July 23, 2025

Via Electronic Correspondence

Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Drug Affordability Review Process

Dear Chair Mitchell:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Maryland Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing the rising cost of prescription drugs for Maryland patients. As the Board continues to move forward with its affordability review process for Farxiga and Jardiance, we urge it to ensure that all decisions are evidence-based and that patient feedback is meaningfully prioritized and integrated throughout the process.

I. Ensure Accurate and Sufficient Data Interpretation

While we recognize the complexity of conducting affordability reviews, we are concerned that disregarding consumer input and the safeguards designed to protect patients may erode public trust in the Board's work and discourage future engagement. Although the Board has provided opportunities for public comment, we urge that this feedback not only be received but carefully considered in decision-making.

For example, during the Board's March meeting, members expressed frustration with the time-consuming nature of gathering feedback on the first three elements of the cost-review study. Notably the Chair dismissed additional reporting requirements, which are designed to monitor patient access challenges stemming from upper payment limits ("UPLs"), saying he "doesn't care" as "no one reads any of those reports." [1] Comments like these are troubling, particularly from the Chair, as they suggest transparency and accountability measures that are vital to maintaining public essential to maintaining public trust in the Board and ensuring that it fulfills its role in promoting affordability.

Similar concerns have arisen elsewhere. In the April 2025 meeting of the Colorado PDAB, members acknowledged that data submitted by a pharmacy benefit manager (PBM) had been mischaracterized, creating confusion between Medicare and commercial data sets. Although the Board claimed this error would not affect its affordability reviews, it remained unclear to advocates and consumers how this mischaracterized data would not negatively influence the

[1] Maryland Prescription Drug Affordability Board Meeting 03242025, at 1:37, https://www.youtube.com/watch?v=DEhLIYpB8gk&t=2398s.

review processes. By comparison, the Oregon PDAB opted last year to temporarily pause its affordability reviews to refine its criteria and methodologies. This deliberate step reflects an understanding of the novelty and complexity of PDAB processes and a recognition that meaningful drug affordability reforms require careful development and thoughtful implementation.

As such, Aimed Alliance urges the Board to exercise intentionality as it proceeds with the drug affordability review process. Ensuring both the accuracy of data used during the cost review process and the sufficiency of patient participation, including from diverse patient representatives. Moreover, conclusions regarding affordability drawn from an unrepresentative sample could potentially lead to decisions that do not accurately reflect the lived experiences of Maryland patients. Therefore, we urge the Board to ensure its cost reviews prioritize deliberate, evidence-based cost reviews and decision-making.

II. Prioritize the Patient Voice During the Affordability Review Process

We appreciate the Board's commitment to incorporating the patient voice into the cost review process. Patients are the individuals most directly impacted by affordability determinations, yet their perspectives are too often underrepresented in healthcare decision-making. As such, Aimed Alliance urges the Board to not only engage with patients through information surveys and public comment periods, but to also meaningfully integrate and reconcile patient-reported feedback and data with its final affordability determinations. Reconciling decisions with feedback informs consumers of how their information was helpful and encourages consumers to continually engage with these processes.

This will also help ensure that those most affected by these decisions are genuinely represented and increase the likelihood that the Board's actions meaningfully address the prescription drug affordability challenges faced by Maryland patients.

III. Conclusion

In conclusion, we commend the Board for its leadership in refining its methodologies to ensure an effective and transparent process. Aimed Alliance further urges the Board to maintain a thoughtful, evidence-based approach to drug affordability reviews that centers patient experience and utilizes robust patient data.

We look forward to continued engagement as the Board conducts its affordability reviews. If you have any questions or wish to discuss these matters further, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

DIABETES PATIENT ADVOCACY COALITION

July 23, 2025

Maryland Prescription Drug Affordability Board
6 St. Paul Street, Suite 2102
Baltimore, MD 21202

RE: Public Comment on Preliminary Affordability Determinations for Farxiga and Jardiance — Protecting Access for People with Diabetes

Dear Chair Mitchell and Members of the Maryland Prescription Drug Affordability Board,

On behalf of the **Diabetes Patient Access Coalition (DPAC)** and the millions of Americans living with diabetes—including thousands of Marylanders—we submit this comment regarding the Board's upcoming **preliminary affordability determinations for Farxiga and Jardiance** at your July 28 meeting.

We recognize the Board's responsibility to evaluate prescription drug affordability. However, as you make these preliminary determinations, we urge you to ensure that **access to essential diabetes treatments is not compromised in the pursuit of cost containment.**

Farxiga and Jardiance have transformed the standard of care for people with type 2 diabetes, particularly those at risk of heart failure or kidney disease. For many patients, these therapies are critical for preventing complications, reducing hospitalizations, and improving quality of life. Any action that affects how these medications are priced, covered, or accessed could have unintended harmful effects on diabetes management by restricting formulary access managed through Pharmacy Benefit Managers (PBMs).

Upper Payment Limits (UPLs) or similar affordability actions will likely disrupt the rebate contracts between manufacturers and the PBMs who control plan formularies. PBMs have a well established practice of preferring higher priced drugs that come with a higher rebate for preferential formulary placement. A UPL that results in lowering the rebate received by the PBM may result in that drug being excluded from the formulary or being placed on a higher copayment tier to dissuade the patient from using that medication. Either of those easily anticipated moves by the PBM will restrict patient access and raise patient cost even though you are intending to lower the cost.

Another common PBM practice is to place **restrictive prior authorization requirements** on drugs that they want to steer patients away from. Prior authorizations are proven delay tactics and are detrimental to the management of chronic diseases like diabetes. This is especially

frustrating to patients who have been taking the medication for many months or even years and now must get re-approved to continue their successful therapy.

As a coalition dedicated to protecting **patient access to diabetes treatments**, we respectfully urge the Board to:

- Prioritize patient access and continuity of care in all affordability decisions.
- Evaluate how affordability actions may impact access to these therapies specifically for people with diabetes.
- If a drug is preliminarily determined to present an affordability challenge, we recommend that the draft preliminary cost review report advise policymakers to consider non-UPL options, including:
    - requiring insurers and PBMs to ensure any negotiated savings — whether through rebates, discounts, or other price concessions — are passed directly on to patients at the point of care in cases where a patient's cost share is based on the price of the drug. This approach can cut the costs to patients in half as rebates for branded drugs average 48%.[1]
    - requiring that PBM compensation is de-linked from the list price of drugs. This approach will limit future increases in list price (as it will remove incentives to inflate list prices and provide higher rebates to PBMs) and ensure that patients benefit from the lowered list prices. The chart included in the appendix demonstrates how insulin list prices increased from 2012 to 2021 while the net price decreased because of negotiated savings.

These recommendations would be included in the draft report following the Board's preliminary determination and would be subject to public comment before any final determination and adoption of the cost review report.

We also ask the Board to provide meaningful opportunities for patient and community input—both during and after preliminary determinations. We believe the patient's voice must be central to any process that affects how Marylanders access their medications.

DPAC remains committed to working with the Board to ensure that affordability efforts protect the health and well-being of people with diabetes. We welcome the opportunity to support a process that balances affordability with uninterrupted access to life-changing treatments.

Thank you for your commitment to Maryland patients.

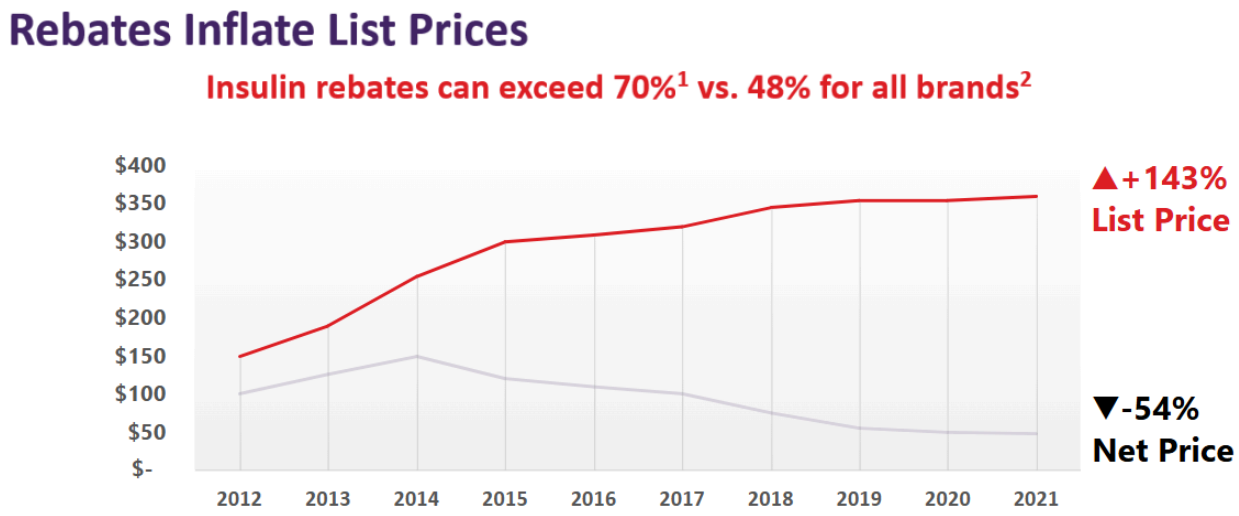
Sincerely,

George Huntley

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

[1] National Bureau of Economic Research working paper 28439 https://www.nber.org/papers/w28439

Appendix



Sources:

1. U.S. Senate Finance Committee on Finance. Insulin: examining the factors driving the rising cost of a century old drug. January 14, 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.
2. Kakani P, Chernew M, Chandra A. Rebates in the pharmaceutical industry: evidence from medicines sold in retail pharmacies in the U.S. March 2020. NBER Working Paper 26846. https://www.nber.org/papers/w26846.
3. Sanofi 2021 Pricing Principles Report. March 3, 2021 https://www.sanofi.us/en/pricing-principles-report. Sanofi is a member of the DLC Industry Advisory Board.

July 23, 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 am deeply concerned that the Board's process for selecting medications and conducting its affordability reviews will leave Maryland patients without access to necessary medications.

I am a board-certified pediatrician and pediatric rheumatologist and spent my career caring for young people with chronic or disabling conditions. Many of my patients, such as those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative and, unfortunately, expensive therapies. 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 prime directives for the Board, as stated by your enabling legislation, are that "… the [cost] review shall determine whether use of the prescription drug product … led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients."

For example, the lack of prioritization of the potential real-world consequences of a UPL is problematic. The creation of the Maximum Fair Price (MFP) within the Inflation Reduction Act has resulted in a 32% increase in out-of-pocket costs to patients.[1] Since a UPL creates a similar situation to the MFP, there is no reason not to expect a similar consequence within Maryland. Similarly, NCPA has reported that many of its member pharmacies will not be carrying medications with a MFP because they cannot afford to do so. This too is likely to occur in Maryland. We also know that insurers and PBMs will likely adjust their formularies if the UPL reduces their profits by shifting such a medication to a higher tier or excluding it from the formulary; how will be the Board respond to such actions and how quickly will you be able to respond?

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[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

Clinicians view the Board's search for "therapeutic alternatives" as inherently misguided and potentially dangerous to patients for whom substitution is not clinically appropriate due to their unique medical situations, genetics and/or treatment needs. The complexities of personalized patient care cannot be considered as these so-called "alternatives" may not be able to address the patient's individual circumstances. Further, unilaterally designating certain medications as "therapeutic alternatives" fundamentally disrupts the clinician's ability to exercise their medical expertise in concert with their patient.

While he dossiers provided for this meeting of Empaglifozin (Jardiance) and Dapagliflozin (Farxiga) are extensive and more transparent than many other PDAB's analyses, they still fail to present clinically relevant alternatives. These drugs are compared to other "treatments," but the analyses do not adequately consider interventions that directly address the full range of approved FDA indications and conditions impacted by these medications. Instead, the comparisons are primarily focused on other diabetes medications with different mechanisms of action and incomplete overlap in therapeutic indications. An easily foreseeable result of your actions could be patients now requiring 2 or 3 drugs to potentially control the multiple medical issues that were previously successfully controlled by one. Will you be tracking these potential financial increases in the State's health care system?

Another area of concern is the treatment comparisons presented lack consideration of the direct and indirect costs of untreated or under-treated diabetes, kidney or cardiovascular disease. While these costs may at times considered be "medical" and not "pharmacological" (and therefore considered within different budgets), the reality is that they will cost the State health system and its residents more than any potential short term drug "savings" might occur from a UPL. These predictable "complications" of being switched to different treatment(s) need to be followed, measured and reported; does the Board have plans and funding to track and report the health and financial outcomes of their decisions? If not, shouldn't it?

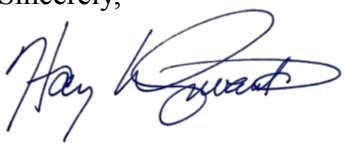
Notably, even the dossiers themselves acknowledge that no true therapeutic equivalents exist for either drug, making any proposed substitution clinically inappropriate and potentially harmful. Throughout the over 80 pages of data analyses, calculations, and other technical details, I did not see meaningful input from the clinicians who prescribe these medications and/or the patients who rely upon them. This disconnect between the data presentation and clinical reality raises significant concerns about the validity and utility of your admittedly extensive review process.

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 with 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

THE BOARD OF GARRETT COUNTY COMMISSIONERS

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Executive Director
Prescription Drug Affordability Board

July 21, 2025

I recently met with the team from the Maryland Citizens' Health Initiative Education Fund and learned of the work of the Maryland Prescription Drug Affordability Board to make high-cost drugs more affordable for state and local governments.

As the County Administrator for Garrett County, I know that prescription drug costs for our county are significant. Making drugs like Farxiga and similar GLP-1 drugs more affordable would improve access and health outcomes.

Thank you for focusing your efforts on GLP-1 class of drugs, drugs that pose affordability challenges for our employees and residents alike.

Thank you for your consideration

Sincerely,

Kevin G. Null