abbvie

June 1, 2026

VIA ELECTRONIC MAIL

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
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Re: Comments on Proposed Revisions to COMAR 14.01.04

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie") appreciates the opportunity to provide comments on the Maryland Prescription Drug Affordability Board's (the "Board's") proposed revisions to COMAR 14.01.04 published on May 1, 2026 governing the Board's cost review study process (the "Draft Regulations").[1] While the Draft Regulations expand the categories of information the Board may consider in connection with its cost review study processes, they fail to cure or even attempt to address fundamental legal and procedural deficiencies in the Board's current framework including, among other things, significant concerns regarding transparency, analytical rigor, and the ability of stakeholders to meaningfully engage in the cost review study process. These deficiencies have already manifested in the Board's cost review activities—including its selection of SKYRIZI®—and, if not addressed, will continue to produce decisions by the Board that lack a rational basis and are vulnerable to legal challenge.

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AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, and neuroscience. 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. 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 is the manufacturer of SKYRIZI® (risankizumab-rzaa), which is currently subject to the Board's cost review study process.

[1] *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 5/1/2026)," at https://pdab.maryland.gov/Pages/proposed-regs.aspx ("Amendments to COMAR 14.01.04 – Cost Review Study Process") (last visited May 31, 2026). Please note that AbbVie intends to comment separately on the Board's proposed revisions to COMAR 14.01.04.01 ("Cost Review Study Process – Circumstances Under Which Use of a Drug May Create an Affordability Challenge") published on May 27, 2026 by the applicable June 26, 2026 deadline. *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (posted May 27, 2026), at https://pdab.maryland.gov/Pages/proposed-regs.aspx (last visited May 31, 2026).

AbbVie has actively participated in the Board's proceedings, including submitting extensive data and analysis regarding SKYRIZI.[2] Based on that experience, the Company is deeply concerned that the Draft Regulations fail to remedy fundamental legal deficiencies that have already manifested in the Board's cost review activities. As currently structured, the Board's process raises serious concerns under the Maryland Administrative Procedure Act ("APA"), principles of due process, and the Board's statutory authority under Md. Code, Health–Gen. §§ 21-2C-01, *et seq*. Unless these deficiencies are addressed—which the Draft Regulations do not do—the Board's actions, including those affecting SKYRIZI, risk being unsupported by substantial evidence, lack a rational basis, and therefore are arbitrary and capricious as a matter of law.

As an initial matter, we continue to have concerns with the clear trend in the administrative record of the Board's highly variable and inconsistent timelines across processes, particularly how it affects the ability of stakeholders to meaningfully participate in the process, as required by the Maryland APA. Whereas earlier process stages allowed longer input (*e.g.*, the response period for the Board's early-stage data requests typically ranged from 30–60 days), the Board has only been allowing stakeholders periods of 7 to 11 business days to comment on final-stage analytical documents. In addition, the Board has frequently issued multiple, overlapping comment requests with aligned or near-aligned deadlines, requiring stakeholders to respond to numerous complex documents concurrently. To date this year, *e.g.*, the Board has issued several staggered but overlapping regulatory actions and associated comment periods—March 16–30, 2026: FARXIGA®/JARDIANCE® UPL regulations (with a comment period of approximately 11 business days); April 22–May 1, 2026: OZEMPIC® cost review study materials (with a comment

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[2] *See, e.g.*, AbbVie's Comments on the Board's Dossier for FARXIGA® (July 3, 2025), at https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's Proposed UPL Regulations (February 10, 2025), at https://pdab.maryland.gov/Documents/comments/2025/January%2010%2c%202025%20Register%20Comment%20Packet.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's Proposed Amended Maryland Prescription Drug Affordability Board Cost Review Regulations (December 2, 2024), at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's Proposed Regulations Issued October 28, 2024 (November 8, 2024), at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf (last visited May 31, 2026); AbbVie's Written Testimony to Maryland Legislative Policy Committee (October 18, 2024), at https://mgaleg.maryland.gov/meeting_material/2024/lpc%20-%20133746007389905217%20-%20All%20Meeting%20Materials.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's Draft UPL Action Plan (August 26, 2024), at https://pdab.maryland.gov/Documents/reports/UPL%20Final%20Comment%20Packet%20%281%29.pdf (last visited May 31, 2026); AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf (last visited May 31, 2026); AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf (last visited May 31, 2026); AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf (last visited May 31, 2026).

period of approximately 8 business days); and May 1–June 1, 2026: COMAR revisions (with a comment period of approximately 22 business days; significantly, the Board initially set a comment period of only 6 business days, but subsequently extended it in response to stakeholder requests which emphasized, among other things, the breadth and depth of the proposed changes). This is just one set of examples of the Board's pattern of issuing continuous rolling deadlines and failure to consolidate related activities which, in turn, requires stakeholders to respond to multiple complex actions that could materially impact them in parallel and on a truncated timeline.

This inconsistency is powerful evidence that the Board's timelines are not tied to complexity or importance. The shortest comment periods have applied to the Board's most complex materials (*i.e.*, full drug dossiers, economic analyses, and pricing methodologies), raising questions as to why the Board seems to be rushing these materials through. For example, the Board provided stakeholders only approximately 11 business days to comment on the FARXIGA dossier—a document exceeding 80 pages and developed over more than 18 months. More recently, the Board provided approximately nine days (or approximately seven business days) for comment on the Ozempic Cost Review Study Report, related UPL analytical materials, and supporting exhibits—all of which were released simultaneously.

Although the Board has, in some instances, extended deadlines in response to stakeholder concerns, these extensions appear to be ad hoc rather than the product of a consistent procedural framework. Collectively, these examples demonstrate that current comment periods are irregular, inconsistent, and often insufficient to allow for meaningful stakeholder engagement on highly technical materials. The Board's cost review study process regulations should establish minimum comment periods tied to document complexity—for example, 60 or more days for cost review study reports, 30 or more days for material revisions to policies or cost review study-related documents. Additionally, the regulations should require synchronization of overlapping rulemakings—*i.e.*, that related regulatory updates be coordinated into unified comment periods, or require that the Board provide an integrated summary of all changes.

I. The Draft Regulations Fail to Establish Clear Methodology and Legally Sufficient Decision-Making Criteria for the Board

Although the proposed revisions to COMAR 14.01.04 expand the range of data, information, and other factors the Board may review, the Draft Regulations still fail to establish any clear methodology, standards, or decision-making criteria to guide how the Board will determine whether and how to set a UPL. Indeed, the Draft Regulations enumerate factors the Board *may* consider but do not specify, among other things, how those factors will be weighted, what thresholds or benchmarks will trigger Board action, or how conflicting evidence will be resolved. This lack of defined analytical framework raises substantial concerns about arbitrariness and unpredictability, undermining stakeholder confidence in the process. For example:

- In its determinations regarding FARXIGA® and JARDIANCE®, the Board cited general indicators such as WAC growth and patient out-of-pocket costs but did not explain how these factors were weighted relative to other evidence or why they were sufficient to

establish an affordability challenge.[3] Without this analytical linkage, it is not possible to understand which evidence was determinative or how similar evidence would be evaluated in future cases.

- Although the Board's cost review study reports summarize the categories of information reviewed and list "indicia" of affordability concern, they do not identify which factors were dispositive or explain how the Board weighed competing evidence.[4] This structure provides a catalog of inputs rather than a transparent explanation of decision-making. Without specifying how these indicia are evaluated or what combination of factors is sufficient to support a determination, the Board's conclusions risk appearing conclusory rather than the product of reasoned analysis.

- During the Board's cost review study of OZEMPIC®, stakeholders raised concerns regarding the absence of defined criteria for determining when an affordability challenge exists. The Board acknowledged these comments but did not provide any explanation or clarification (simply stating that "[t]he PDAB thanks the commenters for their input. The Board's current process aligns with the requirements. The Board may update the process for future rounds of Cost Review Studies to define and standardize the determination that drugs have led or will lead to an affordability challenge). This illustrates the need for regulations requiring the Board to articulate clear decision criteria and respond substantively to issues central to its determinations.[5]

- In selecting drugs for cost review study, the Board has not explained how selected products (including SKYRIZI as discussed further below) compare to other eligible drugs or which criteria were determinative in the selection decision. The absence of any ranking or prioritization analysis prevents stakeholders from understanding why one drug is selected over another and limits the predictability of future decisions.

Taken together, these examples suggest that the Board's current framework provides a summary of inputs, but not a transparent explanation of decision-making. Requiring factor-by-factor analysis

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[3] *See* Maryland Prescription Drug Affordability Board April 13, 2026 Meeting Materials, at https://pdab.maryland.gov/Pages/2026-Board-Meeting.aspx (last visited May 31, 2026).

[4] *See, e.g.*, FARXIGA® Final Cost Review Study Report (Version 2.0) (April 23, 2026), at https://pdab.maryland.gov/Documents/meetings/2026/April%2013%2c%202026/2026.04.13.Farxiga%20Draft%20Cost%20Review%20Study%20Report.v.2.0.CLEAN.Redacted.pdf (last visited May 31, 2026); JARDIANCE® Final Cost Review Study Report (Version 2.0) (April 13, 2026), at https://pdab.maryland.gov/Documents/meetings/2026/April%2013%2c%202026/2026.04.13.Jardiance.Cost%20Review%20Study%20Report.v.2.0.CLEAN.Redacted.pdf (last visited May 31, 2026); OZEMPIC® Final Cost Review Study Report (Version 2.0) (May 11, 2026), at https://pdab.maryland.gov/Documents/meetings/2026/May%2018%2c%202026/2026.05.11-%20Cost%20Review%20Study%20Report%20Ozempic%20Redacted%20%281%29.pdf (last visited May 31, 2026).

[5] *See* Maryland Prescription Drug Affordability Board, Board Staff Presentation: OZEMPIC® Cost Study Review Study Report (May 18, 2026), at 7, at https://pdab.maryland.gov/Documents/meetings/2026/May%2018%2c%202026/2026.05.18%20Ozempic-%20Cost%20Review%20Study.pdf (last visited May 31, 2026).

and identification of dispositive evidence would significantly improve the clarity, consistency, and defensibility of the Board's determinations.

This continues to be a critical deficiency, from a legal perspective with the Board's cost review study activities. Under the Maryland APA, agency action must be the product of reasoned decision-making supported by substantial evidence in the record. An agency acts arbitrarily and capriciously where it fails to identify the factors guiding its decisions, applies no discernible standards, and/or reaches conclusions that cannot be replicated or tested against objective criteria.[6] Here, the Board has not identified any threshold or benchmark for an "affordability challenge," any method for weighing competing evidence, or any criteria governing selection of drugs for review. The absence of such standards is not merely a policy concern—it is a legal defect. Without clear standards, stakeholders cannot meaningfully anticipate, evaluate, or respond to Board actions, and the risk of inconsistent or unsupported decisions remains high.[7]

Importantly, this issue is not theoretical—these deficiencies are evident in the Board's selection of SKYRIZI for cost review, which occurred without any articulated or intelligible criteria and demonstrate the real-world implications of the current regulatory gap. Among other things, the Board did not disclose how SKYRIZI ranked relative to other eligible products, what criteria it found determinative, or how the available data supported its conclusion. Nor is it evident from any of the Board's communications or the data it has made public that any rational selection methodology would have chosen SKYRIZI among the first six drugs to review. As a result, the selection of SKYRIZI or cost review lacks a discernible evidentiary foundation and reflects arbitrary decision-making inconsistent with Maryland APA requirements.[8]

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[6] *Harvey v. Marshall*, 389 Md. 243, 299, 884 A.2d 1171, 1205 (2005) (emphasis added); *see also id.* (stating that agency actions must be "reasonable [and] rationally motivated"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise"). *Compare Maryland Dep't of the Env't v. Cty. Comm'rs of Carroll Cty.*, 465 Md. 169, 227, 214 A.3d 61, 96 (2019) (upholding the Maryland Department of the Environment's permit requirement because it derived from two standards that "were the result of significant deliberation among various stakeholders" and a discussion of the practicability and feasibility of the requirement that spanned at least three years) *with Baltimore Policy Department v. Open Justice Baltimore*, 485 Md. 605, 620, 666, 301 A.3d 201, 209, 236 (2023) (holding the Department's decision to deny a fee waiver was arbitrary and capricious because it based its denial "on mere conclusory statements" and "failed to meaningfully consider all relevant factors"); *Sheriff Ricky Cox v. Am. Civ. Liberties Union of Maryland*, 263 Md.App. 110, 138, 321 A.3d 1255, 1272 (Md. App. Ct. 2024) (holding that the Sheriff's lack of consideration of all the "other relevant factors" in his determination of a fee request was arbitrary and capricious").

[7] *See Harvey v. Marshall*, 389 Md. 243, 303-04 (2005).

[8] *See e.g.*, AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf (last visited May 31, 2026); AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf (last visited May 31, 2026); AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf (last visited May 31, 2026); AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at

The Draft Regulations could be improved by incorporating clearer procedural safeguards and analytical structure. In particular, introducing defined methodologies, enhanced transparency measures, and more structured opportunities for stakeholder engagement would improve the predictability, consistency, and evidentiary robustness of the Board's determinations, while preserving the flexibility necessary to evaluate diverse drug markets. For example, the Draft Regulations should include a requirement that the Board articulate in advance a structured analytical framework to guide determinations of affordability challenges that identifies all factors considered, explains how those factors are weighted or prioritized, and specifies how conflicting evidence is resolved. To provide predictability and replicability, the Board should be required to define "affordability challenge" thresholds or benchmarks—*i.e.*, establish indicative thresholds or guideposts, even if non-binding (*e.g.*, out-of-pocket burden benchmarks) as well as be required to explain its decisions relative to these criteria—*i.e.*, for each determination, require a factor-by-factor explanation and disclosure of why certain evidence was dispositive.

II. The Draft Regulations Fail to Address Deficiencies Associated with the Board's Prior Cost Review Study Processes

Notwithstanding the non-exhaustive set of examples discussed below of the Board's demonstrated shortcomings in its recent cost review study processes, the Draft Regulations do not introduce any safeguards or corrective mechanisms, such as data quality standards, requirements for contemporaneous and complete datasets, transparency regarding how evidence is evaluated, and/or guardrails for meaningful stakeholder input. For example, the Draft Regulations merely permit, but do not require, Board Staff to "provide the Board with recently available information that updates the dossier or dashboard."[9] Board Staff should not simply have discretion to provide such updates to the Board, but should be required to update such evidence that could have material impact for stakeholders. Absent such improvements, stakeholders cannot be confident that future reviews will be grounded in sound, current, and comprehensive evidence, and that the Board's processes meet the minimum requirements of the Maryland APA.

A. The Board's Use of Incomplete or Unreliable Data and Its Lack of Understanding of the Pharmaceutical Supply Chain Dynamics Violates the "Substantial Evidence" Standard

The Board's cost review study activities demonstrate a pattern of reliance on incomplete, outdated, or unreliable data, and the Draft Regulations do not address these significant data integrity concerns. For example, with respect to products it has selected for cost review study, including SKYRIZI, the Board has: relied on datasets that appear to be incomplete; utilized NDC lists containing discontinued or non-commercial products, indicating insufficient data validation; and relied on list price trends (*i.e.*, list price increases relative to inflation) as indicators of system cost despite repeated stakeholder feedback highlighting that such list price trends do not reflect negotiated rebates, net prices, or actual payer expenditures, meaning they do not reflect real world costs.

