Centering the Process on Patient Burdens and Affordability

We continue to encourage the board to center cost reviews around the lived experiences of patients and the real-world affordability challenges they face. A review that focuses solely on systemic or payer-level costs risks overlooking the most meaningful aspect of affordability: the context behind affordability concerns, including the impact on people's ability to access and adhere to their prescribed medications.

The compiled dossiers include limited data on patient out-of-pocket costs and how assistance programs impact patient costs. Most importantly, the data only tells a small part of the story. Findings from our recent Patient Experience Survey underscore why patient input is critical to effective affordability reviews. According to patients, affordability is often shaped less by the drug's price and more by insurance barriers, cumulative health costs, and individual life circumstances. Whether patients paid $0–$10 per month or $250 a month, they still reported unaffordability due to insurance denials, utilization management, collective healthcare costs, or other access challenges that largely were unrelated to the retail or net cost of the drug.

We encourage the board to utilize the results of our study as a foundation when determining patient costs in their ongoing reviews, particularly as continued attempts to gain patient insights have proved challenging. Only by starting with patient input can the board appropriately address patient needs. For these reasons, we invite the MD PDAB to collaborate with EACH/PIC and our efforts to relaunch the Patient Experience Survey, utilizing data we collect to ensure patient testimony is included.

Therapeutic Alternatives Are Not Interchangeable

The course of treatment for each patient is as unique as the individual and their disease. Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their

health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Therefore, we urge the board to carefully evaluate the needs of all patients. Failure to do so can result in limiting options within a therapeutic class to only one option - which might not be the right option for many patients.

Protect Patient Access to Care

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Maryland patients.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies.

We encourage the board to take the necessary time and care to ensure this process supports, not disrupts, continuity of care. Patients must not face unintended consequences from policy decisions that limit treatment options or impose additional burdens.

To that end, we strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how they will implement UPLs to identify in advance any potential adverse impact to patients.

We also continue to urge the board to make good on its commitment to consider multiple policy interventions, by utilizing the cost review process to clearly identify the root causes of affordability and access challenges for patients for each drug under review.

Finally, we invite the board to utilize this organization and its EACH and PIC members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as we have the best understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

We appreciate your commitment to this work and offer our coalition as a continued resource in elevating patient voices and informing thoughtful, patient-centered policymaking.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
tiffany@aiarthritis.org

EACH PIC COALITION

Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

EACH PIC COALITION

September 4, 2025

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

RE: Public Comments on Trulicity Dossier

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.

On behalf of our national network of patient organizations, we appreciate the opportunity to provide comments to the board on Trulicity. We continue to urge the board to carefully evaluate the impact implementing UPLs could have on patients in the state and to consider the concerns of patient organizations as they proceed with cost reviews and consideration of UPLs.

Centering the Process on Patient Burdens and Affordability

We continue to encourage the board to center cost reviews around the lived experiences of patients and the real-world affordability challenges they face. A review that focuses solely on systemic or payer-level costs risks overlooking the most meaningful aspect of affordability: the context behind affordability concerns, including the impact on people's ability to access and adhere to their prescribed medications.

The compiled dossiers include limited data on patient out-of-pocket costs and how assistance programs impact patient costs. Most importantly, the data only tells a small part of the story. Findings from our recent Patient Experience Survey underscore why patient input is critical to effective affordability reviews. According to patients, affordability is often shaped less by the drug's price and more by insurance barriers, cumulative health costs, and individual life circumstances. Whether patients paid $0–$10 per month or $250 a month, they still reported unaffordability due to insurance denials, utilization management, collective healthcare costs, or other access challenges that largely were unrelated to the retail or net cost of the drug.

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health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

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We appreciate your commitment to this work and offer our coalition as a continued resource in elevating patient voices and informing thoughtful, patient-centered policymaking.

Sincerely,

Tiffany Westrich-Robertson

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EACH PIC COALITION

Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Testimony PDAB (11/17/2025)

larry zarzecki [redacted] Wed, Nov 12, 2025 at 2:37 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>
Cc: [redacted]

Thank you to the Board for all that has been accomplished in preparation to make high cost drugs more affordable for Marylanders.
I testified for the original 2019 PDAB law, as the $3,000 per month cost to me was devastating.
I strongly urge you, to as quickly as humanly possible
put upper payment limits on what state and local governments pay for Jardiance and Farxiga. As you are aware once you have done this the clock starts ticking so that one year later you can help All Marylanders afford their high cost drugs.
Now on Medicare, I am protected by the new inflation
Reduction Act measures.
Please act now to help Marylanders, that are where I was before Medicare coverage.
Remember drugs don't work if people can't afford them!
Kindly

Larry Zarzecki
Advocate for Marylander's
[redacted]

Sent from Yahoo Mail for iPhone

November 12, 2025

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

TO: Members of the Maryland Prescription Drug Affordability Board

As a physician with decades of experience caring for patients whose families often struggle to access and afford necessary medications, I remain concerned that the Board's process for selecting medications and conducting affordability reviews will leave Maryland patients without access to necessary medications and potentially increase their total health care costs.

