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Maryland Prescription Drug Affordability Board
Comments on COMAR 14.01.04 Cost Review Study Process
June 2026

The 850,000 members of AARP Maryland applaud the Maryland Prescription Drug Affordability Board's (PDAB) proposed revisions to COMAR 14.01.04.01 Cost Review Study Process. The new language is very clear and inclusive, and it provides excellent specifics on which measures to use to determine when the use of a drug may create an "affordability challenge" and thus warrant action under the law.

Among the things that the new language does well is assessing whether a drug is not producing sufficient value to the state's health care system. The new provisions have specific measures to determine that, including whether it is cost-effective at the "current average net price." The draft language wisely lays out measures to assess a drug's value relative to therapeutic alternatives, appropriately linking the value to clinical outcomes.

The proposed language also correctly accounts for factors related to the drug that inhibit market competition. This category includes patent extensions, manufacturer conduct, and regulatory actions that delay or prevent full competition.

The section on barriers to affordable access to drugs for insured patients is also well thought out, though some of the language may be confusing. For example, the phrase "coverage of the prescription drug product is not coextensive with FDA-approved indications" should be rephrased to eliminate the word "coextensive" and explain exactly what kind of problem the language seeks to prevent. But this section also has good measures, such as looking at the prevalence of required prior authorization and claim rejection, along with evidence that the drug in question isn't covered by some payers because of its high cost. Howard County, for instance, isn't covering Ozempic for weight loss, although it is covered for other purposes, because the drug would otherwise become unaffordable for the county government.

The proposed language includes a strong final section that addresses circumstances indicating a need for regulatory action. This wisely open-ended Section D includes such factors indicating a drug is unaffordable as (1) average out-of-pocket costs for the drug comprising a large proportion of the average income of covered persons, and (2) a large proportion of patients not taking the drug prescribed. And this section wisely concludes with an open-ended provision to cover any other circumstances that have or will lead to too-high out-of-pocket costs for patients.

AARP Maryland appreciates the comprehensiveness and specific details in the proposed language throughout this chapter and urges its adoption as soon as feasible.

June 26, 2026

VIA ELECTRONIC MAIL

Maryland Prescription Drug Affordability Board
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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.

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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.

ARTHRITIS AND RHEUMATISM ASSOCIATES, P.C.

June 26, 2026

Maryland Prescription Drug Affordability Board
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VIA EMAIL: comments.pdab@maryland.gov

RE: Amendments to COMAR 14.01.04.01 — Cost Review Study Process: Circumstances Under Which Use of a Drug May Create an Affordability Challenge.

Dear PDAB Members,

Arthritis and Rheumatism Associates, P.C. appreciates the opportunity to comment on the draft regulations regarding "Circumstances Under Which Use of a Drug May Create an Affordability Challenge."

ARA P.C. is the largest rheumatology practice group in the Mid-Atlantic region. We are dedicated to the diagnosis and treatment of people with disorders of the joints, muscles, tendons, and other connective tissue. Our practice integrates excellent medical care with comprehensive services, including specialty drug pharmacy dispensing, a full-service laboratory, x-ray facilities, a physical therapy division, seven centers for the diagnosis and treatment of osteoporosis, and seven infusion centers. We care for more than 30,000 patients each year at five of our centers located in Maryland.

Based on our review, the proposed draft regulations would provide the Board with broad criteria for determining when a drug's price, spending impact, access barriers, market conditions, or patient costs may make the drug unaffordable for the State health care system or for patients.

As we have noted in previous comments, the costs borne by providers for the acquisition and storage of these drugs should not be overlooked. Our ability to provide these services on behalf of our patients must remain unchanged. The ability to recoup these costs from insurers is essential to maintaining access to appropriate medications, which is critical for the short- and long-term health of our patients.

Health care practices such as ours directly administer medications in outpatient settings and dispense specialty drugs. To do this we must pre-purchase drugs and bill payers for reimbursement once the medication is administered to a patient. For practices like ours it is essential to maintain patient access to our pharmacy when they prefer it or are unable to use mail order/chain specialty pharmacy services.