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https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf (last visited May 31, 2026).

[9] Proposed COMAR 14.01.04.05F(2).

With respect to FARXIGA®, for example, the Board relied on incomplete, outdated, and non-comparable data, raising serious questions about the reliability of its conclusions and, more broadly, why the product remained in the cost review study process as long as it did. Over a year ago, the Board posted revised Version 1.1 of the FARXIGA dossier on June 18, 2025, giving stakeholders a mere 11 business days to comment on a more than 80-page document the Board had been developing for more than 18 months. On this truncated timeline, the Board did not afford stakeholders adequate opportunity to validate or provide feedback or additional context to any data and/or data elements cited in the dossier. The Board forged ahead nonetheless, even with stakeholders like AbbVie identifying clear errors in the NDC-11 codes listed for FARXIGA and highlighting readily available public information that definitively answered questions the Board's dossier characterized as ambiguous.[10]

Then, two years after selecting FARXIGA and after months of the Board's time reviewing FARXIGA using incomplete and outdated data to determine that it led to an affordability challenge, on April 13, 2026, the Board heard testimony from AstraZeneca concerning the launch of multiple generic products entering the market with FARXIGA® as the reference listed drug.[11] The Board did not move forward in setting a UPL after nearly two years of review time. Critically, this April 13 testimony was not the first time the Board was presented with information about FARXIGA®'s impending loss of exclusivity, nor was it the first time the Board acknowledged this impending, likely material, change. For example, although the Board explicitly recognized in the product's cost study review report that FARXIGA®'s primary patents were expected to expire in 2026 and that generic entry was possible, the record indicates that this information was treated only descriptively. The cost review dossier and report for FARXIGA® do not model post-generic pricing, do not incorporate timing assumptions regarding potential generic entry, and do not explain how impending loss of exclusivity was considered in the Board's affordability determination. Instead, the Board's analysis relies entirely on current and historical pricing, utilization, and out-of-pocket cost metrics, with no forward-looking adjustment for near-term market changes. As a result, while the Board was aware of potential generic entry, there is no evidence that this factor meaningfully influenced its analysis or conclusions. There is no reason the Board could not have delayed its review of the product to better understand the impact of this likely material change.

Not only does the Board's treatment of FARXIGA® serve as another example of the Board's ongoing failure to meaningfully consider stakeholder evidence and feedback, as addressed further in subsection II.B below, but the Board's treatment of FARXIGA®—where an initial determination of affordability concern was not followed by a pricing action after market changes—illustrates the need for explicit explanations of how new evidence alters prior conclusions and which factors are outcome-determinative. At minimum, given the protracted review periods that have characterized the Board's work to date, the cost review study process regulations should

[10] *See* Maryland Prescription Drug Affordability Board, "Farxiga (dapagliflozin) Dossier (June 18, 2025, Version 1.1)," at 5 (stating that "Staff found conflicting information concerning the availability of authorized generics for Farxiga. The FDA's published list of authorized generics identifies no authorized generic for Farxiga. However, based on the labeler codes, a subset of the NDCs included in this dossier may be authorized generics.").

[11] Maryland Prescription Drug Affordability Board, April 13, 2026 Meeting Recording, at https://www.youtube.com/watch?v=llkEug5nwZ8 (last visited May 31, 2026) (at time stamp 5:32 to 7:18).

establish staged decision-making—*i.e.*, formalize phases (*e.g.*, "Data Collection;" "Draft Findings;" "Stakeholder Comment;" "Final Determination") with required updates at each stage.

Under Maryland law, agency decisions must be supported by substantial evidence, meaning reliable, relevant, and probative evidence in the record. Where the underlying dataset is incomplete, or the analytical inputs do not correspond to real-world conditions, the resulting determinations by the Board lack a sufficient evidentiary basis. Moreover, the Board's continued reliance on such data renders its conclusions unsupported by substantial evidence and therefore arbitrary.[12] The Draft Regulations do not impose minimum data quality standards, requirements for completeness or validation, or transparency regarding data sources and limitations. Without such protections, the Board's conclusions vulnerable to legal challenge. The Draft Regulations fail to offer any potential solutions for this demonstrated issue. At minimum, the regulations should require:

- Board Staff to update material data prior to the Board making determinations, as discussed above, as well as the Board's explicit consideration of new market developments occurring after initial data collection but prior to final determination (including, but not limited to patent expiry, generic/biosimilar entry, and significant product price changes);

- The Board to adopt minimum data quality standards including, but not limited to validation of NDC lists (*e.g.*, exclude discontinued/non-commercial products), use the most recent available datasets at the time of its determinations, and explicitly identify and disclose known data limitations;

- The Board to use net price data or validated proxies whenever possible and expressly identify and disclose if gross/WAC data is used instead and any associated limitations and/or assumptions; and

- The Board to document and disclose any assumptions it makes with respect to modeling or adjustments to data sets upon which it relies (including a sensitivity analysis, where applicable).

[12] *See, e.g., State Dept. of Health v. Walker*, 238 Md. 512, 523, 209 A.2d 555, 561 (1965) (upholding that the Department's ad hoc decision to deny a permit application was arbitrary); *Maryland Real Estate Comm'n v. Garceau*, 234 Md.App. 324, 365, 172 A.3d 496, 521 (finding the Commission's sanction was arbitrary and capricious because it failed to consider exculpatory factors in its decision); see *Cnty. Council of Prince George's Cnty. V. Palmer Road Landfill, Inc.*, 247 Md. App. 403, 419, 236 A.3d 766, (Md. Ct. Sp. App. 2020) (reversing a time limitation that the Council initially "waived and failed to abide themselves" but later sought to enforce); *Forman v. Motor Vehicle Admin.*, 332 Md. 201, 220, 630A.2d 753, 763 (1993) (reversing license revocation because agency failed to indicate what it found or how it reached the conclusion with respect to material issues); *Dashiell v. Maryland State Dept. of Health and Mental Hygiene*, 327 Md. 130, 137-38 (Md. Ct. App. 1992) (finding the Department's decision to terminate two employees was so unsupported that it renders the determination "essentially arbitrary and capricious").

B. The Draft Regulations Do Not Address the Continued Lack of Sufficient Transparency in the Board's Decision-Making Processes and Other Activities

As we have communicated in many prior submissions to the PDAB and PDASC, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's APA. Among other examples, the Board's lack of transparency regarding its decision-making processes and other PDAB activities is contrary to the public interest and has deprived AbbVie and all other impacted stakeholders, including Maryland resident patients of the ability to effectively and predictably participate in the Board's cost and policy review processes.[13]

For example, in connection with its cost review study of a selected drug, the Draft Regulations suggest that the Board may consider information from "structured interviews, focus groups, field observations, surveys, and ethnographic studies"[14] But there is no corresponding requirement that the Board provide stakeholders with any visibility into this information. To improve this and other transparency issues identified in AbbVie's prior comment submissions,[15] the cost review study process regulations should require the Board to, among other things: define the relevant administrative record and ensure all relied-upon materials are included; disclose all non-public analytical inputs and, to the extent practicable, provide public summaries of qualitative data sources and describe how such information was incorporated into the analysis; and include in its final cost review study report key factors and weights**,** evidence it relied upon in reaching its conclusions**,** responses to contrary evidence**,** and explanation of outcome, among other elements.

III. The Board's Proposed Approach to Identification of Therapeutic Alternatives Is Standardless, Arbitrary, and Clinically Unsound

The Draft Regulations propose to permit the Board to identify "therapeutic alternatives" for a product under cost study review without establishing, among other things, clinical comparability standards, evidentiary requirements, or reliance on expert clinical guidance. This creates a risk that the Board will group together therapies that are not clinically interchangeable and rely on cost comparisons that lack medical relevance. Arguably any conclusions derived from such comparisons lack a reliable analytical foundation and are therefore arbitrary under the Maryland APA. At minimum, the cost review study process regulations should propose clinical comparability criteria and seek stakeholder feedback and require clinical expert input (*i.e.*, incorporate independent clinical experts or reliance on recognized clinical guidelines).

Additionally, the Draft Regulations propose to allow the Board to anchor a drug's UPL not only to its own Maximum Fair Price ("MFP"), but also to the MFPs of the very "therapeutic alternatives."[16] identified in the standardless process discussed above. We strongly object to this approach. First and foremost, the existence of an MFP does not create a statutory basis for cost

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13 *See supra* notes 2 and 8.

14 Proposed COMAR 14.01.04.05B(2)(h).

15 *See supra* notes 2 and 8.

16 Proposed COMAR 14.01.04.05C(1)(c)(ii) ("To the extent practicable, the Board may consider the following *historic and current* data, information, and analyses in conducting a cost review study: … The WAC, AWP, NADAC, SAAC, ASP, *National VA Contract, Big 4 Price, MFP,* and FSS at which each therapeutic alternative has been sold in the State.").

review selection.[17] In addition, and among other things, using the MFP of one product to set the price of another disconnects pricing from the clinical and economic realities of the specific product under review, ignores important differences in indications, patient populations, and therapeutic value, and fails to account for differences in product lifecycle stage, including whether a therapy is newly launched, expanding indications, or facing imminent generic/biosimilar competition. Moreover, even within a therapeutic class, products may not be clinically interchangeable or appropriate substitutes. As we have noted in the federal context and maintain here as well, cross-product price referencing using MFPs is fundamentally flawed, particularly when applied to therapies that are not clinically comparable or are at materially different stages of development and market maturity. This approach risks distorting incentives for innovation and may result in UPLs that are misaligned with clinical value or patient needs. At minimum, the cost review study process regulations should clarify limits on cross-product pricing comparisons (*i.e.*, if MFP or other benchmarks are considered, require explanation of clinical relevance and prohibit comparisons where products are not substitutable).

IV. The Board's Proposed Consideration of Orphan Drug Designations Is Far Too Narrow and Fails to Account for Incentives to Research Rare Diseases and Conditions

The Board proposes to revise COMAR § 14.01.04.03B(1)(d) as follows:

"(d) Whether the prescription drug product is designated ***for a rare disease or condition*** by the Secretary of the ~~**FDA**~~ ***U.S. Department of Health and Human Services***, under 21 U.S.C. §360bb, ~~**as a drug for a rare disease or condition**~~ ***and is approved for an indication treating that rare disease or condition***[.]"

This change would substantially narrow what qualifies as an orphan drug for purposes of including such information in the set of data and information reviewed by the Board in connection with its cost study review of a selected drug. Currently, any product with orphan designation could be flagged as such. If revised as proposed, in order for orphan drug status to be identified for the Board by Board Staff in the dashboard, the drug would need to have orphan designation **and** be approved for that same rare disease indication. The Maryland PDAB statute implicitly contemplates clinical context and disease characteristics, including rarity, patient populations, and therapeutic need. Narrowing the orphan drug definition as proposed would effectively reduce the weight of orphan status as a categorical flag, and instead treat it as a contextual indicator tied to use.[18] The Maryland legislature arguably intended orphan status to serve as a protective or contextual factor, given the unique economics of rare disease drugs. The proposed revision improperly narrows that protection by excluding drugs with legitimate orphan designation but perhaps not yet an indication. Moreover, the proposed change would effectively lead to the arbitrary treatment of multi-indication drugs with both orphan and non-orphan indications. Effectively, the proposed change would only give weight to orphan designation if it is aligned with the approved indication under review.

The Board has failed to adequately explain or provide any support as to why it is restricting orphan status relevance. The Board does not appear to articulate a policy rationale or explain why

[17] Md. Code Ann., Health-Gen. § 21-2C-08(c).
[18] *See* Md. Code Ann., Health-Gen. §21-2C-09.

the current treatment is insufficient in any materials it has published to date (*e.g.*, meeting materials, rulemaking documents, or otherwise) nor has it made any explicit statements explaining why it is restricting orphan drug relevance (*i.e.*, requiring both designation *and* approval for that indication). Instead, the change appears in the draft regulation without an accompanying formal justification narrative. Maryland APA jurisprudence indicates that courts expect agencies to provide a reasoned explanation for significant policy changes. Conversely and notably, stakeholders have indicated pressure for *greater* consideration of orphan status. For example, in a comment letter submitted to the Board regarding the proposed regulations ultimately adopted as the current version of COMAR 14.01.04, the National Organization for Rare Disorders ("NORD") urged "more explicit consideration of orphan drug status" and greater clarity on how it would be used in selection and review."[19]

Finally, selecting orphan-designated drugs for affordability reviews disincentivizes innovators from conducting further research on drugs that treat rare diseases. Health policy should encourage innovation by allowing manufacturers to explore different indications for drugs that treat rare diseases, including new indications for drugs that treat non-rare diseases as well. Subjecting orphan-designated drugs to a burdensome affordability review would deter innovation of such drugs for smaller patient populations[20]—the very patients these treatments are designed to help. The Board should be aware of all such designations when reviewing a prescription drug.

* * * * *

The deficiencies in the Draft Regulations discussed above are not merely technical. They reflect a fundamental failure to translate statutory authority into an administrable regulatory framework. Accordingly, we urge the Board to not adopt them. Thank you for the opportunity to provide written comments on the Draft Regulations. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

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

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[19] NORD's Comments on Proposed COMAR 14.01.04 (October 23, 2023), at https://pdab.maryland.gov/documents/regulations/NORD_comm.pdf (last visited May 31, 2026).

[20] *See* Charles River Associates, "The Impact of Price Controls on Rare Disease Medicines Access and Lessons for the U.S. (Sept. 2025)," at ii, 14, at https://media.crai.com/wp-content/uploads/2025/09/25124214/CRA-RDCC-Price-Referencing-Report-September2025.pdf (last visited May 31, 2026); *see also* ADVI, "The Unintended Consequences of Drug Pricing Policies on Orphan Drug Development (June 2025)," at 4-7, at https://advi.com/wp-content/uploads/2025/06/Report-IRA_Impact_Orphan_Drug_Innovation.pdf (last visited May 31, 2026).

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VIA Electronic Delivery

June 1, 2026

Mr. Van Mitchell, Chair

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

Re: Maryland PDAB Proposed Revisions to COMAR 14.01.04 Cost Review Study Process

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s Proposed Revisions to COMAR 14.01.04 Cost Review Study Process (Draft Cost Review Process).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO appreciates the Board's decision to extend the comment period for the Draft Cost Review Process but reiterates the need to provide sufficient time for future regulatory changes. Many of the PDAB's draft regulations have been subject to a very limited comment period, with as little as a week given for public input, which is insufficient for stakeholders to conduct thorough review and provide meaningful comment. It is critical that the Board provide adequate notice and comment period for meeting materials and other draft regulations, as these proposals have real consequences for patients and the pharmaceutical supply chain and require meaningful stakeholder engagement.

While the proposed changes in the Draft Cost Review Process are well-intentioned, BIO is concerned that these changes will introduce greater uncertainty and potential inconsistency in the drug selection process. In addition, the introduction of more granular data reporting elements for manufacturers create increased risk for compromising patient privacy and market competition, undue burden and integrity for intellectual property.

Problematic Inclusion of IRA Medicare Negotiation Drugs as Automatically Eligible for Cost Review

The Draft Cost Review Process proposes to allow a drug to be selected for affordability review simply because it is subject to the Inflation Reduction Act (IRA)'s Medicare Drug Price Negotiation Program. BIO has significant concerns about this proposal, which represents an expansion of federal price controls to the state level while ignoring the Maryland population's health needs, Maryland-specific payer mix, and other state-specific conditions. BIO and our members have long argued that the underlying structure of the IRA's Maximum Fair Price (MFP) does not represent a true negotiation, nor a transparent evaluation of a drug's value. The IRA's MFP is also only scoped for the national Medicare population, with different drug eligibility criteria under the Medicare Drug Price Negotiation Program, which may not reflect the needs and experiences of Marylanders. For instance, A drug with a negotiated MFP may already be affordable in Maryland. This mechanically imports a federal process designed for a different population (Medicare beneficiaries) and a different statutory mandate (the IRA) into a state program with its own distinct charge. Automatic eligibility based solely on federal selection substitutes CMS's judgment for the Board's own statutory obligation to assess state-level affordability.

In addition, BIO is concerned by the estimation of net cost using the MFP and Federal Supply Schedule (FSS) pricing data within cost review determinations. The draft approach appears to oversimplify the estimation of "net cost" based directly on the published MFP, when in reality, net cost to payors, patients, or manufacturers is extraordinarily complex. This is particularly difficult to determine at the state level where utilization patterns, benefit design, and applicable price concessions vary substantially. Further, MFP applies to Medicare beneficiaries and does not reflect the broader market dynamics across Medicaid, commercial insurance, or other federal programs. Medicaid pricing is governed by separate statutory rebate formulas that determine rebate-per unit amounts, while additional federally mandated discounts exist under the 340B program and through federal procurement pricing under FSS contracts. Commercial contracts are also individually negotiated at a national level and incorporate confidential rebates, volume commitments, and other terms that cannot be extrapolated within a state adjudication framework. As a result, relying on published MFP or FSS benchmarks risks creating inaccurate and potentially misleading assessments of affordability.

Discrepancies in Drug Selection Considerations

The Draft Cost Review Process adds additional references to the Department of Veterans Affairs (VA) Contracts and "Big 4" prices at other federal healthcare programs/agencies. BIO opposes these additional references, which differ from those set forth under the MD PDAB statute and introduce discrepancies in drug selection considerations. Legislative history shows that the VA's deeply discounted prices were specifically designed by Congress to be preferential rates not extended to other federal healthcare programs/agencies. When states copy parameters from federal programs designed to get the lowest possible prices for certain federal agencies, they upset the balance struck by Congress and the ability of the federal government to achieve its goals.

Lack of Transparency with Proposed Process of Staff Creating a "Curated List"

BIO opposes the new proposed process whereby Board staff will create a curated list of eligible drugs, make recommendations on which drugs to refer to the Stakeholder Council,

and prepare a recommendation memoranda that will frame the Board's votes. This proposed process transfers core decision-making functions from the Board to its staff, which undermines transparency and due process. Because Board staff are not subject to Maryland's open meetings law, these recommendations would be developed entirely off the record, with no opportunity for public comment or correction of errors before the Board acts on them. Further, as written, the staff are given unlimited discretion on priority setting and development of this curated eligible list, which allows for highly subjective drug selection. This compounds existing transparency concerns, given that the Board has already made preliminary affordability determinations in closed session. The result is a process where the most consequential analytical work happens behind closed doors, and the Board's on-the-record deliberations become a rubber stamp. As such, staff would be directed to drive much of the drug consideration and selection process with even less transparency.

Further, there is insufficient information about how lists would be curated and what the criteria will be for narrowing the list of drugs under consideration for cost review at the staff level, which is extremely concerning for stakeholders. Due to the critical importance of transparency throughout the process, BIO urges the Board to not finalize this proposed process.

The Proposed Expansion Information Requests Do Not Address Underlying Methodological Issues

BIO is concerned that the newly proposed data elements within the Draft Cost Review Process represent risks to patient privacy, market competition, and integrity for intellectual property, and would be highly burdensome to report, with no benefits for Marylanders or to the Board’s mission. For instance, reporting on certain net pricing metrics may conflict with government price reporting laws and/or regulations, or otherwise compromise a highly sensitive market environment.

The Draft Cost Review Process would add the ability to request additional data from manufacturers that are highly confidential, proprietary information and have no bearing on whether a drug is affordable for Maryland patients. Rather than addressing previously identified data and methodological issues, the Board is instead seeking more irrelevant information, such as information tax benefits related to the manufacturer’s patient access programs. Demanding tax information about charitable programs designed to help patients signals an intent to penalize manufacturers for providing patient assistance. Further, certain information on patient assistance program disclosures or net pricing details may compromise privacy protections for patients. Having this information public may further be misused by copay maximizer programs and Alternative Funding Programs (AFPs) nationwide, to the detriment of patients.

The Draft Cost Review Process also requests information on the total amount of direct-to-physician marketing costs for the product under review, which has nothing to do with what patients or the state pay for a drug, and requests for such metrics may not be feasible to accommodate.

Problematic Requests for International Price Data

As BIO has stated in other comments, we strongly oppose the Board’s use of international reference pricing for its cost review. The Draft Cost Review Process states that the Board will request and review the “invoice and net price” for drugs sold in the UK, Germany, France, and Canada. These countries do not have comparable health systems to the U.S.,

and utilizing such prices does not account for possible variations in drug pricing due to differences in healthcare systems, market sizes and conditions, such as competition or negotiation practices, and pricing structures between countries. Additionally, international reference prices may not account for variations in purchasing power, healthcare expenditures, cost of living, or currency exchange rate fluctuations. Utilizing international pricing for cost reviews is particularly problematic as many rare disease drugs may not be available or priced similarly in other countries due to even smaller patient populations. Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines in other countries. For example, one study has shown that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom.[1] It is evident that metrics used in ex-US countries to assess prices are not applicable to the U.S. market and risks importing barriers on patient access to life-saving therapies.

New Section on Consideration of Cost-Sharing and Insurance Benefit Design

The Draft Cost Review Process contains a new section on cost-sharing and insurance benefit design, including the mean, median, and 90th percentile out-of-pocket costs per patient compared to state incomes, and other factors. With respect to cost-sharing and insurance benefit design, the Board should include language to reinforce that the review of such information be evaluated in the context of health plan and PBM decisions. Health plans and PBMs design and administer all patient out-of-pocket obligations, including deductibles, copayments and coinsurance, formulary tier placement, and utilization management. Thus, they determine the extent of patient cost exposure and barriers to access. Accordingly, any assessment of these data should recognize and remain in the context of health plan and PBM decisions that drive patient costs and impact patient access.

Compliance Challenges and Confidentiality Concerns

As BIO has stated in previous comments to the Board, we continue to be concerned by the extensive amount of information that will be collected from manufacturers as a part of the cost review process, including potentially confidential, proprietary, and sensitive information. While the Draft Cost Review Process states that "A person submitting information, including data and records, for the Board's consideration shall comply with the procedures for designating confidential, trade-secret, and proprietary information set forth in COMAR 14.01.01.04," the Draft itself does not provide any guidance for how confidentiality of such information will be maintained. Given that the request for manufacturer information in 14.01.04.04 contains highly sensitive and confidential information that is not even typically disclosed in a company's financial statements, BIO requests that the information request be limited to information that is only available in public domain.

Further, the request for manufacturer net sales information in 14.01.04.04 presents significant practical and operational challenges because there is no single definition of "net sales" that applies across all reporting contexts. Calculating net sales requires numerous assumptions, estimates, and allocation methodologies related to fees, chargebacks, government pricing obligations, and other financial adjustments that may vary across

[1] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." Value in Health Journal. 2014. https://www.valueinhealthjournal.com/article/S1098-3015(14)03070-8/fulltext

channels and over time. In addition, many data elements to develop net sales estimates are maintained across third-party entities, such as rebate information, and are not readily available by manufacturers. As a result, any net sales figures may require substantial interpretation and the use of assumptions that is extremely burdensome to determine and validate and may not accurately reflect market dynamics. Similarly, BIO is concerned that the other requests for information from manufacturers are overly extensive and burdensome to produce. The Draft Cost Review Process also states a request for "any additional factors or information the manufacturer proposes that the Board consider," which is overly broad and ambiguous.

***

BIO appreciates the opportunity to provide feedback to the Board through this Cost Review process. We look forward to continuing to work with the Board to ensure that Marylanders can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Melody Calkins

Director, Health Policy

Biotechnology Innovation Organization (BIO)

COMMUNITY ACCESS NATIONAL NETWORK

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June 1, 2026

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

RE: Cost Review Study Process Revisions

Dear Honorable Members of the Maryland Prescription Drug Affordability Board,

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

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

Today, we write with comments on amendments to COMAR 14.01.04 - Cost Review Study Process. The proposed revisions to COMAR 14.01.04 Cost Review Study Process, in some ways, add clarity and detail to the process. However, some of the changes, and in some areas the lack of change, raise concerns and leave questions. What follows are notable areas of concern.

14.01.04.02 Identifying Drugs Eligible for Cost Review

This section lists multiple aspects of the MCDB to be used to identify drugs eligible for cost review. Since the submission of data from self-insured employer-sponsored health plans is not mandated due to the federal Employee Retirement Income Security Act (ERISA), a significant blind spot exists in the MCDB data. According to the Maryland Insurance Administration's 2025 "Number of Insured and Self-Insured Lives" report, roughly 32% of Maryland residents under age 65 with commercial health coverage were in self-insured employer-sponsored plans.

Additionally, the section states that eligible data sets will also include "the data obtained from governmental and commercial databases, other databases, and other data sets as available". Since the details about these specific other databases are not typically publicly disclosed, there is concern that knowledgeable stakeholders would not be able to voice issues regarding potential problems of their use. While we know that the Board and staff are well-intentioned, the opacity of other data being considered gives us pause.

We appreciate the change under the description of Patient Out-of-Pocket Costs to focus on the top 100 prescription drug products with the highest and highest average total patient out-of-pocket costs in the most recent calendar year. However, because this information is based on MCDB claims data, out-of-pocket costs are not fully captured, as various patient assistance avenues are not included in those numbers. Moreover, out-of-pocket costs that patients endure but that standard claims processes do not capture are also not included.

The inclusion criterion of "Any prescription drug product subject to the Medicare Drug Price Negotiation Program (MDPN), under the Inflation Reduction Act (IRA)" is also concerning. The MDPN is based on data not specific to Maryland's needs, and it has not yet generated substantive outcomes data to justify or inform its utility.

14.01.04.03 Selecting Drugs for Cost Review

We appreciate the detail added under part A, "Priority Setting and Development of Curated Eligible List". Concern remains with the lack of standardization. Priority setting and list curation lend themselves to being arbitrary and not a repeatable, systematic process, which we feel weakens the integrity and efficacy of the drug selection process.

14.01.04.04 Request for Information for Cost Review

The vast amount of information to be potentially requested regarding manufacturers' "documents and research explaining the relationship between the pricing of the prescription drug product and the cost of development, documents and research explaining the relationship between the pricing of the prescription drug product and the cost of development" appears to be logistically burdensome to produce. Additionally, it is unclear how this information would contribute to determining whether or not a drug poses an affordability challenge.

Under section B(1), the request for manufacturer information regarding state and national gross and net sales, profit margins, tax benefits from activities, and even direct-to-consumer marketing cost information is also puzzling. The requests present themselves as a focus on deciding what the Board would deem an acceptable revenue level for a manufacturer should be instead of examining patient and system affordability. This is particularly evident in B(1)(i) "The invoice and net price per unit for the prescription drug product charged to purchasers in the United Kingdom, Germany, France, and Canada, reported in U.S. dollars." As has been discussed repeatedly, pricing outside the U.S. involves many factors not relevant to the U.S. system and that are unchangeable by any PDAB statutory authority.

14.01.04.05 Cost Review Study

Section B(1)g) states that data elements derived from reports generated by foreign governmental and quasi-governmental agencies and foreign non-profit organizations may be considered. This inclusion is highly likely to lead to inadvertent backdoor use of QALY-paradigmatic insights, other discriminatory analyses, or the consideration of variables and systems that are not relevant to the U.S. The unambiguous purpose of cost reviews, drug selection, and the PDAB's work is cost containment. Maryland is prohibited by the ADA from utilizing pricing equations that include QALYs for the purposes of cost containment.

The current limited scope of UPL application which includes Medicaid, would go against CMS and HHS rules with the integration of QALY data. CMS and HHS expressed this explicitly in rules applying to § 84.57 [2024-09237 (89 FR 40066) and 2024-08711 (89 FR 37522)]:

"While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities."

and

"That is, where a value assessment uses methods that penalize patients or groups of patients on a ground protected by section 1557 and where such methods then result in limiting access to an aid, benefit, or service, they may violate section 1557. In response to commenters, we note that value assessment tools cannot be used to, to deny or afford an unequal opportunity to qualified individuals with disabilities or on the basis of age with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available."

Section C(2)(e-iii) regarding the incremental costs associated with a therapeutic equivalent prescription drug product should be a factor considered in the cost review of all drugs, for cost review, not just therapeutic equivalents. "Including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of the standard of care" should be a major part of all affordability and cost reviews, given these things are all a part of patient out-of -pocket costs.

Overall, the cost review study process remains heavily focused on system spending and policing manufacturers' financial bottom lines, and it still lacks robust consideration of patient needs. Moreover, regarding system spending, the focus is on the amount of spending rather than the machinations of the system that support and result in it, beyond just the price of the medications in question.

Respectfully submitted,

Ranier Simons
Director of Patient-Centered Drug Pricing and Healthcare Access Policy
Community Access National Network (CANN)

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

DIABETES PATIENT ADVOCACY COALITION

June 1, 2026

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

RE: Comments and Proposed Amendments to COMAR 14.01.04 from the Diabetes Patient Advocacy Coalition

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

On behalf of the Diabetes Patient Advocacy Coalition (DPAC), we respectfully submit the following comments and proposed amendments regarding the draft regulations for COMAR 14.01.04 concerning prescription drug cost review procedures.

DPAC strongly supports efforts to improve prescription drug affordability for Maryland patients. Patients living with chronic, serious, rare, disabling, and medically complex conditions frequently experience substantial financial burdens associated with prescription medications, specialty therapies, medical technologies, and ongoing clinical management necessary to maintain health and avoid preventable complications.

At the same time, affordability policies must avoid creating unintended barriers that disrupt access to medically necessary therapies, individualized treatment regimens, and continuity of care. Many chronic conditions require highly individualized care plans, and even temporary disruptions in treatment access, formulary coverage, or utilization management requirements can result in worsening health outcomes, avoidable hospitalizations, disease progression, and increased healthcare utilization.

The following proposed amendments are intended to strengthen patient protections, improve transparency, incorporate real-world patient care considerations into affordability reviews, and ensure the Board fully evaluates the impact of affordability-related actions on patient access, health equity, continuity of care, and clinical outcomes.

Proposed Amendments to COMAR 14.01.04.03 Selecting Drugs for Cost Review

Proposed New COMAR 14.01.04.03B(8) for Consideration of Treatment Delivery and Patient Dependency

DPAC proposes adding new §B(8) as follows:

(8) In evaluating prescription drug products used to manage chronic conditions, the Board shall consider:

(a) Whether interruption in access may create immediate or significant clinical risk for patients;

(b) The degree to which patients depend on continuous access to therapy to maintain daily functioning or avoid disease progression;

(c) Whether treatment interruption may increase avoidable emergency care utilization or hospitalization;

(d) The extent to which the therapy is integrated into routine patient self-management; and

(e) The availability of clinically appropriate alternatives without disruption to continuity of care.

Rationale: People living with diabetes often depend on uninterrupted access to therapies and technologies to safely manage their condition on a daily basis. Even temporary disruptions in treatment access may create significant clinical risks and destabilize disease management.

Proposed New COMAR 14.01.04.03I(8) for Consideration of Real-World Access Stability

DPAC proposes adding new §I(8) as follows:

(8) In selecting prescription drug products for cost review, the Board shall consider:

(a) Whether patients experience frequent coverage instability or formulary changes affecting the product;

(b) The extent to which patients rely on the product for long-term disease management;

(c) Reported barriers associated with obtaining medically necessary refills, supplies, or related treatment components;

(d) The impact of treatment access disruptions on continuity of care; and

(e) Whether access barriers may disproportionately affect medically vulnerable populations.

Rationale: People living with diabetes frequently experience disruptions associated with formulary changes, refill barriers, and coverage instability that may not be fully reflected in pricing or claims data alone. Evaluating real-world access stability would provide the Board with a more complete understanding of patient impact.

Proposed Amendments to COMAR 14.01.04.04 Request for Information for Cost Review

Proposed New COMAR 14.01.04.04B(2)(g) for Reporting on Mid-Year Coverage and Formulary Changes

DPAC proposes adding new §04B(2)(g) as follows:

(g) Health insurance carriers, HMOs, MCOs, and PBMs shall report:

(i) The frequency of mid-year formulary or coverage changes affecting prescription drug products under review;

(ii) Whether patients are permitted to remain on existing therapy following a formulary change;

(iii) Policies governing continuity of care following formulary modification;

(iv) Patient notification practices related to formulary or coverage changes; and

(v) Exceptions or transition processes available for medically vulnerable patients.

Rationale: People living with diabetes may experience significant clinical disruption when formulary or coverage changes interfere with established treatment regimens. Mid-year coverage instability may create confusion, treatment delays, and barriers to maintaining effective disease management.

Proposed Amendments to COMAR 14.01.04.05 Cost Review Study

Proposed New COMAR 14.01.04.05C(1)(g) for Evaluation of Utilization Management Barriers Affecting Patient Care

DPAC proposes adding new §05C(1)(g) as follows:

(g) Utilization Management Practices.

In conducting a cost review study, the Board may consider utilization management practices affecting patient access to prescription drug products, including:

(i) Prior authorization requirements;

(ii) Step therapy protocols;

(iii) Non-medical switching requirements;

(iv) Quantity limits;

(v) Formulary exclusions;

(vi) Restrictions affecting access to medically necessary therapies, devices, or technologies;

(vii) Specialty pharmacy restrictions;

(viii) Delays associated with coverage determinations or appeals; and

(ix) Fail-first requirements.

Rationale: People living with diabetes frequently encounter administrative barriers that delay access to medically necessary treatment, monitoring technologies, and supplies. Utilization management restrictions can directly undermine adherence, continuity of care, glycemic management, and patient safety.

Proposed New COMAR 14.01.04.05C(1)(h) for Review of Utilization Management Impact on Treatment Stability

DPAC proposes adding new §05C(1)(h) as follows:

(**h) Impact of Utilization Management Practices.**

In evaluating utilization management practices under §C(1)(g) of this regulation, the Board may consider whether the practices may:

(i) Interrupt established treatment regimens;

(ii) Delay access to medically necessary care;

(iii) Increase administrative burden on patients, caregivers, or providers;

(iv) Reduce adherence or persistence with treatment; or

(v) Increase the risk of avoidable emergency department utilization or hospitalization.

Rationale: Individuals living with diabetes often require consistent access to therapies, monitoring technologies, supplies, and coordinated care to safely manage their condition. Delays or disruptions associated with utilization management may destabilize disease management and create preventable patient safety risks.

Proposed New COMAR 14.01.04.05C(2)(g)(viii) for Evaluation of Care Coordination and Treatment Fragmentation

DPAC proposes adding new §05C(2)(g)(viii) as follows:

(viii) In conducting a cost review study, the Board shall consider:

A. Whether patient access to treatment requires coordination across multiple providers, vendors, pharmacies, or suppliers;

B. The extent to which treatment interruptions may result from fragmented coverage or delivery systems;

C. Administrative barriers affecting continuity of care;

D. The impact of treatment delays on patient self-management and disease stability; and

E. Whether affordability-related actions may increase fragmentation in care delivery.

Rationale: Individuals living with diabetes often rely on coordinated access to medications, monitoring technologies, supplies, providers, and pharmacy services. Fragmentation in coverage or care delivery may create barriers that undermine continuity of care and patient safety.

Additional Diabetes Community Concerns

DPAC also encourages the Board to further consider several broader concerns reflected throughout the proposed regulations, including:

- Overreliance on short-term financial metrics without sufficient consideration of long-term health outcomes and continuity of care;
- Insufficient recognition of the cumulative burden associated with chronic disease management and ongoing treatment needs;
- Inadequate consideration of the risks associated with treatment disruption, delays in care, and coverage instability;
- Insufficient evaluation of utilization management barriers that may interfere with timely access to medically necessary treatment;
- Limited protections for patients stable on existing treatment regimens;
- Underdeveloped evaluation of health disparities affecting medically vulnerable and historically underserved populations;
- Insufficient consideration of caregiver burden, quality-of-life impacts, and the daily realities of managing chronic disease; and
- Limited recognition of the importance of individualized treatment and provider clinical judgment.

DPAC appreciates the Board's efforts to improve prescription drug affordability for Maryland patients. However, affordability initiatives must preserve patient safety, continuity of care, individualized treatment decision-making, and timely access to medically necessary therapies and technologies.

Diabetes-Specific Rationale Supporting the Proposed Amendments

Although the proposed amendments are intended to apply broadly across disease states and patient populations, DPAC believes the diabetes community illustrates many of the real-world risks associated with affordability policies that do not sufficiently account for continuity of care, individualized treatment needs, and utilization management barriers.

Continuous and Lifelong Treatment Requirements

Unlike many acute conditions, diabetes management requires uninterrupted and lifelong access to medications, devices, monitoring technologies, and ongoing clinical support. Even temporary disruptions in access to insulin, glucose-lowering therapies, continuous glucose monitors (CGMs), insulin pumps, or related supplies can result in serious and potentially life-threatening consequences.

Patients living with diabetes often cannot safely pause treatment while navigating prior authorization delays, appeals, formulary changes, or non-medical switching requirements.

Risks Associated with Treatment Disruption

Interruptions in access to diabetes therapies may lead to:

- Severe hypoglycemia;
- Diabetic ketoacidosis (DKA);
- Emergency department utilization;
- Hospitalization;
- Accelerated disease progression; and

- Increased risk of long-term complications.

Patients stabilized on a specific insulin regimen, CGM, or insulin pump system may experience substantial clinical instability when forced to switch therapies or devices for non-medical reasons.

Individualized Patient Response

Diabetes management is highly individualized. Patients often respond differently to:

- Insulin formulations;
- Adjunctive glucose-lowering therapies;
- Insulin delivery systems;
- Continuous glucose monitoring technologies; and
- Treatment timing and dosing strategies.

Clinical equivalence at a population level does not necessarily translate into safe interchangeability for individual patients.

Utilization Management Barriers

Patients with diabetes frequently encounter utilization management barriers including:

- Prior authorization requirements;
- Step therapy protocols;
- Quantity limits;
- Formulary exclusions;
- Non-medical switching;
- Specialty pharmacy restrictions; and
- Delays in coverage determinations and appeals.

These barriers may undermine adherence, delay medically necessary treatment, increase provider administrative burden, and contribute to avoidable complications.

Long-Term Clinical and Economic Consequences

Effective diabetes management reduces the risk of:

- Kidney disease;
- Cardiovascular disease;
- Neuropathy;
- Blindness; and
- Lower-extremity amputation.

Affordability analyses focused primarily on short-term spending metrics may fail to account for the long-term clinical and economic benefits associated with maintaining consistent access to treatment and preventing complications.

Health Equity Considerations

Diabetes disproportionately affects underserved populations, including:

- Low-income communities;
- Rural populations;
- Communities with limited specialist access;
- Racial and ethnic minority populations; and
- Individuals facing barriers to consistent insurance coverage.

Policies that increase administrative complexity or disrupt continuity of care may worsen existing health disparities.

Importance of Patient-Centered Affordability Policies

DPAC supports policies that improve affordability and reduce patient out-of-pocket costs. However, affordability initiatives should not unintentionally create barriers that limit access to medically necessary care, undermine individualized treatment decisions, or destabilize patients who are clinically stable on existing therapies.

The diabetes community's experience demonstrates the importance of incorporating patient access protections, continuity-of-care standards, utilization management review, and individualized clinical considerations into the Board's affordability review framework.

Sincerely,

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

EACH PIC COALITION

June 1, 2026

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

RE: COMAR 14.01.04 Cost Review Study Process

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

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

We appreciate the board's decision to extend the public comment period for the proposed rulemaking on changes to the cost review process.

Prioritize Patient Experiences and Hardships to Determine Affordability

Ultimately, the board's cost review is about increasing affordability of prescription medications. A narrow focus on systemic or payer-level costs overlooks the most meaningful measure of affordability, whether individuals can obtain and adhere to the medications they need is the most critical metric. Therefore, we urge the board to prioritize patient costs as a key determinant of affordability and focus specifically on patient out-of-pocket (OOP) costs.

Further, we urge the board to focus on patient-reported obstacles to care and address the underlying factors that contribute to patient hardship in affording and accessing their needed medications.

Our recent Patient Experience Project: Patient-Reported Affordability & Unaffordability Survey 2.0 aimed at better understanding **why** patients report medications affordable or unaffordable. Patients described the role of insurance coverage rules, cost-sharing structures, cumulative healthcare expenses, income, financial assistance availability, and changes in life circumstances in shaping their ability to remain on treatment over time. These contextual factors frequently determined affordability far more than the price of the medication itself.

Determining these factors that influence patient affordability will ultimately better equip the board to address them through tailored policy remedies. Drawing conclusions without this data or basing decisions on state or system costs risks overlooking real patient problems and could ultimately exacerbate existing barriers.

Therapeutic Alternatives

While we understand the need to gather data on therapeutic alternatives as part of the cost review process, we strongly urge the board to ensure that they do not consider drugs within the same class to be interchangeable. We also urge that the board carefully evaluate whether policies they put in place could encourage payers to consider these treatments as

interchangeable or increase the likelihood that they will require patients to switch medications within the class.

The course of treatment for each patient is as unique as the individual and their disease. Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. For these reasons, patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

In fact, our Patient Experience Project found that, among respondents who tried multiple treatments, over 80% described their medication as valuable, often “exceptionally valuable,” with most emphasizing its unique value to them rather than general effectiveness. Patients reported that non-medical switching, caused them harm due to disease recurrence, side effects, worsened health outcomes, and adverse events when required to switch medications due to insurance plan design.

For these patients, therapeutic alternatives may not be alternatives at all. We encourage the board to take the complexity of each individual into account when deliberating on affordability reviews and not treat therapeutic alternatives as interchangeable.

Incorporate Patient Input Directly into Cost Reviews

We encourage the board to incorporate patient input directly into their review process, beyond the current ability to simply nominate drugs for cost reviews.

To do so, we urge the board to create multiple avenues for engaging with patients and capturing their input on drug affordability and access, including public meetings, focus groups, comment periods, public testimony, and surveys. These events should be held at varied times and locations to get input on the drugs under review. This will ensure members of the public are given adequate opportunity to attend and provide patients with the opportunity to share their experiences on each drug directly with board members and staff.

We recommend that the process for patient engagement be conducted separately from other stakeholders to avoid overwhelm and any potential confusion regarding what is expected from their participation. We also think the board should establish a minimum threshold for patient information submissions on each drug to ensure that they are receiving adequate input from patients.

Public awareness and engagement are critical to the legitimacy and success of the cost review process. We stand ready to assist the board in establishing patient engagement processes.

Conclusion

We share the board’s goal of improving prescription drug affordability for Marylanders. Achieving that goal requires a process is singularly focused on identifying patient challenges, determining their root cause, and addressing those issues directly. Our coalition stands ready to

work with the board as it begins the next review cycle to ensure that patient-centered evidence and engagement inform the policies of the board.

Sincerely,

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

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

[redacted] [redacted]

Maryland

PDAB Regs <pdab.regs@maryland.gov>

HealthHIV Comments on Draft COMAR 14.01.04 Revisions

1 message

Scott Bertani <scottb@healthhiv.org> Mon, Jun 1, 2026 at 4:49 PM
To: pdab.regs@maryland.gov

Dear Maryland PDAB team,

Please find HealthHIV's comments below in response to the Draft Proposed Regulations for Comment, posted May 1, 2026, regarding proposed revisions to COMAR 14.01.04, Cost Review Study Process.

We appreciate the Board's extension of the comment period and the opportunity to provide input.

Sincerely and appreciatively said,

Scott

Scott D Bertani, MNM, PgMP (He/Him)

Director of Advocacy

[redacted]

scottb@healthhiv.org | HealthHIV.org

HealthHIV supports the Board's goal of improving affordability and continues to weigh in through the lens of our work with Maryland partners to strengthen HIV treatment and prevention access.

That matters in Maryland because the state's Integrated HIV Prevention and Care Plan depends on people being able to start and consistently stay connected to affordable HIV treatment and prevention services. As stakeholders and contributors to the state's HIV planning body and its vision, HealthHIV has seen how decisions can affect progress toward Ending the HIV Epidemic in the U.S. goals, Ryan White implementation efforts and the safety-net programs that help people remain engaged in care.

Although the draft regulations do not specifically identify HIV medications, they establish a process for identifying, referring and selecting prescription drug products for cost review that could include HIV treatment and prevention medications. If cost review focuses too narrowly on price or payer cost, it can create different costs, unmet needs and access barriers elsewhere in the system. Recent examples involving formulary restrictions and dispensing models in Florida's AIDS Drug Assistance Program (ADAP) have shown how state payer changes can affect HIV coverage, prior authorization, utilization management and access to widely used HIV medications. So, too, Colorado's Department of Health Care Policy and Financing (HCPF) has proposed reinstating prior authorization determination processes for HIV medications under Medicaid. Each example raises

the same practical concern: state-level affordability, coverage or utilization management decisions can affect access to widely used HIV medications.

The draft uses therapeutic class, therapeutic equivalents, NDCs, active moiety and active ingredient as part of the review process. For HIV medications, those categories do not tell the full clinical or access context. Treatment decisions depend on resistance history, prior treatment experience, drug-drug interactions, tolerability, hepatitis B status, renal and metabolic considerations, adherence needs and patient-provider decision-making. A regimen that appears comparable in a dashboard may not be comparable for the person taking it every day, especially when resistance history is not fully captured across counties, states and care systems.

Therapeutic equivalence may look clean on paper, but in HIV it can hide costs the system has not examined when benefit design or access decisions lead to non-medical switching, unmet medical need, adherence disruption, additional monitoring or resistance testing, or increased transmission risk tied to avoidable access instability. For people who rely on lifelong HIV treatment or prevention medications, access is then further and repeatedly re-tested by annualized plan design, pharmacy access to specific or preferred sites, carrier rules, eligibility processes, refill cycles, benefit changes and consultation requirements. Those recurring checks can turn stable treatment or prevention into an ongoing administrative burden, including through Ryan White and Medicaid eligibility determinations, and can shape both the person's HIV care continuum and the payer and provider systems expected to support it. Coverage disruption is not a single event; it can become the monthly and annual grind of staying on HIV treatment or prevention.

Single-tablet regimens and regimen stability also matter as a matter of practice, especially for people with complex health needs, polypharmacy and multiple medications, unstable coverage or long treatment histories. For many people with HIV, the question is not whether another regimen exists on paper, but whether a change disrupts adherence, pharmacy access or long-standing treatment stability. Cost review should therefore account for regimen simplicity and stability, not only gross spending, WAC, payer cost or patient out-of-pocket cost.

Small disruptions in HIV medication access are not clinically neutral. Coverage changes, formulary movement, prior authorization, pharmacy access problems or pressure to switch regimens can affect viral suppression, resistance risk and continued engagement across the HIV care continuum.

With that, HealthHIV's concern continues to be straightforward: if HIV treatment or prevention medications are considered for cost review, affordability decisions have to be evaluated by how they affect patient access, adherence, viral suppression, PrEP use and the programs that help people stay connected to care and prevention. Within HIV care, affordability is not experienced in one uniform way across the state. Across populations, communities and even ZIP codes, adherence shapes health outcomes, longevity and onward transmission risk across a lifetime. Changes that disrupt access can affect the long arc of treatment stability and HIV prevention.

HealthHIV also appreciates that the draft provides a 30-day comment window for public input on staff-developed therapeutic alternatives. *That opportunity matters*. But for HIV treatment and prevention medications, determining whether a proposed therapeutic alternative is meaningful in real life is not a simple paper review. It requires more than comparing products by therapeutic class, price or formulary placement. The Board would need to evaluate whether the alternative is clinically appropriate, whether it addresses the same clinical need, whether people can access it through their coverage or pharmacy, and whether changes would affect ADAP, Ryan White providers, Medicaid programs or other safety-net systems that help sustain HIV care. That access question is not simple in HIV, because the system determining who is affected is fragmented across payers, pharmacies, public programs and safety-net providers.

Much of that information is not available in one place and may require targeted outreach, provider and patient input, payer context and some level of qualitative or quantitative data collection. A 30-day window may allow organizations to flag concerns, but it may not be enough time to produce

the condition-specific, real-world evidence the Board would need to understand whether a listed therapeutic alternative is actually workable for HIV treatment or prevention.

Cost review should account for outcomes that are central to HIV care and prevention, including adherence, viral suppression, PrEP use, prevention value, treatment stability and uninterrupted access. These outcomes may not be fully captured by price, rebate, claims or gross spending data. In HIV, affordability cannot be separated from whether people can start, stay on and continue the medications that support individual health and prevent new infections.

HealthHIV recommends that the final regulations make clear that therapeutic alternatives and future affordability actions will be evaluated for clinical context, patient access and safety-net impact. Maryland can pursue prescription drug affordability while protecting the treatment stability and public health gains that sustained HIV treatment and prevention make possible.

MARYLAND TECH COUNCIL
ADVANCING LIFE SCIENCES AND TECHNOLOGY

June 1st, 2026

Andrew W. York, PharmD, JD
Executive Director Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Proposed Amendments to COMAR 14.01.04, Cost Review Study Process

Dear Dr. York and Members of the Board,

The Maryland Tech Council (MTC) appreciates the opportunity to comment on the Board's proposed amendments to COMAR 14.01.04, and we thank the Board for extending the comment period to allow for more meaningful stakeholder review. MTC is the largest technology and life sciences trade association in Maryland, representing more than 800 member companies, including biopharmaceutical manufacturers whose products may be subject to the Board's cost review authority.

Our comments focus on three areas where the proposed amendments warrant revision: the expanded Request for Information under COMAR 14.01.04.04, the integration of federal Medicare Drug Price Negotiation Program outputs into both eligibility and cost review analysis, and the restructured cost review factors under COMAR 14.01.04.05.

1. **Request for Information for Cost Review, COMAR 14.01.04.04**

The new direct-to-physician marketing cost disclosure at .04B(1)(q) should be struck or substantially narrowed. To the extent the Board is seeking information about manufacturer payments or transfers of value to physicians, much of that information is already reported through the federal Open Payments program and made publicly available by CMS. The Board has not explained why those public data sources are insufficient for its cost review analysis, or why a separate state-level request for manufacturer-reconstructed "direct-to-physician marketing costs" is necessary.

The proposed language also uses a term that does not correspond cleanly to the federal Open Payments framework. Open Payments captures reportable payments and transfers of value to covered recipients, but "direct-to-physician marketing costs" could be read more broadly to include sales force activity, speaker programs, educational materials, samples, agency costs, field activity, or other commercial overhead. Those categories are not necessarily tracked or allocated to individual products in a standardized manner across manufacturers. If the Board retains any version of this provision, it should rely on publicly available Open Payments data rather than requiring manufacturers to submit duplicative reports or reconstruct broader commercial, promotional, or overhead costs that are not maintained as product-specific physician marketing expenditures.We note that the analogous direct-to-consumer marketing cost disclosure preserved at .04B(1)(r) raises similar concerns. While this provision is carried forward from existing regulations rather than newly introduced, the relevance and feasibility issues are largely the same. The proposed category of direct-to-consumer marketing costs eligible for federal tax treatment does not correspond to a standard product-level line item in manufacturer financial systems and would need to be reconstructed from tax filings on a product-specific basis. We respectfully suggest that the present rulemaking presents an opportunity for the Board to reconsider this requirement alongside the new direct-to-physician disclosure.

The Board should also confirm that several expanded cost data requests can be reasonably produced by manufacturers in the form specified before adopting them in final form. Several provisions in .04B(1) presuppose manufacturer capability to produce information at a level of granularity and in a format that may not align with how

the data is maintained in manufacturer financial systems. These include the requirement at .04B(1)(d) to report net price received by the manufacturer for the drug product in the State, accounting for all price concessions, discounts, and rebates, reported by payor type and in aggregate; the requirements at .04B(1)(g) and (h) to report the total dollar amount of gross and net sales of the prescription drug product into the State and nationally; and the requirement at .04B(1)(i) to report the invoice and net price per unit charged to purchasers in the United Kingdom, Germany, France, and Canada in U.S. dollars.

In practice, the producibility of this information varies significantly across manufacturers and across product categories. State-level allocation of net pricing and of gross and net sales requires reconstruction from sales channels and rebate flows that are not always tracked at the state level in manufacturer financial systems. International pricing data may be held by foreign affiliates, may reflect different commercial terms and currency conventions, and may be subject to confidentiality obligations with foreign purchasers or governmental authorities. Before adopting these provisions in final form, the Board should engage directly with manufacturers and industry representatives to confirm that the requested information can in fact be reliably produced in the format specified. To the extent the Board's analytical needs can be met with alternative data formats or alternative levels of granularity, building that flexibility into the regulatory text would reduce compliance friction without compromising the Board's ability to conduct its statutory cost review.

Net price and revenue reporting by payor type should permit aggregated submissions and should not extend to entire product families. The provisions at .04B(1)(d), (l), (m), and (n) require manufacturers to produce utilization, net prices, and gross and net revenue by payor type for the drug under review, and significantly, for all authorized generics for that drug and for all other ANDAs, BLAs, and NDAs that pertain to the same active moiety and the same manufacturer.

Manufacturers are routinely subject to contractual confidentiality provisions with commercial payors, pharmacy benefit managers, and Medicaid managed care organizations that may restrict disclosure of payor-specific net price and rebate information to third parties without counterparty consent, regardless of the protections available to that information once submitted. The final regulations should expressly provide that the Board will accept aggregated submissions where payor-specific reporting would conflict with contractual obligations to third parties. This is a workable accommodation that preserves the Board's access to the underlying information while avoiding contractual notice, consent, dispute, or compliance issues by permitting aggregated submissions where appropriate.

Additionally, the proposed extension of payor-type reporting to authorized generics and to all same-moiety ANDAs, BLAs, and NDAs significantly expands the scope of manufacturer disclosure beyond the drug actually under review. For a manufacturer with a successful product, this provision could be read to require production of detailed payor-specific data covering an entire product family any time one product in that family is selected for cost review. The connection between this expanded scope and the affordability analysis for the specific drug under review is not apparent. We recommend that the Board either narrow these provisions to the drug under review, or limit reporting on authorized generics and same-moiety products to aggregated, non-payor-specific data.

The new patient access program tax-benefit disclosure at .04B(1)(p)(v) should be reconsidered. This provision asks manufacturers to compute and report to a state regulatory body the federal tax effects of their patient assistance programs. The Board has not identified how the tax treatment of patient assistance programs at the federal level bears on whether a prescription drug creates affordability challenges for Maryland patients or the State health care system. The computation itself raises difficult questions, since the tax effect of a patient assistance program is not a discrete line item in manufacturer tax filings and would require allocation and estimation that may not be reliably producible. Requiring this disclosure from manufacturers as a condition of cost review participation creates a record about federal tax treatment more appropriately addressed through federal tax administration than through a state cost review process. We respectfully recommend that this provision be struck from the final regulations.

The patient access program identification requirement at .04B(1)(p)(i) raises related practical concerns and similarly merits clarification before adoption. The provision requires manufacturers to disclose the identity of all patient

assistance programs or charities providing medications to patients that are "operated or supported by the manufacturer." Manufacturer involvement in patient access takes many forms. Some programs are operated directly by the manufacturer, where the relationship and the information flow are well-defined. Others are operated by independent 501(c)(3) charitable foundations that may receive donations from one or more manufacturers but that operate independently of any single donor and often serve patients across multiple manufacturers' products. A manufacturer that contributes to an independent charitable foundation may not have visibility into the foundation's full program portfolio, the identity of all patients served, or the operational details of programs the foundation administers. As drafted, the "operated or supported by" language is broad enough to encompass arrangements where the manufacturer's connection to the program is limited to financial contributions to an independent entity. We recommend that the Board engage manufacturers to determine what level of program identification can reliably be provided, and either narrow the regulatory text to programs operated by or under the direct control of the manufacturer, or specify reduced reporting expectations for arms-length financial relationships with independent patient assistance entities.

Patient access program disclosures more broadly need scope clarification. "Patient access programs" encompasses a wide range of activities, including patient assistance programs, copay support, free drug programs, and bridge programs, each with distinct structures, eligibility criteria, and data systems. The final regulations should specify what categories of programs are within the scope of the disclosure requirement and what level of detail the Board expects, in order to support efficient and consistent responses across manufacturers.

The manufacturer catch-all provision at .04B(1)(s) should be retained. This provision allows manufacturers to identify relevant clinical, market, access, supply chain, or patient affordability considerations that may not be fully captured by the Board's standard information request. We recommend that this language remain in the final regulations.

2. Integration of Medicare Drug Price Negotiation Program Outputs

The proposed amendments integrate federal Medicare Drug Price Negotiation Program outputs into the cost review framework at two distinct points: drugs subject to the federal program are added to the eligibility categories under .02D(4), and CMS-published data underpinning the Maximum Fair Price are added as a considered factor in the cost review study itself under .05C(2)(g)(vii).

Federal selection under the IRA is driven by Medicare spending patterns and federal program criteria that do not necessarily map onto Maryland's affordability landscape, patient access concerns, or state-level health care market conditions. We recommend that the final regulations clarify that federal selection is one factor among several rather than a presumptive or near-automatic pathway onto the cost review list.

The incorporation of CMS data underpinning the MFP as a Board factor under .05 raises a more fundamental question. Health-General § 21-2C charges the Board with conducting an independent, Maryland-specific affordability analysis. Building federal negotiation outputs into the substantive cost review framework risks effectively layering Maryland's review on top of an already-completed federal determination, rather than producing the independent state-level analysis the statute contemplates. We recommend that the Board clarify in the regulations or accompanying guidance how it intends to weigh federally negotiated price data alongside Maryland-specific evidence, and how it will avoid effectively adopting federal negotiation outcomes as Maryland determinations.

3. Restructured Cost Review Factors, COMAR 14.01.04.05

We appreciate the more complete factor framework under .05C(2). The expanded factor set will produce stronger cost review studies if the Board commits to addressing each applicable factor in its written analysis rather than treating the list as a recitation.

We flag one specific concern. The new factor at .05C(2)(e)(iii) calls for the Board to consider the incremental costs of a prescription drug product compared to "the standard of care, and drugs in the same therapeutic class." Expanding the comparator set beyond therapeutic alternatives to encompass entire therapeutic classes broadens the analytic frame in ways that may disadvantage innovative therapies that differ from class incumbents in mechanism of action, indication, patient population, or clinical profile. We recommend that the Board clarify how it will distinguish meaningful therapeutic class comparisons from comparisons that conflate clinically distinct products.

4. Other Proposed Amendments

On the staff-curated priority list under .03A, we recommend that the final regulations require staff to publish the criteria used to develop the list, document the basis for each drug's inclusion, and provide an opportunity for Stakeholder Council input before the list is acted on by the Board. The regulations should also make clear that the Board itself retains final authority over which drugs are prioritized for review, with the curated list serving as a staff recommendation rather than a presumptive selection. These additions would preserve administrative efficiency while maintaining the transparency and Board-level accountability expected of a quasi-legislative process.

We also ask the Board to clarify the source of the estimate called for at .03B(3)(k), which would include in the dashboard the estimated percentage of manufacturer national net sales to gross sales of a prescription drug product. Net-to-gross ratios are not generally publicly disclosed at the product level, and if the dashboard is intended to be developed from publicly available information, the basis for this estimate should be specified so that stakeholders can evaluate its reliability.

MTC and our member companies are committed to working with the Board to ensure that the Cost Review Study Process produces sound determinations through a workable, transparent, and legally defensible framework. We welcome the opportunity to discuss these concerns with staff or the Board directly.

Respectfully,

Kelly M. Schulz
Chief Executive Officer

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 28, 2026

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

Via email: pdab.regs@maryland.gov

RE: COMAR 14.01.04 Cost Review Study Process

To the Members of the Maryland Prescription Drug Affordability Board:

On behalf of the chain pharmacies operating in Maryland, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the proposed revisions to COMAR 14.01.04 regarding the Cost Review Study Process. Community pharmacies are a foundational part of Maryland's healthcare system, serving as one of the most accessible healthcare providers in many neighborhoods and offering medication access, counseling, chronic disease support, immunizations, and various clinical services. As such, NACDS proposes the following recommendations to Maryland Prescription Drug Affordability Board ('the Board') to help ensure affordable access to medications through community healthcare settings such as pharmacies, for Marylanders:

- **Recommendation #1: COMAR 14.01.04.04- Enhance PBM Transparency Requirements**
- **Recommendation #2: COMAR 14.01.04.05- Incorporate Pharmacy Reimbursement Analysis into the Cost Review**

Recommendation #1: COMAR 14.01.04.04- Enhance PBM Transparency Requirements
The proposed revisions to Regulation .04 significantly enhance data collection across the pharmaceutical supply chain from manufacturers to insurance companies to pharmacy benefit managers (PBMs). However, there remains a critical gap in transparency regarding how PBMs reimburse pharmacies. Specifically, the Board should compile the necessary information to enhance visibility and awareness into PBMs' pharmacy payment structures. As a critical reminder, pharmacy reimbursement should be comprised of two parts: 1) the product cost; and 2) a professional dispensing fee across payer markets (e.g., Medicaid, Medicare, commercial) to help ensure reasonable reimbursement at a level that allows pharmacies to serve patients. The dispensing fee is typically calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient counseling, and other cost elements necessary to provide quality patient care.

It should also be noted that setting an Upper Payment Limit (UPL) without establishing a clear pharmacy reimbursement methodology could force pharmacies to operate at a loss, impact their ability to continue stocking the medication, and eventually close their doors. This would lead to reduced medication access, medication adherence, and worsening health outcomes for Marylanders. Thus, it is essential for the Board to have PBMs report such information to fully understand how funds flow through the system and whether reimbursement levels are sufficient to support pharmacy operations as the Board determines the affordability of these medications.

Recommendation #2: COMAR 14.01.04.05- Incorporate Pharmacy Reimbursement Analysis into the Cost Review
The cost review study provisions, listed within COMAR 14.01.04.05, will be instrumental in evaluating the impact of proposed affordability measures on – in addition to the public access to – prescription drugs. It is extremely important to review all aspects of the supply chain that are associated with the provision of a prescription drug to the patient. Thus, NACDS strongly recommends that Regulation .05 be expanded to include a dedicated section requiring the Board to evaluate pharmacy reimbursement and dispensing cost data as part of the Cost Review Study. Pharmacies serve as the final access point in the pharmaceutical supply chain. This information will provide the Board a more comprehensive understanding of market impacts that affect pharmacies' ability to provide Marylanders with the medications they deserve. Accurate and timely information is crucial as the reimbursement methodologies directly affect public access to medications, especially in rural, underserved, and medically vulnerable communities.

NACDS appreciates the opportunity to submit comments on the proposed regulations pertaining to prescription drug affordability. Including the recommended provisions above would improve transparency, ensure affordability policies account for the full pharmaceutical supply chain, and maintain sustained quality community access to essential medications. We welcome the opportunity to discuss and engage further on these important policies that impact affordability and patient access.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores (NACDS)

PhRMA
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By Electronic Submission

June 1, 2026

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

RE: Draft Regulations – Proposed Revisions to COMAR 14.01.04

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Maryland Prescription Drug Affordability Board's (the "PDAB's" or "Board's") request for written comments on its draft revisions regarding the Cost Review Study Process (COMAR 14.01.04) ("Draft Regulations").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a

[1] *See* Draft Proposed Amendments to COMAR 14.01.04 for Comment (May 1, 2026), *available at* https://pdab.maryland.gov/Documents/regulations/2026/5.1.26%2014.01.04-Draft%20Cost%20Review%20Regulations%20for%20Public%20Comment%20%281%29.pdf; In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Md. Code Ann., Health-Gen. §§ 21-2C-01–16 (the "PDAB Statute") and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute. *See, e.g.*, Letter from PhRMA to Board Regarding Draft Cost Review Study Report for Comment (May 1, 2026); Letter from PhRMA to Board Regarding Draft Regulation – New Regulation COMAR 14.01.07.02 (Upper Payment Limit); Ozempic: Calculations and Analyses Underpinning Potential UPL Values (May 1, 2026); Letter from PhRMA to Board Regarding Draft Regulations – New Regulation COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits); New Regulation – COMAR 14.01.07 (Upper Payment Limit) (Mar. 30, 2026); Letter from PhRMA to Board Regarding Draft Cost Review Study Reports for Comment (Mar. 30, 2026); Letter from PhRMA to Board Regarding UPL Amount and Methodology Documents (Mar. 4, 2026); Letter from PhRMA to Board Regarding Cost Review Study Process and Policy Review Process (Feb. 10, 2026); Letter from PhRMA to Board Regarding Proposed Rules – Amendments to COMAR 14.01.01.01 (Definitions); New Regulation COMAR 14.01.01.06 (Hearing Procedures); New Chapter COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Feb. 10, 2025); Letter from PhRMA to Board Regarding Proposed Regulation – Amendments to COMAR 14.01.04.05 (Cost Review Study Process) (Dec. 2, 2024); Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR 14.01.01.01 (Definitions); New Regulation COMAR 14.01.01.06 (Hearing Procedures); New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 12, 2022).

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

PhRMA appreciates the Board's decision to extend the deadline for submitting comments on these Draft Regulations. This additional time affords stakeholders greater opportunity to review and meaningfully respond to the complex set of proposed regulatory changes reflected in the Draft Regulations.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA has previously expressed in detail our concerns regarding the cost review study process, and we incorporate these prior comments by reference and encourage the Board to consider them.[3] In addition, we provide below non-exhaustive comments and concerns in response to this request for comment.

I. Delegation of Board Responsibilities to Staff

The Draft Regulations reflect a significant shift toward delegating core Board functions to staff, including the identification and prioritization of drugs for review, the curation of information presented to the Board and the Stakeholder Council, and the identification and use of analytical comparators such as therapeutic alternatives. While staff may support the Board, the degree of delegation contemplated here raises significant statutory, procedural, and transparency concerns.

A. Statutory Concerns with Delegation of Core Board Responsibilities

PhRMA is concerned that unfettered delegation of critical and discretionary decisions to Board staff may undermine the statutory role of the Board. While the Board is authorized to hire staff for support, the PDAB Statute assigns responsibility for evaluating drug affordability *to the Board itself*.[4] There is no indication in the statute that the Board can divest itself of its duty to discharge key statutory responsibilities by granting staff unrestrained discretion over critical decisions and authority to curate the information made available to the Board.[5] Without adequate regulatory safeguards and a clear process for Board review and adoption of staff decision-making, delegation could allow staff to exert significant influence over Board decision-making by controlling the information and options presented to it.[6]

For example, the Draft Regulations would permit staff to provide the Board with a curated list of drugs eligible for selection, and there is no apparent mechanism for the Board to understand the staff's rationale or which eligible drugs were excluded from the curated list.[7] The PDAB Statute specifies that "*[t]he Board*

[2] *See* Md. Code, Health-Gen. §§ 21-2C-01–16.

[3] *See supra* note 1.

[4] *See* Md. Code, Health-Gen §§ 21-2C-03(c)(1), (f)(2) (authorizing the hiring of staff for the Board and contracting for services necessary to carry out the Board's powers and duties); *id.* §§ 21-2C-09(a)-(b) (assigning the relevant cost-review and affordability determinations to the Board).

[5] *See* Md. Code, Health-Gen. §§ 21-2C-08(c), 21-2C-09(a)-(b) (assigning *to the Board* responsibility for identifying prescription drug products eligible for cost review, determining whether to conduct a cost review, and determining whether use of a prescription drug product has led or will lead to affordability challenges).

[6] *See Grant v. Cnty. Council of Prince George's Cnty.*, 465 Md. 496, 516–17, 214 A.3d 1098, 1110 (2019) (finding that "[t]he record contains sufficient evidence of the [administrative body's] deliberation. . . to uphold its decision" where "the District Council met and voted to approve the findings of fact and conclusions of law" prepared by staff.)

[7] *See* Draft COMAR 14.01.04.03A.

shall use the information collected . . . to identify prescription drug products" that are eligible for cost review study.[8] The Draft Regulations would also allow staff to make recommendations to the Board regarding drugs to refer to the Stakeholder Council for eventual selection for cost review study.[9] However, the PDAB Statute similarly provides that "*the Board* shall determine whether to conduct a cost review . . . for each identified prescription drug product by . . . [s]eeking Stakeholder Council input."[10] It is unclear how the Board would satisfy its duties without access to all information and reasoning underlying the recommendations and independent evaluation and adoption of the staff's decisions.

PhRMA appreciates that the Draft Regulations clarify that the Board would not be limited to reviewing staff-recommended drugs.[11] However, we are concerned that, if the Board relies too heavily on staff recommendations—particularly without access to all underlying information and reasoning—the Board could effectively abdicate its statutory duties, including the duty to determine whether to conduct a cost review for each eligible drug.[12] PhRMA appreciates the Board's request that it still receive the full list of eligible drugs, in addition to the staff-curated list.[13] However, PhRMA urges the Board to revise the Draft Regulations to require that staff provide the Board all information and reasoning underlying their decisions and recommendations, as well as any other information necessary for the Board to independently assess the staff's conclusions. Staff decisions should not be effective unless and until the Board has reviewed and approved in accordance with its standard decision-making processes, including notice, public hearing, and opportunity for stakeholder comment. As part of its review process, the Board should publish the staff's conclusions, reasoning, and underlying information to the extent they are not protected as confidential, proprietary, or trade secret.[14]

A. Risk of Diminished Transparency and Public Accountability

By allowing Board staff to exercise broad discretion in making recommendations and determining what information is shared with stakeholders and the Board, the Draft Regulations risk reducing transparency and limiting opportunities for stakeholder engagement. For example, providing the Stakeholder Council only a staff-curated subset of information—rather than a complete dataset derived from established criteria—impairs meaningful stakeholder engagement.[15] Without an understanding of the rationale underlying staff conclusions, stakeholders cannot effectively evaluate, comment on, or respond to that information.

Additionally, the Draft Regulations do not ensure that stakeholders will receive opportunities to comment on the staff's methodological choices, analyses, and recommendations. For instance, the contemplated deletion of COMAR 14.01.04.03(C)(4) would remove explicit language providing that "[t]he public may provide oral and written comments" on drugs proposed for referral to the Stakeholder Council "in

[8] Md. Code, Health-Gen. § 21-2C-08(c) (emphasis added).
[9] *See* Draft COMAR 14.01.04.03C(2).
[10] Md. Code, Health-Gen. § 21-2C-09(a)(1)(i) (emphasis added).
[11] *See* Draft COMAR 14.01.04.03C(3).
[12] *See* Md. Code, Health-Gen. § 21-2C-09(a)(1) ("After identifying prescription drug products as required by § 21–2C–08 of this subtitle, the Board shall determine whether to conduct a cost review[.]"); *see also Grant v. Cnty. Council of Prince George's Cnty.*, 465 Md. 496, 516–17, 214 A.3d 1098, 1109–10 (2019) (cautioning that "more deliberation by the public body—rather than the very bare minimum—is always encouraged" when a public body adopts staff-prepared findings and conclusions).
[13] Maryland PDAB, May 18, 2026 meeting video recording, https://www.youtube.com/watch?v=RRXyLr52N9E (time code 48:18)
[14] *See* Md. Code, Health-Gen. § 21-2C-10 (statutory protections for non-public information).
[15] *See* Draft COMAR 14.01.04.03A.

accordance with the procedures and timelines in" COMAR 14.01.01.05.[16] Removing this language raises concerns that public comment could be limited or solicited in a manner that does not comply with the procedural requirements of COMAR 14.01.01.05 or staff's stated goal of improving public engagement.[17]

Providing only general public comment opportunities (e.g., comment at Board meetings) is insufficient to address these concerns. Without adequate regulatory safeguards, critical analyses, deliberations, and decisions could be conducted in closed meetings and off the record, with limited (if any) opportunity for public visibility or input. Even in subsequent open Board meetings, stakeholders would be unable to provide meaningful comment, as they would lack insight into the staff's underlying processes and reasoning.

The Board is subject to Maryland's Open Meetings Act, and, under the PDAB Statute, certain Board actions—including deliberations on whether to subject a prescription drug product to a cost review and any Board decision—must occur in open session.[18] However, the Draft Regulations do not make clear that staff deliberations and decisions would be subject to the same open meeting requirements. In effect, this would undermine the intent of the legislature in requiring the Board to engage in open public meetings.[19]

For these reasons, the Board should revise the Draft Regulations to provide that, if the Board delegates its authority to staff, staff deliberations and decisions are governed by the same open meeting requirements as the Board (including exceptions for consideration of confidential, proprietary, and trade secret information).[20] PhRMA urges the Board to restore explicit provisions for stakeholder comment consistent with the procedural requirements of COMAR 14.01.01.05, in addition to providing clear, consistent, and meaningful opportunities for manufacturers and other stakeholders to directly engage on and challenge key staff determinations.[21]

B. Lack of Clear Standards Governing Staff Discretion

In addition to our overarching, fundamental concerns regarding the contemplated delegation of Board authority detailed above, PhRMA is concerned that the Draft Regulations do not establish meaningful standards to guide how staff would exercise such authority. For example, staff appear to have significant discretion in:

- prioritizing drugs for review,[22]

[16] COMAR 14.01.04.03(C)(4).

[17] For example, at the February 10th Information Hearing regarding the cost review study and policy review processes, Executive Director York stated that Board staff has been thinking about how to facilitate patient input and make Board resources more accessible. *See also, e.g.*, Updates to Cost Review Study Process and Policy Review Process at 3 (Presentation for Board Meeting on May 18, 2026), *available at* https://pdab.maryland.gov/Documents/meetings/2026/May%2018%2c%202026/2026.05.18%20Cost%20Review%20Study%20Updates.pdf (encouraging "continued public engagement").

[18] *See* Md. Code, Gen. Prov., §§ 3-101–501; *see* Md. Code, Health-Gen. § 21-2C-03(e)(1)(iii) (requiring certain Board actions to be made in open session).

[19] *See* Md. Code, Health-Gen. § 21-2C-03(e)(1)(i) (requiring the Board to "meet in open session at least four times a year").

[20] *See supra* note 26; Md. Code, Health-Gen. § 21-2C-10.

[21] This is particularly true where meaningful engagement requires input from manufacturers, clinical experts, and patients, as with the identification of therapeutic alternatives or other comparators. General public comment opportunities are insufficient forums for sharing complex technical, clinical, and patient experience input.

[22] *See* Draft COMAR 14.01.03A.

- selecting and defining therapeutic alternatives and determining appropriate comparators,[23] and
- curating and presenting data to the Board and Stakeholder Council.[24]

Maryland law requires that agency decision-making be guided by "a relevant or applicable set of norms" to ensure that actions are reasonable, consistent, and not arbitrary.[25] These requirements are subverted where an agency fails to adopt standards to guide its decision-making or adopts standards so vague as to prevent consistent and reasoned decision-making. Here, the absence of articulated criteria for key functions creates a substantial risk that drugs will be treated differently without a rational basis, or that decisions will vary based on *ad hoc* staff judgments rather than consistent principles.[26]

II. Lack of Justification for Regulatory Changes

The Draft Regulations introduce a number of substantive changes beyond increasing reliance on staff discretion, such as expanded data requests and new analytical approaches, without providing a clear justification for those changes. For example, the Board proposes to request new categories of information (e.g., direct-to-physician marketing and patient access program data), as well as more granular data (e.g., pricing information per-unit), without specifying why such amendments are necessary or how the Board would use this information to assess affordability under the PDAB Statute. Maryland courts have recognized that agency action must reflect a "rational connection between the facts found and the choice made" and that the agency's reasoning must be reasonably discernible.[27] Failure to do so may render agency action arbitrary and capricious.

Without a clear explanation of the purpose and expected impact of these changes, stakeholders cannot meaningfully assess or comment on the Draft Regulations. PhRMA urges the Board to provide a detailed justification for each significant amendment and to clearly articulate how each change advances the Board's statutory mandate to assess affordability challenges.[28]

III. Confidentiality

Consistent with our prior comment letters, PhRMA emphasizes the importance of developing safeguards against the disclosure of confidential information.[29] In the Draft Regulations, the Board contemplates requesting a significant amount of additional confidential, proprietary, and trade secret information for consideration in its cost reviews.[30] They do not, however, adequately address how the Board intends to

[23] *See* Draft COMAR 14.01.03H, 14.01.04.05C(1)(e)(i). *See also infra* Section IV.B for further discussion of PhRMA's concerns regarding the selection and use of therapeutic alternatives or "any comparator."
[24] *See* Draft COMAR 14.01.04.03A; 14.01.04.03B; 14.01.04.03G(3).
[25] *Harvey v. Marshall*, 389 Md. 243, 299 (2005).
[26] *See, 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."); *Hines v. Petukhov,* No. 0594, Sept. term, 2020, 2021 WL 4428781, at *8 (Md. Ct. Spec. App. Sept. 27, 2021) (holding it arbitrary and capricious where an agency "applied different standards and drew irreconcilable and inconsistent conclusions" in its review of a second licensing request, relative to the review of the first request).
[27] *Md. Off. of People's Counsel v. Md. Pub. Serv. Comm'n*, 246 Md. App. 388, 412 (2020).
[28] *See* Md. Code, State Gov't § 10-112(a)(3) (requiring the notice of proposed adoption to include, among other things, a statement of purpose, an estimate of the regulation's economic impact on State and local government units and affected groups, and an opportunity for public comment before adoption).
[29] *See, e.g.*, Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 2; Letter from PhRMA to Board (July 12, 2024) *supra* note 1 at 4; Letter from PhRMA to Board (June 30, 2023) *supra* note 1 at 6-7; Letter from PhRMA to Board (May 4, 2023) *supra* note 1 at 1-3.
[30] *See* Draft COMAR 14.01.04.04.

protect against the unlawful disclosure of such information that it may receive from manufacturers, payors, pharmacy benefit managers ("PBMs"), and wholesale distributors.[31]

The PDAB Statute sets forth strict confidentiality protections for information and data obtained or accessed by the Board.[32] Indeed, "[o]nly Board members and staff may access trade secrets and confidential and proprietary data and information . . . that is not otherwise publicly available," and "[a]ll [non-public] information and data" obtained by the Board shall be "considered to be a trade secret and confidential and proprietary information" and "[i]s not subject to disclosure under the Public Information Act."[33] We urge the Board to clarify in the Draft Regulations how confidential, proprietary, and trade secret information will be protected from disclosure, consistent with the requirements of the PDAB Statute and other state and federal law.[34]

PhRMA provides below a non-exhaustive list of areas where the Draft Regulations would request information and data that raise heightened confidentiality concerns.

- **Pricing Information.** The Draft Regulations would authorize the Board to request that payors, PBMs, and wholesale distributors report the average price concession, discount, and rebates that the manufacturer or relevant entity provides, expressed in dollars per-unit and as a percent of the wholesale acquisition cost ("WAC")—despite the PDAB Statute only contemplating that the Board consider such information expressed as a percent of WAC.[35] The Draft Regulations would also permit the Board to request the net price received by the manufacturer for the drug "accounting for all price concessions, discounts, and rebates, reported by payor type and in aggregate."[36] Requiring these types of pricing information to be reported at this level and without sufficient safeguards risks disclosure of highly confidential competitive information.

- **"Patient Access Program" Information.** The Draft Regulations would authorize the Board to request information "concerning the manufacturer's drug-specific patient access programs," including the "value of all coupons, free samples, and drug donations to charities provided by the manufacturer" and the total tax benefits realized due to the program for the most recent year.[37] Like pricing information, this information can be highly sensitive. As PhRMA has previously explained, manufacturers' internal policies—and associated decisions related to patient access

[31] *Id*.
[32] *See* Letter from PhRMA to Board (June 30, 2023) *supra* note 1 at 6-7.
[33] Md. Code, Health-Gen. § 21-2C-10(a)–(b).
[34] It has long been recognized that manufacturers' confidential, trade secret, and proprietary information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. *See, e.g.*, 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act). *See also* PDAB Statute § 21-2C-10(a)–(b); COMAR 14.01.01.04; Md. Code, Com. Law §§ 11-1201–1209 (Maryland Uniform Trade Secrets Act). As courts have also made clear, "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality . . . can amount to an unconstitutional 'taking' of property." *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted); *see also Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1002–04 (1984) (Fifth Amendment uncompensated taking). PhRMA provides a more detailed discussion of its concerns regarding protections for confidential, trade secret, and proprietary information in its May 2023 comments to the Board. *See* Letter from PhRMA to Board (May 4, 2023) *supra* note 1.
[35] *See* Draft COMAR 14.01.04.04B(2)(a), (3)(a), (4)(b); Md. Code, Health-Gen. §§ 21-2C-09(b)(2)(ii), (iii).
[36] Draft COMAR 14.01.04.04B(1)(d).
[37] Draft COMAR 14.01.04.04B(1)(p).

programs—may include proprietary and trade secret information, thereby raising significant confidentiality concerns.[38]

- **National VA Contract Price and Big 4 Price.** The Draft Regulations would allow the Board to consider information about a selected drug and its therapeutic alternatives' National VA Contract Price and Big 4 Price in cost reviews.[39] The Board fails to acknowledge that this is highly confidential pricing information that is protected from public disclosure under federal law, including by the federal health care programs that have direct access to such information.[40] PhRMA has serious concerns about the Board's contemplated use of federally reported pricing information in a manner that Congress disallows, even under those federal health care programs where the information is collected. Further, there are drug prices and discounts extended under those programs pursuant to confidential federal procurement contracts that are protected by confidentiality provisions preventing their disclosure.

The Board must address how it will protect confidential, proprietary, and trade secret information consistent with state and federal law and incorporate clear standards for doing so in the Draft Regulations.

IV. Other Concerns

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

As expressed in prior letters, PhRMA is concerned with the Board's overarching shift toward increased alignment with drug selections under the Medicare Drug Price Negotiation Program ("MDPNP") and reliance on Medicare Maximum Fair Prices ("MFPs") in its cost reviews.[41] PhRMA and its members oppose the MDPNP price-setting process. It is not a true negotiation because if a manufacturer does not accept the MDPNP price or participate in the process, the manufacturer is subjected to steep penalties, crushing taxes, or both. In addition, by relying on drug selections under the MDPNP, the Board would be disregarding the unique market dynamics and affordability challenges that patients in Maryland may be facing. MFPs are specifically developed for the Medicare program and patient population under the statutory framework of the Inflation Reduction Act, but the Draft Regulations would apply these prices to an entirely different market, patient population, and statute (i.e., the PDAB Statute).

MFP-based upper payment limits ("UPLs") raise serious concerns for patient access, especially if expanded to the commercial market. Although it will be years before the effects of MFPs on patient affordability and access are fully understood, recent evidence shows that out-of-pocket costs for Medicare patients have

[38] *See* Letter from PhRMA to Board (Dec. 2, 2024) *supra* note 1 at 4-5. *See id.* for further discussion of the role these programs play in promoting patient access and adherence to medicines.
[39] Draft COMAR 14.01.04.05C(1)(a)(i), (c)(ii).
[40] Under the Veterans Health Care Act, the prices reported to the Secretary must be kept confidential "except as the Secretary determines necessary to carry out this section and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided." 38 U.S.C. §§ 8126(e)(2), (4). The Medicaid statute reinforces the restrictions on VA pricing disclosures in connection with these programs. 42 U.S.C. § 1396r-8(b)(3)(D) ("Information disclosed by manufacturers [] under this paragraph or under an agreement with the Secretary of Veterans Affairs [in compliance with 38 U.S.C. § 8126] . . . is confidential and shall not be disclosed by the Secretary of Veterans Affairs or a State agency" with limited exceptions.
[41] *See* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 10.

increased and the number of patients benefiting from MFPs has remained relatively small. Indeed, Avalere Health's analyses of 2025 and 2026 Part D plan formularies found Part D plans were tightening access to branded medicines, changes that could translate into fewer therapeutic alternatives within classes that contain drugs with an MFP.[42] Many operational and legal issues with MFPs remain unresolved because the MDPNP is still at an early stage, and MFPs for the initial set of drugs only recently went into effect. The use of MFP as a benchmark for UPL-setting and in the Board's cost review study process generally is therefore premature, and PhRMA is concerned with the Board relying on drug selections under the MDPNP without fully understanding the patient impact from the MDPNP.

B. Concerns Regarding the Selection and Use of Therapeutic Alternatives or Comparators

The Board proposes to add a new provision to the Draft Regulations that would permit Board staff to examine cost and comparative effectiveness analyses using "any comparator including, but not limited to, therapeutic alternatives identified under COMAR 14.01.04.03C(1)(e), in performing analyses under" Draft COMAR 14.01.04.05.[43] If finalized, this would significantly expand the scope of the Board's comparative evaluations without establishing guardrails to prevent inappropriate comparisons between products.

The risk of inappropriate comparisons is particularly acute where, as here, the Draft Regulations lack clear standards for identifying appropriate comparators. By permitting staff to examine analyses using "any comparator," the Draft Regulations would seem to authorize open-ended comparisons to any therapy that staff deems a comparator without clear standards or criteria for identifying appropriate comparators. Such broad discretion could result in inappropriate comparisons between dissimilar therapies. Further, the lack of consistent standards for identifying comparators risks inconsistent and *ad hoc* application of the comparative evaluation process, which could result in such reviews being conducted in a manner that is arbitrary and capricious.[44] Maryland courts have long held that agency action can be found to be arbitrary and capricious if similarly situated entities or products are treated differently without a rational basis for such differential treatment,[45] and have likewise struck down decisions that have unexplained inconsistencies with prior agency decisions.[46] PhRMA has serious concerns that, without clear standards for identifying and evaluating comparators for selected drugs, there are few, if any, guardrails against inconsistent and arbitrary and capricious decision-making.

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[42] *See* Avalere Health, 2025 Part D Formularies Shift to More Coinsurance and UM, Oct. 2024; Avalere Health, Part D Formulary Management Tightens in 2026, Nov. 2025. Avalere's 2026 Part D plan formulary analysis also found Part D plans increased utilization management for some selected drugs along with slight shifts in tier placement. *See id.* In addition, a 2025 physician survey by Avalere found that nearly all providers (92%) would be somewhat or very likely to stop stocking Part B drugs subject to an MFP. Avalere Health, White Paper: Provider Survey on Part B Negotiation, Sept. 2025. Further, Magnolia Market Access recently reported that, "[i]n 2026, about [66%] of Part D beneficiaries are enrolled in a standalone prescription drug plan (PDP) or Medicare Advantage Prescription Drug (MA-PD) plan that has shifted coverage of IPAY 2026 selected drugs from a fixed copay to coinsurance between 2023 and 2026. Among these beneficiaries, about 60% are projected to face higher cost-sharing after reaching the deductible and before the maximum out-of-pocket cap…than they would have faced in 2023." Magnolia Market Access, When Lower Prices Don't Mean Lower Costs: How Part D Benefit Changes Are Shifting Out-of-Pocket Spending in 2026 Under the Inflation Reduction Act, 2026.

[43] Draft COMAR 14.01.04.05C(1)(e)(i).

[44] *See Harvey,* 389 Md. at 302.

[45] *See Maryland State Bd. of Soc. Work Examiners v. Chertkov,* 121 Md. App. 574, 588 (1998).

[46] *See, e.g.*, *Christopher v. Montgomery Cnty. Dep't of Health & Human Servs.,* 381 Md. 188, 215 (2004).

Additionally, PhRMA strongly recommends that the Board use caution when considering information regarding "therapeutic alternatives" or "any comparator" for selected medications.[47] A patient who can safely and effectively use one drug may experience negative outcomes with another drug that may be considered a therapeutic alternative. Patients respond differently to treatments because of an array of factors, such as genetics, age, sex, socioeconomic status, drug interactions, diet, environment, and co-morbidities. This means that a treatment that is the best option for one individual may not be as effective for others. For these reasons, PhRMA is concerned that the Board's approach to therapeutic alternatives could risk inappropriate comparisons that could lead to distorted UPLs, particularly if the therapeutic alternatives are not supported by clinical evidence and consistent with standard practice.[48]

PhRMA's concerns about the expanded scope of the Board's comparative evaluations are exacerbated by the Draft Regulations' changes to the process for identifying therapeutic alternatives. The Draft Regulations eliminate the requirement that "*[t]he Board* . . . determine the therapeutic alternatives for each prescription drug product selected for a cost review study" and leave identification of therapeutic alternatives to staff.[49] This delegation of authority raises the types of concerns discussed above in Section I because the PDAB Statute expressly states that therapeutic alternatives are a factor "*the Board* shall consider" when performing a cost review study.[50] To satisfy its statutory duties, the Board must understand how staff identified particular therapeutic alternatives, independently review the information underlying staff decisions, and approve staff decision-making. PhRMA is also concerned that, as detailed above,[51] stakeholders do not have sufficient opportunity to review, challenge, or comment on the staff's decision-making in identifying therapeutic alternatives, which is particularly concerning where staff-selected inputs may materially shape the Board's cost review analysis, as is the case here.[52]

C. Cost-Effectiveness Analyses Ignore the Personal Needs of Patients and Interfere with Physician Judgments

Finally, PhRMA is concerned with the Board's proposal to consider in its cost review "[i]nformation derived from health economics and outcomes research that may address the effectiveness" of the drug in "treating the conditions for which it is prescribed" and "compared with therapeutic alternatives."[53] As PhRMA has explained previously, policies, including UPLs, that are based on cost-effectiveness determinations can prevent patients from accessing the treatments that best meet their personal needs and preferences and override physician judgment in making individualized treatment decisions.[54] For example, cost-effectiveness analyses often fail to account for important elements of value that matter to patients and

[47] *See* Letter from PhRMA to Board Regarding Draft Regulations (May 1, 2023) *supra* note 1 at 11.
[48] PhRMA also notes that the proposed provision, as currently drafted, includes a cross-referenced cite to Draft COMAR § 14.01.04.03C(1)(e) that appears to be incorrect as that provision does not exist, either under existing regulations or the draft amendments. Draft COMAR 14.01.04.05C(1)(e)(i). Before finalizing, PhRMA urges the Board to revise the proposed provision to correct the cross-referenced cite.
[49] Draft COMAR 14.01.04.03H(5) (emphasis added). *See also, e.g.*, DRAFT COMAR 14.01.04.03I(8), 14.01.04.03H(1).
[50] Md. Code, Health-Gen. § 21-2C-09(b)(2)(iv), (v), (ix).
[51] *See supra* Section I.B.
[52] Md. Code, Health-Gen. § 21-2C-09(b)(2)(iv), (v), (ix).
[53] Draft COMAR 14.01.04.05C(1)(e)(iii).
[54] *See* Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 1 at 9-10; *see also* Letter from PhRMA to Board (May 1, 2023) *supra* note 1 at 12-13.

obscure important differences that are disproportionately faced by underserved populations, such as the elderly and patients with disabilities.[55] The Board has not detailed how it will prevent these and other potential biases from affecting its cost reviews.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns with the Draft Regulations and cost review study process in general, we continue to stand ready to be a constructive partner in this dialogue. Please contact Kristin Parde at Kparde@phrma.org with any questions.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director – Law

[55] *See id*.

June 1, 2026

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

RE: Comments and Proposed Amendments to COMAR 14.01.04

Dear Members of the Maryland Prescription Drug Affordability Board:

On behalf of the Value of Care Coalition ("VCC"), we respectfully submit the following comments and proposed amendments regarding the draft regulations for COMAR 14.01.04 concerning prescription drug cost review procedures.

VCC supports the Board's efforts to address prescription drug affordability challenges in Maryland. To provide the best opportunity to accomplish that goal, VCC believes the proposed regulations should more fully account for patient access, continuity of care, provider participation, and the clinical realities associated with medically necessary treatment decisions. The following proposed amendments are intended to strengthen transparency, stakeholder engagement, equity considerations, and patient protections within the Board's cost review framework.

Proposed Amendments to COMAR 14.01.04.02 Identifying Drugs Eligible for Cost Review

Proposed Amendment to COMAR 14.01.04.02(D)(4) — Eligibility Based on IRA Drug Price Negotiation

VCC proposes amending §(D)(4) as follows:

(D)(4) A prescription drug product subject to the Medicare Drug Price Negotiation Program under the Inflation Reduction Act shall not be deemed automatically eligible for cost review on that basis alone. The Board may consider a drug product's status as an IRA-negotiated drug as one factor in assessing eligibility, provided that the Board makes an independent finding that the drug product presents an affordability challenge to patients or payers in Maryland's commercial or state-regulated insurance markets.

Rationale: The addition of §(D)(4) to the eligibility criteria represents the single most consequential structural change in the proposed regulations. By making IRA-negotiated status a freestanding basis for cost review eligibility, the regulation effectively delegates Maryland's drug selection process to the Centers for Medicare and Medicaid Services — a federal agency operating under an entirely different statutory mandate and patient population.

CMS selects drugs for the Medicare negotiation program based on Medicare program spending and budget scoring criteria established by the Inflation Reduction Act. The statutory selection criteria prioritize drugs accounting for the highest Medicare Part D expenditures that lack generic or biosimilar competition within a qualifying period. These criteria reflect Medicare's programmatic spending priorities and budget impact — not state-level patient access concerns, the clinical needs of commercially insured patients, or Maryland-specific affordability data.

A drug's selection by CMS for Medicare price negotiation is therefore not evidence that the drug presents an affordability challenge in Maryland's commercial or state-regulated markets. The populations, coverage structures, benefit designs, and reimbursement dynamics in Medicare and Maryland's commercial markets differ substantially.

Permitting automatic eligibility based on IRA selection also risks creating a pipeline in which any drug entering the federal negotiation program is automatically queued for state cost review, regardless of whether it presents a demonstrated or documented affordability challenge to Maryland patients. This is not a narrowly tailored eligibility standard — it is an open-ended expansion of Board jurisdiction tethered to federal programmatic decisions that were never designed with state affordability review in mind.

VCC's proposed amendment preserves the Board's ability to consider IRA status as one relevant data point while requiring an independent, Maryland-specific affordability finding before eligibility is conferred. This ensures the Board's selection process remains grounded in the statutory authority of the Maryland PDAB Act.

Proposed Amendments to COMAR 14.01.04.03 Selecting Drugs for Cost Review

Proposed New COMAR 14.01.04.03A(3) for Transparency and Prioritization Methodology Disclosure

VCC proposes adding new §A(3) as follows:

(3) The Board shall publish:

(a) The methodology used to prioritize prescription drug products for inclusion on the curated eligible list;

(b) The weighting criteria used in prioritization decisions;

(c) A description of the data sources relied upon; and

(d) A summary explanation for exclusion of prescription drug products otherwise meeting statutory eligibility criteria.

Rationale: Transparency regarding prioritization criteria would improve accountability, stakeholder confidence, and public understanding of how affordability priorities are determined.

Proposed New COMAR 14.01.04.03C(2) for Public Comment and Stakeholder Engagement Prior to Referral

VCC proposes adding new §C(2) and renumbering subsequent subsections accordingly:

(2) Prior to voting on referral of a prescription drug product to the Stakeholder Council, the Board shall:

(a) Provide an opportunity for written public comment of not less than 14 calendar days;

(b) Permit oral public comment during the open meeting at which referral is considered;

(c) Publish the proposed basis for referral consideration; and

(d) Provide a summary of patient access concerns raised during the comment period.

Rationale: Earlier patient and provider engagement would improve transparency and help ensure affordability reviews incorporate real-world treatment experiences before products advance through the review process.

Proposed New COMAR 14.01.04.03G(4) for Stakeholder Council Patient and Provider Participation Requirements

VCC proposes adding new §G(4) as follows:

(4) The Stakeholder Council process shall include in a timely and accessible manner meaningful opportunities for participation by:

(a) Patients;

(b) Caregivers;

(c) Patient advocacy organizations; and

(d) Providers with experience treating the conditions associated with the prescription drug products under review.

Rationale: Claims data and pricing analyses alone may not fully reflect patient experiences navigating treatment access barriers, financial toxicity, or adherence challenges.

Proposed New COMAR 14.01.04.03H(5) and (6) for Clinical Considerations in Therapeutic Alternative Assessments

VCC proposes adding new §§H(5) and H(6) as follows:

(5) Identification of therapeutic alternatives under this regulation may not be interpreted as establishing clinical equivalence or interchangeability for individual patients.

(6) In identifying therapeutic alternatives, the Board shall consider:

(a) Differences in route of administration;

(b) Variability in patient response;

(c) Adverse event profiles;

(d) Comorbidities;

(e) Adherence considerations;

(f) Patient quality-of-life considerations; and

(g) Provider clinical judgment.

Rationale: Financial comparators do not reflect clinical interchangeability for individual patients.

Proposed Change to COMAR 14.01.04.03B(6) for Contextual Interpretation of Medicare Maximum Fair Prices

VCC proposes amending existing §B(6) as follows:

Medicare Maximum Fair Prices established under the Inflation Reduction Act shall be interpreted within the context of the Medicare program's statutory framework and shall not be presumed to reflect appropriate reimbursement levels for commercially insured patients, providers, or State-regulated markets.

Rationale: Medicare Maximum Fair Prices are produced through a federal negotiation process that operates exclusively within the Medicare program's statutory structure. The MFP reflects Medicare utilization patterns, federal rebate dynamics, and program-specific budget impact criteria — none of which translate directly to commercial or State-regulated insurance markets. Critically, the MFP is accompanied by Medicare-specific patient protections — including the Part D out-of-pocket cap and Low-Income Subsidy — that do not exist in Maryland's commercial market. Those protections help beneficiaries within the federal program; without them, the

price number alone does not carry the same meaning or produce the same outcomes for patients outside Medicare.

Displaying the MFP on the Board's drug selection dashboard without this context risks treating a Medicare-specific construct as a market-neutral pricing benchmark. A drug product's MFP reflects CMS's assessment of appropriate Medicare program spending — not an independent determination that the price is clinically or economically appropriate for commercially insured Maryland patients, community pharmacies, or specialty providers operating outside the Medicare payment system. Early evidence from the first cohort of MFP-subject drugs shows that commercial payers have responded to MFP reference pricing by raising patient out-of-pocket costs and restructuring benefit designs in ways that increase patient cost-sharing burdens — outcomes inconsistent with the affordability goals the Board is charged with advancing.

For these reasons, the MFP should inform the Board's deliberations only with explicit acknowledgment of the structural differences between the Medicare program and the markets the Board regulates.

Proposed Amendments to COMAR 14.01.04.04 Request for Information for Cost Review

Proposed Change to COMAR 14.01.04.04B(1)(i) on Consideration of International Healthcare System Differences

VCC proposes amending existing §04B(1)(i) as follows:

In considering international pricing information, the Board shall also consider differences in:

(1) Patient access;

(2) Treatment availability;

(3) Launch timing;

(4) Reimbursement systems; and

(5) Coverage restrictions across international health systems.

Rationale: International pricing information does not capture meaningful differences in healthcare delivery systems or patient access.

Proposed Amendments to COMAR 14.01.04.05 Cost Review Study

Proposed Change to COMAR 14.01.04.05C(1)(d) for Patient Access and Care Delivery Impact Evaluation

VCC proposes amending existing §05C(1)(d) as follows:

(iv) The Board shall evaluate the potential impact of affordability-related findings or recommended actions on patient access, including for patients dependent on the product under review, to medically necessary therapies;

(v) The Board shall consider whether affordability-related actions may contribute to:

A. Treatment delays;

B. Interruptions in therapy;

C. Reduced adherence;

D. Reduced provider participation;

E. Challenges in maintaining continuity of care for patients who are stable on therapy;

F. Non-medical switching of treatment; or

G. Adverse clinical outcomes associated with delays, interruptions, disruptions, or changes to medically appropriate treatment.

(vi) The Board shall consider the effects of affordability-related actions on continuity of care for patients who are stable on therapy and on timely access to treatment, including in community-based care settings.

Rationale: These amendments ensure that the Board evaluates affordability-related actions through a patient-centered lens by considering the potential effects on access to medically necessary treatment, continuity of care, and clinical outcomes. Affordability interventions can have unintended consequences, including treatment delays, interruptions, non-medical switching, and reduced provider participation, which may adversely affect patient health and care delivery. Explicitly incorporating these factors will support more balanced decision-making that advances affordability goals while safeguarding timely access to appropriate care.

Proposed Change to COMAR 14.01.04.05C(1)(e) for Protections for Patients with Rare, Chronic, Progressive, or Disabling Conditions

VCC proposes amending existing §05C(1)(e) as follows:

(i) Staff shall avoid reliance on methodologies that may undervalue treatments for individuals with disabilities, rare diseases, chronic illnesses, or progressive conditions.

(ii) In conducting affordability analyses involving therapies for rare, chronic, progressive, or disabling conditions, the Board shall consider:

A. Availability of alternative treatment options;

B. Disease severity and progression;

C. Unmet medical need;

D. Caregiver burden;

E. Small patient population considerations; and

F. Potential impacts on future development of therapies for medically underserved populations.

Rationale: Traditional affordability and cost-effectiveness frameworks may not fully capture the needs of patients with rare or medically complex conditions.

Proposed New COMAR 14.01.04.05C(2)(e)(vii) in Recognition that an affordability determination must account for the full cost picture

VCC proposes adding new §05C(2)(e)(vii) as follows:

(vii) In assessing affordability challenges associated with a prescription drug product, the Board shall consider whether the cost review accounts for the relationship between access to the drug product and downstream healthcare utilization, including:

(A) Healthcare costs associated with treatment non-adherence or discontinuation;

(B) Hospital admissions, emergency department utilization, or disease progression attributable to inadequate treatment;

(C) Costs associated with management of preventable complications; and

(D) The extent to which the cost of the drug product offsets other healthcare utilization costs when used as indicated.

Rationale: A cost review that does not account for these factors may not present a complete picture of the drug product's net impact on the State health care system. **T**he current framework focuses on aggregate drug spending, list and net price, and patient count — metrics that measure the cost of treatment but not the cost of inadequate treatment. A finding of an affordability challenge based solely on spending metrics, without accounting for downstream cost offsets, risks overstating the net burden of the drug product on the State health care system.

Proposed Amendment to COMAR 14.01.04.05(C)(2)(g)(vii) — Use of CMS MFP Analytical Data

VCC proposes amending §(C)(2)(g)(vii) as follows:

(C)(2)(g)(vii) The Board may consider information, analyses, and data published by the Centers for Medicare and Medicaid Services in connection with the Medicare Drug Price Negotiation Program, provided that:

(A) Staff prepare and publish a written explanation of the material respects in which Medicare program conditions, patient populations, benefit structures, and reimbursement dynamics differ from those in Maryland's commercial and state-regulated insurance markets;

(B) Staff identify any adjustments made to CMS data or analyses to account for those differences; and

(C) The Board does not treat MFP analytical data as establishing an appropriate benchmark for commercial or state market pricing, reimbursement, or affordability determinations without an independent Maryland-market analysis.

Rationale: The proposed regulations at §(C)(2)(g)(vii) create an "other information" category that permits the Board to rely on the information and analyses CMS produces to underpin MFP determinations. VCC's concern is not that CMS produces this data — it is that importing it without adjustment or qualification risks introducing Medicare-specific analytical assumptions into a state cost review framework where they do not belong.

The analyses underlying MFP determinations are developed using Medicare program data: Medicare Part D utilization patterns, Medicare rebate structures, Medicare plan design dynamics, and federal budget impact modeling. These inputs are not analogous to the commercial insurance and state-regulated plan data that governs Maryland's market. The MFP itself is produced through a negotiation process in which CMS has statutory authority to set binding prices — authority the Maryland PDAB does not possess and cannot replicate. The analytical foundations of the MFP are therefore calibrated to a negotiation context and program structure that has no direct state-market equivalent.

There is also a methodological concern. CMS cost-effectiveness assessments and the analyses informing MFP are adjacent to, and in some cases explicitly informed by, cost-per-outcome frameworks that federal statute restricts in other contexts. The Medicare program is prohibited from using quality-adjusted life year thresholds to make coverage or reimbursement decisions under 42 U.S.C. § 1182(e). The Maryland PDAB has no equivalent statutory restriction. Allowing unrestricted reliance on CMS MFP analytical data could permit the indirect use of QALY-adjacent reasoning in Maryland's cost review process through a provision that carries no methodological guardrails.

VCC's proposed amendment does not prohibit the Board from considering CMS data — it requires transparency and adjustment. Staff should be required to explain, in writing, how the

Medicare-specific analytical assumptions embedded in CMS MFP data have been accounted for before that data is used in a Maryland affordability determination. This ensures the Board's findings are grounded in Maryland market conditions rather than in federal programmatic judgments that were never designed for state cost review purposes.

Proposed New COMAR 14.01.04.05F(3) for Stakeholder Review of Non-Confidential Staff Analyses

VCC proposes adding new §05F(3) as follows:

(3) Prior to issuance of a preliminary determination, entities submitting information under Regulation .04 shall have an opportunity to review and respond to non-confidential staff analyses and factual findings relied upon by the Board. Staff analyses shall be made available no fewer than 21 days prior to a preliminary determination, and submitting entities shall have no fewer than 14 days to submit written responses.

Rationale: Allowing stakeholders to review factual analyses would improve accuracy and support fair and transparent decision-making.

Proposed New COMAR 14.01.04.05I for Patient Access and Continuity of Care Protections

VCC proposes adding new COMAR 14.01.04.05I as follows:

I. Patient Access Protections.

(1) In implementing this chapter, the Board shall prioritize maintaining:

(a) Patient access to medically appropriate treatment options;

(b) Continuity of care; and

(c) Timely availability of prescription drug products.

(2) A determination that a prescription drug product may create affordability challenges may not by itself support policies that could:

(a) Restrict medically appropriate access to treatment;

(b) Limit provider ability to furnish medically necessary therapies;

(c) Disrupt continuity of care for stable patients; or

(d) Reduce availability of treatment options for patients with serious, chronic, rare, or life-threatening conditions.

Rationale: Explicit patient protections would help ensure affordability reviews remain focused on improving patient outcomes and access rather than creating unintended treatment disruptions.

Additional Patient Access Concerns

VCC encourages the Board to further consider several broader concerns reflected throughout the proposed regulations, including:

- Overemphasis on financial metrics without sufficient analysis of patient access outcomes, continuity of care, or provider participation;
- Limited protections for patients stable on existing therapies;
- Limited evaluation of provider acquisition costs, inventory management challenges, and impacts on community-based care delivery;
- Insufficient evaluation of the downstream healthcare costs associated with treatment non-adherence or discontinuation, including hospital admissions, disease progression, and management of preventable complications attributable to inadequate treatment.

VCC appreciates the Board's consideration of these recommendations and its ongoing efforts to improve prescription drug affordability; however, the Board must preserve patient access, continuity of care, and equitable treatment outcomes for Maryland patients.

Respectfully,

Derek Flowers