I am a board-certified pediatrician whose career focused on caring for young people with chronic or disabling conditions. My primary focus is always ensuring the well-being of my patients, but as a result of your legislative charges, I fear that the Board's analyses and decisions cannot reflect this same mandate.

The Board's narrow approach to measuring cost savings raises concerns that could undermine the entire initiative. If the objective is to create health care financial savings for Maryland, the Board must develop and establish the metrics for comparing pharmaceutical reductions against total healthcare costs. The current framework appears to focus on short-term drug prices without adequate consideration of the implications and total costs down the road. When drug manufacturers proactively lower list prices or offer direct to consumer sales, the Board risks expending years of effort and taxpayer resources pursuing regulatory interventions that market corrections have already rendered obsolete. Further, the currently selected medications, Jardiance and Farxiga, don't just treat diabetes - they also help prevent heart disease and kidney failure. When a single medication influences multiple serious conditions, restricting access based solely on the drug's list price inadequately considers the potential health and financial consequences. There may be substantial additional health care costs as patients could require multiple substitute medications for the other conditions as well as experience complications if their diseases progress. Without plans and adequate resources to track and report both the health and financial outcomes of this decision, reconsidering whether to implement policies that could shift costs from one state budget line item to another would be prudent.

Several states are developing and one is in the process of implementing "prescription drug affordability programs". Maryland risks enacting theoretical and untested approaches other

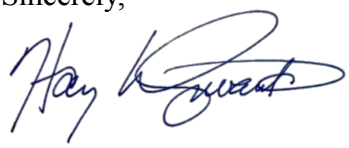
jurisdictions have already refined or are reconsidering. Analyzing and improving upon what has worked (or not) in other states and what challenges have emerged would allow Maryland to avoid repeating preventable and potentially expensive missteps. The Board's current trajectory suggests its policies are being developed in relative isolation rather than leveraging the collective experience of states that have been engaged in this work for several years.

The Board's limited authority continues to raise questions whether its proposed interventions can achieve meaningful cost reductions. The current process focuses exclusively on establishing upper payment limits for state purchases without addressing the fundamental pricing dynamics within the supply chain. For example, how will the Board integrate the current and changing federal proposals on list prices into its recommendations? If the Board believes Maryland has sufficient market leverage to influence drug pricing, why haven't the state's pharmacy benefit managers and health insurers already negotiated better prices?

Everyone shares your goal to lower prescription drug costs, but the current myopic process that only focuses on the drug list prices and not the total cost to patients risks limiting access to essential medications while creating longer term negative health outcomes. Since the Board is unable to address the roles of all participants within the drug pricing and supply ecosystem, I fear your many efforts will be for naught. All clinicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs on a more thoughtful, patient-centered approach. As it stands, however, the Board's actions could inadvertently restrict access to effective cost-saving medications for those Maryland residents who need them the most. We encourage the Board to address the multiple deficiencies and restrictions placed upon it by asking the legislature to consider expanding your ability to develop methods of lowering actual drug costs, not just the list prices of drugs purchased by the State and Marylanders.

Thank you for your attention to this critical issue.

Sincerely,



Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network

November 12, 2025
By Electronic Submission

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

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Re: Materials for Board Meeting on November 17, 2025

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments on the Board's updated cost review dossier for Trulicity® (dulaglutide) (the "Trulicity Dossier") and initial upper payment limit ("UPL") frameworks ("UPL Frameworks") published on the Board's website on November 4, 2025.[1]

Lilly is proud to make Trulicity, a once-weekly injectable prescription medicine for certain patients with type 2 diabetes to improve blood glucose or to reduce the risk of major cardiovascular ("CV") events. Trulicity is widely affordable and accessible, including for patients and health care entities in Maryland. In particular, Lilly highlights the recent announcement that Lilly will offer Trulicity on a direct-to-patient basis at a discount of 50-60% off current list prices. Lilly shares the Board's goal of improving patient outcomes by making effective treatments accessible, but Lilly continues to have serious concerns that the Board's cost review and UPL-setting activities threaten to jeopardize patients' access to vital medicines, including Trulicity.[2] To that end, Lilly urges the Board to take into consideration the concerns and recommendations outlined below in its review of Trulicity and any UPL-setting activities.

