Exhibit 6C-

Written Comments

(Request September 4, 2025)

September 4, 2025

VIA ELECTRONIC MAIL

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

Re: Dossier Comment – OZEMPIC® (semaglutide) and TRULICITY® (dulaglutide)

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations and provide patients and their physicians with actionable diagnostic tools, treat disease and to respond to unmet patient needs. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review").

On behalf of AbbVie Inc., we appreciate the opportunity to submit comments regarding the Board's cost review dossiers for Ozempic® (semaglutide) and Trulicity® (dulaglutide). We write to affirm that all the critiques and concerns detailed in our prior comment letter on the Farxiga® dossier,[1] dated July 3, 2025, are equally and fully applicable to the Ozempic and Trulicity dossiers.

As detailed below, the Ozempic and Trulicity dossiers were prepared by the Board through substantially similar processes and methodologies as the Farxiga dossier. As such, they manifest the same procedural and substantive deficiencies we identified previously. Our principal concerns include:

1. **Process Transparency and Stakeholder Engagement**

[1] https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf

- The Board continues to provide inadequate time for meaningful stakeholder review and public comment. As with the dossiers created for Farxiga and Jardiance, the Ozempic and Trulicity dossiers are lengthy, highly technical documents for which stakeholders had very limited time to review and respond to revisions. This truncated timeline impedes meaningful feedback and undermines confidence in the Board's process.
- Like Farxiga and Jardiance, the Board provides no detailed redlining or documentation of changes between dossier versions, impeding transparency and effective analysis by affected parties.

2. **Data Quality and Source Reliability**
   - All four dossiers for the Phase 1 diabetes drugs exhibit similar deficiencies in vetting data sources, with potential inclusion of incomplete, inconsistent, or incorrectly attributed data (e.g., NDC lists, utilization, and pricing fields with unexplained redactions or ambiguities). This raises concerns regarding the reliability and accuracy of the Board's analyses and conclusions.
   - Documentation on methodologies for weighing and validating data is insufficiently specific, both in general data tables and in calculations of spending, utilization, and budget impact.
3. **Inconsistent or Incomplete Consideration of Statutory Factors**
   - Consistent across the dossiers is a lack of clarity as to how the Board is applying required statutory factors—particularly patient out-of-pocket spending, the impact of patient assistance programs, and cost impacts to state/local entities. For all dossiers, it is unclear how the Board differentiates or prioritizes data relevant to public payers versus the broader commercial market, which risks exceeding statutory authority.
   - The methodology for inclusion and assessment of Health Economics and Outcomes Research (HEOR) and literature is under-described for all dossiers. There is no clear explanation of search strategies, inclusion/exclusion criteria, or weighting of study quality—replicating the transparency gap raised in our comments on the Farxiga dossier.
4. **Stakeholder and Patient Input**
   - Each dossier, including Ozempic and Trulicity, provides only summary statements or spreadsheets regarding public and patient group feedback. There is minimal evidence that stakeholder concerns have been meaningfully incorporated or addressed.
5. **Budget Impact and Real-World Context**

- As with Farxiga and Jardiance, the Board concedes that non-uniform budget data and missing contextual information impede robust assessment of impact on public budgets and patient access. Yet, the dossiers proceed with incomplete analysis rather than taking appropriate steps to obtain reliable data or revise the analytic approach.

* * * *

The OZEMPIC® and TRULICITY® dossiers continue to amplify the significant concerns we have with the Board's process for developing these data compilations, which clearly lack rigor, consistency and thoroughness and thus fall short of representing a drug's full value to patients. The Board is well aware of these concerns through comments and other stakeholder engagement throughout the cost review process but continues to ignore this feedback. Indeed, the Board even acknowledges the flaws in its dossier in public meetings yet fails to take any action in its work product to address them, or to take the additional time needed to address even the concerns raised by the Board's own members.

For all of these reasons, we maintain that the foundational flaws, procedural shortcomings, and substantive analytic gaps outlined in our Farxiga dossier comments remain equally present in the Board's cost review dossiers for both Ozempic and Trulicity. We respectfully urge the Board to revisit its review process, enhance transparency and stakeholder engagement, establish robust data vetting standards, and provide clear, meaningful opportunity for public input prior to making any affordability determinations.

As the PDAB has selected SKYRIZI for the Phase 2 drugs affordability review, AbbVie remains concerned about the dossier preparation process for SKYRIZI. We respectfully request the opportunity to review all SKYRIZI-related materials, including staff-prepared dossiers, prior to any public release. Ensuring both accuracy and the protection of confidential information are our top priorities, and we are committed to collaborating with the Board on these important matters.

Thank you for the opportunity to provide this feedback. Please feel free to contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc.

[redacted] [redacted]

Maryland

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

DOSSIER COMMENT – Ozempic

Kerstin Haskell - WBHT [redacted] > Wed, Aug 27, 2025 at 3:42 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing to share my personal experience with Ozempic and the affordability challenges it presents for patients like me.

My doctor prescribed Ozempic as part of my treatment plan, but the out-of-pocket cost was $1,300 per month. This was simply exorbitant and not sustainable. Because of the price, I was forced to seek the medication through a compounding pharmacy in order to obtain a more affordable version. Even then, the process was burdensome, long, and frustrating.

The cost of Ozempic highlights how patients are bearing an unreasonable financial burden. Drug companies are profiting significantly from the high demand for this medication and its proven effectiveness, while many patients struggle to access it. For those without comprehensive insurance coverage, or for whom this medication is not fully covered, the costs become a barrier to care and can compromise health outcomes.

In my experience, the affordability challenges are real and severe. The high cost of Ozempic does not just strain individuals—it has a broader impact on the healthcare system as patients are forced to delay or alter treatment.

I appreciate the Board's work to examine these issues and strongly encourage action to reduce costs so that patients can access life-changing medications like Ozempic without financial hardship.

Sincerely,

Kerstin Traum Haskell

Anne Arundel County Resident

September 4, 2025

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

TO: Members of the Maryland Prescription Drug Affordability Board

Having reviewed the dossiers for Ozempic and Trulicity, I am providing this information for the Board's review out of significant concern regarding the potential implementation of Upper Payment Limits (UPLs) for these two medications. I applaud the Board in convening these hearings to receive input, information, and opinions from stakeholders to address affordability challenges. Yet I am particularly troubled by what the dossier analysis reveals about the Board's approach to these essential therapies. Your impressive analyses only focus on the drugs' list prices without also assessing the total economic and health patient costs nor the drug pricing and supply ecosystem. Based on our comments in July, many of the concerns we raised about the Board's methodology and approach to evaluating these medications remain unaddressed in the current dossier analysis.

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, the National Community Pharmacists Association has reported that many of its member pharmacies will not be carrying medications with a MFP because they cannot afford to do so.[2] This too is likely to occur in Maryland. We also know that insurers and pharmacy benefit managers 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?

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

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

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

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.

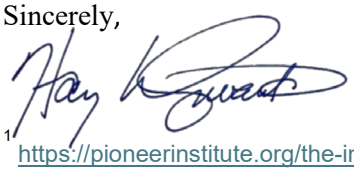
While the dossiers provided for this meeting are extensive and more transparent than many other PDAB’s analyses, they still fail to present clinically relevant alternatives. These drugs are compared to other diabetic “treatments,” but the analyses do not adequately consider interventions that directly 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 and reporting these potential financial increases in the State’s health care system? How will the secondary morbidities treated by theses drugs be measured and reported?

The Board's narrow focus on state budgetary savings fundamentally misrepresents and underestimates the true financial impact of establishing UPLs access to these medications. While the dossier analysis demonstrates potential savings on pharmaceutical line items, it fails to examine the broader fiscal implications for Maryland's overall healthcare expenditures. By concentrating solely on immediate drug costs rather than comprehensive health outcomes, the Board risks creating an illusion of savings while simply shifting expenses from one budget category to another, without considering the significantly higher costs down the road. The Board's approach appears designed to benefit state budget planners and insurance entities in the short term while transferring both financial burdens and health risks to patients who can least afford such shifts. This cost-shifting strategy may yield modest pharmaceutical savings today, but it virtually guarantees exponentially higher healthcare expenditures in future budget cycles when undertreated patients require more intensive and expensive medical interventions.

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 itby 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,



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

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

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

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

[2] https://www.ncpa.co/pdf/2025/ncpa-comments-cms-part-d.pdf

MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
Baltimore, MD 21202
marylandhbe.com

September 4, 2025

Re: MHBE - DOSSIER COMMENT – OZEMPIC (semaglutide)

The Maryland Health Benefit Exchange (MHBE) respectfully submits this comment letter for – Dossiers for prescription drug product Ozempic (semaglutide).

MHBE recognizes the importance of state-wide efforts to address high costs of prescription drug products and health care costs generally. We know that prescription drugs, in particular brand name drugs, are a significant driver of premium costs in the individual market and state costs via the state reinsurance program. A report from the Maryland Health Care Commission determined that **prescription drugs accounted for almost a third (30%) of total per capita spending** for privately insured markets in Maryland in 2020.[1] In an MHBE analysis of 2022 Maryland individual market claims, **brand name drugs accounted for** 21% ($343M) of all claims costs by all enrollees and **27% ($279M) of all claims costs by enrollees in the state reinsurance program (SRP)**.

In the MHBE analysis, Ozempic accounted for a significant portion of total drug claims costs in 2022 in the individual market - **2,077 enrollees received at least one prescription of various formulations of Ozempic**[2], accounting for 2.5% ($8.62M) of brand name prescription drug claims costs in the individual market. Further, Ozempic accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **756 enrollees who received at least one prescription of various formulations of Ozempic** accounted for **1.3% ($3.62M)** of brand name prescription drug claims costs by SRP enrollees.

Lower prices for higher-cost prescription drugs could reduce commercial insurers' per capita spending, putting downward pressure on average monthly premiums, along with out-of-pocket drug costs for consumers. Recent polling by the Kaiser Family Foundation found that more than a quarter of adults taking prescription drugs report difficulty affording their medication, including 40% of those with annual household incomes below $40,000.[3]

Lowering certain prescription drug costs would also potentially decrease costs associated with the reinsurance program, which works to mitigate the impact of high-cost enrollees on premium rate increases in the individual market. Specifically, lower prescription drug costs could reduce the number of individuals whose annual costs exceed the threshold at which reinsurance payments made by the State to an individual's insurer kicks in ($21,000 for plan year 2025),[4] and, for those individuals who reach the threshold, reduce the claims costs that the reinsurance program reimburses.

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[1] Maryland Health Care Commission: Spending and Use Among Maryland's Privately Insured Report, 2020 (2022).
[2] OZEMPIC 2 MG/1.5 ML, 4 MG/3 ML, and 8 MG/3 ML.
[3] Kaiser Family Foundation: Public Opinion on Prescription Drugs and Their Prices (August 2023).
[4] Maryland Health Benefit Exchange: 2025 Reinsurance Parameters (July 2024).

MARYLAND HEALTH BENEFIT EXCHANGE

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For further discussions or questions, please contact Johanna Fabian-Marks, Director of Policy and Plan Management at johanna.fabian-marks@maryland.gov.

Sincerely,

Michele Eberle

Michele Eberle
Executive Director

[redacted] [redacted]

Maryland

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

Dossier Comments Ozempic

1 message

Vinny DeMarco <demarco@mdinitiative.org> Thu, Sep 4, 2025 at 1:23 PM

[redacted]

September 4, 2025

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

The Maryland Health Care for All Coalition (HCFA) is pleased to offer our support for the work the Prescription Drug Affordability Board (PDAB) and its staff are doing to complete the Cost Review Study for Ozempic, including the dossier published ahead of the scheduled September 29 PDAB meeting.

Ozempic is widely used for treating diabetes, heart failure, and chronic kidney disease. Its high cost is a burden on Maryland patients and is a direct contributor to the immense strain that expensive prescription drugs place on our state and local government budgets. Comment submitted by Public Citizen for the January 2025 Board meeting indicated that Ozempic has generated billions in revenue for manufacturers, largely from charging patients in the United States ten times more than in comparable countries.

We have held forums across the state in past years, and routinely heard from patients about their struggle to afford Ozempic.

We know this issue extends beyond the pharmacy counter for patients, as anti-diabetics are the single biggest expenditure for the state health plan, meaning our state and local governments are burdened by the skyrocketing costs of these medications. It is important that the Board acts quickly to establish an upper payment limit for this prescription drug so that taxpayers can begin to save millions of dollars that are essential for other critical services.

Our coalition thanks the PDAB for its great work so far and encourages thoughtful, swift action on this matter. Should the Board and Staff wish to speak to Maryland patients regarding their experiences with Ozempic, we would be happy to connect you with consumers willing to provide feedback.

Vincent DeMarco
Maryland Citizens' Health Initiative
[redacted]

[redacted]

September 4, 2025

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

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

RE: DOSSIER COMMENT- Ozempic®

Dear Members of the Maryland Prescription Drug Affordability Board:

Novo Nordisk, Inc. (NNI) respectfully submits this letter in response to the Maryland Prescription Drug Affordability Board's (PDAB) cost review study dossier for Ozempic®. As a global healthcare company with a 100-year history of innovation, we are committed to preventing, treating, and ultimately curing diabetes, and to improving the lives of those living with serious chronic conditions, including hemophilia, growth disorders, and obesity.

Ozempic®, developed and manufactured by Novo Nordisk, is currently subject to a cost review by the Board. We support the PDAB's efforts to improve patient access and affordability—objectives we wholeheartedly share— but we maintain that the Board's current approach will not translate into meaningful results for patients.

The ongoing changes to the review timeline have made it challenging to provide the comprehensive feedback that such a significant process warrants. Nevertheless, we feel it is important to highlight key issues regarding the development and quality of the dossier, as these concerns raise substantive questions about its validity. If the Board's goal is to achieve an accurate assessment of a drug subject to review, a more rigorous and consistent process will be essential. We offer these comments as constructive feedback and hope they will be carefully considered in the ongoing effort to serve Maryland patients.

The Dossier Contains Several Errors That Undermine Its Accuracy

While PDAB staff have had several months to prepare the cost review study dossier for Ozempic®, there are notable errors in the document regarding the accuracy and completeness of basic information and data. **Our initial concern is the incorrect inclusion of Trulicity® information in the Ozempic® cost review dossier.** This is evidence of content being copied and pasted from the dossier for Trulicity®. For example, on Page 43 under Factor 6.4: "Staff re-

viewed published cost-effectiveness literature in the United States to identify the potential incremental costs associated with the use of *Trulicity (dulaglutide)*," and again on Page 53 under Factor 7.1, literature review: "Staff conducted a literature review using Google Scholar and PubMed for articles using the search term 'Co-payment Adherence *dulaglutide*.'" Such errors may be unintentional, but they highlight broader issues regarding the dossier's reliability, raising concerns about its suitability as a foundation for making affordability determinations. As we explain below, Ozempic is the only drug that treats multiple conditions not addressed together by any other single molecule.

It is critical to underscore the significant issues with the selection of NDC-11s included in the PDAB's cost review for Ozempic®. Strikingly, only **three** of the NDCs presented are actually saleable, whereas the majority identified by the PDAB are discontinued, pertain to other manufacturers, or represent only product inserts. This selective inclusion is not a benign oversight—it fundamentally undermines the validity of the cost data upon which the Board intends to base its affordability determinations. The reliance on non-saleable NDCs raises the risk that the resulting analysis does not accurately capture the costs relevant to Maryland patients. A saleable NDC is not just an abstract identifier; it uniquely designates the "unit of sale"—the specific individual package of a drug that is purchased, stocked, dispensed, and ultimately reaches the patient. By contrast, other NDCs may refer to bulk components, sample packaging, or configurations not reflective of actual market transactions. Therefore, the credibility and utility of the Board's analysis depend on its focus on saleable NDCs, which represent the true point of patient access and expense.

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength	
00169-4132-90	Ozempic	Semaglutide	0.5 MG/1ML	Discontinued
00169-4181-03	Ozempic	Semaglutide	0.5 MG/3ML	Inner Package
00169-4181-90	Ozempic	Semaglutide	0.5 MG/3ML	Sample
00169-4772-90	Ozempic	Semaglutide	2.86 MG/ML	Sample
50090-5138-00	Ozempic	Semaglutide	0.5 MG/1.5ML	Other M'er
50090-5139-00	Ozempic	Semaglutide	1 MG/1.5 ML	Other M'er
70518-2143-00	Ozempic	Semaglutide	2 MG/1.5 ML	Other M'er
00169-4181-97	Ozempic	Semaglutide	0.68 MG/ML	Sample
00169-4132-97	Ozempic	Semaglutide	1.34 MG/ML	Discontinued
00169-4132-11	Ozempic	Semaglutide	2 MG/1.5ML	Discontinued
00169-4132-12	Ozempic	Semaglutide	2 MG/1.5ML	Discontinued
00169-4136-02	Ozempic	Semaglutide	2 MG/1.5ML	Discontinued
00169-4136-11	Ozempic	Semaglutide	2 MG/1.5ML	Discontinued
00169-4181-13	Ozempic	Semaglutide	2 MG/3ML	Saleable
00169-4772-97	Ozempic	Semaglutide	2.68 MG/ML	Sample
00169-4130-01	Ozempic	Semaglutide	4 MG/3ML	Inner Package
00169-4130-13	Ozempic	Semaglutide	4 MG/3ML	Saleable
50090-5949-00	Ozempic	Semaglutide	4 MG/3ML	Other M'er
00169-4772-11	Ozempic	Semaglutide	8 MG/3ML	Inner Package
00169-4772-12	Ozempic	Semaglutide	8 MG/3ML	Saleable
50090-6051-00	Ozempic	Semaglutide	8 MG/3ML	Other M'er

The effectiveness of the PDAB's decision-making is inherently dependent on the quality of its data. It is notable that during its drug selection and cost review process, the PDAB has consistently failed to clearly define how it will assess the accuracy, reliability, and validity of the data sources it references. Furthermore, there has been insufficient detail regarding how the PDAB will restrict its use of data and information from these sources to only those factors specified in statutes and implementing regulations.

The Dossier Does Not Recognize the Transformative Value of Ozempic®

Ozempic® has no therapeutic alternatives, as it offers the only comprehensive patient benefit compared to other drugs within its class and beyond. **Semaglutide treats multiple conditions not addressed together by any other single molecule and is therefore not comparable to any potential alternative treatment(s).** Notably, GLP-1 medications are differentiated by their cardiovascular benefits, which are now a cornerstone in evaluating medicines for type 2 diabetes (T2D). Since 2008, cardiovascular outcomes trials (CVOTs) have been required by regulatory

agencies to ensure T2D drugs do not increase cardiovascular risk. Semaglutide has undergone extensive evaluation through three CVOTs in T2D populations (SUSTAIN-6, PIONEER-6, and SOUL) and one in the overweight/obese population (SELECT), all demonstrating its clear superiority in reducing major adverse cardiovascular events compared to the standard of care.

Furthermore, Ozempic® is the only GLP-1 receptor agonist proven to slow the progression of kidney disease in patients with T2D and chronic kidney disease (CKD).[1] [2] Clinical studies showed a 24% reduction in the risk of kidney failure, kidney disease progression as evidenced by sustained eGFR decline, or kidney or cardiovascular death, compared to placebo. When focusing specifically on kidney events, semaglutide achieved a 21% greater reduction over placebo.

Real-world studies reinforce these outcomes. In one study of T2D and CKD patients with an average age of 65, those treated with weekly semaglutide for 12 months saw albuminuria decrease by over 50% among those with macroalbuminuria—a key marker for CKD.[3] Another study found that weekly semaglutide led to a 4.5-point improvement in estimated glomerular filtration rate (eGFR) and a 1.2% decrease in hemoglobin A1c blood tests after a year of treatment.[4]

Crucially, many of the medications considered by the PDAB as therapeutic alternatives have already failed for patients prior to those patients' being prescribed Ozempic®, making direct comparisons medically inaccurate. For example, older patients with T2D often do not achieve sufficient blood sugar control with metformin, leading to the use of Ozempic®, which brings additional benefits like reduced cardiovascular risk and weight loss. The ability of Ozempic® to prevent costly cardiovascular hospitalizations—including heart attacks and strokes, which can

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[1] Perkovic V, Tuttle KR, Rossing P, Mahaffey KW, Mann JFE, Bakris G, Baeres FMM, Idorn T, Bosch-Traberg H, Lausvig NL, Pratley R. Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes. N Engl J Med [Internet]. 2024 Jul 11 [cited 2025 Feb 11];391(2):109–21. Available from: https://pubmed.ncbi.nlm.nih.gov/38785209; Davies M, Færch L, Jeppesen OK, Pakseresht A, Pedersen SD, Perreault L, Rosenstock J, Shimomura I, Viljoen A, Wadden TA, Lingvay I. Semaglutide 2·4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial. Lancet [Internet]. 2021 Mar 13;397(10278):971–84. Available from: https://pubmed.ncbi.nlm.nih.gov/33667417/

[2] Chu L, Bradley RM, Auerbach P, Abitbol A. Real-world impact of adding a glucagon-like peptide-1 receptor agonist compared with basal insulin on metabolic targets in adults living with type 2 diabetes and chronic kidney disease already treated with a sodium-glucose co-transporter-2 inhibitor: The Impact GLP-1 CKD study. Diabetes Obes Metab [Internet]. 2024 Oct 1; 26(10). Available from: https://pubmed.ncbi.nlm.nih.gov/39113258/

[3] Aviles Bueno B, Soler MJ, Perez-Belmonte L, Jimenez Millan A, Rivas Ruiz F, Garcia De Lucas MD. Semaglutide in type 2 diabetes with chronic kidney disease at high risk progression-real-world clinical practice. Clin Kidney J [Internet]. 2022 Aug 1 [cited 2025 Feb 12];15(8):1593–600. Available from: https://pubmed.ncbi.nlm.nih.gov/35892023/

[4] Data on file. Novo Nordisk.

cost $55,000–$75,000 per event and about $108 billion nationally[5]—is unmatched by drugs such as metformin.

The Dossier Does Not Support Informed Discussions Regarding Affordability Challenges

While the dossier is structured to satisfy statutory requirements, it fails to fully capture the broader market forces actively working to reduce the price of semaglutide. For instance, on August 18th, NNI introduced a new self-pay program for Ozempic®, allowing patients with a prescription to access the medication for $499 per month. This initiative specifically supports T2D patients who lack commercial insurance and who would otherwise pay prices at or above the WAC. Beyond this, NNI offers both a patient assistance program and copay assistance for patients for patients living with TD2. This includes offerings that reduce the price at the pharmacy counter to as little as $25 for a one-month supply of Ozempic® for patients with commercial insurance facing large co-pays. Additionally, the company's Patient Assistance Program (PAP) provides free Ozempic® to patients in need who are uninsured or receive insurance through Medicare and whose household income falls below 400% of the federal poverty line (approximately $120,000 for a family of four).[6] Such measures underscore the essential link between access and affordability, and any meaningful discussion about patient costs must include an examination of insurance benefit design and payer-related barriers.

Where the dossier references patient affordability concerns, these challenges are largely attributed to insurance benefit design—such as copays, coinsurance, and deductibles—rather than the list price of Ozempic® itself. For many patients, out-of-pocket expenses remain modest, with supportive programs available to qualifying individuals. As noted previously, Ozempic® is currently covered by 99 percent of commercial insurance plans in the United States. Since its launch in 2018, the net price—the actual amount Novo Nordisk receives for its medicines—has decreased by approximately 40%. Today, 80 % of U.S. patients with insurance coverage for Ozempic® pay $25 or less per prescription, and 90 percent pay $50 or less. In Maryland specifically, 82.5% of insured patients pay $25 or less. Among Medicaid patients, 99.6% pay less than $5 for Ozempic®.

Diabetes and its comorbidities place a significant financial burden on the US Healthcare System. In 2022 the total direct medical costs associated with those living with diabetes was $307 billion[3]. Of that $307 billion only 8%, or $24.7 billion, was associated with the costs of non-insulin

[5] National Costs for Cardiovascular-Related Hospitalizations and Inpatient Procedures in the United States, 2016 to 2021 Haidar, Amier et al. American Journal of Cardiology, Volume 234, 63 - 70

[6] See NovoCare, Patient Assistance Program, Novo Nordisk, https://www.novocare.com/diabetes/help-with-costs/pap.html.

antidiabetic medications such as Ozempic®. On the other hand, medical expenses such as inpatient hospital care, ER visits, and outpatient office visits accounted $169.5 billion, or 55.2% of the direct medical costs.

It is apparent that any drug therapies able to reduce the prevalence of these expensive and deadly diseases will provide enormous personal, economic, and societal value to individuals, families, and communities across the country. According to a recent analysis by Goldman Sachs increased utilization of GLP-1 medications could add as much as an additional 1% to U.S. gross domestic product over the next four years due to a reduction in health problems like heart attacks, strokes, and diabetes.[7] One study estimates that for each Medicare patient able to receive anti-obesity treatment, the Medicare system would see $6,800 to $7,200 of cost savings over 10 years from reduced usage of ambulatory care and prescription drugs—again, that's per patient.[8] Therefore, apart from the essential human impact, drugs that could meaningfully address the diabetes epidemic also have the potential to be fiscally transformative. That means discussions about the cost of treatment must necessarily start with the value, tangible and intangible, as well as the savings, that GLP-1 medications provide.

* * * *

In closing, it is essential that any evaluation of Ozempic® reflect its transformative impact on patient outcomes, its unmatched therapeutic advantages, and the considerable efforts NNI has undertaken to enhance affordability and access. Discussions about value and cost must consider the broader context—including real-world benefits, evolving insurance coverage, and proactive support programs.

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[7] Matthew Fox, The more Americans who take Ozempic, the faster the US economy could grow, Goldman Sachs says, Business Insider (April 26, 2024), https://www.businessinsider.com/us-economy-faster-growth-ozempic-glp-1-weight-loss-drugs-2024-2.

[8] Fang Chen et al., Ten-year Medicare budget impact of increased coverage for anti-obesity intervention, J. Med. Econ. (Aug. 19, 2019), https://pubmed.ncbi.nlm.nih.gov/31378108/.

September 4, 2025

Maryland Prescription Drug Affordability Board

16900 Science Drive, Suite 112-114

Bowie, MD 20715

Re: SEMAGLUTIDE COST REVIEW DOSSIERS

Dear Members of the Board,

The Partnership to Advance Cardiovascular Health (PACH) is a nonprofit coalition of patients, providers, and advocacy organizations with the shared mission of promoting public policies and practices that drive innovation and enhance outcomes for individuals living with heart disease. Representing 20 member organizations, PACH serves as a collaborative platform to advance reforms at the federal, state, and health plan levels that expand access to care for patients with cardiovascular and related conditions.

Recognizing that high prescription drug costs remain a significant barrier to treatment, we support the Maryland Prescription Drug Affordability Board's (PDAB) commitment to ensuring medications are accessible and affordable *for Maryland residents*. Consistent with our mission to champion both access and innovation in cardiovascular medicine, we write today to provide important context regarding a medication currently under review by the Maryland PDAB.

The Cardiovascular Disease Burden:

Cardiovascular disease remains the leading cause of death in Maryland and the United States.[1] America's progress in decreasing the death rate due to heart disease and stroke has stalled. In fact, the death rate for cardiovascular disease, including heart disease and strokes, has fallen just 4% since 2011 after dropping more than 70% over the prior six decades. What is particularly alarming is that certain age and demographic groups are seeing increases in the rate of cardiovascular-related death. These trends are worse for minority communities, rural communities and those with lower socioeconomic status.[2] Ensuring that patients have access to cardiovascular primary and secondary preventative treatment, as well as promoting innovation and new modalities for treatment, are of the utmost importance to PACH and our partners.

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[1] National Center for Health Statistics. (2025, August 20). *Maryland | Stats of the States*. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/state-stats/states/md.html#cdc_data_surveillance_section_3-leading-causes-of-death

[2] National Center for Chronic Disease Prevention and Health Promotion. (2024, October 24). *Heart disease facts.* Centers for Disease Control and Prevention. https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html#:~:text=In%202023%2C%20919%2C032%20people%20died%20from%20cardiovascular%20disease.,services%2C%20medicines%2C%20and%20lost%20productivity%20due%20to%20death

Innovation in Cardiovascular Disease Management

GLP-1s are some of the most impactful innovations in healthcare today and, while they are known for treating type II diabetes, they also have significant cardiovascular benefits. Semaglutide is FDA approved to be used by patients with type 2 diabetes mellitus and established cardiovascular disease to prevent major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. The specific GLP-1 the board is reviewing is one of only three drugs in their class that are recommended in the American Diabetes Association and American Association of Clinical Endocrinology guidelines to be used as first-line therapy for these cardiovascular events, making it particularly crucial for the cardiovascular patient community.[3]

The link between type II diabetes and cardiovascular disease is significant: type II diabetes increases the odds of having high blood pressure, abnormal cholesterol, and high triglycerides, which all greatly contribute to the risk of developing cardiovascular disease.[4] Individuals diagnosed with diabetes are twice as likely to have a heart attack or stroke.[5]

Why Prevention Matters

Data shows that effectively managing cardiovascular disease not only saves lives but saves money to the healthcare system over time. Harvard economics professor David Cutler published data in Health Affairs that examined why spending growth declined over a decade starting in 2005 in Medicare. He found that nearly "half of the spending slowdown was attributable to slower growth in spending for cardiovascular diseases." He concluded that "roughly half the reduction in major cardiovascular events was attributable to medications controlling cardiovascular risk factors." In conclusion, he states that "medically driven prevention can save money over time."[6]

Dr. Cutler's research suggests that if the PDAB's goal is to save the state money, ensuring greater access to therapies like GLP-1s is of the utmost importance.

Comprehensive Approach to Affordability and Access

Affordability reviews and price capping have already been attempted at the federal level with the passage of the Inflation Reduction Act. In fact, semaglutide has already been selected by the Centers for Medicare and Medicaid Services to be included in the 2025 "Maximum Fair Price"

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[3] Maryland Prescription Drug Affordability Board, Mitchell, Van T., *Ozempic (Semaglutide) - Dossier*, 2025, p. 8.
[4] "Cardiovascular Disease and Diabetes." *www.Heart.Org*, 8 Jan. 2025, www.heart.org/en/health-topics/diabetes/diabetes-complications-and-risks/cardiovascular-disease--diabetes
[5] "Diabetes Can Affect Your Heart." *www.Diabetes.Org*, www.diabetes.org/health-wellness/diabetes-and-yourheart/diabetes-affect-your-heart
[6] Cutler, David. *Explaining the Slowdown in Medical Spending Growth among the Elderly, 1999–2012 | Health Affairs Journal*, www.healthaffairs.org/doi/10.1377/hlthaff.2018.05372.

drug negotiations. The unintended consequences of this law are already impacting Medicare formularies, and more importantly, beneficiaries.

In fact, 7 of the 10 medications first selected for MFP negotiation were cardiometabolic treatments. Data provided by IQVIA and published by the Pioneer Institute shows that *patient out-of-pocket costs* for all seven of these treatments have gone up despite being price capped.[7] In the absence of larger pharmacy benefit reform, market pressures from Medicare redesign and price-negotiation are actually having the opposite effect that federal lawmakers intended.

We believe that this same scenario will translate to the state level. This would mean that Maryland's affordability assessment and upper payment limit designation will limit both access and make medications more unaffordable *for patients.*

Actions to Protect Patients and Increase Affordability and Access

A more holistic approach to address affordability should include reviewing health insurer and pharmacy benefit manager practices like step-therapy and prior authorization protocols, prohibiting spread pricing, requiring pass-through savings directly to patients, and prohibiting co-pay accumulator or "maximizer" programs so that any dollars spent toward a patient's deductible count toward their out-of-pocket limit. Until the medication supply chain is more transparent, we believe efforts to designate medications as unaffordable and promulgating UPLs at the state level will not achieve the board's goal of lowering costs *for patients.* Furthermore, it is crucial to remember that the most effective way to reduce healthcare costs is to prevent serious diseases before they become more dangerous and more expensive.

Thank you for your attention to this matter. We welcome any discussion on this issue and hope that the board will consider our recommendations when making further decisions regarding semaglutide.

Sincerely,

Sarah Hoffman

Senior Director

Partnership to Advance Cardiovascular Health

[7] "Patient Out of Pocket Costs." *Pioneer New England Legal Foundation*, pioneerlegal.org.

September 4, 2025

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

Re: OZEMPIC COST REVIEW DOSSIER

Dear Members of the Board,

On behalf of the Value of Care Coalition (VCC), a broad network of patient, caregiver, and health care provider advocacy organizations, thank you for the opportunity to comment on the recently published cost review dossier for Ozempic. We appreciate the Board's commitment to reviewing aspects of health care affordability in Maryland and value the opportunity to submit these comments.

The dossier offers a solid foundation on clinical indications, disease burden, pricing benchmarks, and utilization. However, two essential dimensions are underdeveloped: (1) the value this therapy provides to patients and clinicians, and (2) the role of insurance benefit design in real-world access and affordability.

First, on value. As outlined in VCC's July 2024 comments (included as Exhibit 6A) discussions of affordability are incomplete without a rigorous assessment of value as defined by the lived experience of patients who benefit from treatment and by clinicians who balance individual risks, comorbidities, and long-term outcomes. In the current dossier, perspectives from those closest to care delivery appear only in exhibits containing a handful of written comments. There is little to no analysis of why clinicians prescribe GLP-1 therapies, why patients choose them, or how outcomes would change without access to them. This gap risks skewing the affordability conversation toward price alone, rather than overall clinical and societal impact.

Second, on benefit design. The dossier's regression analysis appropriately notes that adherence declines as copays or coinsurance rise. Yet it stops short of fully examining how today's health plan benefit structures expose patients to higher costs or restrict access. Specifically, the dossier does not address:

- **Deductibles and Plan Structure**: Large up-front cost spikes that delay treatment initiation.
- **Formulary Tiering**: Placement of GLP-1 receptor agonists on higher tiers that impose substantial cost sharing.

- **Utilization Management:** Prior authorization, step therapy and other tactics – especially consequential for the GLP-1 class – that can delay or deny clinically appropriate care.

Without analyzing the impact of these utilization management levers, affordability discussions risk focusing too narrowly on top-line prices while missing the supply-chain and formulary dynamics that ultimately determine whether a patient can start and stay on guideline-consistent therapy.

Clinicians share these concerns. In a recent survey of specialists – including endocrinologists – in states with active PDABs (presented to the Board on July 28, 2025 via public oral comments), 93% reported insufficient knowledge-sharing between boards and providers. A majority (56%) of endocrinologists indicated they would not switch stable patients to another drug in the same class, while two-thirds expressed concern that PDAB actions could constrain treatment availability and clinical choice.

We were heartened to hear one PDAB Board Member, Dr. Eberechukwu Onukwugha, comment during the July 28 meeting underscoring that benefit design is central to patient access and should be incorporated into future dossiers.[1] We strongly agree.

Recommendations

To strengthen the Ozempic dossier – and future reviews – we respectfully urge the Board to:

1. **Integrate a structured value assessment.** Incorporate patient-reported outcomes, clinician decision-rationales, and scenario analyses of untreated or undertreated disease (e.g., complications avoided, quality-of-life gains, productivity effects).
2. **Add a benefit design impact analysis.** Evaluate how deductibles, coinsurance, tier placement, prior authorization, and step therapy influence initiation, adherence, and outcomes—using Maryland-specific plan designs where possible.
3. **Formally engage frontline stakeholders.** Establish a process for routine input from treating specialists, primary care clinicians, and patients (e.g., advisory panels, roundtables, or structured surveys) to inform both evidence selection and interpretation.
4. **Model real-world access scenarios.** Pair price analyses with access scenarios that reflect typical Maryland formularies and utilization management, quantifying expected changes in adherence and health outcomes.
5. **Report equity implications.** Assess how benefit design and access barriers differentially affect populations experiencing health disparities and propose mitigation strategies.

[1] Maryland Prescription Drug Affordability Board, *July 20 2025 Meeting,* July 2025, https://www.youtube.com/live/wtSm-_A3_kU?si=fG3ZcwoBYif-L_73&t=10393

In sum, affordability determinations require a full view of value and of benefit design — the two elements that most directly shape whether patients receive and maintain effective therapy. Refining the dossier along these lines will better support affordability, equity, and continuity of care for Maryland patients.

Thank you for your consideration.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition