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.

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.

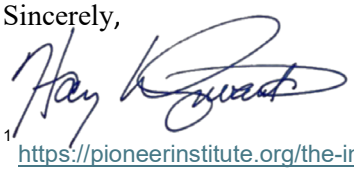
While the dossiers provided for this meeting are extensive and more transparent than many other PDAB’s analyses, they still fail to present clinically relevant alternatives. These drugs are compared to other diabetic “treatments,” but the analyses do not adequately consider interventions that directly 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

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September 4, 2025

By Electronic Submission

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

Re: DOSSIER COMMENT – TRULICITY

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 cost review dossier for Trulicity® (dulaglutide) (the "Trulicity Dossier") published on the Board's website on August 20, 2025.[1]

Lilly is proud to make Trulicity, a once-weekly injectable prescription medicine for certain patients with type 2 diabetes to improve blood sugar (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. 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 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.

I. Trulicity Is Affordable in Maryland

The Board is directed to assess various cost factors to determine whether Trulicity is affordable for state payors and patients.[3] As detailed below, the applicable cost review factors demonstrate Trulicity's affordability across Maryland, including for State health care system entities and other health care entities and patients.

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[1] *See* Board, Trulicity Dossier (Aug. 20, 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 (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 6–8 (Feb. 10, 2025).

A. Trulicity Is Affordable for Patients in the State Health Care System

The primary focus of any cost review by the Board should be on patients, and Trulicity is broadly 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]

The Board should not find an affordability challenge based on Trulicity's 90th percentile patient out-of-pocket ("OOP") costs compared to net costs. The PDAB statute directs the Board to consider "[t]he *average* patient copay or other cost-sharing" and "[t]he impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design."[6] 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.[7] While the Board may issue regulations identifying additional cost review factors, its regulations refer to 90th percentile OOP costs only in comparison to patient incomes and not as a standalone factor, much less a *sufficient* factor for finding an affordability challenge.[8]

B. 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 upper payment limit ("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").[9] 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

[4] *See* Trulicity Dossier 60.
[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] Md. Code, Health-Gen. § 21-2C-09(b)(2) (emphasis added).
[7] As one Board member has acknowledged, the OOP cost data cannot be directly contextualized with information about patients' financial status, such that *affordability* cannot be assessed. July 2025 Meeting Recording 2:47:52. The dossier also entirely fails to identify the drivers of the purportedly "disproportionate" 90th percentile costs.
[8] Md. Code, Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05.C(1)(g)(vi) (listing as factor "[t]he mean, median, and 90th percentile out-of-pocket costs per patient *compared to State incomes*" (emphasis added)).
[9] 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.

("WAC") increases that may outpace inflation.[10] 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%.[11] The increase in average net price as a percentage of list price to 40% in 2024 was a direct result of actions Lilly took to improve patient access, including lowering the list price of our most commonly used insulins by 70%, and paying lower rebates.[12] 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 in the next few years, and increased competition will further reduce prices in the ordinary course of the pharmaceutical lifecycle.[13]

The Board should not identify an affordability challenge based on Trulicity's WAC.[14] Although the Board may consider WAC 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 WAC.[15] 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).[16] It is unclear how WAC increasing faster than inflation could have "the effect of increasing the cost to

[10] Health General Article § 21-2C-13(d) – Prescription Drug Affordability Board – Upper Payment Limit Action Plan 3 (Sept. 10, 2024) ["UPL Action Plan"], available here; COMAR 14.01.05.02.D.
[11] Lilly, 2024 Sustainability Report 38 (2025), available here.
[12] *Id.* For example, Lilly reduced the list price of insulin lispro to $25 per vial. *Id.*
[13] Lilly, Form 10-K at 28 (Feb. 19, 2025), available here.
[14] *See* Board, Notice of Informational Hearing 2 (Aug. 19, 2025) ["Notice of Informational Hearing"], available here.
[15] Md. Code, Health-Gen. § 21-2C-09(b)(2)(i); *see Md. Off. of People's Couns. v. Md. Pub. Serv. Comm'n*, 461 Md. 380, 399–40 (2018) (explaining that an agency may not exercise discretion "unreasonably or without a rational basis" and reviewing courts "may look for consistency with the policy goals stated in the pertinent statutes or regulations").
[16] Supply Chain Report – Health General Article § 21-2C-07 at 11 (Sept. 10, 2024) ["Supply Chain Report"], available here.

the healthcare system" when WAC does not measure the cost to the system[17] (and given the net prices paid by many state purchasers generally accommodate inflation impact, as noted above). Similarly, ***the Board should not identify an affordability challenge based on Trulicity's percentage of gross prescription drug spending***.[18] Gross spending, like WAC, does not reflect entities' true financial circumstances and, as such, does not supply a reasoned basis for finding an affordability challenge.[19] For example, a drug could comprise a substantial portion of a payor's total spending due to high utilization simply because the drug is highly effective at treating a widespread condition. This should not reasonably be deemed to present an affordability challenge unless that portion of total drug spending is inappropriate for its utilization and value.

C. Trulicity Is Affordable Across Health Care Entities and Patients in Maryland

Lilly maintains, as discussed further below, 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. We nevertheless offer the following support for Trulicity's affordability across health care entities and patients in Maryland, in addition to the data provided above:

- ***Patient OOP Costs and Access.*** Commercial patients in Maryland pay an average of $21 per month for Trulicity.[20] In general, Maryland patients who take Trulicity pay on average between $1 and $43 per month.[21] Moreover, Trulicity is covered by the vast majority of commercial plans in Maryland.[22]

- ***Patient Assistance.*** The Trulicity Savings Card program helps reduce patient OOP costs for commercially insured patients, including those covered by health benefit plans making payments on behalf of a unit of state or local government. Patients that qualify for the Trulicity Savings Card pay as little as $25 per month for Trulicity.[23] Lilly also offers vouchers and electronic point-of-sale benefits that reduce patients' costs for Trulicity.

[17] July 2025 Meeting Recording 2:38:10; *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."). Lilly continues to urge the Board to focus on net costs to assess affordability in accordance with its statutory purpose. *See* Letter from Lilly to Board 7 (Jan. 10, 2025); Letter from Lilly to Board 6, 12 (Aug. 26, 2024).
[18] *See* Notice of Informational Hearing 2.
[19] *See Md. Off of People's Couns.*, 461 Md. at 399. Board members commented that 1% or more represents a "significant" portion of drug spend but did not explain how it determined that threshold nor make any attempt to contextualize that spending. July 2025 Meeting Recording 2:42:19. It is not clear that the Board even cross-referenced these percentages to patient counts much less weighed the data against the burden of disease, reductions in health care expenditures, or other relevant factors. One Board member noted the drugs' effectiveness, but there was no meaningful discussion of how the data combine to impact affordability. *See* July 2025 Meeting Recording 2:50:25. Presumably, the threshold at which the portion of total spending indicates an affordability challenge differs based on the particular medicine under review, but it is not evident how the Board is taking these considerations into account, if at all.
[20] IQVIA PCD.
[21] *Id.*
[22] Data on File with Lilly as of September 3, 2025.
[23] Lilly, *Trulicity Savings Card*, available here (last visited Aug. 28, 2025).

Between January 2023 and July 2025, 13,980 Trulicity prescriptions filled in Maryland received Lilly-provided assistance. About 83% of those claims reached an OOP cost of between $25 and $30, with OOP costs of $50 or less for 91% of claims.[24]

- ***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.[25]

D. 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. Diabetes is the most expensive chronic condition in the United States, with over $6 billion in Maryland annually on direct diabetes expenditures alone.[26] 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.[27] Trulicity's affordability is also a reflection of the value that it offers to health care system entities and their patients. Trulicity is a once-weekly injectable prescription medicine for individuals 10 years of age and older with type 2 diabetes that is used along with diet and exercise to improve blood glucose.[28] Trulicity is also used to reduce the risk of major CV events such as death, heart attack, or stroke in adults with type 2 diabetes who have heart disease or multiple CV risk factors.[29] Lilly appreciates that the Trulicity Dossier recognizes the medicine's proven effectiveness,[30] 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.[31]

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[24] Data on file with Lilly.
[25] Lilly Cares Foundation, 2023 State-Level Results (Mar. 2024), available here; Lilly Cares Foundation, 2024 State-Level Results (Mar. 2025), available here.
[26] Trulicity Dossier 10; *Health and Economic Benefits of Diabetes Interventions*, CDC (July 11, 2024), available here.
[27] *Health and Economic Benefits of Diabetes Interventions*, CDC (July 11, 2024), available here.
[28] *See* Trulicity Prescribing Information (May 2025), available here.
[29] Trulicity is the only glucagon-like peptide-1 ("GLP-1") receptor agonist that combines powerful A1C reduction across 4 doses with proven CV benefit in both primary and secondary prevention patients, simply delivered. Trulicity acts like the natural human hormone, GLP-1, helping the body do what it is supposed to do naturally: reduce hepatic glucose production, slow gastric emptying, and release glucose-dependent insulin. Studies have demonstrated Trulicity's effectiveness at improving outcomes for patients with type 2 diabetes and reducing the risk of CV events, which is particularly important given that type 2 diabetes patients are at higher risk of heart disease. Trulicity's affordability extends beyond its price—it delivers substantial value by improving quality of life and reducing the need for costly medical interventions.
[30] *See* Trulicity Dossier Exhibit 5B.
[31] Mody R, Huang Q, Yu M, 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. BMJ Open Diab Res Care 2019;7:e000884. doi:10.1136/bmjdrc-2019-000884

II. Substantive and Procedural Concerns Undermine the Cost Review Process

A. Current Cost Reviews Are Statutorily Limited to State Payors and Purchasers

Although Lilly has included comments here regarding Trulicity's affordability for non-State health care entities and their patients, we believe the Board is required to focus only on the "State health care system" entities whose pharmaceutical expenditures can be subject to a UPL and their patients.[32] It is neither logical nor consistent with the PDAB statute to evaluate affordability from the perspective other entities, such as private health plans or other private purchasers for which a UPL would have no bearing. Recent amendments to the PDAB statute do not alter this constraint on the pending cost reviews. Those amendments potentially expand the Board's UPL-setting authority *in the future*, but such expansion depends on events that have yet to occur.[33] Unless and until the predicate events occur, the Board lacks authority to set UPLs for non-state entities and, as such, lacks authority to assess affordability from the perspective of entities for which it may apply not a UPL. For all of these reasons, the cost review process designed for the Board's current UPL authority is an inappropriate framework for assessing affordability more broadly.

B. Lilly's Substantive and Procedural Concerns Remain Unaddressed

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.[34] These shortcomings become ever-more apparent as the Board attempts to apply its vague standards. 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.[35]

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[32] *See* Md. Code, Health-Gen. §§ 21-2C-13(a), 21-2C-14(a) (limiting UPLs to transactions involving certain state or local government entities); *see also* UPL Action Plan 7 ("Board staff may analyze the contextual issues related to the driver(s) of the affordability challenge, the ability of a UPL to address these issues, the relevant regulatory criteria, and the use of the drugs by Eligible Governmental Entities.").

[33] Once the bill is effective October 1, 2025, the provisions potentially expanding the Board's UPL authority depend on the Board setting two UPLs under the current UPL regime, each UPL being in effect for one year, and the Board notifying the Department of Legislative Services by September 30, 2030 that such conditions are met, or the provisions become null and void. S.B. 357 § 3 (2025), available here. The Board is at least several months away from setting a UPL, given the required steps and comment periods within the policy review and UPL-setting processes. *See* UPL Action Plan 2–3, 15–16. And even if the conditions are met by the deadline, the amendments do not confer expanded authority unless and until the Board, among other things, consults with the Stakeholder Council to make a formal determination that "it is in the best interest of the State" to establish an expanded UPL-setting process. S.B. 357 § 1.

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

[35] *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 7 (Feb. 10, 2025); Letter to Lilly from Board 6 (Nov. 8, 2024).

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.[36] As noted, the Board's preliminary affordability determinations for Farxiga® and Jardiance® rested on isolated data points untethered from any ascertainable governing principle. For example, the Board identified affordability challenges in part because total gross spending for these medicines for state and local governments exceeds 1% and 1.8% of these payors' total prescription drug spending, respectively.[37] 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.[38] 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.[39]

C. The Dossier Data Are Unreliable and Incomplete for Assessing Affordability

Lilly cautions the Board against basing its affordability determinations on certain data that raise reliability and comparability concerns and, as such, do not facilitate sound and principled agency decision-making. For example:

- There are inherent shortcomings in relying on prescription claims data. The Board aims to understand the *drivers* of affordability challenges, but claims data are inherently limited, showing trends in utilization at a specific moment in time and excluding uninsured patients.[40] In addition, claims data frequently are inaccurate with respect to patient OOP costs, because secondary insurance or patient assistance programs that further reduce patient cost-sharing are not reflected.[41] Claims data therefore do not facilitate the identification of the drivers of affordability challenges.
- The Trulicity Dossier also emphasizes inappropriate data points in potentially misleading ways. For example, the dossier focuses on "total gross spending," but gross spending is not

[36] *See, e.g.*, *Harvey*, 389 Md. at 302.
[37] *See* Notice of Informational Hearing.
[38] *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"). As other examples, the Board determined that the change in each drug's WAC over time is "substantially larger" than the rate of inflation, and that certain patient OOP costs are "disproportionate" to the net cost paid by payors.
[39] *See* Md. Code, Health-Gen. § 21-2C-13(b)(1).
[40] The Board's policy review processes contemplate that the cost review will have already identified the drivers to be addressed. *See, e.g.*, UPL Action Plan 6 (explaining that policy review begins by "confirm[ing] . . . the drivers and market failures causing the affordability challenge phenomena"). While Lilly appreciates the attempts to assess how benefit design impacts patient access, we agree with Board members that little can be gained from simply comparing patient OOP costs to utilization when so many variables are at play. *See* July 2025 Meeting Recording 2:53:25.
[41] *See, e.g.*, Luke Zarzecki, *Maryland PDAB Dossiers for Ozempic, Trulicity Accepting Comments*, Inside Health Policy (Aug. 29, 2025) (indicating the Board has "no way to validate" true OOP costs).

a reasonable affordability metric as it reflects neither actual spending nor patient OOP costs.[42]

- Furthermore, the Trulicity Dossier presents information in ways that fail to facilitate "apples-to-apples" comparisons. For example, metrics are broken down by NDCs that represent different quantities or number of days' supplies, are used by different numbers of Maryland patients, or differ in other important ways that the dossier fails to contextualize.[43]

D. Non-Saleable Trulicity NDCs Should Be Removed from the NDC List

Lilly also remains concerned that certain Trulicity NDCs continue to be erroneously included in the list of NDCs subject to the cost review (the "NDC List").[44] The NDC List includes NDCs not marketed in Maryland which therefore should not be considered in the cost review. The Trulicity Dossier misleadingly suggests that some of these NDCs lack published data due to low sample size when, in reality, it is because these NDCs are not available for sale at all.[45] Lilly refers the Board to its prior letter for a complete list of NDCs that should be removed from the NDC List along with comments on the basis for their removal.[46]

* * *

Lilly appreciates the opportunity to comment on the Board's cost review of Trulicity 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

Cynthia Ransom
Senior Director, Government Pricing & Payer

[42] *See* Supply Chain Report 11, 26. Further, fixating on total spending ignores context like the overall disease burden and the costlier health care expenses, such as hospitalization, that effective prescription medications can help avoid.
[43] The raw utilization data do not allow the Board to draw meaningful conclusions, e.g., average per-patient gross spending can be calculated but requires the reader to perform that additional step. These issues remain unaddressed despite Board members in prior cost reviews asking staff to revise the format to address these issues for cost reviews.
[44] *See* Letter from Lilly to Board 5–6 (Sept. 2024); Trulicity Dossier 5.
[45] *See* Trulicity Dossier 21–23.
[46] Letter from Lilly to Board (Sept. 2024).

MARYLAND HEALTH BENEFIT EXCHANGE

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

September 4, 2025

Re: MHBE - DOSSIER COMMENT – TRULICITY (dulaglutide)

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

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 2022 MHBE analysis, Trulicity accounted for a significant portion of total drug claims costs in the individual market - **1,915 enrollees received at least one prescription of various formulations of Trulicity**[2], accounting for 2.6% ($8.95M) alone of brand name prescription drug claims costs in the individual market. Further, Trulicity accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **749 enrollees who received at least one prescription of various formulations of Trulicity** accounted for **1.5% ($4.06M)** alone 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] TRULICITY 0.75 MG/0.5 ML, 1.5 MG/0.5 ML, 3 MG, /0.5 ML and 4.5MG/0.5 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. Trulicity

1 message

Vinny DeMarco <demarco@mdinitiative.org> Thu, Sep 4, 2025 at 1:27 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 Trulicity, including the dossier published ahead of the scheduled September 29 PDAB meeting.

Trulicity is widely used for treating diabetes and heart failure. 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 Trulicity 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 Trulicity.

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 Trulicity, we would be happy to connect you with consumers willing to provide feedback.

Vincent DeMarco
Maryland Citizens' Health Initiative
[redacted]

[redacted]

ELECTRONIC SUBMISSION

September 4, 2025

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

Subject: Dossier Comment-Trulicity

Dear Chair Mitchell:

The National Minority Quality Forum (NMQF) is a 501(c)(3) not-for-profit research and advocacy organization based in Washington, DC. The mission of NMQF is to reduce patient risk by assuring optimal care for all. Our vision is an American health services research, delivery and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life.

NMQF is committed to ensuring equitable access to beneficial treatment and care for Marylanders and communities nationwide. We are proactive, focused and strategic in identifying issues and opportunities to advance our vision. Our engagements are framed by a comprehensive strategy that addresses the fundamental challenge that contemporary healthcare policy enables and perpetuates systemic barriers to optimal health outcomes, particularly in marginalized and underserved population cohorts and geographic areas.

The intersecting, often interwoven efforts to reduce the costs of prescription drugs, are one such issue. The costs of healthcare, including but not limited to prescription drugs, are an appropriate component of health system redesign efforts. NMQF is concerned, however, that a singular focus on administrative interventions to impose reductions in a state's payments for prescription drugs will trigger changes in coverage and prescribing that will redound negatively to patient access and compliance, to health outcomes, and to the sustainability of the health systems that exist to serve them.

As stated on your website, the Maryland Prescription Drug Affordability Board (PDAB) is an independent unit of state government tasked with protecting Marylanders and the Maryland health care system from the high costs of prescription drug products. One of the tools available to you is establishing Upper Payment Limits for drugs that have led or will lead to affordability challenges. The National Minority Quality Forum is concerned about the affordability of all care. But those efforts cannot take priority over protecting the lives and health of the individuals the system was created to serve.

Ensuring the affordability of high quality, efficacious medications is essential to the elimination of inequities in health care and outcomes. This affordability, however, must not be effectuated by promulgating public policy that increases the health and financial costs to vulnerable populations and communities in Maryland, particularly rural, Black and brown communities who are reliant upon an equity-centric public policy construct. Price setting policies that confound access to care are a barrier to inclusion in data collection and investment in research efforts that improve the quality of care for historically excluded populations.

Thank you for the opportunity to comment. The National Minority Quality Forum would welcome an opportunity to partner with the State of Maryland to explore effective and sustainable policy avenues to improving the quality and outcomes of care for all Marylanders.

Please direct your questions to Gretchen C. Wartman, NMQF Vice President for Policy and Program (gwartman@nmqf.org).

Sincerely,

Gary A. Puckrein, PhD
President and Chief Executive Officer

September 4, 2025

Maryland Prescription Drug Affordability Board

16900 Science Drive, Suite 112-114

Bowie, MD 20715

Re: DULAGLUTIDE 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. Dulaglutide 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, 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

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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.

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 dulaglutide.

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: TRULICITY 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 Trulicity. 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 Trulicity 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