I. Trulicity Is Affordable in Maryland

Lilly reiterates that the statutory cost review factors demonstrate Trulicity's affordability across Maryland, including for State health care system entities and other health care entities and patients.[3]

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[1] *See* Board, Trulicity Dossier (Nov. 4, 2025), available here; Board, Farxiga UPL Framework (Nov. 4, 2025), available here; Board, Farxiga UPL Framework Presentation (Nov. 10, 2025), available here; Board, Jardiance UPL Framework (Nov. 4, 2025), available here; Board, Jardiance UPL Framework Presentation (Nov. 10, 2025), available here.

[2] In filing this letter, Lilly expressly reserves all available arguments regarding the legality of the PDAB statute and its implementation, and reasserts and incorporates by reference its prior comments. *See* Letter from Lilly to Board (Sept. 4, 2025); Letter from Lilly to Board (Feb. 10, 2025); Letter from Lilly to Board (Nov. 8, 2024); Letter from Lilly to Board (Aug. 26, 2024); Letter from Lilly to Board (July 17, 2024).

[3] Md. Code, Health-Gen. § 21-2C-09(b). As highlighted in Lilly's prior comments, the Board has not developed a process for methodically and consistently evaluating these factors to assess affordability. *See, e.g.*, Letter from Lilly to Board at 6–8 (Feb. 10, 2025).

- ***Trulicity is affordable for patients in the State health care system.*** Trulicity is unquestionably affordable for Maryland patients. As the Trulicity Dossier reports, most patients in the State and Local Government Employee payor segment pay $50 or less for their prescription.[4] Although the dossier inexplicably omits the Medicaid segment from the patient cost sections, Lilly notes that Medicaid patients who take Trulicity pay an average of $1 per month.[5]

- ***Trulicity is affordable for State health care system entities.*** State health care system entities can already access Trulicity at deeply discounted prices. The Board has recognized current prices for many payors and purchasers are lower than any potential UPL, indicating that Trulicity is already affordable to these entities.

    - ***Medicaid.*** The Maryland State Medical Assistance Program does not face any affordability challenges with Trulicity due to the significant rebates paid under the Medicaid Drug Rebate Program ("MDRP").[6] The Board will not set a UPL that impacts Medicaid Best Price, confirming that the Maryland State Medical Assistance Program is already accessing Trulicity at a low price, inclusive of rebates to account for any wholesale acquisition cost ("WAC") increases that may outpace inflation.[7] Furthermore, Lilly offers supplemental rebates for Trulicity to Maryland and other state Medicaid programs through the Top Dollar Program ("TOP$"), guaranteeing an affordable net unit price for the Maryland State Medical Assistance Program beyond that which is required under the MDRP.

    - ***340B Program.*** Many Maryland health care entities participate in the 340B Program, which is designed to ensure the price offered to 340B entities includes the same total discount as Medicaid, guaranteeing that these entities likewise get the benefit of the Medicaid Best Price (the calculation of which contemplates price increases that exceed the rate of inflation).

    - ***Broader Pricing Trends.*** For those entities that do not receive the Medicaid rebate or 340B price, broader pricing trends for Trulicity and across Lilly's medications demonstrate the affordability of our products. Between 2017 and 2023, the average net price across Lilly's medications as a percentage of list price steadily dropped from 49% to 34%.[8] This downward trend in net pricing reflects Lilly's ongoing efforts to ensure that its medications, including Trulicity, remain affordable in Maryland and elsewhere. Furthermore, Trulicity will lose significant exclusivities

[4] *See* Trulicity Dossier at 57–62.
[5] Based on data licensed from IQVIA: Patient Cost Disclosure ("PCD") for Aug. 2024 to July 2025 reflecting estimates of real-world activity [hereinafter "IQVIA PCD"]. All rights reserved.
[6] The Medicaid rebate formula ensures that state Medicaid programs, including the Maryland State Medical Assistance Program, access the Medicaid Best Price, i.e., the lowest price available to most other purchasers. See Lilly's September 2024 letter for additional discussion on how MDRP rebates absolve the need for a UPL for Medicaid.
[7] Health General Article § 21-2C-13(d) – Prescription Drug Affordability Board – Upper Payment Limit Action Plan at 3 (Sept. 10, 2024) ["UPL Action Plan"], available here; COMAR 14.01.05.02.D.
[8] Lilly, 2024 Sustainability Report at 38 (2025), available here.

in the next few years, and increased competition will further reduce prices in the ordinary course of the pharmaceutical lifecycle.[9]

- ***Trulicity is affordable across health care entities and patients in Maryland.***[10]
    - ***Patient OOP Costs and Access.*** Commercial patients in Maryland pay an average of $21 per month for Trulicity.[11] In general, Maryland patients who take Trulicity pay on average between $1 and $43 per month.[12] Moreover, Trulicity is covered by the vast majority of commercial plans in Maryland.[13]
    - ***Patient Assistance.*** Lilly appreciates the inclusion of additional patient assistance information in the updated Trulicity Dossier.[14] As noted, thousands Trulicity prescriptions filled in Maryland each year receive ample Lilly-provided assistance, resulting in OOP costs of $50 or less for 91% of claims receiving assistance.[15] Patients that qualify for the Trulicity Savings Card pay as little as $25 per month for Trulicity,[16] and Lilly also offers vouchers and electronic point-of-sale benefits that reduce patients' costs for Trulicity.
    - ***Free Medicine.*** Lilly donates medicines to tax-exempt organizations such as the Lilly Cares Foundation which provide Lilly medications for free to qualifying patients. In Maryland, Lilly Cares helped over 2,000 eligible patients access their diabetes medication in 2023, and over 1,700 patients in 2024.[17]
    - ***Direct-to-Patient Option.*** Lilly recently announced an agreement with the U.S. government to expand access to Trulicity and other Lilly medicines and reduce patient costs. Among other measures, Lilly will make Trulicity available through LillyDirect and TrumpRx at a discount of 50-60% off of the list price.[18]
- ***Trulicity brings proven value to health care entities and patients.*** A reasoned assessment of Trulicity's affordability must include meaningful consideration of both its costs and benefits.[19] Diabetes is the most expensive chronic condition in the United States, with over

[9] Lilly, Form 10-K at 28 (Feb. 19, 2025), available here.
[10] Lilly maintains that the Board's current cost reviews must be limited to the "State health care system" entities that could be subject to a UPL under the Board's present authority. *See* Letter from Lilly to Board at 6 (Sept. 4, 2025). We nevertheless offer support for Trulicity's affordability across health care entities and patients in Maryland.
[11] IQVIA PCD.
[12] *Id.*
[13] Data on File with Lilly as of September 3, 2025.
[14] Trulicity Dossier
[15] IQVIA PCD.
[16] Lilly, *Trulicity Savings Card*, available here (last visited Aug. 28, 2025).
[17] Lilly Cares Foundation, 2023 State-Level Results (Mar. 2024), available here; Lilly Cares Foundation, 2024 State-Level Results (Mar. 2025), available here.
[18] Press Release, Lilly, Lilly and U.S. Government Agree to Expand Access to Obesity Medicines to Millions of Americans (Nov. 6, 2025), available here; The White House, Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients (Nov, 6, 2025), available here.
[19] *See* Letter from Lilly to Board at 5 (Sept. 4, 2025).

$6 billion in Maryland annually on direct diabetes expenditures alone.[20] Effective blood glucose management, achieved in part through medication, can significantly reduce the risk of eye disease, kidney disease, CV disease, and other costly conditions.[21] Lilly appreciates that the Trulicity Dossier recognizes the medicine's proven effectiveness,[22] and we urge the Board to account for such value in the cost review process. At a minimum, the Board must meaningfully weigh Trulicity's clinical benefits and cost-saving potential against any affordability concerns. In fact, real-world evidence demonstrates that Trulicity delivers greater and clinically meaningful HbA1c reductions at a lower cost per unit of improvement than basal insulin—highlighting both its clinical and economic value.[23]

- ***The Board must assess Trulicity's affordability holistically.*** Lilly also reiterates that the Board should not rest affordability determinations on narrow data points rather than a complete and accurate picture of Trulicity's affordability. For the reasons outlined in Lilly's prior comments, the Board should *not* find an affordability challenge based on Trulicity's (1) WAC,[24] (2) 90th percentile patient out-of-pocket ("OOP") costs,[25] and (3) gross spending.[26] Although the Board *may* consider some of these factors in the cost review process, its ultimate statutory directive is to identify whether a drug "has led or will lead to affordability challenges," which determination cannot reasonably rest on any of these factors.[27]

[20] Trulicity Dossier at 10; *Health and Economic Benefits of Diabetes Interventions*, CDC (July 11, 2024), available here.
[21] *Health and Economic Benefits of Diabetes Interventions*, CDC (July 11, 2024), available here.
[22] *See* Trulicity Dossier at Exhibit 5B.
[23] Reema Mody, et al., Clinical and Economic Outcomes Among Injection-Naïve Patients with Type 2 Diabetes Initiating Dulaglutide Compared with Basal Insulin in a US Real-World Setting: The DISPEL Study, 9 BMJ Open Diabetes Res. & Care (2019), available here.
[24] Letter from Lilly to Board at 3 (Sept. 4, 2025). As the Board acknowledges, WAC does not "represent the final net cost of the drug" because rebates and other price concessions "can dramatically impact the final 'net cost'" incurred by payors (including state payors). Supply Chain Report – Health General Article § 21-2C-07 at 11 (Sept. 10, 2024) ["Supply Chain Report"], available here. It is unclear how WAC increasing faster than inflation could have "the effect of increasing the cost to the healthcare system" when WAC does not measure the cost to the system (and given the net prices paid by many state purchasers generally accommodate inflation impact, as noted above). July 2025 Meeting Recording at 2:38:10, available here; *see generally, e.g.*, *Harvey v. Marshall*, 389 Md. 243, 302 (2005) ("[A]n agency action nonetheless may be 'arbitrary or capricious' if it is irrationally inconsistent with previous agency decisions.").
[25] Letter from Lilly to Board at 2 (Sept. 4, 2025). Consistent with the PDAB statute and the Board's own regulations, the Board *may* consider the average patient cost-sharing obligation, but nothing authorizes the Board to find an affordability challenge (as it did in its first two cost reviews) based on the 90th percentile OOP costs relative to net costs under an undefined threshold.
[26] Letter from Lilly to Board at 4 (Sept. 4, 2025). Gross spending, like WAC, does not reflect entities' true costs nor the drivers of overall spending and, as such, does not supply a reasoned basis for finding an affordability challenge. With respect to Farxiga and Jardiance, the Board itself concluded that "Gross Spending is High Because these Drugs have High Utilization," due to their "special place in therapy for treating patients with comorbidities, which represents a large portion of patients with diabetes." Board, Cost Review Study Process Preliminary Policy Recommendations at 33 (Sept. 24, 2025), available here.
[27] Md. Code, Health-Gen. § 21-2C-09(b)(2)(i).

II. Substantive and Procedural Considerations for Trulicity's Cost Review

Lilly reiterates that the Board should address substantive and procedural concerns with the cost review process. Lilly continues to believe that price controls such as UPLs are bad policy that harm patients, both by limiting access to medicines and by suppressing the development of new and potentially transformative treatments, and we remain concerned that inadequate standards governing the Board's processes will not mitigate these significant risks.[28] Failure to meaningfully define key terms inhibits meaningful stakeholder input and needlessly amplifies the risk that the Board will ultimately apply its policies in an arbitrary and inconsistent manner in violation of the Maryland Administrative Procedure Act.[29]

These concerns were apparent in the Board's initial cost review discussions, and Lilly urges the Board to adjust its approach before proceeding with additional cost reviews, including of Trulicity. For example, the Board identified affordability challenges in part because total gross spending for Farxiga and Jardiance for state and local governments exceeds 1% and 1.8% of these payors' total prescription drug spending, respectively.[30] But the Board has not explained, among other things, why gross spending is an appropriate metric of affordability; why 1% is the threshold that presents an affordability challenge; or why costs were not weighed against the savings generated by the drugs nor even considered within the context of the number of patients treated.[31] The Board's vague standards neither adequately explain its current decision-making nor provide meaningful guardrails for consistent decision-making going forward, creating unnecessary and excessive risk that the Board would impose a UPL or other policy measure on a medicine that does not actually pose an affordability challenge, threatening the health and lives of patients in Maryland.[32] At a minimum, the Board must clearly explain its reasoning for any determinations rendered with respect to Trulicity.

III. UPL Frameworks

Lilly understands that the Board decided to direct its staff to develop these frameworks as a purely exploratory exercise, and we appreciate Board members' statements that they will not move forward with establishing a UPL without additional, Maryland-specific data supporting the soundness of a UPL policy.[33] Lilly nevertheless strongly cautions the Board against implementing any UPLs in accordance with the initial frameworks advanced for Farxiga and Jardiance.

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[28] *See* Letter from Lilly to Board at 1–2 (Feb. 10, 2025)

[29] *See, e.g.*, *Harvey*, 389 Md. at 302. For example, a cost review's central purpose must be to assess whether a prescription drug presents an "affordability challenge," yet the Board has not meaningfully defined that term. *See* Md. Code, Health-Gen. § 21-2C-09(b)(1). As noted in Lilly's prior comments, the definition of "affordability challenge" set forth in the Board's regulations merely restates statutory language in a circular and ultimately standardless fashion. Letter from Lilly to Board at 6 (Sept. 4, 2025); Letter from Lilly to Board at 7 (Feb. 10, 2025); Letter to Lilly from Board at 6 (Nov. 8, 2024).

[30] *See* Notice of Informational Hearing.

[31] *See generally Md. Dep't of the Env't v. Cnty. Comm'rs*, 465 Md. 169, 201–02 (2019) (explaining that a reviewing court defers to an agency "when the record supports [its] findings and inferences").

[32] *See* Md. Code, Health-Gen. § 21-2C-13(b)(1).

[33] Sept. 2025 Meeting Recording, available here.

Lilly continues to have reservations about the use of Domestic Reference Pricing as a UPL framework for any drug.[34] Any domestic reference UPL should account for any performance requirements that are a condition of that domestic reference UPL being made available to other U.S.-based entities. Otherwise, using such a reference UPL could result in apples-to-oranges comparisons that fail to consider the context in which the reference price is being provided. In other words, a non-arbitrary domestic UPL reference price should focus on similarly situated entities to those state and local government entities that will be the target of UPLs under the PDAB statute.

For these reasons, Lilly also continues to stress that a UPL should not be set at the MFP itself.[35] When Congress enacted the Inflation Reduction Act ("IRA"), it expressly chose to limit the scope of the MFP to the Medicare population, which differs significantly in demographics, age, and diversity from the Maryland patients who would be affected by a UPL. Extension of the MFP to non-Medicare populations by states would fundamentally disrupt the careful balance that Congress struck in enacting the IRA, compromising patient access to and hindering innovation of new and potentially life-saving medicines. In addition to being unsound public policy, use of the MFP would raise serious preemption concerns by expanding the reach of the MFP beyond what Congress ever intended, thereby fundamentally disrupting the structure of the federal scheme and create increasing disincentives to participation in the Medicare program.

Furthermore, as the Board staff's cost estimates show, MFP-based UPLs are unlikely to generate substantial cost savings.[36] Even if UPLs achieve limited savings,, these savings would be offset, in whole or in part, by the costs of implementing the UPL. Payors may also respond to the UPL by implementing benefit design changes that impact patient access, thereby reducing total savings. Additionally, a recent survey of independent pharmacies indicates most are considering not stocking drugs subject to MFPs, creating a further risk to access if a UPL is set at the MFP.[37]

Lilly appreciates the opportunity to comment on the Board's cost review of Trulicity and UPL frameworks and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or need clarifications.

Sincerely,

Cynthia Ransom
Senior Director, Government Pricing & Payer

[34] *See* Letter from Lilly to Board at 11 (Aug. 26, 2024).
[35] *See* Letter from Lilly to Board at 9 (Aug. 26, 2024).
[36] *See* Board, Farxiga UPL Framework at 4–6 (Nov. 4, 2025), available here; Board, Jardiance UPL Framework at 4–5 (Nov. 4, 2025), available here.
[37] National Community Pharmacists Association. Report for Medicare Drug Price Negotiation Program and Financial Health of Pharmacy, available here.

November 11, 2025

TO: Maryland Prescription Drug Affordability Board

FROM: Vincent DeMarco, President, Maryland Health Care For All Coalition

RE: Comments for November 17, 2025 PDAB Board Meeting

On behalf of the over 450 faith, community, labor, business and health care organizations in the Maryland Health Care For All Coalition, I am writing to commend the Maryland Prescription Drug Affordability Board (PDAB) for all the great work you have done as you prepare to make high cost drugs more affordable for state and local governments in Maryland. We have reviewed and applaud your staff for the great work done in preparation for the November 17 meeting on Jardiance, Farxiga, Ozempic and Trulicity. As you know all of these drugs are very high cost and therefore drain the budgets of state and local governments. That is why we strongly urge you to move as quickly as you can to use your upper payment limit authority to cap how much state and local governments must pay for these critically needed medications. As we are sure the prices of these drugs will continue to go up as they have done in the past at a rapid rate, the amount which the upper payment limits will save state and local governments will also increase over time, we think substantially.

We also urge you to move as quickly as you can to set the upper payment limits for Jardiance and Farxiga for state and local governments because, as you know, when you do so, that will start the one year time to begin to run after which you can set upper payment limits to help all Marylanders pursuant to the new legislation which Governor Wes Moore signed into law this past Session of the Maryland General Assembly. Drugs don't work if people can't afford them, and as much as 40 percent of Marylanders have trouble affording their necessary drugs. That is why it is urgent that you set the upper payment limits for Jardiance and Farxiga for state and local governments as soon as possible so that you can soon start helping all Marylanders afford their high cost drugs.

As you know, on October 3, the Colorado Prescription Drug Affordability Board set an upper payment limit on what all Coloradans will pay for the auto immune deficiency drug Enbrel. Advocates have calculated that this will save Coloradans over $32 million per year. We very much look forward to you making similar progress for Marylanders.

Once again, thank you so much for the great work you have done to get to this point and we are here to help in any way we can as you continue this life-saving work.

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NATIONAL **A**CTIVE AND **R**ETIRED **F**EDERAL **E**MPLOYEES
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PAUL K. SCHWARTZ NARFE REGION II VICE-PRESIDENT

November 12, 2025

To: Maryland Prescription Drug Affordability Board

From: Edward Holland, President
Maryland NARFE Federation

Thank you for the opportunity to provide comments on the information provided to the public docket for your November 17, 2025 Board Meeting.

The Maryland National Active and Retired Federal Employees (NARFE) Federation represents the interests of approximately 317,000 Federal annuitants and employees in the state. Maryland NARFE continues to support the work of the PDAB to exercise its authority to cap the costs of drugs purchased by state and local governments, and with the new authority from legislation passed earlier this year, to work toward setting upper payment limits on private plans beginning in 2026, which will bring down drug costs for all Marylanders.

We understand that the PDAB staff has conducted a study, consistent with your regulations, of six prescription drugs (with more detailed study of Jardiance and Farxiga) to allow the Board to determine whether use of the prescription drug product has led or will lead to affordability challenges to the State health care system; or high out-of-pocket costs for patients. If such a determination is made, the Board can establish price caps (Upper Payment Limits or UPLs) on such drugs. The staff looked at the prices negotiated by Medicare for 2026 as the Maximum Fair Price (MFP) for the affected drugs as the maximum price that state and local government health would pay. We agree with the conclusion of our partners at Maryland AARP that "the Medicare MFPs, as the PDAB research points out, may be just the starting point on price relief for patients covered by Medicare, since drug plans may negotiate additional discounts. With this in mind, the

use of the new Medicare-negotiated maximum prices for Jardiance and Farxiga is a very justifiable action that would rapidly help state and local governmental entities in Maryland — and the people they employ and serve."[1]

We urge the Board to adopt the staff's UPL framework for Jardiance and Farxiga to apply to the state and local government health plans in the state, so that those price requirements for the affected prescription drugs to be extended to all Maryland citizens after an additional year, as the law now allows.

Thank you again for the opportunity to provide comments.

[1] Public Comment from Jim Guttman, Maryland AARP, undated, submitted to the Maryland PDAB public docket for the November 2025 Board Meeting.

Value of Care Coalition

November 12, 2025

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

Re: Unintended Consequences of the Medicare "Maximum Fair Price" and the Need for a Concurrent Non-UPL Policy Framework

Dear Members of the Board:

As a broad network of patient, caregiver, and health care provider advocacy organizations, the Value of Care Coalition (VCC) writes to share comments regarding the recently published UPL Frameworks for Farxiga and Jardiance. We recognize the importance of lowering health care costs and appreciate the work of the Board toward that goal.

MFP REFERENCE PRICING DOES NOT SOLVE PATIENT AFFORDABILITY

Despite its name, "Maximum Fair Price" (MFP) is simply a list-price benchmark. It sets a price limit on what the federal government will pay for a medicine, but it does not address the primary drivers of patients' out-of-pocket costs or treatment delays – premiums, deductibles, copays and coinsurance, prior authorization, and step therapy. It also fails to impact broader costs of care such as clinician visits, medical devices, imaging, surgeries, or hospitalization. Focusing on list price alone narrows attention to a single component of a complex health care system and guarantees neither meaningful savings at the pharmacy counter nor timely access to life-changing medicines.

In fact, early federal experience with MFP shows that it has negative impacts on patient cost and patient access:

- **Increased cost:** In 2025, patient out of pocket costs have risen by an average of 32% for the first set of drugs subjected to the MFP as health plans prepare for the shift to MFP pricing.[1]
- **Plan design shifts:** A white paper from the University of Southern California details how Medicare Part D plans are responding to government price caps. The paper notes a "sharp increase in annual deductibles" in 2025 paired with a sharp increase in plans that require co-insurance rather than co-pays, further shifting prescription drug cost burdens onto patients.[2]

[1] Pioneer Institute. Key Findings to Date: The Inflation Reduction Act (IRA). May 2025. https://pioneerinstitute.org/the-inflation-reduction-act-ira-key-findings-to-%20date/
[2] USC Leonard D. Schaeffer institute for Public Policy & Government Service. *Most Medicare Beneficiaries May Pay More for Drugs Under the IRA*. June 2025. https://schaeffer.usc.edu/research/medicare-part-d-drug-costs-ira/

- **2026 trend:** An analysis of 2026 Medicare plans by Avalere shows the trend of shifting costs to patients continues, with most covered drugs being placed on a co-insurance tier. Their review of management for MFP drugs found increased utilization management for some products.[3]
- **Decreased access:** A September 2025 survey by the National Community Pharmacists Association found that nearly one-fifth of independent pharmacies won't carry drugs subjected to Medicare's maximum fair price, and another 67% said they may not.[4]

These are not hypothetical concerns; they are early warning signs of how MFP-based reference pricing plays out in practice.

USING MFP AS A FLOOR FOR UPLs CREATES INCONSISTENCY AND RISK

UPL Frameworks for Farxiga and Jardiance note Maryland's PDAB rule states the Board "shall not set a UPL lower than the Medicare Maximum Fair Price." During the Board's September 2024 meeting, it was explained that this safeguard exists to avoid being a "best price," which could trigger complex rebate and access complications under government programs.

The Framework under consideration for Farxiga and Jardiance notes "most additional frameworks…produced results that are below the Medicare Maximum Fair Price".

This highlights that, even as a floor, the MFP has limits:

- **Scope:** MFP was designed for Medicare and does not translate cleanly to state, commercial, or Medicaid markets.
- **Variation:** It does not account for regional cost differences.
- **Market effects:** As noted above, MFP has already prompted stocking challenges and cost-shifting via benefit redesign.

Most importantly, the Board's principle - that sub-MFP pricing risks unintended consequences - does not vanish when a drug lacks an MFP. Any benchmark that yields a sub-MFP-equivalent price raises the same concerns. While MFP offers a convenient anchor when available, relying on it opportunistically risks inconsistency with the Board's stated principles for products without an MFP.

Recommendation: Before proceeding, revise the UPL Action Plan to establish a consistent, principle-aligned pricing floor applicable across drugs - with or without a published MFP - so the Board does not inadvertently create "best price" or access issues.

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[3] Avalere Health. *Part D Formulary Management Tightens in 2026.* November 2025. https://advisory.avalerehealth.com/insights/part-d-formulary-management-tightens-in-2026

[4] National Community Pharmacists Association. *Independents may opt not to stock MDPNP drugs, NCPA warns CMS.* September 2025. https://ncpa.org/newsroom/qam/2025/09/08/independents-may-opt-not-stock-mdpnp-drugs-ncpa-warns-cms

NON-UPL OPTIONS NEED A CONCRETE PLAN AND TIMELINE

Board discussions have repeatedly emphasized that non-UPL options are available to improve affordability and reduce patient costs. At the September 29 meeting, the Board identified several such options and asked staff to propose an implementation plan. While these options could be positive, staff also noted that many would require action by other agencies or the legislature. This calls into question the long-standing characterization of UPL as only one tool among many available to the PDAB.

The November 17 meeting materials chart a path to setting a UPL but do not provide a corresponding plan for the non-UPL approaches identified in September. This feeds the perception that PDAB is focused on price-setting rather than the broader drivers of patient cost and may erode public confidence in adherence to the Board's own statements and decisions.

Recommendation: Publish alongside any UPL proposal, a specific, time-bound implementation plan for non-UPL strategies (responsible entity, required authority, milestones, and metrics for patient impact).

EVALUATE AND UPDATE THE PRICING FRAMEWORK

The materials before the Board underscore the need to refine current policies and processes. To ensure a comprehensive and consistent approach to affordability the Board should:

- **Advance affordability options in parallel:** Evaluate non-UPL options alongside any UPL proposal, with clear sequencing and measures of success focused on patient out-of-pocket spending and access.
- **Reassess reference points:** Given new evidence about how prescribed reference options interact with MFP, re-evaluate those options for pricing frameworks. Establish a process to prevent inadvertent violations of the Board's pricing principles when a convenient floor (such as MFP) does not exist.
- **Center patient impact:** For every pricing option, require an explicit analysis of expected effects on plan design (deductibles, copays/coinsurance), utilization management, pharmacy stocking, and practical access.

We appreciate the Board's commitment to affordability and the opportunity to provide feedback through public comment.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition