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VIA ELECTRONIC MAIL

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Re: Comments on Proposed Amendments to COMAR 14.01.04 Published in the September 4, 2026, Maryland Register

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 ("Board's" or "PDAB's") proposed amendments to COMAR 14.01.01.05(B)(4)(b) and COMAR 14.01.04 published in the September 4, 2026 issue of the Maryland Register.[1] The proposal would repeal existing COMAR 14.01.04.01 and adopt a new regulation, amend Regulations .02 through .05, and adopt new Regulation .06 governing the Board's cost review study process.

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 the manufacturer of SKYRIZI® (risankizumab-rzaa), which is currently subject to the Board's cost review study process. AbbVie has actively participated in Maryland PDAB proceedings for several years and has submitted numerous comments regarding the Board's regulatory activities, drug selection processes, therapeutic alternative determinations, affordability analyses, and upper payment limit ("UPL") framework.

As a threshold matter, AbbVie incorporates by reference and reasserts all comments submitted in connection with the Board's proposed revisions to COMAR 14.01.04 (*see* Exhibit A)[2] and its proposal to adopt new COMAR 14.01.04.01 (*see* Exhibit B).[3] Many of the provisions

[1] Prescription Drug Affordability Board, General Provisions, 53:18 Md. Reg. 905, 906 (Sept. 4, 2026) (proposed COMAR 14.01.01.05(B)(4)(b)), at https://dsd.maryland.gov/MDRIssues/5318/Assembled.aspx (last visited Oct. 5, 2026); Prescription Drug Affordability Board, Cost Review Study Process, 53:18 Md. Reg. 906, 907–22 (Sept. 4, 2026) (proposed COMAR 14.01.04), at https://dsd.maryland.gov/MDRIssues/5318/Assembled.aspx (last visited Oct. 5, 2026).

[2] AbbVie's Comments on the Board's Proposed Revisions to COMAR 14.01.04 (June 1, 2026), at https://pdab.maryland.gov/media/1324 (last visited Oct. 5, 2026).

[3] AbbVie's Comments on the Board's Proposed New COMAR 14.01.04.01 (June 26, 2026), at https://pdab.maryland.gov/media/1417 (last visited Oct. 5, 2026).

that were the subject of those submissions remain substantially unchanged in the Maryland Register proposal. Accordingly, nothing in this letter supersedes or limits those prior comments. Rather, this submission is intended to preserve and supplement AbbVie's objections with respect to the precise regulatory language now formally proposed under Maryland's Administrative Procedure Act.

AbbVie further requests that this submission, the comments incorporated by reference, all nonprivileged materials presented to or considered by the Board or its staff in developing the proposed regulations, and the Board's responses to material comments be included in the administrative record supporting any final action, so that the factual and legal basis for the Board's action is transparent and susceptible to meaningful review.

AbbVie acknowledges that the Board has made certain revisions to the proposed regulations. Most notably, the Board has removed the standalone cost effectiveness criterion from proposed COMAR 14.01.04.01 and has eliminated provisions that would have expressly relied upon patents, regulatory exclusivities, DEA scheduling decisions, risk evaluation and mitigation strategies ("REMS"), and related concepts as indicators of affordability concerns. Those changes represent improvements over earlier drafts. At the same time, by removing several previously enumerated considerations without establishing how the remaining considerations will be applied, prioritized or reconciled when they point in different directions, the proposal places even greater practical importance on the standards that remain, including "sufficient value" and therapeutic alternative comparisons, while leaving those standards materially undefined. Nevertheless, many of the core legal, methodological, and procedural concerns identified in AbbVie's prior submissions remain unresolved. AbbVie remains concerned that the proposed regulatory provisions continue to rely on overly broad and undefined standards, fail to establish objective and publicly disclosed evidentiary thresholds, weighting rules, or decision criteria, and introduce analytically unsupported concepts such as generalized "value" determinations and assessments of competitive conduct, which lack a clear statutory basis or methodological foundation, and would afford the Board virtually unbounded discretion in identifying affordability challenges through, *e.g.*, the repeated use of open-ended standards and catch-all provisions, while limiting the ability of stakeholders to understand, predict, or meaningfully engage with the Board's decision-making process. These deficiencies have already manifested in the Board's prior activities and, if not addressed, will continue to produce determinations that lack a reasoned, evidence-based foundation and are vulnerable to legal challenge. Accordingly, AbbVie respectfully urges the Board to withdraw the proposed regulations or substantially revise them before adoption.

Without limiting the concerns addressed in AbbVie's prior submissions or elsewhere in this letter (including, but not limited to the Company's June 1, 2026 and June 26, 2026 comments), AbbVie highlights several particularly critical, but non-exhaustive, revisions we urge the Board to implement to its proposal: (1) identify the statutory authority for each substantive criterion and explain how that criterion implements, rather than expands, the Board's assigned statutory functions; (2) establish objective and publicly disclosed standards for any "sufficient value" determination; (3) require clinically valid, transparent, and Board-approved "therapeutic alternative" determinations; (4) subject every comparator used in the Board's analyses to the same clinical and procedural safeguards; (5) require an independent, Maryland-specific analysis before

any information from the Medicare "Drug Price Negotiation Program" is used in a cost review; (6) establish legally sufficient safeguards concerning the consideration of public and governmental submissions; (7) require written findings and reasoned responses to material stakeholder evidence at each product-specific decision point; and (8) repropose any material methodology, criterion, form, or procedure not disclosed in the current proposal. These illustrative, high-priority revisions address several of the proposal's most consequential deficiencies, but neither supersede nor limit AbbVie's other comments.

The central problem is not simply that the proposal leaves some operational details unresolved. Rather, it authorizes consequential product selection, comparator, valuation, and affordability determinations without establishing the substantive standards that will govern those determinations. A regulatory framework cannot provide meaningful notice, support consistent decision-making, or permit effective stakeholder participation when its operative methodologies remain unstated and unpredictable. AbbVie therefore respectfully requests that the Board articulate those standards in the regulations themselves or repropose them for public comment before relying upon them in any product-specific proceeding.

For each criterion, factor, methodology, or decision point included in the proposed framework, the Board should identify the specific statutory provision it is implementing and explain how the criterion bears on the statutory determination whether use of a prescription drug product has led or will lead to an affordability challenge. Merely identifying a potentially relevant consideration does not establish that the consideration falls within the Board's statutory mandate or explain how it may affect a product-specific determination. The regulations should also require the Board, at each material stage, to issue written findings identifying the governing standard, the evidence on which the Board relied, the material contrary evidence submitted by stakeholders, the Board's response to that evidence, and the basis for the resulting determination. If the Board treats comparable products differently, including products considered during the Board's initial round of six selected drugs, it should identify and explain the material distinctions supporting that treatment. The Board should not rely on generalized grants of authority or broad statements of purpose alone but should explain how each challenged criterion is tied to an identifiable statutory directive enacted by the General Assembly.

I. The Proposed "Sufficient Value" Framework Remains Undefined and Standardless

Although the Board removed the standalone provision that would have treated the absence of cost effectiveness as an independent indicator of insufficient value, the Maryland Register proposal continues to authorize affordability determinations based upon whether a product allegedly provides "sufficient value." Proposed COMAR 14.01.04.01B(2) retains the underlying value framework while providing no methodology, evidentiary threshold, analytical criteria, or decision rules governing how such determinations will be made.[4] The "sufficient value" concept operates at the threshold affordability determination stage, rather than as an express methodology for setting a UPL. That distinction does not cure the absence of standards. An inadequately defined

[4] 53:18 Md. Reg. 905-06 (Sept. 4, 2026).

threshold criterion may determine whether a product advances to subsequent policy review and potential remedial action, including consideration of a UPL.

The regulations do not identify what evidence is sufficient to establish value, how competing evidence will be weighed, what level of clinical differentiation is required to justify differences in pricing, or how the Board will evaluate conflicting evidence. The Board does not explain how it intends to determine whether approval of the drug was based on "limited evidence" despite an FDA approval decision. The proposal likewise fails to explain how any purported value determination connects to the Board's statutory authority under Maryland law to determine whether a drug may create an affordability challenge. The Board should identify the statutory provision it believes authorizes a freestanding inquiry into whether a drug provides "sufficient value" and explain how its proposed value inquiry carries out, rather than expands, the affordability inquiry assigned by the General Assembly. Even assuming the Board possesses authority to consider factors bearing on affordability, the proposal does not explain why an assessment of "sufficient value" is an appropriate proxy for affordability, what connection exists between value and affordability for purposes of Maryland law, or how the Board will distinguish value-based considerations from independent affordability considerations. Without that explanation, the proposal leaves unresolved whether "sufficient value" is a permissible means of implementing the statutory affordability standard or an additional substantive criterion that supplements, rather than implements, the framework enacted by the General Assembly. The proposal currently assumes the relevance of "value" without identifying where the General Assembly authorized the Board to elevate that concept into an operative regulatory criterion.

The absence of objective standards creates substantial uncertainty for regulated parties and heightens the risk of arbitrary or inconsistent application. The term "value" does not have a single, universally accepted meaning; its content may vary depending on the decision context, stakeholder perspective, outcomes considered, and the weight assigned to clinical, economic, societal, and other considerations.[5] As recognized by leading value assessment organizations and health economics literature, assessments of value necessarily reflect judgments regarding which dimensions of value should be considered and how those dimensions should be weighed in a particular decision context. The significance of those judgments is underscored by the existence of multiple value assessment frameworks that employ different perspectives, methodologies,

[5] Indeed, even among established U.S. value-assessment organizations, there is recognition that value is stakeholder-dependent and that no single framework captures all relevant dimensions of value. *See, e.g.*, Darius N. Lakdawalla *et al.*, *Defining Elements of Value in Health Care: A Health Economics Approach*, 21 *Value Health* 131, 131–39 (2018) (recognizing that value assessments require judgments regarding which elements of value are relevant and how those elements should be weighted in a particular decision context); Int'l Soc'y for Pharmacoeconomics & Outcomes Rsch., *Initiative on U.S. Value Assessment Frameworks* (describing perspective, elements of value, aggregation, thresholds, and opportunity costs as distinct components of value assessment); Nat'l Pharm. Council, *Value Assessment Frameworks* (explaining that "value" may differ for patients, clinicians, and payers and that value assessment frameworks vary according to the decisionmaker, decision context, methods, data, and inputs); Office of Health Econ., *Value Frameworks: Value in Health Special Issue* (Mar. 29, 2018) (explaining that competing interpretations of value exist and that the relevant perspective and elements of value depend on the decision context). *See also* Inst. for Clinical & Econ. Rev., *2023 Value Assessment Framework* (updated Sept. 25, 2023) (describing a distinct conceptual structure and methodology for evaluating evidence and assessing value).

evidentiary inputs, and evaluative criteria. AbbVie does not contend that the Board should adopt any particular health technology assessment framework. Rather, those sources demonstrate that "value" is not a self-defining regulatory standard and that a value-based criterion cannot be meaningfully applied without first identifying the governing framework and methodology.

Yet the proposal invokes "sufficient value" as a potentially outcome-determinative regulatory criterion without defining the concept, identifying the dimensions of value the Board will consider, articulating the evidentiary standards that will govern the inquiry, or explaining how competing considerations will be weighed. Stakeholders therefore cannot meaningfully determine what evidence may influence the Board's analysis, predict how that evidence will be evaluated, or understand why one product may be deemed to create an affordability challenge while another may not. The proposal therefore fails to provide discernible standards capable of promoting consistent decision-making or constraining administrative discretion.

At minimum, the Board should establish clear analytical criteria, identify the statutory authority and evidentiary standards applicable to value determinations, explain how competing evidence will be evaluated, identify the evidence relied upon in any product-specific value determination, and provide meaningful transparency regarding the methodology used to support affordability findings. As proposed, the regulations identify "sufficient value" as a substantive regulatory standard while leaving the methodology for applying that standard entirely unspecified. If the Board intends to operationalize "sufficient value" through future cost effectiveness methodologies, value frameworks, weighting systems, clinical benefit metrics, comparative effectiveness thresholds, or other evaluative criteria, those standards should be disclosed through additional rulemaking before they are applied. Stakeholders cannot meaningfully comment on an undefined standard whose operative criteria will be developed only after adoption of the regulation itself.

This concern is particularly acute because the Board previously proposed, and then removed, an express cost effectiveness criterion. The current proposal therefore leaves unresolved what analytical framework, if any, ultimately will be used to evaluate whether a drug provides "sufficient value." If the Board subsequently adopts substantive standards governing that determination, those standards should be reproposed and subjected to public comment before implementation.

II. The Board's Therapeutic Alternative Framework Remains Clinically Unsound, Methodologically Opaque, and Arbitrary

The Maryland Register proposal continues to rely heavily upon therapeutic alternative comparisons throughout the affordability challenge framework, the drug selection framework, and the broader cost review process. Yet the regulations still fail to establish meaningful standards governing how therapeutic alternatives will be identified, evaluated, approved, or used.[6]

[6] 53:18 Md. Reg. 905-10 (Sept. 4, 2026).

The proposal assumes clinical comparability without first requiring a clinically valid determination that the products being compared are, in fact, appropriate comparators. The regulations do not establish required clinical comparability criteria, define what outcomes are of interest or what constitutes similarity in those clinical or humanistic outcomes, identify applicable evidentiary standards, require consultation with independent clinical experts, or explain how differences in patient populations, indications, treatment lines, safety profiles, or treatment responses will be addressed. As a result, the proposal risks creating false equivalence among therapies that may differ materially in ways that affect patients, caregivers, the healthcare system and society and that are not comparable in the practice of medicine.

The proposal is particularly problematic because therapeutic alternatives serve as the foundation for several other proposed affordability analyses, including the Board's evaluation of "sufficient value." Consequently, any methodological flaws in comparator selection are likely to cascade throughout the Board's affordability review process and materially affect the Board's ultimate conclusions.

AbbVie has consistently maintained that therapeutic alternatives should be defined using objective and clinically meaningful criteria.[7] The Board should identify therapeutic alternatives using a more transparent and science-driven methodology that appropriately credits the innovation of a drug subject to review. It should ensure that it is evaluating the full weight of the innovation achieved with the drug under review and use comprehensive pharmaceutical evidence to determine what are clinically equivalent comparators. The proposed regulations adopt none of these principles. Instead, they permit comparator selection through an effectively standardless process.

The proposal also fails to explain what information sources will govern comparator selection. The Board should, at a minimum, disclose the data sources, expert consultation criteria, clinical guidelines, literature relied upon, and its reasons for including or excluding specific candidate comparators. The Board's decision to retain a staff-centered therapeutic alternative selection process without requiring express Board approval of the comparators ultimately used in affordability analyses raises additional transparency and accountability concerns.[8] Those concerns are heightened to the extent that staff responsible for identifying or recommending therapeutic alternatives are not required to possess relevant clinical expertise or obtain input from qualified, independent clinicians. Comparator determinations may rest upon turn on indication-specific evidence, line of therapy, contraindications, disease severity, treatment history, safety, route of

[7] *See, e.g.*, 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 Oct. 5, 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 Oct. 5, 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 Oct. 5, 2026).

[8] *See* Md. Code Ann., Health–Gen. §§ 21-2C-08(c), 21-2C-09(a)–(b) (assigning to the Board responsibility for identifying eligible products, determining whether to conduct a cost review, and making the prescribed cost review determination); *Grant v. Cnty. Council of Prince George's Cnty.*, 465 Md. 496, 516–17, 214 A.3d 1098, 1109–10 (2019) (addressing a public body's review and adoption of staff-prepared findings and conclusions).

administration, patient characteristics, and current clinical practice. The regulations therefore should require documented review by appropriately qualified, independent clinical experts possessing experience relevant to the disease state, patient population, and therapeutic category under review and should make clear that generalized comparator classifications do not establish clinical interchangeability or displace patient-specific medical judgment.

These safeguards are particularly important because the proposed framework contemplates comparator determinations that may substantially influence subsequent affordability analyses and affordability challenge determinations, even though comparator selection frequently depends on complex clinical judgments concerning indications, disease severity, treatment history, line of therapy, patient heterogeneity, contraindications, safety considerations, durability of response, and expected treatment outcomes. The regulations do not presently require that such determinations be made, reviewed, or validated by individuals possessing relevant clinical expertise. Where therapeutic alternative determinations may materially affect downstream affordability conclusions, the Board should require documented clinical support for those determinations and explain the basis for concluding that a purported comparator is clinically appropriate for the purpose at issue. Those determinations should not rest solely on economic analyses, generalized treatment categories, or publicly available summaries that do not address product-specific clinical considerations. Otherwise, the proposal risks allowing consequential affordability analyses to rest on comparator judgments that have not been subjected to appropriate clinical scrutiny.

Further, because the Board's process and proposed regulations place such critical emphasis on comparator selection, including the likelihood of materially affecting downstream affordability conclusions, stakeholders should know whether such determinations represent formal Board judgments or staff-level analytical decisions. At a minimum, the regulations should require Board approval of the final therapeutic alternative list and a public explanation of the basis, and appropriate support, for each comparator selected.

While clinical guidelines can be instructive in viewing the full landscape of available treatment options, they come with key limitations and cannot substitute for a rigorous review of all available and up-to-date pharmaceutical evidence, including physician perspectives on how products are actually used in practice. Guidelines may be updated only periodically, may not reflect the latest and most available data, and frequently identify broad categories of treatment options that are not clinically interchangeable. The existence of multiple therapies within a guideline does not establish that those therapies are truly clinically appropriate price comparators.

Moreover, the Board should not identify products as therapeutic alternatives that failed a clinical study for use in a condition for which a drug under review is approved. A failure to demonstrate safety and/or efficacy in a given condition, where the selected product succeeded, is the very definition of a lack of clinical appropriateness—both within that specific condition and also across all conditions for which the selected product is approved. It simply evidences that the purported comparator is not a clinically appropriate comparator to the selected product.

Similar concerns arise where products differ materially in mechanism of action, approved indications, administration route, line of therapy, durability of response, safety profile, or patient

selection criteria. The regulations provide no framework for addressing these issues. Concepts reflected in the Board's proposal are similar to issues currently being debated in other government pricing programs, where comparator selection remains one of the most consequential and controversial aspects of the analytical framework.

The Board should therefore establish objective clinical comparability standards and explain the statutory basis for treating therapeutic alternative comparisons as evidence relevant to affordability rather than merely one possible source of information in a broader affordability analysis. The Board should identify the statutory and evidentiary criteria governing comparator selection, disclose the information relied upon by staff, require formal Board approval of therapeutic alternative determinations, and provide stakeholders a meaningful opportunity to challenge proposed comparators before those comparators are used in affordability analyses. For each therapeutic alternative determination, the Board should issue written findings identifying the statutory authority and governing standard applied, explaining why each selected product satisfies the applicable clinical criteria, identifying the evidence relied upon, addressing material contrary evidence submitted by the manufacturer or other stakeholders, and explaining any departure from the Board's treatment of clinically comparable products in prior reviews, including products considered during the Board's initial round of six selected drugs.

The absence of these standards is especially significant because the regulations would authorize the Board to make therapeutic alternative determinations before stakeholders know the clinical criteria that will govern comparator selection. If the Board ultimately adopts clinical comparability standards, weighting criteria, evidentiary thresholds, expert consultation requirements, comparator selection methodologies, or other substantive standards not contained in the current Maryland Register proposal, those requirements should be reproposed and subjected to public comment before implementation. Such standards would constitute substantive elements of the regulatory framework rather than merely ministerial implementation details.

III. The Proposal Continues to Grant the Board Unbounded Comparator Authority

The Maryland Register proposal further provides in Proposed COMAR 14.01.04.05C(1)(e) that staff may utilize "any comparator" in conducting cost and comparative effectiveness analyses.[9] This provision is especially problematic because it extends beyond the therapeutic alternatives identified through the Board's own comparator selection process. Thus, even if the Board were to improve its therapeutic alternative methodology, the proposal would still permit staff to rely on other unidentified comparators selected pursuant to no articulated standards. This provision threatens to render any protections associated with the therapeutic alternative process largely illusory. Establishing safeguards for that process provides little protection if staff may reach the same analytical result by designating a product as another form of comparator outside the process.

The breadth of this provision is particularly concerning because it contains no meaningful limiting principle. If staff may rely upon any comparator deemed informative, subject to no

[9] 53:18 Md. Reg. 909 (Sept. 4, 2026).

articulated standards and outside the therapeutic alternative process, stakeholders cannot reasonably predict what comparators may be used, evaluate whether comparators were selected consistently across products, or determine whether affordability conclusions are rooted in clinically meaningful comparisons. The absence of objective standards also impedes meaningful review of Board decisions because neither stakeholders nor reviewing bodies can assess whether comparator selection decisions are being made according to discernible principles rather than ad hoc judgment.

If the Board may disregard its own therapeutic alternative process and instead rely upon any comparator it deems appropriate, stakeholders have no meaningful ability to predict, evaluate, or respond to the analyses upon which the Board may ultimately rely. Such discretion is inconsistent with transparent administrative decision-making and increases the risk of arbitrary outcomes. At minimum, any comparator used in the Board's analyses should satisfy the same clinical comparability requirements applicable to therapeutic alternatives and should be disclosed sufficiently in advance to permit meaningful stakeholder review and comment. The lack of objective standards is particularly problematic because the Board has not identified what criteria will govern use of a comparator that falls outside the therapeutic alternative process. If the Board subsequently adopts standards governing when staff may utilize an alternative comparator, how such comparators will be selected, or what degree of clinical comparability must be demonstrated, those standards should be reproposed and subjected to public comment before implementation.

The Board also should identify the statutory authority on which it relies to permit staff to select and use "any comparator" outside the therapeutic alternative process and explain how that authority is consistent with the standards governing the Board's statutory cost review determination. For each additional comparator used, the Board should make written findings identifying the comparator, the clinical and analytical basis for its use, the evidence supporting comparability, the material contrary evidence submitted by stakeholders, and the reasons for accepting or rejecting that evidence. The Board also should explain any material inconsistency between the comparator selected and comparators used for similarly situated products in prior reviews.

IV. The Staff-Centered Product Selection and Referral Process Lacks Adequate Standards, Transparency, and Board Accountability

The proposal continues to authorize Board staff to develop a curated list of eligible products, recommend products for referral to the Stakeholder Council, and substantially frame the information presented to the Board during the selection process. Yet the proposed regulations do not establish the criteria staff must use to prioritize products, the standards governing inclusion or exclusion from the curated list, the information that must accompany a staff recommendation, or the process by which the Board will independently evaluate that recommendation.

This structure also raises a statutory delegation concern. Maryland law assigns to the Board the responsibility for identifying eligible prescription drug products, determining whether to conduct a cost review, and determining whether use of a product has led or will lead to affordability

challenges.[10] Although staff may provide analytical and administrative support, the Board should not permit undisclosed staff judgments to substitute for the Board's independent exercise of those assigned responsibilities. The regulations therefore should require the Board to review the underlying information and reasoning, deliberate publicly to the extent required by law, and expressly approve or reject each material staff recommendation.

These omissions are consequential. The selection and referral of a product initiate a resource-intensive regulatory process that may culminate in an affordability challenge determination and subsequent policy action. The operative criteria for initiating that process should not be supplied through undisclosed staff practices or ad hoc judgments. These deficiencies are not merely prospective. For the first six drugs selected for cost review, the Board has not publicly articulated a comprehensive, replicable, and prospectively disclosed methodology identifying how candidate products were ranked, prioritized, selected, referred, deselected, or otherwise advanced through the review process. Nor has the Board publicly explained why certain eligible products were selected while other apparently comparable products were not, what evidence was relied upon, what criteria were considered outcome-determinative, or how competing considerations were weighed. To date, the Board has not provided a complete product-specific explanation of the data, methodology, decision criteria, or reasoning supporting its selection and deselection decisions. As a result, stakeholders cannot meaningfully evaluate whether the Board applied consistent standards, exercised its discretion in a reasoned manner, considered material contrary evidence, or treated comparable products similarly. The regulations should correct that deficiency prospectively by requiring written, product-specific findings for selections, non-selections, referrals, and deselections that identify the governing criteria, the evidence relied upon, the material contrary evidence considered, and the reasons supporting the Board's decision.

The proposal also does not ensure a meaningful product-specific opportunity for stakeholders to respond before referral. A post-referral comment period does not cure the absence of notice and an opportunity to address factual errors, incomplete data, inappropriate assumptions, or material market developments before the Board takes the action that advances the product into the formal review process. This concern is heightened because the proposal permits an eligible product to be raised by a Board member during an open meeting without advance product-specific notice.

Once the Board has publicly referred a product, the referral itself may shape public perceptions, frame the subsequent inquiry, and establish an analytical trajectory that is difficult to correct after the fact. Meaningful product-specific notice and an opportunity to comment therefore should precede, rather than merely follow, the referral decision.

The regulations should therefore require advance public notice of each product proposed for referral, disclosure of the factual and analytical basis for the proposed referral, a meaningful written comment period before the Board votes, and an express Board finding adopting or rejecting staff's recommendation. Staff may support the Board's work, but substantive selection and referral

[10] *See* Md. Code Ann., Health–Gen. §§ 21-2C-08(c), 21-2C-09(a)-(b); *Grant v. Cnty. Council of Prince George's Cnty.*, 465 Md. 496, 516-17, 214 A.3d 1098, 1109-10 (2019).

decisions should remain transparent, reviewable judgments of the Board itself. The Board's written findings should identify the statutory basis and governing criteria for the decision, explain why the evidence relied upon satisfies those criteria, respond to material evidence submitted by manufacturers and other stakeholders, and explain any departure from the Board's treatment of comparable products, including products considered during the Board's first round of selections.

V. The Proposal Continues to Permit Reliance on Medicare Drug Negotiation Information Outside Its Federal Statutory Context

The Maryland Register proposal continues to authorize consideration of information, "analyses," and data published by CMS in connection with the Medicare "Drug Price Negotiation Program," including "Maximum Fair Prices" ("MFPs") and CMS's public explanations and published data related to those prices[11] AbbVie continues to object to this approach. The Medicare Drug Price Negotiation Program reflects a highly specific federal statutory framework applicable to particular products, populations, and reimbursement systems. MFPs result from a federal program implementing distinct statutory requirements and policy objectives and cannot reasonably be presumed to reflect product value, affordability, or appropriate pricing in another statutory and market context. The Board should identify the specific provision of Maryland law that authorizes reliance on each category of Medicare-related information and explain how that information is probative of the particular Maryland affordability determination the Board is charged with making.

These concerns are compounded when the Board seeks to use MFP-related data not only for the product under review but also for purported therapeutic alternatives. Such cross-product price referencing disconnects pricing from the clinical and economic realities of the specific therapy under review, ignores meaningful differences in patient populations and indications, and risks importing methodological assumptions from a separate federal program that serve different statutory purposes. The Board should remove or substantially narrow these provisions.

Likewise, the Board should not treat therapeutic alternatives identified by CMS as presumptively appropriate comparators for a Maryland cost review. CMS identifies therapeutic alternatives for purposes of a product-specific federal program governed by different statutory factors, and related to different covered populations, utilization patterns, and reimbursement rules. Further, the public CMS record does not reflect the full course of manufacturer engagement or any internal reassessment done by CMS during the process. The Board should therefore make and disclose its own clinically supported comparator determination rather than importing CMS's published comparator set.

At a minimum, the regulations should provide that neither a product's selection for the Medicare Drug Price Negotiation Program, nor an MFP, nor any published explanation of an MFP creates any presumption regarding affordability, value, or appropriate pricing in Maryland. They should also require the Board to determine independently the comparators for a drug under cost review in Maryland, rather than relying on initial determinations made by CMS for a selected drug. Before relying on such information, the Board should be required to conduct and disclose an

[11] Proposed COMAR 14.01.04.05C(2)(g)(vii),53:18 Md. Reg. 909-10 (Sept. 4, 2026).

independent Maryland-specific analysis that addresses differences in covered populations, indications, utilization, benefit design, reimbursement systems, statutory factors and objectives, and applicable market conditions. The Board should also identify any adjustments made to federal data or assumptions and explain why the federal information is probative of the particular Maryland affordability question under review. If the Board relies upon Medicare-related information in a product-specific review, it should explain why that information is probative of the specific Maryland affordability question under consideration and address material evidence challenging the relevance or applicability of the federal information.

VI. The Proposed Public and Governmental Reporting Mechanisms Lack Essential Reliability and Procedural Safeguards

The newly proposed reporting process in COMAR 14.01.04.06 permits members of the public and governmental entities to submit affordability concerns and related information to the Board.[12] Although stakeholder input may be valuable, the proposal does not establish standards governing validation, verification, attribution, representativeness, disclosure, or opportunities for response. Nor does it specify how such submissions will be evaluated, weighted, or incorporated into Board decision-making.

These concerns are particularly significant where submissions may influence referral decisions, affordability analyses, or future Board actions. The regulations should establish procedures ensuring transparency, data quality, and a meaningful opportunity for stakeholders to review and respond to information that may materially affect Board determinations. Without such safeguards, anecdotal reports or unverified submissions may be afforded undue weight despite lacking methodological rigor or broader representativeness.

The proposal likewise provides no indication regarding the forms, validation procedures, submission criteria, evidentiary thresholds, referral standards, or analytical methodologies that ultimately may govern operation of Regulation .06. If the Board intends to develop such requirements following promulgation of the regulations, those requirements should be separately disclosed and reproposed before implementation. Otherwise, interested parties will have been denied the opportunity to comment on substantive standards that may materially influence future Board actions.

AbbVie does not suggest that every technical instruction, filing convention, or ministerial implementation detail necessarily requires separate rulemaking. But where a subsequently developed methodology, form, guidance document, scoring system, or staff practice establishes or materially affects the standards governing product selection, comparator selection, evidentiary weight, value, affordability, or the outcome of a cost review, it constitutes a substantive component

[12] 53:18 Md. Reg. 910-11 (Sept. 4, 2026).

of the regulatory framework and should be disclosed through notice-and-comment rulemaking before it is applied in any product-specific proceeding.[13]

At minimum, the regulations should require the Board to: (1) identify the source and date of each submission; (2) distinguish personal experience reports from representative or empirical evidence; (3) disclose the nonconfidential substance of any submission on which staff or the Board may rely; (4) identify the validation steps undertaken and any known limitations; (5) explain the weight assigned to the submission; and (6) provide the manufacturer and other materially affected stakeholders a reasonable opportunity to correct, contextualize, or rebut the submission before it is used in a referral, cost review, or affordability determination.

If the Board relies on a submission in making a referral, comparator, cost review, or affordability determination, its written findings should identify the submission's role in the decision, explain why the Board concluded the information was sufficiently reliable to warrant consideration, and respond to material evidence challenging its accuracy, representativeness, methodology, or relevance. The Board also should explain any materially different treatment of comparable submissions or comparable products in prior proceedings. Anonymous, unverifiable, duplicative, materially incomplete, or otherwise unreliable submissions should not be treated as evidence supporting regulatory action absent independent corroboration and an explanation of why the Board concluded that the information was sufficiently reliable to influence its decision-making. The Board should identify the corroborating evidence on which it relied and explain why that evidence was sufficient to support consideration of the submission in the particular decision under review. If the Board elects to rely upon such information notwithstanding identified limitations, it should explain the basis for doing so and address any material challenges concerning the submission's accuracy, representativeness, methodology, or relevance.

These protections can and should be implemented without disclosing personally identifiable information, protected health information, or legitimately confidential commercial information. Where redaction is necessary, the Board should provide a sufficiently detailed nonconfidential summary to permit affected stakeholders to understand and respond to the substance of the information upon which staff or the Board proposes to rely.

VII. The Proposed Fifteen-Day Comment Period Does Not Provide a Meaningful Opportunity for Stakeholder Participation

The Board additionally proposes to amend COMAR 14.01.01.05 to require only a fifteen-day comment period when the Board requests public comments through website postings.[14] While AbbVie supports the Board's recognition that some minimum period should apply to such requests,

[13] *See* Md. Code Ann., State Gov't §§ 10-101(g), 10-111, 10-112; *Calvert Cnty. Planning Comm'n v. Howlin Realty Mgmt., Inc.*, 364 Md. 301, 322, 772 A.2d 1209, 1221 (2001) (explaining that agency rules should be formally adopted in written form and made available in advance to persons dealing with the agency); *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123, 711 A.2d 158, 168 (1998) (explaining that notice-and-comment procedures provide fair notice and a meaningful opportunity to comment while supplying the agency with information from a broad range of interests).

[14] 53:18 Md. Reg. 904 (Sept. 4, 2026).

the proposed fifteen-day standard remains insufficient to ensure meaningful stakeholder participation in many Board proceedings.

The Board routinely addresses matters involving extensive scientific, economic, legal, reimbursement, and clinical analyses. Stakeholders are frequently asked to review large data compilations, complex policy proposals, draft dossiers, affordability analyses, cost review study reports, therapeutic alternative determinations, and proposed regulatory changes that may have significant consequences for patients, manufacturers, providers, payers, and governmental entities. Meaningful review of such materials often requires consultation with medical experts, economists, statisticians, reimbursement specialists, legal counsel, and other internal and external stakeholders. Given the stakes with establishing a UPL—for patients, providers, and manufacturers—a truncated comment period of only 15 days for such reviews is wholly inadequate.

AbbVie has previously expressed concerns regarding the Board's pattern of abbreviated and inconsistent comment periods, including instances in which stakeholders were afforded only a limited number of business days to review highly technical materials.[15] The Board's experiences with its recent affordability reviews and rulemaking activities demonstrate that the complexity of many Board actions cannot reasonably be addressed through a fixed fifteen-day comment period. Indeed, the Board itself previously extended certain comment periods in response to stakeholder concerns regarding the time necessary to prepare informed submissions.

A uniform fifteen-day minimum also fails to account for significant variation in the complexity of matters presented for comment. A brief procedural notice may require substantially less review than a lengthy cost review study report, affordability analysis, affordability challenge determination, proposed UPL methodology, or major regulatory revision. The proposed amendment nevertheless treats all such matters alike.

More fundamentally, meaningful stakeholder participation is a core objective of administrative notice-and-comment processes. Comment periods that are too short to permit informed review undermine the quality of the administrative record and increase the risk that relevant scientific, economic, and legal considerations will not be adequately presented to the Board before decisions are made.

Accordingly, AbbVie recommends that the Board revise COMAR 14.01.01.05 to establish minimum comment periods tied to the complexity, volume, and consequences of the matter presented, calculated from the date on which the Board has released the complete nonconfidential supporting record. At a minimum, the Board should require not less than thirty days for

[15] *See, e.g.*, AbbVie's Comments on the Board's Dossier for FARXIGA® 1–2 (July 3, 2025) (objecting that the Board provided stakeholders "a mere 11 business days to comment on a more than 80 page document" and explaining that the truncated period did not provide an adequate opportunity to validate, contextualize, or respond to the dossier's data), at https://pdab.maryland.gov/Documents/comments/2025/Farxiga%20Dossier%20Comments%207.3.2025.pdf (last visited Oct. 5, 2026); AbbVie's Comments on the Proposed Amendments to COMAR 14.01.04.05, "Cost Review Study Process" (Dec. 2, 2024) (reiterating concerns regarding the Board's "truncated timelines" and inadequate opportunities for stakeholder engagement), at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf (last visited Oct. 5, 2026).

affordability challenge determinations, cost review study reports, therapeutic alternative determinations, proposed regulations, and other substantive policy actions.[16] The Board should also recognize that some categories of Board action routinely involve complex scientific, economic, actuarial, reimbursement, utilization, and legal analyses that cannot reasonably be evaluated within thirty days. For cost review study reports, major affordability analyses, proposed upper payment limit actions, and significant regulatory revisions, the Board should provide not less than sixty days for review and comment. The regulations should further authorize extensions where necessary to facilitate meaningful stakeholder participation and development of a complete administrative record.

The proposed rule also measures the minimum period in calendar days without accounting for weekends, State or federal holidays, the volume of materials released, or concurrent Board deadlines. A nominal fifteen-day period may therefore in some instances provide materially fewer working days for review. The regulations should measure substantive comment periods in business days or, at a minimum, prohibit the Board from using weekends, holidays, or overlapping requests in a manner that materially compresses the practical review period. Related materials should be released together, not on a rolling and unpredictable basis, and the comment period should run from the date on which the complete supporting record is made available.

If the Board declines to adopt the differentiated minimum periods described above, it should, at an absolute minimum: (1) characterize fifteen days as a floor rather than the presumptive period; (2) require the Board to consider the volume, complexity, and significance of the materials at issue; (3) permit stakeholders to request reasonable extensions; (4) require a public explanation when an extension request is denied; and (5) prohibit the comment period from beginning before the complete nonconfidential record has been released.

VIII. The Board Should Repropose Any Material Methodologies or Standards Not Contained in the September 4, 2026 Proposal

Finally, the Board should commit to reproposing any substantive methodologies, standards, criteria, or procedures that are not contained in the September 4, 2026 Maryland Register notice but are subsequently developed to implement the regulations. Several provisions rely upon broad discretionary concepts while leaving the operative standards unspecified. For example, the proposal does not identify:

- The methodology that will govern determinations of whether a drug provides "sufficient value";

[16] In the context of the federal Administrative Procedure Act, "a 30-day comment period is generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment." *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1117 (D.C. Cir. 2019). Maryland's Administrative Procedure Act similarly requires an agency proposing a regulation to "permit public comment for at least 30 days." Md. Code Ann., State Gov't § 10-111(a)(3). Although those requirements do not necessarily govern every website-posted request for comment, they provide a useful benchmark for assessing whether a 15-day period permits meaningful participation on complex substantive matters.

- The clinical comparability standards, evidentiary requirements, or decision criteria applicable to therapeutic alternative determinations;
- The standards governing use of "any comparator" in cost review analyses;
- The validation, verification, and analytical procedures applicable to affordability reports submitted pursuant to proposed Regulation .06; or
- Any weighting, prioritization, or decision framework governing how these concepts will be applied in practice.

The regulations likewise do not prescribe the findings and explanations that must accompany product-specific decisions. At each material stage, the Board should be required to identify the statutory authority and standard applied; make written findings supported by the disclosed record; identify the material evidence on which it relied; respond to material contrary evidence; and explain any material departure from its treatment of comparable products. These safeguards are essential both to permit meaningful stakeholder participation when the decision is made and to create a record showing whether the Board acted consistently and within the authority conferred by statute.

The problem is compounded by the absence of a predictable publication schedule. Stakeholders may have no reliable advance notice of when a dossier, therapeutic alternative determination, affordability analysis, or related supporting material will be released. A short comment period beginning upon an unannounced or irregular posting makes it difficult to reserve appropriate clinical, economic, legal, and technical resources and may materially impair the quality of the resulting comments. The regulations should therefore require reasonable advance notice of anticipated publication dates, prompt notice to interested stakeholders when materials are posted, sufficient time to prepare comments in light of the complexity of the material published and a predictable schedule for major stages of each product-specific review.

If the Board subsequently develops such methodologies, standards, forms, criteria, guidance documents, scoring systems, evaluation frameworks, or procedures, those requirements would constitute substantive elements of the regulatory framework upon which interested parties have not had an opportunity to comment. Accordingly, the Board should repropose any such material additions or revisions and provide stakeholders with a meaningful opportunity to comment before those requirements are implemented.

This issue is particularly important here because several central features of the proposed framework—including the Board's value determinations, therapeutic alternative analyses, comparator selection decisions, and reporting mechanisms—depend upon standards that have not yet been articulated. The Board should not rely upon future guidance documents, internal methodologies, dashboards, staff practices, or other extra-regulatory mechanisms to supply substantive criteria that are absent from the proposed regulations themselves. If such criteria are necessary to administer the regulations, they should be disclosed through notice-and-comment rulemaking.

abbvie

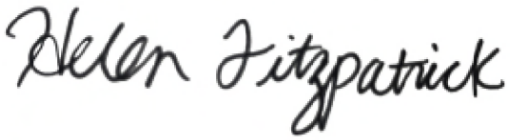
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The proposal incorporates several welcome changes, but it continues to reserve the most consequential elements of the Board's framework for later development. The standards governing value, clinical comparability, comparator selection, evidentiary reliability, product referral, and stakeholder participation should be established before, not during, a product-specific review.

AbbVie respectfully urges the Board to decline to finalize the proposed regulations in their current form and instead substantially revise and repropose them as necessary to ensure that any final regulations establish objective standards, transparent methodologies, clearly identified statutory authority, and appropriate procedural protections consistent with Maryland law. The Board should address the material factual, legal, clinical, and methodological issues raised by commenters, explain the basis for accepting or rejecting principal alternatives, and repropose any material new methodology or criterion before applying it in a product-specific proceeding.

Thank you for the opportunity to provide comments on the proposed regulations. Please contact me at hfitzpatrick@abbvie.com with any questions.

Respectfully submitted,



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

Exhibit A:
AbbVie's June 1, 2026 Comments on Proposed Revisions to COMAR 14.01.04

abbvie

June 1, 2026

VIA ELECTRONIC MAIL

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

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.

* * * * *

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 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).

Exhibit B:
AbbVie's June 26, 2026 Comments on Proposed Revisions to COMAR 14.01.04.01

June 26, 2026

VIA ELECTRONIC MAIL

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

Re: Comments on Draft Regulations to COMAR 14.01.04.01 (Cost Review Study Process; Circumstances Under Which Use of a Drug May Create an Affordability Challenge)

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 amendments to COMAR 14.01.04.01 published on May 27, 2026 governing the Board's cost review study process (the "Draft Regulations").[1] The Draft Regulations purport to identify the circumstances under which the Board may determine that use of a prescription drug has led or will lead to an affordability challenge for Maryland and/or high out-of-pocket costs to patients, as well as additional data and factors the Board may evaluate to make such determination. Critically, the Draft Regulations do not cure—nor do they meaningfully attempt to address—fundamental legal, methodological, and procedural deficiencies in the Board's existing framework.

In particular, the Draft Regulations continue to rely on overly broad and undefined standards, fail to establish objective and transparent evidentiary thresholds, and introduce analytically unsupported concepts such as generalized "value" determinations and assessments of competitive conduct, which lack a clear statutory basis or methodological foundation. The Draft Regulations also risk exceeding the Board's statutory authority by effectively transforming a threshold "affordability challenge" inquiry into a broad policy assessment encompassing value judgments, competitive conduct, and market structure—matters not contemplated by the Board's enabling statute, and, as detailed further herein, matters which the Board was not composed with the necessary expertise, statutory mandate, or legal authority to evaluate.

Significantly, as currently written, the Draft Regulations would afford the Board virtually unbounded discretion in identifying affordability challenges through, *e.g.*, the repeated use of open-ended standards and catch-all provisions, while limiting the ability of

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[1] *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 5/27/2026)" ("Amendments to COMAR 14.01.04.01, Cost Review Study Process – Circumstances Under Which Use of a Drug May Create an Affordability Challenge) (last visited June 22, 2026).

stakeholders to understand, predict, or meaningfully engage with the Board's decision-making process. These deficiencies have already manifested in the Board's prior activities and, if not addressed, will continue to produce determinations that lack a reasoned, evidence-based foundation and are vulnerable to legal challenge. AbbVie therefore urges the Board to withdraw or substantially revise the Draft Regulations as described below.

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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.

AbbVie has actively participated in the Board's proceedings, including submitting extensive data and analysis regarding SKYRIZI®.[2] Based on those experiences, AbbVie is deeply concerned that the Draft Regulations fail to remedy fundamental legal deficiencies. These deficiencies are not theoretical—they have already manifested in the Board's evaluation of SKYRIZI®, where the absence of clear standards and defined analytical frameworks has made it difficult to discern the basis for the Board's conclusions, including even the basis for SKYRIZI®'s selection for cost review study. 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

[2] *See, e.g.*, AbbVie's Comments on the Board's Proposed Revisions to COMAR 14.01.04 (June 1, 2026) (last visited June 22, 2026); AbbVie's Comments on the Board's Dossier for FARXIGA® (July 3, 2025) (last visited June 22, 2026); AbbVie's Comments on the Board's Proposed UPL Regulations (February 10, 2025) (last visited June 22, 2026); AbbVie's Comments on the Board's Proposed Amended Maryland Prescription Drug Affordability Board Cost Review Regulations (December 2, 2024) (last visited June 22, 2026); AbbVie's Comments on the Board's Proposed Regulations Issued October 28, 2024 (November 8, 2024) (last visited June 22, 2026); AbbVie's Written Testimony to Maryland Legislative Policy Committee (October 18, 2024) (last visited June 22, 2026); AbbVie's Comments on the Board's Draft UPL Action Plan (August 26, 2024) (last visited June 22, 2026); AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024) (last visited June 22, 2026); AbbVie's Comments on the Board's List of SKYRIZI® Therapeutic Alternatives (May 13, 2024) (last visited June 22, 2026); AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024) (last visited June 22, 2026); AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024) (last visited June 22, 2026).

affecting SKYRIZI®, risk being unsupported by substantial evidence, lacking a rational basis, and therefore being arbitrary and capricious as a matter of law.

Across the Draft Regulations, a central deficiency is the absence of any required alignment between the identification of an affordability challenge and the policy intervention selected to address it. The Board's framework permits findings based on a wide range of factors—many unrelated to manufacturer pricing—without requiring a demonstrated causal link between those factors and the proposed remedy. This disconnect risks producing policy responses, including upper payment limits ("UPLs"), that are untethered to the underlying drivers of the perceived affordability challenge and therefore ineffective or counterproductive. Such an approach is inconsistent with the requirement that agency action reflect reasoned decision-making supported by a rational connection between the facts found and the choices made.[3]

I. The Draft Regulations are Impermissibly Broad and Lack Clear, Objective Standards, Permitting the Board to Make Overly Speculative Determinations

The Draft Regulations enumerate a wide range of "circumstances" that "may" indicate "that use of a drug has led or will lead to an affordability challenge"[4] (including "high spending," questions of "value," alleged "conduct that delays or prevents market competition," and "barriers to affordable access") without specifying any standard of proof, evidentiary threshold, or requirement of causation or materiality. This, in turn, permits the Board to make determinations based on highly subjective judgments (*e.g.*, what constitutes "sufficient value," a "large proportion" of spending, and "substantial price increases") and speculative future impacts (*i.e.*, "will lead") without requiring a defined time horizon or demonstration of materiality. The absence of a clear evidentiary standard undermines transparency, creates significant regulatory uncertainty, and risks arbitrary or inconsistent application and decision-making. At a minimum, the regulations should require that any finding of an affordability challenge be supported by substantial, objective, and verifiable evidence and accompanied by a written explanation demonstrating how the evidence satisfies each applicable standard.

A. The Rule Lacks a Coherent Decision Framework

The Draft Regulations do not specify how factors are to be weighed or what combination of factors is sufficient to support a determination of an affordability challenge. This continues to be a critical deficiency with the Board's cost review study activities. As we have commented previously, under the Maryland APA, agency action must be the

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[3] *See Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983); *Harvey v. Marshall*, 389 Md. 243, 299-304 (2005).

[4] Proposed COMAR 14.01.04.01A.

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.[5] 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.[6] The absence of a defined decision framework also impedes meaningful judicial review, as courts are unable to assess whether the Board's determinations are consistent, reasoned, or based on established criteria. AbbVie recommends that the Board adopt a clear analytical framework specifying how factors will be evaluated and applied.

B. The Use of "May Be Indicated By" Undermines Evidentiary Rigor

Throughout the Draft Regulations, the Board proposes to determine findings that "**may** be indicated by" certain conditions.[7] This framing permits determinations based on inference rather than evidence. AbbVie recommends instead requiring that any findings the Board relies upon to determine an affordability challenge exists must be "demonstrated by objective, verifiable evidence."

C. Catch-All Provisions Create Unbounded Discretion

The Draft Regulations include catch-all provisions that permit the Board to rely on "any other circumstance" it identifies.[8] This language creates effectively unlimited discretion and undermines transparency and predictability. Such open-ended authority

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[5] *Harvey v. Marshall*, 389 Md. at 299; *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").

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

[7] *See, e.g.*, Proposed COMAR 14.01.04.01B(1); Proposed COMAR 14.01.04.01B(2); Proposed COMAR 14.01.04.01B(3); Proposed COMAR 14.01.04.01(B)(4); Proposed COMAR 14.01.04.01D (emphasis added).

[8] Proposed COMAR 14.01.04.01.

raises serious concerns under principles of due process and fair notice, as stakeholders cannot reasonably anticipate the standards that will be applied or tailor their conduct accordingly. AbbVie recommends that these provisions be removed or replaced with a requirement for future rulemaking.

II. "High Spending" Factors Are Undefined and Rely on Misleading Metrics

The Draft Regulations identify "high spending" indicators based on concepts such as a "large proportion" of a budget and wholesale acquisition cost ("WAC") increases.[9] These provisions are problematic because they rely on undefined terms without any quantification (including, *e.g.*, "large proportion" and "substantially faster"), focus on WAC (or "list" prices) rather than net price, and fail to distinguish between price-driven and utilization-driven spending increases. As a result, clinically valuable therapies that are widely used may be inappropriately flagged based on blunt, incomplete, or misleading metrics. Rather than providing an affordability challenge, high aggregate spending may instead reflect appropriate clinical utilization of effective therapies, particularly for common, serious or chronic conditions, rather than any affordability concern. Without controlling for utilization, patient outcomes, or avoided downstream costs, these metrics risk penalizing drugs that reduce overall health care expenditures. AbbVie therefore urges the Board to base any analysis on net prices and total cost of care, establish quantitative thresholds, and require differentiation between price and utilization drivers. An agency action that relies on undefined and unquantified metrics, without establishing thresholds or controlling for confounding variables, fails to provide a meaningful standard for decision-making and frustrates both stakeholder participation and judicial review.[10] The Draft Regulations' reliance on such metrics therefore presents not only a policy concern, but a legal deficiency.

III. The Proposed "Value" Framework Is Methodologically Flawed and Exceeds the Board's Expertise

The Draft Regulations would allow the Board to find an affordability challenge where a drug does not provide "sufficient value," including where it is "not cost-effective" or priced above "therapeutic alternatives."[11] At the same time, the Draft Regulations do not identify which cost-effectiveness model or thresholds apply, or how patient heterogeneity or unmet need will be considered. In effect, this proposed language introduces a de facto health technology assessment framework without defined evidentiary standards. The provision referencing drugs approved with "limited evidence of improvement" is particularly concerning because it invites the Board to second-guess FDA's rigorous

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9 Proposed COMAR 14.01.04.01B(1).

10 *See Harvey*, 389 Md. at 303–04.

11 Proposed COMAR 14.01.04.01B(2).

approval standards. This is especially problematic for therapies approved under accelerated pathways or addressing rare diseases, where smaller or more targeted evidence bases are both appropriate and necessary. Absent a clearly articulated and validated framework, these provisions create significant risk of inconsistent and unreliable determinations. AbbVie therefore recommends that the Board either remove these provisions or limit their application to analyses conducted under formal, transparent, and consistently applied standards established through rulemaking.

IV. The Therapeutic Alternative Comparisons Permitted by the Draft Regulations are Standardless, Arbitrary, and Clinically Unsound

The Draft Regulations permit comparisons to "therapeutic alternatives that provide similar clinical outcomes" without defining how such comparability will be established.[12] This approach assumes clinical equivalence without requiring clinically validated determinations of comparability and fails to account for differences in patient populations, indications, and treatment responses. It is imperative that the Board adopt a definition that ensures that only a true clinical equivalent to the selected drug is chosen, if one exists. The Board should also be transparent about the data, information, and resources it uses to select therapeutic alternatives.

To be clinically comparable to a selected drug, a therapeutic alternative must be a branded therapy that shares the same mechanism of action and is medically appropriate for the same group of patients in each of the FDA-approved indications as the selected drug. The differences in efficacy and safety outcomes between the selected drug and a therapeutic alternative treatment should be small and not clinically meaningful. Drugs that operate through the same biological pathway are more likely to exhibit similar therapeutic effects and have comparable side effect profiles. The Board should define therapeutic alternatives by mechanism of action, as opposed to its current lack of any standard or processes for determining its list of purported therapeutic alternatives.

Without establishing, among other things, clear clinical comparability standards and evidentiary requirements, the Board risks grouping together therapies that are not clinically interchangeable and relying on cost comparisons that lack clinical relevance. As a result, the Draft Regulations risk creating false equivalence across therapies that differ meaningfully in mechanism of action, treatment line, patient response, and safety profile, leading to conclusions that mischaracterize both clinical value and appropriate treatment options.

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[12] Proposed COMAR 14.01.04.01B(2)(b).

V. The Competition-Related Provisions Raise Significant New Legal Concerns

The Draft Regulations include as new factors "conduct that delays or prevents market competition," including patent rights, regulatory exclusivities, and—significantly and inexplicably—"[u]se of regulatory tools that have the effect of delaying or preventing competition, **such as the scheduling of drugs by the Drug Enforcement Agency ('DEA') and risk evaluation and mitigation strategies [("REMS")] approved by the FDA**.[13] This provision effectively transforms the Board into an arbiter of complex federal legal regimes—including patent law, FDA- and DEA-administered safety frameworks, and federal competition policy—well beyond its statutory mandate, legal authority, and institutional expertise.

The Draft Regulations' treatment of these federally mandated safety programs is particularly problematic and represents a significant and unsupported expansion of the Board's analytical framework. As an initial matter, DEA scheduling requirements and REMS programs are not economic or competitive mechanisms; they are safety-based regulatory frameworks established by Congress and administered by expert federal agencies to protect public health. The Controlled Substances Act directs the DEA to classify drugs based on their potential for abuse, accepted medical use, and safety under medical supervision, while REMS programs are imposed by FDA where necessary "to ensure that the benefits of a drug outweigh the risks."[14] These frameworks reflect deliberate federal balancing of access and safety and are subject to ongoing agency oversight. Treating such programs as indicia of "conduct that delays or prevents market competition" fundamentally mischaracterizes their statutory purpose. Absent any finding of misuse or illegality, treating these federally mandated safety programs as indicia of anticompetitive conduct risks labeling bona fide safety compliance as suspect or pretextual, a determination that the Board is neither equipped nor authorized to make.

Moreover, the Draft Regulations appear to adopt a categorical inference that the existence or use of these federal safety requirements may signal anticompetitive conduct. That approach finds no support in federal law. While courts and regulators have considered narrow, fact-specific antitrust claims involving the alleged misuse of REMS—most notably in the context of a manufacturer's refusal to provide product samples to potential generic competitors—those cases do not treat REMS themselves as inherently suspect or anticompetitive. Rather, they require detailed, case-specific inquiry into particular conduct under established antitrust standards.[15] By contrast, the Draft Regulations would permit the Board to draw generalized conclusions about competition based on the mere presence or

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13 Proposed COMAR 14.01.04.01B(3) (emphasis added).

14 *See* 1 U.S.C. §§ 801, *et seq*. (Controlled Substances Act); 21 U.S.C. § 355-1 (REMS).

15 *See, e.g., FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (emphasizing the need for rule-of-reason analysis in complex pharmaceutical competition cases).

operation of federally mandated safety programs, without any defined evidentiary standard or analytical framework.

There is even less support for the inclusion of DEA scheduling within this framework. Unlike REMS, which has been the subject of limited and highly specific antitrust litigation, DEA scheduling decisions have not been recognized as a basis for competition analysis at all. Scheduling determinations are made through formal federal rulemaking processes based on scientific and medical evidence and apply uniformly across market participants. They do not represent company-specific conduct and cannot be meaningfully attributed to individual manufacturers as a competitive strategy. Treating DEA scheduling as a potential indicator of anticompetitive conduct thus lacks any doctrinal foundation and represents a category error in conflating federal regulatory classifications with private market behavior.

Moreover, any determination that such programs are being used in a manner that improperly restricts competition would require complex, fact-intensive adjudication and the application of federal competition law—matters squarely within the jurisdiction and expertise of federal courts and agencies, not the Board.[16] The Draft Regulations would nonetheless permit the Board to reach such conclusions without any defined evidentiary framework, statutory mandate, or statutory authority to do so.

Allowing the Board to second-guess FDA and DEA determinations also raises significant preemption concerns. State action is preempted where it conflicts with federal objectives or stands as an obstacle to the accomplishment of congressional purposes.[17] Here, federal law establishes comprehensive and uniform frameworks governing drug safety, distribution, and abuse prevention. Authorizing the Board to characterize compliance with those frameworks as evidence of an affordability problem or competitive harm risks undermining federal objectives and creating inconsistent state-level judgments regarding nationally regulated programs.

In addition, the Draft Regulations create perverse and counterproductive incentives by suggesting that compliance with federally mandated safety requirements could itself be treated as evidence of an affordability challenge. The Board should not position itself to evaluate whether such programs are "legitimate" or "pretextual," as such determinations are neither within its expertise nor its statutory authority. Accordingly, the Board should withdraw Proposed COMAR 14.01.04.01B(3)(b).

Finally, the inclusion of these factors appears to represent a novel and unvetted expansion of the Board's authority. Accordingly, the Board should remove references to

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16 *See FTC v. Actavis, Inc.*, 570 U.S. at 136.

17 *See Arizona v. United States*, 567 U.S. 387, 399 (2012).

DEA scheduling and REMS from this provision. At a minimum, the Board should limit consideration of competition-related conduct to circumstances where such conduct has been determined to violate applicable law by a court or appropriate federal enforcement authority and should refrain from treating federally protected patents and exclusivities and federally mandated safety frameworks themselves as evidence of anticompetitive behavior.

VI. The Draft Regulations Misattribute Affordability Challenges by Ignoring Supply Chain Dynamics

The Draft Regulations identify access barriers such as prior authorization requirements, claims rejection rates, and coverage decisions as indicators of affordability challenges.[18] These factors are primarily driven by payers and PBMs, not manufacturers. For example, prior authorization requirements, formulary exclusions, and claims rejection rates are established by payers and PBMs as part of benefit design and rebate negotiations and are frequently used to manage utilization and maximize negotiated discounts rather than to reflect the underlying price of a drug. AbbVie recommends that the Board require explicit attribution analysis across supply chain participants and avoid attributing such dynamics to manufacturers absent a demonstrated causal relationship.

AbbVie also recommends that if the Board recognizes the role these market dynamics can play in creating an affordability challenge, the Board also acknowledge that it has not developed the tools necessary to address such a challenge. The Board's emphasis on establishing a UPL is a policy mechanism fundamentally mismatched to address such causes. A UPL would not address the underlying driver of such an affordability challenge and may, in fact, exacerbate it by distorting negotiated rebates, shifting costs across market participants, or restricting patient access. The state legislature seemed to recognize this risk when it enacted legislation last year requiring additional reporting concerning the effects of a UPL on 340B covered entities.[19] Surely if UPLs were a sound policy for addressing all affordability challenges, regardless of their cause, such additional reporting considerations would not be necessary.

Administrative law requires a rational connection between the problem identified and the remedy imposed. [20] Without a demonstrated causal relationship between manufacturer pricing and the identified affordability challenge, the imposition of a UPL risks being arbitrary and capricious. The Draft Regulations should therefore require (1) a demonstrated causal nexus between the identified affordability challenge and manufacturer pricing, and (2) an evidence-based explanation of how any proposed UPL would alleviate, rather than exacerbate, that challenge. In cases where the Board identifies an "affordability

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18 Proposed COMAR 14.01.04.01B(4).

19 Md. Code, Health–Gen. § 21-2C-09(d)(7) (2025).

20 *See State Farm*, 463 U.S. at 43; *Harvey*, 389 Md. at 299.

challenge" arising from factors unrelated to manufacturer pricing—such as payer utilization management, coverage restrictions, or other supply chain dynamics—the Board should adopt regulations that then require the Board to create an appropriate recommendation to address that challenge, and that forbid it to pursue the setting of a UPL that not only might not address, but indeed may well exacerbate the affordability challenge the Board has identified. Where the Board determines that an affordability challenge is primarily driven by factors other than manufacturer pricing, the regulations should require the Board to identify those drivers and evaluate policy responses tailored to address them.

VII. Lack of Clear Analytical Distinction Between System-Wide and Patient-Level Affordability Factors

The structure of Proposed COMAR 14.01.04.01 conflates distinct categories of affordability considerations by failing to clearly distinguish between system-level indicators and patient-level financial burden. While Proposed COMAR 14.01.04.01B appears to address system-wide measures of spending and utilization, Proposed COMAR 14.01.04.01C and Proposed COMAR 14.01.04.01D more specifically relate to patient-level affordability impacts, including out-of-pocket costs and adherence-related measures. The Draft Regulations should explicitly clarify this distinction and require that system-level and patient-level factors be evaluated under separate, clearly defined standards. Absent such clarification, the framework risks collapsing materially different concepts into a single, undifferentiated inquiry, undermining analytical rigor and transparency.[21] Moreover, the Board should be required to demonstrate a clear nexus between system-level spending indicators and patient out-of-pocket burden, rather than treating these categories as interchangeable proxies for one another.

VIII. Patient Out-of-Pocket Provisions Do Not Reflect Benefit Design Realities

The Draft Regulations include patient-focused affordability indicators such as out-of-pocket costs relative to income and adherence patterns.[22] These measures are not appropriate proxies for manufacturer-driven affordability, as patient cost exposure is largely determined by insurance benefit design (*e.g.*, deductibles and coinsurance) as opposed to manufacturing pricing. Indeed, there is often a significant disconnect between a drug's net price and a patient's out-of-pocket cost, particularly in high-deductible or coinsurance-based plans, such that patient affordability challenges may persist even where net prices are stable or declining. AbbVie recommends requiring a demonstrated nexus between manufacturer pricing and patient financial burden. Consistent with the foregoing, where patient affordability challenges are driven by benefit design—such as deductibles, coinsurance, or formulary restrictions—rather than manufacturer pricing, the Board should

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21 *See Harvey*, 389 Md. at 299-304.

22 Proposed COMAR 14.01.04.01D.

be required to demonstrate how a UPL would directly address those factors before proceeding with such a remedy. Absent such a showing, reliance on UPLs risks failing to improve, and potentially worsening, the identified patient affordability concerns.

* * * * *

Thank you for the opportunity to provide written comments on the Draft Regulations. As detailed above, the deficiencies in the Draft Regulations above are not merely technical—they reflect a fundamental failure to translate statutory authority into an administrable regulatory framework. Indeed, the Draft Regulations fail to establish clear and objective standards, ensure methodological rigor and transparency, and reflect the full complexity of the pharmaceutical supply chain as well as rely on legally and analytically unsupported factors. Accordingly, AbbVie respectfully urges the Board to decline to finalize the Draft Regulations in their current form and instead undertake further rulemaking to address the deficiencies identified above. 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.

Written Testimony

Maryland PDAB Special Meeting

October 5, 2026

Candie Finnegan
ED, State Government Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.

Re: Maryland Prescription Drug Affordability Board's proposed revisions to COMAR 14.01.01.05 Public Comment Procedures and COMAR 14.01.04 Cost Review Study Process.

At Boehringer Ingelheim, we recognize the burden high out-of-pocket costs place on patients. While action is needed to make medicines more affordable, government-imposed price controls are not the most effective path forward. We support solutions that improve patient access and affordability while sustaining medical innovation.

The Maryland Prescription Drug Affordability Board (PDAB) has proposed revisions to COMAR 14.01.04, governing the cost review study process. The revisions address the circumstances under which use of a medicine may create an affordability challenge.

Boehringer appreciates the Board's efforts to refine the proposed regulations. We support recognizing that affordability challenges may arise when health plans cover fewer uses or conditions than evidence-based clinical guidelines recommend. Coverage restrictions and formulary exclusions can limit access, disrupt treatment, and increase patients' out-of-pocket costs regardless of a medicine's price.

Patients within the US healthcare system face access and affordability barriers due to the business practices of PBMs. In particular, utilization management (UM) practices, including prior authorization requirements, step therapy, and formulary design, are key determinants of patient access and out-of-pocket costs yet are not controlled by manufacturers. By relying on indicators such as high claims rejection rates, limited coverage, or elevated patient cost-sharing as evidence of an affordability challenge, the proposal may inadvertently attribute access barriers created by plans and PBMs to manufacturers.

Boehringer supports the Board's mission to improve affordability for Maryland patients, but believes the cost review, reporting, and an upper payment limit are not

how it will be accomplished. We remain committed to collaborative solutions that protect patient access and sustain medical innovation.

Regards,



Candie Finnegan
Executive Director, State Government Affairs and Advocacy

EACH PIC COALITION

September 23, 2026

Christina Shaklee, Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on Proposed Regulation – Circumstances Under Which Use of a Drug May Create an Affordability Challenge

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.

The undersigned organizations appreciate the opportunity to comment on the board's proposed regulation establishing the circumstances under which use of a drug may create an affordability challenge. We commend the board for continuing to refine its affordability framework and for seeking greater clarity around the factors that may warrant review and policy consideration.

As the board undertakes this effort, we encourage it to ensure that affordability determinations remain focused on patient affordability. While healthcare spending is an important consideration for policymakers, spending metrics alone do not demonstrate that patients are experiencing affordability challenges. Affordability reviews should therefore be grounded primarily in evidence that patients are struggling to afford treatment.

Spending Metrics Alone Do Not Demonstrate Patient Affordability Challenges

The proposed regulation allows a drug to be deemed an affordability challenge based on factors such as spending levels, spending growth, value assessments, and market competition concerns.

These metrics may provide insight into healthcare system spending, but they do not necessarily demonstrate that patients are experiencing affordability hardships. Spending measures do not reveal whether patients can afford their medications, whether they are delaying or abandoning treatment due to cost, or whether they face barriers that make treatment unaffordable.

The purpose of an affordability review should be to identify and address affordability challenges experienced by patients. A finding that spending is high does not demonstrate that patients are struggling to afford a medication.

Evidence of Patient Affordability Challenges Should Be Required Before a UPL May Be Considered

As drafted, the regulation permits affordability challenge determinations based entirely on system spending metrics without evidence that patients are experiencing affordability challenges.

The board's reviews of Ozempic and Trulicity illustrate this concern. In both cases, the affordability challenge determination was driven primarily by healthcare system spending metrics rather than evidence that patients were experiencing affordability hardships associated with those therapies.

At the same time, upper payment limits (UPLs) have the potential to affect the patients who rely on these medications. As a result, patients may ultimately bear the consequences of affordability determinations that were not based on evidence of patient affordability challenges in the first place.

For that reason, we encourage the board to require that at least one patient affordability criterion be satisfied before a drug may advance to consideration of a UPL or other affordability intervention. If a policy is being pursued in the name of improving affordability, there should first be evidence that patients are experiencing affordability challenges associated with that drug.

Establishing this safeguard would help ensure that affordability reviews remain focused on improving patient affordability rather than solely reducing healthcare system spending.

Understanding the Drivers of Patient Affordability Challenges

Patients repeatedly described affordability as a function of insurance design, cost-sharing obligations, financial assistance availability, and changing life circumstances rather than the cost of a medication alone. This highlights an important reality: understanding that a patient is experiencing an affordability challenge is only the first step. Policymakers must also understand what is causing that challenge if they hope to design policies that effectively address it.

We appreciate that the proposed regulation includes patient-focused affordability criteria. However, patient affordability challenges are often driven by factors that are not fully captured through spending, utilization, or out-of-pocket cost metrics alone. Patients may discontinue or avoid treatment for very different reasons, including coverage denials, prior authorization requirements, changing cost-sharing obligations, loss of financial assistance, or other insurance-related barriers.

A patient-centered affordability framework should therefore seek to understand not only whether patients are experiencing affordability challenges, but why those challenges occur. Without understanding the underlying drivers, policymakers risk designing solutions that address symptoms rather than causes and may ultimately fail to resolve the affordability barriers patients face.

Conclusion

We appreciate the board's efforts to improve and clarify its affordability framework. As this work continues, we encourage the board to ensure that patient affordability remains the central focus of affordability determinations and to require that at least one patient affordability criterion be satisfied before a drug may be deemed to create an affordability challenge.

Thank you for the opportunity to provide comments. We look forward to continuing to engage with the board on policies that meaningfully improve affordability for Maryland patients.

EACH/PIC COALITION

Sincerely,

EACH/PIC Coalition
AiArthritis
Autoimmune Association
Biomarker Collaborative
Caring Ambassadors
Coalition of State Rheumatology Organizations
Community Liver Alliance
Crohn's & Colitis Foundation
Exon 20 Group
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MET Crusaders
National Infusion Center Association
Neuropathy Action Foundation (NAF)
NRG1 Energizers
PDL1 Amplifieds
Rare Access Action Project (RAAP)
The AIP BIPOC Network
The Bonnell Foundation: Living with Cystic Fibrosis

Healthcare Distribution Alliance

HEALTH DELIVERED

September 25, 2026

Andrew W. York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112
Bowie, Maryland 20715

Re: Comments of the Healthcare Distribution Alliance on Proposed Amendments to COMAR 14.01.04 – Cost Review Study Process (53:18 Md. R. 905; Notice No. 26-133-P)

Dear Executive Director York and Members of the Board:

The Healthcare Distribution Alliance (HDA) appreciates the opportunity to provide comments on the Maryland Prescription Drug Affordability Board's ("PDAB" or "Board") proposed amendments to COMAR 14.01.04, which govern the Cost Review Study Process.

HDA represents pharmaceutical distributors that serve as a critical link between manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and other healthcare providers, including over 9,000 locations across Maryland. HDA supports the Board's work to develop an evidence-based understanding of prescription drug affordability. However, the Board's proposed amendments will impose reporting requirements that are unnecessary to the Board's affordability analysis, include reporting requirements that would mischaracterize wholesale distribution economics, and require disclosure of competitively sensitive information.

HDA respectfully urges the Board not to adopt the proposed wholesaler reporting provisions as drafted. In particular, the proposed reporting of product-specific gross-to-net revenue and discounts as a percentage of Wholesale Acquisition Cost (WAC) which would not provide a meaningful measure of a wholesaler's role in drug affordability and risk producing misleading conclusions and exposing competitively sensitive information.

HDA offers the following comments on the proposed language:

Health-General Article § 21-2C-09 provides that, when public information is insufficient to conduct a cost review, the Board may request information "as appropriate" from a wholesale distributor or other supply-chain participant that possesses relevant information about how a prescription drug's cost is established in Maryland. The proposed regulations, however, appear to contemplate routine requests for detailed wholesaler information once a drug is selected for review,

moving beyond the statutory framework and creating unnecessary reporting that would add little substantive value to the Board's affordability analysis. HDA urges the Board to preserve the statute's limitations and request nonpublic wholesaler information only when public information is insufficient and the wholesaler possesses information relevant to the affordability issue under review.

Further, HDA is highly concerned that requiring discounts and concessions to be reported as a percentage of WAC would mischaracterize wholesale distributor economics. WAC is set by the manufacturer and does not necessarily reflect a distributor's economics or the value it retains from a transaction. Reporting wholesaler concessions against a manufacturer-established benchmark could therefore create a misleading impression and provide inaccurate data to the Board without providing any additional meaningful information related to a drug's affordability. HDA strongly urges the Board to remove the WAC-percentage reporting requirement.

The proposed regulations would also allow the Board to request product-specific "gross and net wholesale distributor revenues." Although § 21-2C-09 identifies these revenues as information the Board may consider, gross-to-net revenue is not a meaningful measure of wholesaler margin, profit, or retained value. Wholesale distributors operate under fundamentally different commercial arrangements than manufacturers and PBMs, and gross-to-net figures are not comparable across these entities and could be interpreted differently. Requiring this information could therefore add significant data to the Board's review process without providing a reliable measure of a wholesaler's contribution to drug affordability. HDA urges the Board to remove the proposal requesting routine product-specific gross-to-net reporting for wholesalers from the amendments.

The proposed requirements also raise significant concerns about disclosure of confidential commercial information. Product-specific details, such as customer discounts, concessions, units sold, and revenues, could reveal or allow sophisticated market participants to infer sensitive contractual terms. While HDA recognizes the existing confidentiality protections provided under Maryland law, collecting highly granular information creates unnecessary risk where the information itself is not necessary to the Board's analysis. The Board should avoid collecting such information and ensure that any information it determines is necessary is protected from direct or indirect disclosure.

Finally, HDA requests greater transparency in the proposed process for Board staff to develop a "curated list" of drugs eligible for selection. HDA recognizes that staff analysis can support the Board's work. However, because the curated list may influence which products advance to cost review, the criteria used to develop it should be transparent, objective, and consistently applied.

HDA respectfully urges the Board not to adopt the proposed wholesale distributor reporting provisions as drafted and specifically remove the proposed WAC-percentage reporting requirement and routine collection of product-specific gross and net wholesale distributor revenues. These data do not provide a meaningful measure of wholesale distributor margin, retained value, or contribution to drug affordability and risk creating misleading conclusions while requiring disclosure of commercially sensitive information. Any request for wholesale information should instead adhere to the statutory standard and be limited to information necessary and relevant to the specific affordability issue under review.

HDA appreciates the Board's consideration of these comments and welcomes the opportunity to work with the Board and its staff to ensure that information about wholesale distribution is collected and interpreted in a manner that accurately reflects the industry's role and economics and is appropriately tailored to the Board's statutory affordability analysis.

Sincerely,

Juan Carlos Payero
Director, State Government
Healthcare Distribution Alliance
jcpayero@hda.org

PhRMA
RESEARCH • PROGRESS • HOPE

670 Maine Ave SW WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

By Electronic Submission

October 5, 2026

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

RE: Proposed Regulations – Revisions to COMAR 14.01.04 (Cost Review Study Process)

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 proposal to repeal existing Regulation .01 and adopt new Regulation .01, amend Regulations .02-.05, and adopt new Regulation .06 under COMAR 14.01.04 (Cost Review Study Process) ("Proposed 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 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 $900 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

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

[1] *See* Notice of Proposed Action, COMAR 14.01.04 Cost Review Study Process (26-133-P) (Sept. 4, 2026), *available at* https://dsd.maryland.gov/MDRIssues/5318/Assembled.aspx#_Toc239082153. 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 (July 27, 2026); Letter from PhRMA to Board (July 13, 2026); Letter from PhRMA to Board (June 26, 2026); Letter from PhRMA to Board (June 1, 2026); 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 (Mar. 4, 2026); Letter from PhRMA to Board (Feb. 10, 2026); Letter from PhRMA to Board (Feb. 10, 2025); Letter from PhRMA to Board (Dec. 2, 2024); Letter from PhRMA to Board (Nov. 8, 2024); Letter from PhRMA to Board (Aug. 26, 2024); Letter from PhRMA to Board (July 16, 2024); Letter from PhRMA to Board (July 12, 2024); Letter from PhRMA to Board (May 10, 2024); Letter from PhRMA to Board (Apr. 24, 2024); Letter from PhRMA to Board (Oct. 23, 2023); Letter from PhRMA to Board (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 (May 1, 2023); Letter from PhRMA to Board (Sept. 12, 2022).

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

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. Circumstances Under Which Use of a Drug May Create an Affordability Challenge

A. Lack of Clear, Specific, and Meaningful Standards

PhRMA is concerned that the Proposed Regulations fail to provide sufficiently clear, specific, and meaningful standards and a methodology for consistent evaluation and decision-making regarding the circumstances that may create an affordability challenge. . The "circumstances" contemplated in the Proposed Regulations are non-exhaustive and rely on vague and undefined terms. For example, the Proposed Regulations provide that "circumstances under which use of a drug has or will lead to high out-of-pocket costs for patients may be indicated by, but not limited to" circumstances in which "[t]he average total out-of-pocket costs for a drug are *disproportionate* to the average State household income" or "[a] *significant proportion* of patients do not take the drug as prescribed," without specifying what constitutes "disproportionate" or a "significant proportion."[4] Similarly, the Proposed Regulations refer to "disparities in patient out-of-pocket costs or utilization . . . in *priority populations*," without defining "priority populations" or explaining how such populations would be identified.[5] These examples illustrate a broader pattern of vague and undefined terms throughout the Proposed Regulations.

Moreover, because the circumstances are non-exhaustive, they lack sufficient procedural clarity and neither provide stakeholders with adequate notice of how certain provisions may be applied nor provide meaningful guardrails on Board discretion.[6] Specifically, the Proposed Regulations include broad, undefined "catch-all" provisions that would allow the Board to find that use of a drug has led or will lead to an affordability challenge or high out-of-pocket costs based on "[a]ny other circumstance identified by the Board through the cost review study."[7] These provisions do not provide stakeholders with sufficient notice of the standards that the Board will apply and risk enabling unrestrained discretion and arbitrary decision-making, rather than reasoned analysis.[8]

PhRMA remains concerned that this absence of clear standards creates a significant risk of inconsistent application and arbitrary decision-making.[9] This raises concerns under the Maryland Administrative Procedure Act ("APA"), which requires agencies to provide a reasoned basis for—and apply standards

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[3] *See supra* note 1.
[4] *See* Proposed Regulations, COMAR 14.01.04.01D(1), (3) (emphasis added).
[5] *Id.* 14.01.04.01D(4) (emphasis added).
[6] *See* Letter from PhRMA to Board (June 26, 2026) at 6.
[7] *See* Proposed Regulations, COMAR 14.01.04.01B(4), D(5).
[8] *See* Letter from PhRMA to Board (Aug. 26, 2024) at 2; *see also, e.g.*, *Calvert Cnty. Plan. Comm'n v. Howlin Realty Mgmt., Inc.,* 364 Md. 301, 322 (2001) (explaining that agency rules should be "formally adopted . . . in written form" and "made available in advance to persons dealing with the agency," as only then can there be assurance against arbitrary and capricious conduct). *See, e.g.*, *Myers v. State*, 248 Md. App. 422, 437 (2020) (due process prevents even legislatures, much less agencies, from establishing rules "so standardless that it invites arbitrary enforcement"); *Rodriguez v. Prince George's Cnty.*, 79 Md. App. 537, 550, 558 A.2d 742, 748 (1989) ("It is not permissible for the Council, or any administrative body, simply to parrot general statutory requirements or rest on broad conclusory statements").
[9] *See, e.g.*, Letter from PhRMA to Board (June 26, 2026) at 2; Letter from PhRMA to Board (Mar. 30, 2026) at 2; Letter from PhRMA to Board (Feb. 10, 2026) at 3; Letter from PhRMA to Board (Feb. 10, 2025) at 2.

consistently in—their decision-making.[10] PhRMA therefore urges the Board to adopt clear, objective standards for evaluating whether a drug has led or will lead to an affordability challenge in a consistent and non-arbitrary manner.

Additionally, if the Board adopts and later seeks to invoke a catch-all provision, it should provide a detailed explanation of the specific circumstances and evidence supporting its determination that a drug has led or will lead to an affordability challenge.[11] Without such explanation, stakeholders cannot meaningfully assess or comment on the Board's decisions. The Proposed Regulations should clearly establish opportunities for stakeholder comment on the Board's analysis and determinations before the Board renders a preliminary affordability determination.[12]

B. Consideration of Circumstances Not Meaningfully Related to "Affordability"

As part of its cost review authority, the Board is charged with determining whether use of a drug has led or will lead to affordability challenges.[13] However, several proposed circumstances do not correlate with affordability—for patients or the State health care system. For example, list prices typically do not reflect the net costs to payors or patients' out-of-pocket expenses, which are driven by a range of factors, including insurance benefit design. Consequently, certain proposed circumstances—such as "wholesale acquisition cost (WAC) increasing significantly faster than inflation"—do not demonstrate that a drug creates an affordability challenge.[14]

To comply with the PDAB Statute, the circumstances for determining whether use of a drug has led or will lead to affordability challenges should bear a clear and demonstrable relationship to affordability for patients or the State health care system.[15] The Board may exceed the scope of its statutory mandate if it relies on circumstances that do not clearly relate to patient out-of-pocket costs or State spending. PhRMA urges the Board to articulate whether and how each proposed circumstance is directly connected to affordability for patients or the State health care system and to strike any circumstances that are not clearly tied to either.

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[10] *See* Md. Code, State Gov't §§ 10-101–10-305; *see also, e.g.*, *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023) (requiring "factual findings . . . to support the agency's conclusion"); *Mortimer v. Howard Res. & Dev. Corp.*, 83 Md. App. 432, 442 (1990); *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).

[11] *See Elbert*, 259 Md. App. at 509 ("A reviewing court may not . . . uphold an agency's decision if a record of the facts on which the agency acted or a statement of reasons for its action is lacking.").

[12] *See Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998) (explaining that notice-and-comment "procedures are designed, on the one hand, to afford fair notice and a meaningful opportunity to comment to all persons who may be affected by the proposed regulation and, on the other, to give the agency free-flowing information from a broad range of interests").

[13] Md. Code, Health-Gen. § 21-2C-09(b)(1) ("If the Board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to *affordability challenges for the State health care system or high out–of–pocket costs for patients*." (emphasis added)).

[14] *See* Proposed Regulations, COMAR 14.01.04.01B(1)(c). Rebates and discounts, which totaled approximately $416 billion in 2025, largely offset modest increases in WAC. *See* Adam J. Fein, Drug Channels Institute, *The 2026 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2026).

[15] *See* Md. Code, Health-Gen. § 21-2C-09(b)(1) (requiring the Board to determine whether use of a drug "has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients").

C. The Board Should Pursue Policy Options that Address the Drivers of Affordability Challenges

Many of the circumstances in the Proposed Regulations are driven by factors other than drug pricing. For example, circumstances in which "[i]nsurance plans cover fewer uses or conditions for this drug than what the FDA has approved or what clinical guidelines recommend," there is a "[h]igh occurrence of required prior authorization or high claims rejection rate," or "patient out-of-pocket cost in certain markets are disproportionate to the average net cost paid by payors" are largely the result of decisions made by insurers and pharmacy benefit managers ("PBMs").[16] Indeed, utilization management (including formulary design and restrictions) is exclusively controlled by insurers and PBMs. PhRMA has previously emphasized the importance of considering the many utilization management and benefit design factors that can affect access and affordability.[17] Adherence issues (e.g., where "[a] significant proportion of patients do not take the drug as prescribed") may also result from insurers' benefit design choices.[18] Upper Payment Limits ("UPLs") do not address these underlying drivers of affordability challenges, do not expand coverage, and may exacerbate access barriers.[19] Accordingly, the Board should address affordability challenges driven by benefit design with policies that target the root causes of those challenges, not UPLs.

II. Therapeutic Alternatives

A. Consideration of Therapeutic Alternatives

PhRMA continues to have concerns with the Board's consideration of therapeutic alternatives in its cost review process, including the Board's broad definition of "therapeutic alternative" and the lack of clarity regarding how it determines which drugs meet that definition for a particular drug under review.[20] Specifically, the Proposed Regulations would allow the Board to consider whether the "average net price of the drug exceeds the average net price for therapeutic alternatives that provide similar clinical outcomes" or whether the drug "was approved with limited evidence of improvement in clinical outcomes and has substantial spending" compared to its therapeutic alternatives as circumstances under which use of a drug may lead to an affordability challenge.[21]

As PhRMA has previously explained, some therapies that could be identified as therapeutic alternatives under the Board's definition are not appropriate for all patients and may not be considered comparable

[16] Proposed Regulations, COMAR 14.01.04.01B(3)(a)-(b), D(2).

[17] *See* Letter from PhRMA to Board (Mar. 30, 2026) at 3. PhRMA also notes that the PDAB Statute contemplates that implementation of UPLs could lead to or perpetuate patient access and affordability challenges. *See id.*; Md. Code, Health-Gen. § 21-2C-09(d)(1)-(2), (4), (6) (requiring the first annual Board report on UPL effects to include information on "[p]atient out-of-pocket costs," health insurance premiums and formularies, and patient access, which may include "[w]hether formulary placement or plan design changes made the prescription drug product subject to the upper limit more difficult for patients to access, including if insurance plans preferred a prescription drug product without an upper payment limit over a prescription drug product subject to an upper payment limit").

[18] *See* Proposed Regulations, COMAR 14.01.04.01D(3). Adherence issues may also result from non-cost factors like side effects, contraindications, clinical considerations, or patient preference.

[19] *See supra* note 17; Letter from PhRMA to Board (July 27, 2026) at 5.

[20] *See* COMAR 14.01.01.01B(63) (defining "[t]herapeutic alternative" as "a drug product that has one or more of the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug"); *see also, e.g.*, Letter from PhRMA to Board (June 26, 2026) at 5; Letter from PhRMA to Board (June 1, 2026) at 8-9; Letter from PhRMA to Board (May 1, 2026) at 4; Letter from PhRMA to Board (Mar. 30, 2026) at 3-4; Letter from PhRMA to Board (July 16, 2024) at 4-5; Letter from PhRMA to Board (May 10, 2024); Letter from PhRMA to Board (Apr. 24, 2024) at 3.

[21] Proposed Regulations, COMAR 14.01.04.01B(2)(a)-(b).

treatments.[22] PhRMA is therefore concerned with the Board's proposal to assess affordability by comparing selected drugs against therapeutic alternatives because such comparisons may not be appropriate. So that therapeutic alternatives are identified in a manner consistent with clinical evidence, those determinations should be informed by clinical guidance, physician-driven evidence-based guidelines, and input from manufacturers, patient communities, and other relevant experts.[23] Accordingly, PhRMA reiterates its request that, before finalizing the Proposed Regulations, the Board engage with manufacturers regarding potential therapeutic alternatives and publish criteria for identifying therapeutic alternatives to help ensure the Board's decisions are consistent with clinical evidence.[24]

Further, the Proposed Regulations would permit the Board to make broad decisions about affordability based on aggregate clinical outcomes, without adequately considering patient populations with specific clinical needs, such as immunocompromised patients, pediatric patients, women, and the elderly.[25] Patients in these groups in particular may respond differently to treatments and be limited to one specific drug therapy for their condition.[26] The Proposed Regulations would thereby allow the Board to substitute the best judgment of a patient's physician with its own opinion and may have the impact of limiting patient access to treatment.

B. Selection and Use of Therapeutic Alternatives or Comparators

The Board proposes to add a new provision 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" Proposed COMAR 14.01.04.05.[27] If finalized, this provision would significantly expand the scope of the Board's comparative evaluations without establishing guardrails to prevent inappropriate comparisons between products.[28]

The risk of inappropriate comparisons is particularly acute where, as here, the Proposed Regulations lack clear standards for identifying appropriate comparators. By permitting staff to perform analyses using "any comparator," the Proposed 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.[29] 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

[22] *See, e.g.*, Letter from PhRMA to Board (June 26, 2026) at 5; Letter from PhRMA to Board (June 1, 2026) at 8-9; Letter from PhRMA to Board (Mar. 30, 2026) at 4.
[23] *See*, *e.g.*, Letter from PhRMA to Board (July 16, 2024) at 4-5; Letter from PhRMA to Board (May 10, 2024) at 4.
[24] *See* Letter from PhRMA to Board (June 26, 2026) at 5; Letter from PhRMA to Board (May 1, 2026) at 4; Letter from PhRMA to Board (Mar. 30, 2026) at 3-4; Letter from PhRMA to Board (July 16, 2024) at 4-5; Letter from PhRMA to Board (May 10, 2024) at 4-5; Letter from PhRMA to Board (Apr. 24, 2024) at 3.
[25] *See* Proposed Regulations, COMAR 14.01.04.01B(2)(a)–(b); Letter from PhRMA to Board (June 26, 2026) at 6.
[26] *See* Letter from PhRMA to Board (May 10, 2024) at 4-5.
[27] Proposed Regulations, COMAR 14.01.04.05C(1)(e)(i). PhRMA also notes that the proposed provision, as currently drafted, includes a cross-referenced cite to COMAR 14.01.04.03C(1)(e) that appears to be incorrect as that provision does not exist in either the current regulations or the Proposed Regulations. *See id*. Before finalizing, PhRMA urges the Board to revise the proposed provision to correct the cross-referenced cite.
[28] *See infra* Sec. III.C.
[29] *See Harvey,* 389 Md. at 302.

basis for such differential treatment,[30] and have likewise struck down decisions that have unexplained inconsistencies with prior agency decisions.[31] 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.

Additionally, PhRMA strongly recommends that the Board use caution when considering information regarding "therapeutic alternatives" or "any comparator" for selected medications.[32] 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 affordability determinations, and, potentially, UPLs, particularly if the therapeutic alternatives are not supported by clinical evidence and consistent with standard practice.

III. Delegation of Board Responsibilities to Staff

The Proposed Regulations reflect a significant shift toward delegating core Board functions to staff, including developing a curated list of eligible drugs, recommending drugs for referral to the Stakeholder Council, preparing "[d]ata summaries, rankings, comparisons, and analyses," identifying therapeutic alternatives and other comparators, and preparing recommendations on the Board's affordability determinations.[33] 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.[34] While the Board is authorized to hire staff for support, the PDAB Statute assigns responsibility for evaluating drug affordability *to the Board itself*.[35] 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.[36] Without adequate regulatory safeguards and a clear process

[30] *See Maryland State Bd. of Soc. Work Examiners v. Chertkov,* 121 Md. App. 574, 588 (1998).
[31] *See, e.g.*, *Christopher v. Montgomery Cnty. Dep't of Health & Human Servs.,* 381 Md. 188, 215 (2004).
[32] *See* Letter from PhRMA to Board (May 1, 2023) at 11.
[33] *See, e.g.*, Proposed Regulations, COMAR 14.01.04.03A(1), B(7), C(2), H(1); 14.01.04.05C(1)(e)(i), D.
[34] *See* Letter from PhRMA to Board (June 1, 2026) at 2.
[35] *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).
[36] *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).

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.[37]

For example, the PDAB Statute specifies that "*[t]he Board* shall use the information collected . . . to identify prescription drug products" that are eligible for cost review study.[38] However, the Proposed Regulations would permit the Board to direct staff to develop a curated list of drugs eligible for selection but would not require staff to explain how the Board's priorities were applied to develop this list or which eligible drugs were excluded from the curated list.[39] The PDAB Statute also provides that "*the Board* shall determine whether to conduct a cost review . . . for each identified prescription drug product by . . . [s]eeking Stakeholder Council input."[40] The Proposed Regulations, on the other hand, would allow staff to make recommendations to the Board regarding drugs to refer to the Stakeholder Council.[41] Additionally, the PDAB Statute expressly identifies therapeutic alternatives as a factor "the Board shall consider" in a cost review study, but the Proposed Regulations would eliminate the requirement that "[t]he Board . . . determine the therapeutic alternatives for each prescription drug product selected for a cost review study," presumably leaving identification to staff. [42]

Although the Proposed Regulations clarify that the Board would not be limited to reviewing staff-recommended drugs, PhRMA is 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.[43] To guard against unreasoned or arbitrary decision-making, the Board should understand how staff reached their recommendations, independently review the information underlying staff decision-making, and approve staff decisions. PhRMA urges the Board to revise the Proposed 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 and recommendations should have no effect unless and until the Board has reviewed and approved them 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.[44]

B. Risk of Diminished Transparency and Public Accountability

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[37] *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).

[38] Md. Code, Health-Gen. § 21-2C-08(c) (emphasis added).

[39] *See* Proposed Regulations, COMAR 14.01.04.03A(1)-(3). The Proposed Regulations would also permit—but not require—staff to provide to the Board a dashboard of all eligible drugs. Md. Code, Health-Gen. § 21-2C-09(a)(1)(i) (emphasis added).

[40] Md. Code, Health-Gen. § 21-2C-09(a)(1)(i) (emphasis added).

[41] *See* Proposed Regulations, COMAR 14.01.04.03C(2).

[42] Md. Code, Health-Gen. § 21-2C-09(b)(2)(iv), (v), (ix). *Compare* COMAR 14.01.04.03H(5), *with* Proposed Regulations, COMAR 14.01.04.03H (deleting H(5)); *see also* COMAR 14.01.04.03H(1)-(4).

[43] *See* Draft Proposed Regulations, COMAR 14.01.04.03C(3); 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*, 465 Md. at 516–17 (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).

[44] *See* Md. Code, Health-Gen. § 21-2C-10 (statutory protections for non-public information).

By allowing Board staff to exercise broad discretion in making recommendations and determining what information is shared with stakeholders and the Board, the Proposed Regulations risk reducing transparency and limiting opportunities for stakeholder engagement. For example, providing the Stakeholder Council only "a selected dashboard" for referred drugs—rather than a complete dataset derived from established criteria—impairs meaningful stakeholder engagement.[45] Without an understanding of the rationale underlying staff conclusions, stakeholders cannot effectively evaluate, comment on, or respond to that information.

Additionally, the Proposed Regulations do not clearly provide opportunities for stakeholders to comment on the staff's methodological choices, analyses, and recommendations. For instance, the proposed deletion of COMAR 14.01.04.03C(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 accordance with the procedures and timelines in" COMAR 14.01.01.05.[46] 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.[47]

Providing opportunities for general comments at Board meetings does not substitute for the ability to understand and comment on specific staff analyses and recommendations. 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.[48] However, the Proposed 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.[49]

For these reasons, the Board should revise the Proposed Regulations to require 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 considering confidential, proprietary, and trade secret

[45] *See* Proposed Regulations, COMAR 14.01.04.03G(1).

[46] COMAR 14.01.04.03C(4). Similar concerns arise from the proposed deletion of the provisions allowing a Board member to request that a drug be placed on the Board's meeting agenda for possible referral and allowing the Board Chair to include a drug's name and dose on the agenda. *See* Proposed Regulations, COMAR 14.01.04.03C(2); COMAR 14.01.04.03C(2)–(3). The Proposed Regulations would replace these provisions with one that allows staff to provide recommendations *to the Board* "[p]rior to a Board meeting." Proposed Regulations, COMAR 14.01.04.03C(2) (emphasis added). If staff recommendations are not made public before the meeting, stakeholders may not have opportunity to prepare and provide meaningful comment.

[47] 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").

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

[49] *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").

information).[50] 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.[51]

C. 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 Proposed Regulations do not establish meaningful standards to guide how staff would exercise such authority. For example, staff appear to have significant discretion in the following areas:

- developing a curated list of eligible drugs for review,[52]
- selecting and defining therapeutic alternatives and determining appropriate comparators,[53] and
- curating and presenting data to the Board and Stakeholder Council.[54]

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.[55] 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.[56]

IV. Lack of Justification for Regulatory Changes

The Proposed 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., per-unit pricing information), without specifying why such amendments are necessary or how the Board would use this information to assess affordability under the PDAB Statute.[57] 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.[58] Failure to do so may render its action arbitrary and capricious. PhRMA urges the Board to provide a detailed justification for each

[50] *See supra* note 56; Md. Code, Health-Gen. § 21-2C-10; *see also* Proposed Regulations, COMAR 14.01.04.05D, E(4).
[51] 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.
[52] See Proposed Regulations, COMAR 14.01.04.03A(1)-(2).
[53] *See* Proposed Regulations, COMAR 14.01.04.03H, 14.01.04.05C(1)(e)(i).
[54] *See, e.g.*, Proposed Regulations, COMAR 14.01.04.03B(7), C(2), G(1).
[55] *Harvey*, 389 Md. at 299.
[56] *See, e.g.,* Harvey, 389 Md. at 302 ("[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).
[57] *See* Proposed Regulations, COMAR 14.01.04.04B(1)(p)–(q), (2)(a)–(b), (f), (3)(a), (d), (4)(b).
[58] *Md. Off. of People's Counsel v. Md. Pub. Serv. Comm'n*, 246 Md. App. 388, 412 (2020).

significant amendment and to clearly articulate how each change advances the Board's statutory mandate to assess affordability challenges.[59]

V. Confidentiality

Consistent with our prior comment letters, PhRMA emphasizes the importance of developing safeguards against the disclosure of confidential information.[60] In the Proposed Regulations, the Board contemplates requesting a significant amount of additional confidential, proprietary, and trade secret information for consideration in its cost reviews.[61] They do not, however, adequately address how the Board intends to protect against the unlawful disclosure of such information that it may receive from manufacturers, payors, PBMs, and wholesale distributors.[62]

The PDAB Statute sets forth strict confidentiality protections for information and data obtained or accessed by the Board.[63] "Only 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."[64] We urge the Board to clarify in the Proposed 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.[65]

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

- **Pricing Information.** The Proposed 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.[66] The Proposed Regulations

[59] *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).

[60] *See, e.g.*, Letter from PhRMA to Board (June 1, 2026) at 5; Letter from PhRMA to Board (Feb. 10, 2025) at 2; Letter from PhRMA to Board (July 12, 2024) at 4; Letter from PhRMA to Board (June 30, 2023) at 6-7; Letter from PhRMA to Board (May 4, 2023) at 1-3.

[61] *See* Proposed Regulations, COMAR 14.01.04.04.

[62] *Id*.

[63] *See* Md. Code, Health-Gen. §21-2C-10; Letter from PhRMA to Board (June 1, 2026) at 5; Letter from PhRMA to Board (June 30, 2023) at 6-7.

[64] Md. Code, Health-Gen. § 21-2C-10(a)–(b).

[65] 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* Md. Code, Health-Gen. § 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).

[66] *See* Proposed Regulations, COMAR 14.01.04.04B(2)(a)-(b), (3)(a), (d), (4)(b); Md. Code, Health-Gen. §§ 21-2C-09(b)(2)(ii), (iii).

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."[67] 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 Proposed Regulations would authorize the Board to request information "concerning the manufacturer's drug-specific patient access programs," including "[t]he value of all coupons, free samples, and drug donations to charities provided by the manufacturer" and "[t]he total dollar value of the tax benefits realized as a result of the patient assistance programs [] in the most recent year."[68] Like pricing information, this information can be highly sensitive. As PhRMA has previously explained, manufacturers' internal policies and decisions concerning patient access programs may include proprietary and trade secret information, thereby raising significant confidentiality concerns.[69]

- **National VA Contract Price and Big 4 Price.** The Proposed 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.[70] The Proposed Regulations do not 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.[71] 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.

- **Information Submitted by Eligible Governmental Entities.** The Proposed Regulations would permit eligible governmental entities to refer a drug to the Board "along with drug purchasing data," and to report "drug purchasing data, and other relevant information" during the cost review study and policy review processes, which the Board may then consider in selecting and reviewing drugs.[72] PhRMA is concerned that information submitted by an Eligible Governmental Entity could include confidential, proprietary, or trade secret information obtained from third parties. Although the Proposed Regulations would require the submitting entity to comply with the Board's procedures for designating confidential, proprietary, and trade secret information, they do not address situations in which the submitting entity possesses such information belonging to another entity.[73] In those circumstances, there is a significant risk that the submitting entity may not

[67] Proposed Regulations, COMAR 14.01.04.04B(1)(d).
[68] Proposed Regulations, COMAR 14.01.04.04B(1)(p).
[69] *See* Letter from PhRMA to Board (Dec. 2, 2024) at 4-5. *See id.* for further discussion of the role these programs play in promoting patient access and adherence to medicines.
[70] Proposed Regulations, COMAR 14.01.04.05C(1)(a)(i), (c)(ii).
[71] 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.)
[72] Proposed Regulations, COMAR 14.01.04.06B(1); *see also id.* 14.01.04.03D(6), 14.01.04.05C(2)(g)(vi).
[73] Proposed Regulations, COMAR 14.01.04.06B(3) (requiring an eligible governmental entity to "comply with the procedures for designating confidential, trade-secret, and proprietary information set forth in COMAR 14.01.01.04").

identify and designate all information that is treated as confidential, proprietary, or trade secret by its owner, such as where the information was obtained through contracts or other arrangements to which the drug's manufacturer is not a party. This concern is especially acute where the non-submitting entity receives no notice of the submission of its information or opportunity to protect its interests.[74]

The Board's obligation under the PDAB Statute to protect non-public information—including confidential, proprietary, and trade secret information—from disclosure applies to all such information it receives, even if the submitter did not specifically mark the information as such (e.g., in situations where a governmental entity may not be aware that it is in possession of confidential, proprietary, or trade secret information that was generated by or pertains to another entity).[75] Consistent with this obligation, PhRMA asks the Board to explain how it will uphold its statutory obligations and protect information submitted by an eligible governmental entity from disclosure, regardless of how the entity designates the information. If such information is submitted to the Board, a third party should not be prejudiced by the submitter's failure to invoke or defend its protection as trade secret, confidential, or proprietary information. Accordingly, the Board should clarify that it will not disclose trade secret, confidential, or proprietary information in which a third party has an interest if the third party has not had a meaningful opportunity to challenge the proposed 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 Proposed Regulations.

VI. **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 reliance on Medicare Maximum Fair Prices ("MFPs") in its cost reviews.[76] The Proposed Regulations propose allowing the Board to consider MFP data and Board staff to included MFP-related data to its dashboard..[77] PhRMA and its members oppose the Medicare Drug Price Negotiation Program ("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 MFPs, 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

[74] *See* Letter from PhRMA to Board (May 1, 2023) at 19.
[75] *See* Md. Code, Health-Gen. § 21-2C-10(a).
[76] *See* Letter from PhRMA to Board (July 27, 2026) at 5; Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board (June 1, 2026) at 7–8; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) at 4; Letter from PhRMA to Board (Mar. 4, 2026) at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) at 10.
[77] *See* Proposed Regulations, COMAR 14.01.04.03B(6) (permitting staff to provide MFP information in its dashboard); 14.01.04.05C(1)(a)(i) (allowing the Board to consider MFP for a drug under review), (c)(ii) (allowing the Board to consider MFP for therapeutic alternatives), C(2)(g)(vii) (allowing the Board to consider "[i]nformation, analyses, and data published by the Centers for Medicare and Medicaid Services underpinning the MFP").

under the statutory framework of the Inflation Reduction Act, but the Proposed Regulations would apply these prices to an entirely different market, patient population, and statute (i.e., the PDAB Statute).

MFP-based 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 two-thirds of beneficiaries are enrolled in Part D plans where their cost-sharing is expected to increase for many price-set drugs compared to before the IRA.[78]

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.[79] 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 MFPs without fully understanding the patient impact from the MDPNP.

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

PhRMA remains concerned by the Board's proposal to consider in its cost reviews "[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 or in improving a patient's health, quality of life, or overall health outcomes" and "compared with therapeutic alternatives, the standard of care, drugs in the same therapeutic class, or no treatment."[80] 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.[81] For example, cost-effectiveness analyses often fail to account for important elements of value that matter to patients and obscure important differences that are disproportionately faced by underserved populations, such as the elderly and patients with disabilities.[82] The Board has not detailed how it will prevent these and other potential biases from affecting its cost reviews.

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[78] Magnolia Market Access. (2026). 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. Available here.

[79] *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.

[80] Proposed Regulations, COMAR 14.01.04.05C(2)(e)(iv).

[81] *See* Letter from PhRMA to Board (June 1, 2026) at 9-10; Letter from PhRMA to Board (Aug. 26, 2024) at 9-10; *see also* Letter from PhRMA to Board (May 1, 2023) at 12-13.

[82] *See id*.

C. Reporting of Drug Affordability Issues by Eligible Governmental Entities and the Public

PhRMA is also concerned that the Proposed Regulations do not explain how reports by eligible governmental entities and the public will fit within the Board's existing procedures. As noted above, the Proposed Regulations would permit eligible governmental entities to refer drugs to the Board "for possible study" and submit purchasing data and other information, and the Board may consider such reports, along with reports from individual members of the public, when selecting and reviewing drugs.[83] PhRMA urges the Board to clarify that a referral or report does not, by itself, establish that a drug is eligible for cost review and that referred drugs remain subject to the same statutory metrics and regulatory criteria, and the same selection procedures, that apply to any other drug.[84] The Board should also explain how it will verify, weigh, and disclose such submissions, and should provide manufacturers an opportunity to respond to information submitted about their products before the Board relies on it, consistent with the confidentiality protections discussed above.[85]

* * * * * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns with the Proposed 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

[83] *See supra* Sec. V; Proposed Regulations, COMAR 14.01.04.06B(1)(a)–(b); *see also id.* 14.01.04.03D(5)–(6), 14.01.04.05C(2)(g)(vi).
[84] *See* Md. Code, Health-Gen. § 21-2C-08; Proposed Regulations, COMAR 14.01.04.02–.03.
[85] *See supra* Sec. V.

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October 5, 2026

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

c/o Christina Shaklee
Health Policy Analyst Advanced

Re: Notices of Proposed Action 26-132-P and 26-133-P

Dear Members of the Maryland Prescription Drug Affordability Board:

Regeneron believes that medicines should be priced fairly and that treatments are only useful if patients in need can access and afford them. Regeneron prices its medicines with these beliefs in mind by employing a value-based approach that reflects the medicines' benefits to patients, society, and the health care system. Regeneron also considers the long-term investment and risk inherent in science and technology innovation and invests heavily in research and development. In 2025, Regeneron reinvested approximately $5.9B (~41%) of its revenues into research and development efforts.[1] Through these research and development efforts, Regeneron hopes to discover new novel medicines and uses of existing medicines for patients in need, including Maryland patients.

With these goals and our commitment in mind, Regeneron appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's ("the Board") proposed changes to the Code of Maryland Regulations, Sections 14.01.01 General Provisions and 14.01.04 Cost Review Study Process ("COMAR 14.01.01 and 14.01.04").

<u>The Board should promote a fair and transparent process.</u>

Regeneron urges the Board to prioritize the promotion of fairness and transparency in the cost review study process. This includes in the identification of drugs eligible for cost review, selection of drugs subject to review, the conduct of the cost review study, and the determination of any policy actions with respect to drugs selected for review, such as the implementation of upper payment limits ("UPLs"). While certain revisions proposed by the Board to the regulations would advance these goals by establishing the particular circumstances under which use of a drug may create an affordability challenge, *see* Proposed COMAR 14.01.04.01, and more discretely describing Board staff responsibilities, *see, e.g.,* Proposed COMAR 14.01.04.03(A) *and* 14.01.04.03(B)(7), Regeneron believes additional changes to the existing and proposed regulations are necessary to make the cost review study process fundamentally fair and transparent.

First, the proposed changes to COMAR 14.01.01.05(B)(4)(b) fail to adequately protect stakeholders' interests with regards to the notice-and-comment process for cost review studies. The proposed regulation would provide for "at least 15 days for the submission of comments." Such a limited time

[1] See *Regeneron 2025 Corporate Responsibility Report* at: https://www.regeneron.com/downloads/2025RR.pdf.

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period does not adequately protect due process. There should be a minimum of thirty (30) calendar days between publication of any notice of an opportunity to provide input during the cost review study and the deadline for submission of comments. Thirty days is the minimum timeframe necessary to ensure that stakeholders receive adequate notice of the solicitation and sufficient time to develop and submit comments. Allowing additional time for the submission of comments will help to ensure interested parties have a meaningful opportunity to provide input during the cost review process. Such protection will further the goals of fairness and transparency in the cost review process, while also enabling the Board to receive meaningful feedback to inform development of its final policies.

Additionally, the Board should endeavor to provide greater transparency into the drug selection process. The Board should only consider the objective criteria enumerated in the regulations when making decisions regarding the identification of drugs eligible for cost review; the selection of drugs for cost review; and the determination of whether a drug poses an affordability challenge. The proposal to grant the Board broad discretion to consider "[a]ny other circumstance identified by the Board through the cost review study under which use of a drug has or will lead to an affordability challenge for the State health care system" or "high out-of-pocket costs for patients" would obscure stakeholders' and patients' insight into the data that the Board will consider in making its determinations. Proposed COMAR 14.01.04.01(B)(4), (D)(5). We urge the Board not to move forward with these proposals. Similarly, when evaluating the affordability of a drug, the Board should clearly enumerate the types of data and other information that the Board will consider as part of the cost review process. Stakeholders should also be given the opportunity to weigh in on the accuracy, significance, and relevance of such information.

The Board has proposed that it will consider reports from "individual members of the public" and referrals by Eligible Governmental Entities in determining drug affordability issues. Proposed COMAR 14.01.04.06(A)(1), (B)(1)(a). In addition to considering reports by these parties, the Board should facilitate stakeholder engagement by *all* interested parties, including patients, providers, and drug manufacturers, throughout the cost review study process, including by adopting notice-and-comment procedures that facilitate the comprehensive consideration of those stakeholders' perspectives and expertise with respect to the product under review. For example, patients can offer insights into their experience of care to inform any assessment of the value of the product as part of a treatment regimen. Likewise, health care providers may be able to share important information on the value that a particular product offers to their patients. The manufacturer of a product under review is uniquely situated to offer insights into certain supply chains and other cost considerations for a product that directly affect its pricing decisions. Failure to proactively include these stakeholders in the cost review study process and consider their unique perspectives could result in policy actions that negatively impact Maryland patients' access to important medicines.

<u>The Board should reevaluate the manner in which it seeks additional data elements and information from manufacturers.</u>

Regeneron respectfully urges the Board to pause its efforts to seek or require additional information from manufacturers. Instead, the Board should provide greater clarity and sufficient guidance about the precise methodologies a manufacturer must follow in responding to data and information requirements levied by the cost review process. Moreover, the Board should ensure that its current regulations as well as its proposed regulations, as codified and drafted thus far, provide a uniform methodology for manufacturers to precisely follow as part of the cost review process. A well-defined and consistent methodology, as well as specificity and clarity in the description of data elements required, are critical for consistency in reporting across manufacturers and meaningful comparisons and interpretation of the

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information obtained by the Board. Regeneron supports the Board's interest in obtaining meaningful, comparable data to inform its cost review process. That goal, however, depends on manufacturers receiving clearly defined data elements and a consistent reporting methodology before — not after — new information requirements take effect. As drafted, the Board's proposed regulations do not specify key terms or delineate a methodology by which manufacturers can respond to these data elements (e.g., how are terms like "coupon" and "marketing" defined, specificity into what elements should be included and excluded from certain costs sought, etc.). The result is data that cannot be reliably compared across manufacturers or products, undermining the very purpose for which the Board is collecting it. Accordingly, Regeneron recommends that, before requiring submission of new or expanded data categories, the Board publish technical specifications and a data dictionary defining each requested data element. Resolving this ambiguity in how terms are defined and data is collected would serve the Board's interest in reliable, comparable data, as well as manufacturers' interest in providing accurate and consistent responses.

<u>The Board should protect the confidentiality of all trade secrets and proprietary information submitted during the cost review study process.</u>

As explained above, participation by stakeholders including manufacturers, insurers, and pharmacy benefit managers (PBMs) is essential to the cost review study process. Without the information that can only be provided by such stakeholders, the Board risks developing policy actions that could inadvertently harm patient access to critical therapies. However, to ensure these stakeholders can share certain types of information that are essential to the integrity of the cost review study process, it is critical that the Board ensures that such information is afforded appropriate confidentiality protections. For example, the proposed updates to the Board's regulations contemplate that manufacturers will share with the Board information on tax benefits and favorable tax treatment of patient assistance programs and certain direct-to-consumer marketing costs, *see* Proposed COMAR 14.01.04(B)(1)(p)(v) *and* 14.01.04(B)(1)(r). This information, along with many other requested datapoints, is highly sensitive and is closely held, even within the company.

Any disclosure of this information could have a significant and adverse impact on the business interests of the manufacturer, extending well beyond the drug product under review. Accordingly, robust confidentiality protections are critical to ensure that all proprietary and confidential information that must be submitted to the Board to inform the cost review process is appropriately protected. Therefore, in addition to the proposal that the Board will redact confidential, trade secret, and proprietary information, *see* Proposed COMAR 14.01.04.05(D)(1)(b), Regeneron requests additional protections to safeguard the confidentiality of information submitted. Specifically, COMAR 14.01.04.04 should be updated to state explicitly that all confidential, trade secret, and proprietary information shared by stakeholders during the cost review process will be protected to the fullest extent permitted by applicable law. In addition, Regeneron requests that COMAR 14.01.04.04 be amended to require the Board to provide the manufacturer or any other individual or entity that submits information in connection with the cost review study process with written notice of any request for such information, as well as a reasonable opportunity to assert all legal rights related to the protection of such information, including any opportunity to review all redactions and propose additional redactions as needed to preserve the confidentiality of proprietary or otherwise sensitive information.

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Conclusion

Regeneron appreciates the opportunity to comment on the proposed changes to the Board's regulations and looks forward to continuing to work with the Board to preserve and promote access to innovative and important treatments for Maryland residents.

Sincerely,

Mark O'Rourke

Mark O'Rourke
Director, State Government Relations
Regeneron Pharmaceuticals, Inc.

October 5, 2026

Christina Shaklee
Email: pdab.regs@maryland.gov
Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Proposed Action on Regulations, COMAR 14.01.04 Cost Review Study Process [26-133-P] and COMAR 14.01.01.05 Public Comment Procedures [26-132-P], 53:18 Md. R. 905 (September 4, 2026)

Dear Ms. Shaklee and Members of the Board:

I. Introduction and Summary of Recommendations

Thank you for the opportunity to comment on the proposed amendments to COMAR 14.01.04 and 14.01.01.05. My principal recommendation is that the Board expressly explain how credible comparative evidence on health, medical, and social services costs informs the insufficient-value circumstance in proposed Regulation .01B(2), and document that judgment in the preliminary and final reports. Unless otherwise specified, regulation references below are to the proposal published September 4, 2026. [1]

Health-General Article (HG) §21-2C-09(b)(2)(ix) directs the Board, to the extent practicable, to consider the relative financial impacts to health, medical, or social services costs that can be quantified and compared with the baseline effects of existing therapeutic alternatives. [2] The proposal retains that factor and the existing health economics and outcomes research (HEOR) factor, adds broader-comparator versions of both, and expressly adds medication adherence among the Board factors. Proposed .01B(2) identifies possible indicators of insufficient value, using "as may be indicated by"; those indicators are nonexclusive. It does not expressly explain how comparative evidence on other service costs should inform that judgment. I recommend making that relationship explicit and recording how the evidence affected the finding.

I am a health economist and applied econometrician and the founder, President, and CEO of RxEconomics LLC. Before founding the firm in 2011, I spent approximately nine years at CVS Caremark and its predecessors, ultimately serving as Director of Strategic Research and Health Economist. I received my PhD in public policy (economics) from the University of Maryland, Baltimore County. My research includes pharmacy benefit design, medication adherence, and medical cost offsets from prescription drug use. In August 2026 I filed two comments with the Centers for Medicare & Medicaid Services (CMS) proposing a framework for this evidence in the Medicare Drug Price Negotiation Program. This comment adapts that framework to Maryland's statute, data, and process. [10, 11]

RxEconomics advises pharmaceutical and life-sciences clients. This comment was prepared independently; no client funded, requested, commissioned, or reviewed it.

I offer four principal recommendations:

1. Connect comparative financial impacts to the value finding, using a stated perspective and an equivalent course or period of therapy (Parts II and IV).
2. Apply a proportionate, symmetric two-stage review that distinguishes clinical effects, expenditures, uncertainty, and missing evidence (Part III).
3. Preserve the preliminary evidence summary and explain the evidence synthesis in both preliminary and final reports (Part VI).
4. Obtain proportionate methods documentation and allow adequate time for technical submissions (Part VII).

I also recommend linking non-adherence to patient costs before using it as an affordability indicator, and correcting the comparator and cross-reference issues below (Parts V and VIII).

In the suggested amendments below, additions to the September 4 proposed text are italicized and deletions from that proposed text are bracketed; standalone provisions are proposed additions. The language is offered as a starting point; some implementation detail may be better placed in published guidance.

II. Connect the Value Finding to Comparative Financial Impacts

The two express indicators in .01B(2) concern net price relative to therapeutic alternatives with similar clinical outcomes, or limited comparative evidence of clinical improvement at approval coupled with substantial spending. Neither expressly addresses downstream utilization or expenditures. The financial-impact factor remains available in .05C(1)(e)(ii), and .05C(1)(e)(iii) retains HEOR. New .05C(2)(e)(iii)–(iv) add versions with broader comparator lists; .05C(2)(f)(ii) addresses adherence and utilization management; and .05C(2)(g)(vii) adds CMS information underpinning the Medicare maximum fair price. [1, 3]

HG §21-2C-09(a)(2)(ii) also lists a drug's estimated value or cost-effectiveness among the information the Board may obtain for a cost review. [2] Regulation .05B(2)(f) permits analyses of the Maryland Medical Care Database (MCDB) and other relevant databases. Maryland's MCDB provides a potential source for examining these questions, subject to data completeness and an appropriate comparative design. Authority to use a database does not establish that every population, rebate, outcome, or social-services cost is available and linkable. [3]

Similar clinical outcomes on trial endpoints do not imply similar costs elsewhere in the system. Alternatives may differ in hospitalization, emergency department use, adverse events, monitoring, or site of care and administration. A drug-price comparison can overstate the total financial burden of a drug that reduces other service use and understate that of one requiring more services.

Recognizing these differences creates no presumption of savings. The Congressional Budget Office's 2012 estimate that a 1 percent increase in prescriptions filled reduces Medicare medical-services spending by roughly 0.2 percent was an aggregate relationship for scoring policies that change prescription use, not a drug-level result. [5] My coauthors and I have reported associations between greater medication use or adherence and lower nondrug spending in selected conditions and populations, with confounding, transportability, and design limitations. [7, 8] Our 2018 Medicaid study measured health services utilization, not dollar expenditures. [9] At publication, the 2015 and 2018 studies each had a coauthor from the Pharmaceutical Research and Manufacturers of America, and the 2015 study also had one from the National Association of Chain Drug Stores. [8, 9] The relevant lesson is heterogeneity, not a universal offset.

Evidence will often be thin. Oregon's 2026 Jardiance affordability review reported that no quantifiable data were available to assess relative financial impacts in the Oregon population and that the analysis was not performed. [4] That statement is useful as a description of the evidence gap; it does not establish no effect.

For the drug-cost comparison in .01B(2)(a), I recommend a combined payor-and-patient perspective, using the existing definition of "system net cost." COMAR 14.01.01.01B(45) defines net price as the per-unit amount received by manufacturers; B(44) defines net cost as the per-unit amount paid by payors and purchasers; and B(62) defines system net cost as net cost plus per-unit patient out-of-pocket cost. [3] System net cost should remain distinct from downstream spending; this change does not create an offset formula. The broader reference to net or gross price in the .01B(2) stem can remain. Convert per-unit amounts to an equivalent course or period using clinically appropriate dosing, frequency, duration, indication, and treatment setting. The report should identify the clinically important outcomes, population, and time horizon supporting a finding of similar clinical outcomes; an inconclusive comparison should not, by itself, establish similarity.

Proposed amendments to Regulation .01

B(2)(a) The average **[net price]** *system net cost* of the drug *per equivalent course or period of therapy* exceeds the average **[net price]** *system net cost per equivalent course or period of therapy* for therapeutic alternatives that provide similar clinical outcomes; or

E. Comparative Evidence on Health, Medical, and Social Services Costs.

(1) In determining whether a circumstance under §B(2) of this regulation is present, the Board shall consider, to the extent practicable, credible comparative evidence on the relative financial impacts to health, medical, or social services costs described in Health-General Article, §21-2C-09(b)(2)(ix), Annotated Code of Maryland, whether that evidence indicates lower costs, no material difference, or higher costs relative to therapeutic alternatives.

(2) The Board shall evaluate the evidence described in §E(1) of this regulation in accordance with Regulation .05C(4) of this chapter and may not presume that such evidence exists or that it favors or disfavors the prescription drug product under review.

(3) If relevant comparative evidence is unavailable, inconclusive, or insufficient to quantify the magnitude of a downstream effect, the cost review study report shall distinguish those conditions and shall not characterize them as evidence of no material difference.

III. A Proportionate Symmetric Evidentiary Standard

Comments on the Board's May 27 draft argued that the circumstances rely on vague or undefined criteria; one argued they lack any standard of proof, evidentiary threshold, or requirement of causation or materiality, and objected to "may be indicated by." [12] A neutral response can be a stated review process without universal numerical cutoffs across therapeutic areas. Staff should assess each study's credibility and relevance, then explain what the body of evidence supports. The same process should govern evidence used to establish similar clinical outcomes. [10]

Stage 1: study-level review. Staff would review each study or analysis across eight domains. These are review principles, not pass-fail tests, and no design label determines the result.

Stage 1 domain	Core inquiry adapted to the Maryland cost review
1. Study design and causal identification	Does the design support the claimed treatment effect? Principal threats include confounding by indication, treatment selection, healthy-adherer effects, reverse causation, immortal-time bias, informative censoring, treatment switching, and competing mortality.
2. Population and Maryland applicability	How directly does the study population represent Marylanders in the affected budget (State and local employee plans, Maryland Medicaid, commercial coverage)? Transport from Medicare, other states, or trial populations should be justified by reference to age, comorbidity, severity, benefit design, and care setting.
3. Comparator and treatment contrast	Does the analysis compare the drug with a therapeutic alternative the Board identified, at the margin at issue? Initiation, adherence, persistence, switching, and drug-versus-nonuse questions are different contrasts.
4. Outcome definition and measurement	Are utilization and expenditure endpoints clinically coherent, reliably measured, and reported by category (inpatient, emergency, outpatient, administration, monitoring)? Are disease-specific and all-cause results, and utilization and prices, kept separate?
5. Time horizon and timing	Does follow-up fit the clinical and economic pathway? Are observed, extrapolated, and modeled effects distinguished, with latency, censoring, and discounting described?
6. Economic perspective and cost measurement	Whose spending is measured (Part IV)? What price year, payment source, rebate treatment, and double-counting protections apply?
7. Statistical uncertainty and economic materiality	How stable are the results across intervals, specifications, costing assumptions, and subgroups? Is the magnitude consequential for the affected budget, as distinct from statistically significant?
8. Transparency, sponsorship, and reproducibility	Can staff reconstruct the result? Data provenance, prespecification, post hoc analyses, funder, control of design, analysis and publication, model or code availability, and independent validation.

The domains should be applied in proportion to the claim. A published comparative study may be assessed from the article and supplement; an unpublished analysis or model converting an event effect into long-term costs needs more documentation of structure, parameter sources, and validation. Treatment contrast is the organizing element. Comparing adherent and nonadherent users of one drug may illuminate a pathway without estimating that drug's effect relative to a therapeutic alternative.

Stage 2: body-of-evidence synthesis. Staff would synthesize credible evidence rather than count studies or average estimates answering different questions. Reports should state four descriptive judgments: comparative

direction (favorable to the drug, adverse to the drug, negligible with sufficiently precise support, or indeterminate); economic materiality (whether magnitude is consequential for the affected budget); certainty (identification, consistency, robustness, and reliance on extrapolation); and applicability to the affected population in the State. A nonsignificant result alone does not establish a negligible effect. Staff should check dependence among studies sharing cohorts, models, or sponsors, and selective reporting, and retain unresolved heterogeneity. A permissible conclusion might be that hospitalization evidence is directionally favorable and material, while the dollar magnitude remains uncertain.

Several guardrails keep the standard neutral:

- Symmetry. Evidence may show lower costs, no material difference, or added costs, such as monitoring or treatment-related utilization. The same standards apply to manufacturer, payor, governmental, and public submissions.
- No double counting. An avoided hospitalization can have both a clinical benefit and a financial consequence. The Board should describe each separately, explain their relationship, and avoid treating them as independent corroboration of the same treatment effect or counting the same monetary consequence more than once.
- Observed, extrapolated, and modeled effects remain distinguishable. A well-supported model can be decision-relevant, but it should not borrow the certainty of an observed endpoint.
- Survival is treated explicitly. Longer survival can increase total spending while reducing disease-specific spending. Neither should be hidden in a net figure, and higher spending due to longer survival is not evidence of inferior effectiveness. The report should state whether costs during added survival years enter the estimate.
- Sponsorship triggers neutral scrutiny. The same questions about funding and control of design, data, analysis, and publication apply to industry, academic, consulting, advocacy, and government sources.
- Not a cost-effectiveness ratio. A bounded analysis of utilization and expenditures records payments linked to clinical events. It does not require valuing a health state or a year of life and is distinct from a QALY-type measure. The May 27 draft listed as an indicator that a drug "is not cost-effective at the current average net price"; the September proposal omits it, and this standard would not reintroduce it. [1, 12]

Integration should remain qualitative. The Board should not deduct projected savings from a drug's price dollar for dollar, add projected costs mechanically, or assign a fixed weight. It should record the four Stage 2 judgments and explain whether and how the evidence materially informed the determination. Medicare evidence under .05C(2)(g)(vii) particularly requires an applicability assessment: beneficiary age, comorbidity, benefit design, and payment rules differ from those of State employee plans, Maryland Medicaid, and commercial coverage. The Board can use such evidence while stating how far it transports.

Proposed new Regulation .05C(4)

(4) Evaluation of Comparative Evidence. In considering comparative clinical, utilization, or expenditure evidence under §C of this regulation, including evidence used to assess similar clinical outcomes under Regulation .01B(2)(a) of this chapter, the Board shall, to the extent practicable:

(a) Assess the credibility and relevance of each study or analysis, including its design and causal identification; population and applicability to the State; comparator and treatment contrast; outcome definition and measurement; time horizon; economic perspective and cost measurement; statistical uncertainty and economic materiality; and transparency, sponsorship, and reproducibility, as applicable to the evidence and the inference drawn;

(b) Synthesize the body of evidence with respect to comparative direction, economic materiality, certainty, and applicability to the affected population in the State;

(c) Apply the same standards to evidence regardless of its source or whether it favors or disfavors the prescription drug product under review; and

(d) Integrate the evidence qualitatively, without a presumption, formula, or dollar-for-dollar adjustment.

IV. Economic Perspective and Double Counting

Regulation .01B(1)(a) refers to spending in "the impacted budget." Each report should likewise identify the perspective of a downstream estimate. For the .01B(2)(a) drug-cost comparison, the combined payor-and-patient perspective means system net cost, including patient out-of-pocket cost once. Separate budget and patient views remain informative. "State health care system" is undefined, so each report should identify the population and payments included. The following reporting views overlap and cannot be added together:

- Eligible governmental entity costs, the budgets that current upper payment limit authority reaches under HG §21-2C-14, including Maryland Medicaid under paragraph (3). [2]
- Maryland State Medical Assistance Program costs, shown as a separate, non-additive component of eligible governmental entity costs: total computable spending and the State-funded share, with treatment and allocation of rebates and federal matching funds stated consistently.
- Total allowed spending on covered services in Maryland, identifying payor-paid and patient-paid shares where relevant. This is a broad measure, not a single budget. Payors whose treatment under Board action may differ, such as self-insured employer plans, should be labeled.
- Patient financial effects, with cost sharing and premiums reported separately and not added together without explaining incidence. Patient amounts already included in system net cost or allowed spending must not be added again.
- Other health, medical, or social services costs. The statute expressly includes social services costs; these should be reported separately, with the causal pathway to the drug comparison shown rather than assumed.

The same avoided admission can appear in total allowed spending, the Medicaid State share, and a premium estimate; the same rebate can enter net cost and a savings estimate. The report should identify overlaps and explain how each monetary consequence was counted once within any combined total.

Proposed new Regulation .05C(5)

(5) When the Board considers spending data or analyses under this regulation, the cost review study report shall identify the economic perspective of each estimate relied upon, including whether it reflects eligible governmental entity costs; Maryland State Medical Assistance Program costs as a non-additive component, reported as total computable spending and the State-funded share; total allowed spending on covered services in Maryland, identifying payor-paid and patient-paid shares where relevant; patient out-of-pocket costs or premiums; or other health, medical, or social services costs. Drug-cost comparisons under Regulation .01B(2)(a) of this chapter shall use system net cost for the same combined payor-and-patient perspective and an equivalent course or period of therapy. The report may not combine overlapping estimates without explaining how double counting was avoided, including patient payments, rebates, and federal matching funds.

V. Non-Adherence Should Be Linked to Cost Before It Indicates High Out-of-Pocket Costs

Proposed .01D(3) treats a significant proportion of patients not taking a drug as prescribed as an indicator of high out-of-pocket costs. My benefit-design research found associations between cost-sharing levels and prescription use. [6] But non-adherence has many causes besides cost, including side effects, tolerability, regimen complexity, beliefs about benefit, and access barriers unrelated to price. Claims-based measures such as proportion of days covered record fills, not use, and cannot by themselves separate cost-related from other non-adherence. A drug with high non-adherence and low out-of-pocket costs could meet the indicator even when out-of-pocket costs do not explain the non-adherence.

Evidence supporting attribution might include adherence differences for the same drug across cost-sharing levels or benefit designs; differences relative to alternatives with lower cost sharing; prescription abandonment in relation to out-of-pocket amounts; and patient-reported cost-related non-adherence, using qualitative methods expressly identified in .05B(2)(h). The same causal standards should apply, including attention to healthy-adherer effects and reverse causation. Cost-related non-adherence and its downstream consequences address different questions. The report should explain their relationship and avoid presenting shared data or expenditure estimates as independent corroboration.

Proposed amendment to Regulation .01D(3)

(3) A significant proportion of patients do not take the drug as prescribed*, and evidence considered in the cost review study indicates that patient out-of-pocket costs contribute materially to that non-adherence*;

VI. Transparency in Preliminary and Final Reports

Current .05F(3)(a) requires the draft preliminary determination report to summarize the information considered, deliberations, affordability circumstances or indicia, and preliminary determination. Proposed .05G(3)(a) would delete the information and circumstances summaries. The final report under proposed .05H(3) would still summarize the information considered. [1, 3] Because the public comments on the preliminary report under .05G(3)(b), that report is where a concise evidence account is most useful. I recommend retaining the summary and requiring the four Stage 2 judgments in both reports, subject to COMAR 14.01.01.04 and HG §21-2C-10 confidentiality protections. [2, 3]

Proposed .05D(2) also refers to an undefined “dossier.” Defining it and including a dated study list would give each review a stable evidence record. Consistent disclosure would help show that similar evidence receives similar treatment across reviews, regardless of the determination. This parallels my CMS recommendation. [10]

Proposed amendments to Regulation .05

D(3) In this regulation, “dossier” means the compilation of data, information, and analyses assembled by Board staff for a prescription drug product under study, including a dated list of the studies and analyses considered under §C of this regulation.

G(3)(a) Board staff shall prepare a draft preliminary determination report that summarizes *the information considered by the Board in conducting the cost review study,* the Board’s deliberations, *the circumstances under Regulation .01 of this chapter on which the preliminary determination relies,* and *the* preliminary determination.

G(3)(c) For each circumstance under Regulation .01B(2) of this chapter on which a preliminary determination relies, the preliminary determination report shall, subject to COMAR 14.01.01.04 and Health-General Article, §21-2C-10,

Annotated Code of Maryland, identify the therapeutic alternatives, affected population, time horizon, and economic perspective; summarize the comparative evidence and its principal limitations; report its comparative direction, economic materiality, certainty, and applicability; and explain whether and how that evidence materially informed the determination. The report shall distinguish unavailable or inconclusive evidence, or evidence insufficient to quantify a downstream effect, from evidence of no material difference.

H(4) The final cost review study report shall include the disclosures required by §G(3)(c) of this regulation, updated to reflect the final determination.

VII. Structured Methods Submissions and Comment Periods

The proposal invites quantitative material from manufacturers (.04B(1)(s)); carriers, HMOs, and MCOs (.04B(2)(g)); PBMs (.04B(3)(j)); eligible governmental entities (.05C(2)(g)(vi) and new .06B); and the public (.05C(2)(g)(iv)). [1] Staff need minimum methods information to evaluate a claimed downstream effect. I recommend a short, triggered methods form, issued as guidance much like the data form contemplated in new .06B(2)(a), adapting my CMS-10849 proposal. [11]

The trigger would apply when a submission presents or relies on a respondent-generated, sponsor-controlled, unpublished, or model-derived quantitative result whose core methods needed to evaluate the claim are unavailable in a cited public source. Missing sponsorship, attachment, or Maryland-applicability fields alone should not trigger a full supplement. Contractor and affiliate analyses count as respondent-generated. Fields should map to the eight Stage 1 domains, using categorical responses and short text, with “unknown” and “not applicable” permitted. Respondents describe methods; the Board judges certainty and materiality. Narrative comments, patient reports under new .06A, and adequately documented published citations would be exempt.

Existing articles, supplements, and technical reports should satisfy fields through page or section crosswalks. The form should distinguish public, confidentially available, and unavailable technical materials; permit reuse and multiple-analysis submissions; and request only changed information in later reviews. Staff should assess incremental burden on the triggered subset. Confidential material would remain subject to COMAR 14.01.01.04 and 14.01.01.05B(5); confidential availability would not require public release of proprietary data or code. [3]

The proposed 15-day minimum in COMAR 14.01.01.05B(4)(b) is reasonable for routine requests. Outside the 60-day public-comment period under proposed Regulation .05C(3)(a), which begins when the Board posts its request for comment, 15 days may be too short for a documented analysis. That 60-day period is not a limit on the entire cost review, and the general minimum does not replace it. [1]

Proposed amendment to COMAR 14.01.01.05B(4)

(c) If the request seeks quantitative analyses or other technical information, the notice shall provide a period of at least 30 days for the submission of comments. This provision does not shorten a longer comment period required by law or regulation.

VIII. Technical Corrections to Regulation .05C

1. Comparator consistency. Regulation .05C(1)(e)(ii) retains the statutory comparator, existing therapeutic alternatives; new .05C(2)(e)(iii) restates the factor against the standard of care and drugs in the same therapeutic class. HEOR appears in .05C(1)(e)(iii) and .05C(2)(e)(iv) with different comparator lists; clinical information appears in .05C(2)(a)(i) and (e)(v). Consolidate each into one provision preserving the statutory

comparator as primary, allowing others as supplementary, and documenting when comparator choice changes a conclusion.

2. Cross-reference. Regulation .05C(1)(e)(i) refers to nonexistent COMAR 14.01.04.03C(1)(e). The reference should identify alternatives developed under proposed .03H and approved under .03I(8). Current .03I(8) requires Board approval and is retained; current .03H(5) is deleted in the proposal. [1, 3]
3. Undefined terms. “State health care system,” “dossier,” “standard of care,” and “similar clinical outcomes” are used but undefined in this chapter or COMAR 14.01.01.01. Definitions or a report-level explanation would reduce ambiguity. The Board should clarify whether “standard of care” means the already-defined “standard medical practice” in COMAR 14.01.01.01B(60). [3]

IX. Conclusion

I recommend an explicit, documented connection between comparative financial impacts and the value finding. A symmetric qualitative standard can recognize credible evidence of lower or higher costs without presuming either, and give commenters and the Board a consistent evidence record. I would be glad to discuss these recommendations with Board staff.

Respectfully submitted,

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2. Health-General Article, §21-2C-09, §21-2C-10, and §21-2C-14, Annotated Code of Maryland.

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Value of Care Coalition

October 5, 2026

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

Re: COMAR 14.01.04 – Cost Review Study Process (Notice of Proposed Action 26-133-P, Maryland Register, September 4, 2026)

Dear Ms. Shaklee:

The Value of Care Coalition (VCC) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's proposed amendments to COMAR 14.01.04. VCC commented on drafts on June 1 and June 25, 2026, and those comments remain part of the public record. VCC continues to believe that upper payment limits are not the appropriate mechanism to address prescription drug affordability. We appreciate the Board's recognition throughout its public meetings that protecting patient access is a central consideration, and these regulations are an important test of how that commitment is reflected in practice.

VCC appreciates that the proposal retains a public reporting process in new Regulation .06, as our June 25 comment urged; that Regulation .02D does not make Medicare negotiation status a basis for eligibility, as our June 1 comment urged; and that new Regulation .05C(2)(f) addresses cost-sharing and insurance benefit design, consistent with our longstanding request that the Board examine how benefit design shapes patient affordability.

VCC's June 1 comment proposed new Regulation .03C(2), providing for public comment, in writing and at the meeting, before the Board votes to refer a drug to the Stakeholder Council. The proposal deletes existing Regulation .03C(2) through (4), which placed drugs proposed for referral on the meeting agenda and allowed public comment on them, and replaces them with staff recommendations that the text does not require be published (the Board's proposed Regulation .03C(2)).

The June 1 comment also proposed that the Board publish its prioritization methodology (Regulation .03A) and that submitting entities be allowed to review and respond to staff analyses before a preliminary determination (Regulation .05F(3) in the June draft, now Regulation .05D). The proposal creates a curated eligible list without published criteria (Regulation .03A) and adds a staff memorandum and addendum with no stated publication date and no requirement that submitting entities be allowed to respond before a preliminary determination (Regulations .05D and .05E).

Instead, the Board should publish how drugs are prioritized and give submitting entities time to review and respond to staff analyses.

The June 1 comment proposed that the Medicare Maximum Fair Price (MFP) be interpreted within Medicare's statutory framework and not be presumed appropriate for commercially insured patients, and that CMS data underpinning the MFP be accompanied by a written explanation of how Medicare differs from Maryland's markets. The proposal adds the MFP to the dashboard (Regulation .03B(6)) and to the price lists for the drug under review and each therapeutic alternative (Regulation .05C(1)(a)(i) and (c)(ii)) and allows consideration of CMS data underpinning it (Regulation .05C(2)(g)(vii)), without that context. Instead, the Board should document the differences between Medicare and Maryland's commercial and State-regulated markets and provide rationale for MFP as a price appropriate for Maryland.

The June 1 comment also proposed that therapeutic alternatives not be read to establish clinical equivalence or interchangeability for individual patients (Regulation .03H(5) and (6)). New Regulation .05C(1)(e)(i) instead allows staff to use "any comparator," and new Regulation .05C(2)(e)(iii) and (iv) add "drugs in the same therapeutic class" and "the standard of care" as comparators in incremental cost and outcomes analyses that already appear in Regulation .05C(1)(e)(ii) and (iii). As our June 25 comment stated, value may not be best measured by a system-level price-to-outcomes comparison.

Proposed Regulation .01 retains the provisions VCC addressed on June 25. Spending levels alone are an incomplete proxy for affordability challenges, because spending often reflects higher utilization rather than higher price (Regulation .01B(1)). The authority to identify "any other circumstance" (Regulation .01B(4) and .01D(5)) has no limiting standard. VCC's concerns on both remain.

The proposed text also does not reflect VCC's June 1 recommendations on patient access and continuity of care protections, participation in the Stakeholder Council process by patients, caregivers, and providers with experience treating the conditions associated with the drugs under review, protections for patients with rare, chronic, progressive, or disabling conditions, and international health system differences (Regulation .04B(1)(i)). New Regulation .05C(2)(e)(iii) carries forward the existing reference to "financial impacts to health, medical, or social services as can be quantified" (existing Regulation .05C(1)(e)(i)), which VCC welcomes on downstream costs, but it is permissive and does not require the Board to account for the costs of non-adherence or discontinuation, as VCC proposed on June 1.

We appreciate the opportunity to provide these comments and look forward to continued engagement with the Board.

Sincerely,

Derek Flowers
Value of Care Coalition