Margins for practices engaged in this patient care model are thin. Dispensing specialty drugs and administering drugs in outpatient practice settings is often more cost-effective for payers and safer for immunocompromised patients than administration in hospital-based infusion centers. Moreover, reimbursement must account for acquisition-related costs, including intake and storage, equipment and preparation, staffing, facilities, and spoilage insurance.

Reimbursement rates that do not sufficiently compensate for these costs put health care practices and their patients at risk. To be clear, not every practice has the capacity to provide these services, but patients treated in practices that do provide them find this care to be an invaluable link to better health and efficient treatment.

If health care practice groups like us are forced underwater financially, patients may be cut off from the treatment they rely on. Our patients, many who suffer from rheumatoid arthritis and other autoimmune diseases, pay for disruptions in their treatment plan with their own unnecessary pain and disability. Stopgap measures required to transition patients into a new care setting or treatment model could have lasting impacts on their short- and long-term care.

It is also important to note that practices that directly administer medications in outpatient settings do not drive-up costs. In fact, these services represent only a small fraction of the pharmaceutical delivery system.

Autoimmune diseases are chronic and incurable. Patients who receive medications subject to PDAB regulation have usually already failed less-expensive conventional medications, and switching to a different medication for non-medical reasons goes against the standard of care and risks unnecessary inefficacy and toxicity.

The proposed regulations identify the following factors as considerations:

(2) At its current net or gross price, a drug does not provide sufficient value to the State health care system, as may be indicated by:

- *(a) The drug is not cost-effective at the current average net price;*
- *(b) The average net price of the drug exceeds the average net price for therapeutic alternatives that provide similar clinical outcomes; or*
- *(c) Compared to therapeutic alternatives, the drug was approved with limited evidence of improvement in clinical outcomes and has substantial spending.*

Our strong suggestion is that the Board not look only at the numbers, but also consider the number of patients using the drug and recognize that what is medically efficacious for one patient may be the only option for that patient. The cost-benefit analysis may be best measured by improvements in quality of life and clinical outcomes, rather than by a strict dollars-and-cents review.

Financial cost is an ever-present factor in modern health care delivery, but as physicians, we must also weigh the physical and emotional costs our patients endure every day. We appreciate the opportunity to provide this input to the Board.

If we can be of further assistance, please contact me at 301-942-7600 or aworthing@arapc.com.

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VIA Electronic Delivery June 26, 2026

Mr. Van Mitchell, Chair

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

Re: Maryland PDAB COMAR 14.01.04.01 Cost Review Study Process-Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s draft COMAR 14.01.04.01 Cost Review Study Process- Circumstances Under Which Use of a Drug May Create an Affordability Challenge (Draft Regulation).

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

While BIO appreciates that the Board is attempting to specifically define circumstances related to patient affordability, we are concerned by the lack of clearly defined and objective standards. The Draft Regulation relies on vague and ambiguous criteria that creates a significant risk of arbitrary and inconsistent decision-making by the Board. Moreover, the factors identified do not meaningfully measure patient affordability or access challenges. These issues would be further exacerbated if the Board were to impose UPLs based on such indeterminate criteria. Rather, any affordability determination should be tied to a clear definition of affordability and should focus on the real-world experiences of patients who depend on these therapies for their health and quality of life.

Lack of Clearly Defined Standards

The Draft Regulation uses vague terminology to describe circumstances which may create an affordability challenge, which neither helps stakeholders understand the relevant standards nor provides meaningful guardrails on the Board's discretion. For example, the Draft Regulation targets drugs for review that "makes up a large portion of the impacted

budget," but does not define "large portion," does not specify which budget is being referred to, and does not specify whether "spending" refers to gross or net spend. In prior affordability reviews, the Board determined that a product was "unaffordable" when it was estimated to be around two percent of gross budget spending for a specific payer. It is unclear whether this threshold would continue to be seen as a "large portion" of spending or what the Board would consider as "large" going forward. Rather than this vague language, the PDAB must provide clear criteria and specific thresholds for how the Board will determine whether a drug presents an affordability challenge or high out-of-pocket costs for patients that is tied to a clear definition of affordability.

Another circumstance in the Draft Regulation refers to where "[a]t a certain percentile, patient out-of-pocket cost in certain markets is disproportionate to the average net cost paid by payors." Here, the Draft Regulation does not define "disproportionate" or specify what percentiles and markets would meet this criterion.

The Draft Regulation provides examples for determining whether a drug "does not provide sufficient value to the State health care system." BIO recommends that the Board should include more specificity around the proposed "value" and therapeutic alternative criteria, such as accounting for clinical value, unmet need, disease severity, patient heterogeneity, and the fact that alternatives may not be clinically interchangeable for all patients.

Need to Distinguish between Lawful Regulatory Activity and Anticompetitive Conduct

The Draft Regulation creates an overly broad standard under "conduct that delays or prevents market competition" that treats a wide range of lawful and government-authorized activities as evidence of conduct that may contribute to an affordability challenge, referencing patent and regulatory extensions, DEA scheduling, and other regulatory tools. The Draft Regulation should clearly distinguish between unlawful anticompetitive conduct and legitimate activities undertaken pursuant to federal law and regulatory requirements. Patent protections, FDA-granted exclusivities, Risk Evaluation and Mitigation Strategies (REMS), compliance with DEA scheduling requirements, and other regulatory mechanisms are established by Congress and federal agencies to promote innovation, ensure patient safety, and support appropriate stewardship of medicines. These frameworks often impose obligations on manufacturers and may affect the timing or conditions of market entry, but their existence alone does not constitute anticompetitive behavior. Absent evidence of unlawful conduct, the Board should not presume that lawful patent, REMS, exclusivity, FDA or other regulatory activity is anticompetitive or creates affordability challenges.

Circumstances Unrelated to Affordability

Many of the circumstances identified in the Draft Regulation do not actually measure whether a prescription drug creates an affordability challenge, as required by the statute. The Draft Regulation would grant the Board broad discretion to deem a drug unaffordable based on factors such as high spending, wholesale acquisition cost (WAC) increases, perceived lack of value, limited evidence of clinical improvement, access barriers, patient nonadherence, health disparities, or "any other circumstance" identified by the Board. While these considerations may provide some context, they are not direct measures of affordability. For example, the circumstance that a drug's WAC has increased substantially faster than inflation does not measure affordability challenges for patients or State health care system entities because WAC does not reflect the net prices paid after rebates, discounts, and other price concessions, nor does it indicate actual patient out-of-pocket

costs.

Similarly, the "use of patent or regulatory extensions of a government-granted monopoly" does not measure affordability and instead reflects the operation of the intellectual property system, including patents that may result from continued innovation and improvements that benefit patients. While the Draft Regulation does include the consideration of "[b]arriers to affordable access for insured patients," it includes situations where "coverage is not coextensive with FDA-approved indications." Although such circumstances may affect access for some patients, they do not themselves measure affordability or even whether patients are impacted by the coverage limitations. Similarly, the Draft Regulation also assumes that a drug is unaffordable if "[a] large proportion of patients do not take the drug as prescribed." This is not an appropriate measure of affordability, as this could be related to side effects or other factors completely unrelated to out-of-pocket costs. Rather than these inconsistent and unsupported factors, the Board must create clearer standards, thresholds, data requirements, and procedural safeguards before making any affordability determination.

UPLs May Worsen Access and Affordability

The Draft Regulation identifies patient affordability challenges, including high patient out-of-pocket costs, as a factor in determining whether a prescription drug may create an affordability challenge and potentially warrant the establishment of an Upper Payment Limit (UPL). As BIO has stated in previous comments, UPLs do not address affordability concerns for patients, as patient cost-sharing obligations are determined by health plan benefit design, formulary placement, deductible structures, coinsurance requirements, and pharmacy benefit manager (PBM) practices—not by manufacturers. To the contrary, a UPL could exacerbate affordability and access concerns by disrupting existing rebate arrangements, reducing formulary incentives for coverage, and increasing the likelihood that products subject to a UPL are placed on non-preferred formulary tiers or otherwise subject to utilization management restrictions. As such, the Board should not attribute affordability problems to the drug or manufacturer without examining whether payer or PBM practices are driving the patient burden.

The Draft Regulation also considers whether, at a specified percentile, patient out-of-pocket costs in certain markets are disproportionate to the average net cost paid by payors. Because this factor is driven primarily by insurer and PBM practices, it is not clear how imposing a UPL on manufacturers would remedy the issue. BIO remains concerned that the Board continues to move forward with setting UPLs without sufficiently examining alternative affordability solutions that would prevent disruptions to patient access.

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

Melody Calkins

Director, Health Policy

Biotechnology Innovation Organization (BIO)

Boehringer Ingelheim

June 25, 2026

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Re: Proposed Revisions to COMAR 14.01.04.01 Cost Review Study Process-Circumstances Under Which Use of a Drug May Create an Affordability Challenge.

At Boehringer Ingelheim, we recognize the challenges within the U.S. healthcare system—particularly the burden patients face when confronted with high out-of-pocket costs at the pharmacy counter. While we agree that action is needed to make medicines more affordable, we believe that government-imposed price controls are not the most effective path forward. Instead, we advocate for solutions that improve patient access, affordability, and support medical innovation.

The Maryland Prescription Drug Affordability Board (PDAB) released draft regulation on amendments to COMAR 14.01.04.01 Cost Review Study Process. This draft regulation outlines circumstances under which use of a drug may create an affordability challenge.

Boehringer Ingelheim respectfully urges the Board to reconsider the addition of the proposed framework, which attributes affordability challenges to manufacturers based on factors that extend well beyond manufacturer control. The draft includes a broad set of triggers, such as overall payer spending, arbitrary value assessments, and barriers to access, including prior authorization, coverage restrictions, and patient cost-sharing variability, that are largely driven by health plans and pharmacy benefit managers (PBMs), not manufacturers.

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.

The framework also inappropriately incorporates lawful patent protections and broader system-wide cost drivers. Using patents and related protections as signals of an affordability concern risks undermining their role in supporting ongoing research and development and may discourage future innovation needed to bring new therapies to patients.

Boehringer supports the Board's mission to improve affordability for Maryland patients but believes additional framework for determining affordability is ultimately unnecessary. We remain committed to working collaboratively on solutions that sustain patient access while supporting continued medical innovation.

Regards,

Candie Finnegan
Executive Director, State Government Affairs

Life forward

DIABETES PATIENT ADVOCACY COALITION

June 26, 2026

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

RE: Comments on Proposed Amendments to COMAR 14.01.04

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

The Diabetes Patient Advocacy Coalition (DPAC) appreciates the opportunity to comment on the proposed amendments to COMAR 14.01.04.

DPAC is an organization dedicated to improving the lives of people living with diabetes through policies that promote affordable access to medically necessary care. For the millions of Americans living with diabetes, including thousands of Maryland residents, access to insulin and other diabetes therapies is essential to managing a lifelong condition and preventing serious complications.

DPAC is concerned by the proposed removal of the public reporting process currently contained in COMAR 14.01.04.01. Patients experience affordability challenges in ways that are often not reflected in claims data or spending reports. High out-of-pocket costs, prior authorization delays, formulary restrictions, pharmacy access challenges, and other barriers can prevent patients from obtaining prescribed treatments even when coverage exists.

The current reporting process provides an important opportunity for patients and caregivers to share these experiences directly with the Board. We urge the Board to retain this mechanism or establish an alternative process that ensures patient perspectives remain a meaningful part of affordability reviews.

DPAC appreciates the Board's recognition that affordability challenges extend beyond the price of a medication and may include barriers to access, high patient cost-sharing, claims denials, and disparities among patient populations. For people living with diabetes, these barriers can lead to delayed treatment, medication rationing, reduced adherence, and poorer health outcomes.

As the Board evaluates affordability challenges, we encourage continued consideration of patient-centered measures, including treatment adherence, patient out-of-pocket costs, access barriers, and the experiences of historically underserved populations. Affordability assessments should reflect not only system-level spending, but also whether patients can obtain and consistently access the therapies prescribed by their health care providers.

DPAC believes patient experience is an essential component of understanding affordability. We encourage the Board to maintain robust opportunities for patient engagement and ensure that

patient access and health outcomes remain central considerations throughout its review process.

Thank you for the opportunity to provide comments.

Sincerely,

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

EACH PIC COALITION

June 25, 2026

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

June 12, 2026

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

Re: Comments on Proposed Revisions to COMAR 14.01.04.01 – Circumstances Under Which Use of a Drug May Create an Affordability Challenge

Chair Mitchell and Members of the Board:

On behalf of the Healthcare Distribution Alliance (HDA), we appreciate the opportunity to comment on the Maryland Prescription Drug Affordability Board's proposed revisions to COMAR 14.01.04.01 regarding the circumstances under which use of a drug may create an affordability challenge.

HDA is the national trade association representing healthcare wholesale distributors that serve as the critical link between more than 1,500 pharmaceutical manufacturers and over 330,000 pharmacies, hospitals, clinics, long-term care facilities, and other sites of care nationwide. Our members are responsible for safely and efficiently delivering prescription medicines to patients across Maryland and throughout the United States.

HDA understands the importance of prescription drug affordability and appreciates the Board's desire to establish a framework for identifying drugs that may warrant further review. However, we are concerned that the proposed revisions establish an overly broad and subjective set of circumstances that could create regulatory uncertainty while making it difficult for stakeholders to understand how the Board will identify affordability challenges in practice.

Specifically, the proposed rule includes a non-exhaustive list of factors related to spending levels, net and gross pricing, wholesale acquisition cost (WAC) increases, access and utilization metrics, and market competition. While these factors may provide useful context, many are highly subjective and could be interpreted differently depending on the circumstances. Moreover, the inclusion of a catch-all provision allowing the Board to identify "any other circumstance" that may constitute an affordability challenge makes it difficult for stakeholders to anticipate how the regulation will be applied.

HDA is also concerned that the Board is proposing to significantly expand the scope of affordability challenge determinations before stakeholders have had an opportunity to evaluate the implementation and impact of the Board's existing authorities, including the application of Upper Payment Limits (UPLs). Given the significance of these pending policies and their potential effects on patients, providers, pharmacies, and the pharmaceutical supply chain, we believe the Board should first evaluate the implementation and real-world impacts of existing authorities before substantially expanding the circumstances that may trigger affordability reviews.

A measured approach would allow the Board, stakeholders, and policymakers to better assess whether current tools are achieving their intended objectives and identify any unintended consequences before additional criteria are introduced. Expanding the scope of affordability challenge determinations at this stage risks creating further uncertainty while key elements of the Board's existing framework have yet to be fully implemented and evaluated.

To improve transparency and predictability, HDA respectfully encourages the Board to establish more objective standards or, at minimum, provide additional guidance regarding how these factors will be evaluated and weighted. Clear criteria would help ensure that affordability reviews are conducted consistently and that stakeholders can better understand the basis for Board determinations.

As the Board continues to refine this framework, we respectfully encourage it to ensure that affordability challenge determinations accurately reflect the roles of the various stakeholders involved in bringing prescription medicines to patients. Several of the factors identified in the proposed rule stem from pricing, coverage, reimbursement, and market-access decisions that are outside the control of wholesale distributors. The Board should therefore apply criteria that are clear, objective, and appropriately tailored to the entities responsible for the underlying affordability concerns.

We appreciate the opportunity to provide comments and look forward to continuing to engage with the Board throughout the rulemaking process. HDA remains committed to working collaboratively with policymakers to improve patient access and affordability while preserving a safe, efficient, and resilient pharmaceutical supply chain.

Sincerely,

Bryan Hannon
Director, State Government Affairs
bhannon@hda.org

Infusion Access Foundation

June 22, 2026

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

RE: Comments on Proposed Revisions to COMAR 14.01.04.01 (Cost Review Study Process - Circumstances Under Which Use of a Drug May Create an Affordability Challenge)

Dear Maryland Prescription Drug Affordability Board:

The Infusion Access Foundation appreciates the opportunity to provide comments regarding the Board's proposed regulation outlining the circumstances under which the use of a prescription drug may be considered an affordability challenge. We recognize the Board's ongoing efforts to enhance the transparency and consistency of its affordability review process and to clarify the factors that may warrant additional evaluation or policy action.

The Infusion Access Foundation is a nonprofit patient advocacy organization that supports individuals who depend on infusions and injections to treat chronic, complex, and life-threatening conditions. Through both our advocacy initiatives and direct patient engagement, we work to ensure that patients can access the treatments their healthcare providers prescribe and to address barriers that interfere with timely, affordable care.

As the Board continues refining its affordability framework, we encourage it to prioritize the experiences and realities of patients. Affordability assessments should therefore place primary emphasis on evidence demonstrating that patients are encountering genuine financial obstacles to treatment, and seek to address the root causes of these obstacles.

Centering Patients in Affordability Determinations

The purpose of an affordability review should be to identify and address barriers that prevent patients from accessing the care they need. As currently drafted, however, the proposed regulation allows an affordability challenge determination to be based solely

on healthcare spending indicators, even when there is little evidence that patients are experiencing difficulty affording or accessing treatment.

While spending data can provide useful information about healthcare costs, it does not fully capture the realities patients face when seeking care. Affordability challenges are often driven by factors beyond the price of a medication, including insurance benefit design, cost-sharing obligations, prior authorization requirements, coverage restrictions, specialty pharmacy mandates, and changes in eligibility for financial assistance programs. These barriers can significantly affect a patient's ability to obtain treatment but may not be reflected in spending, utilization, or out-of-pocket cost data alone.

Because the Board's decisions have the potential to affect access to treatment for Maryland patients, affordability determinations should be informed by a clear understanding of patient experience. A patient-centered affordability framework should seek to assess not only whether affordability challenges exist, but also the underlying factors contributing to those challenges. Meaningfully incorporating patient perspectives into affordability reviews will help ensure that the Board's work remains focused on its ultimate goal: improving patient access to affordable care.

Conclusion

The Infusion Access Foundation appreciates the Board’s ongoing efforts to strengthen and clarify its affordability review process. As the Board finalizes this regulation, we respectfully encourage it to ensure that patient affordability remains the central consideration in affordability determinations. Thank you for the opportunity to provide these comments, we look forward to continued engagement with the Board.

Sincerely,

Alicia Barron, LGSW
Executive Director
Infusion Access Foundation

PhRMA
RESEARCH • PROGRESS • HOPE

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

By Electronic Submission

June 26, 2026

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

RE: Draft Regulations – Proposed Revisions to COMAR § 14.01.04.01

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Maryland Prescription Drug Affordability Board's (the "PDAB's" or "Board's") request for written comments on its draft revisions to COMAR § 14.01.04.01 ("Draft Regulations"), which would establish "[c]ircumstances [u]nder [w]hich [u]se of a [d]rug [m]ay [c]reate an [a]ffordability [c]hallenge" for purposes of the cost review study process.[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 $850 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] We have previously expressed in detail our concerns regarding the cost review study process, and we encourage the Board to consider them.[3] In addition, we provide below select comments and concerns in response to this request for comment on the Draft Regulations.

[1] *See* Draft Proposed Amendments to COMAR § 14.01.04.01 for Comment (May 27, 2026), *available at* https://pdab.maryland.gov/Documents/regulations/2026/DRAFT%20PROPOSED.14.01.04.01.Circumstances%20Under%20Which%20Use%20of%20a%20Drug%20May%20Create%20an%20Affordability%20Challenge.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Md. Code Ann., Health-Gen. §§ 21-2C-01–16 (the "PDAB Statute") and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute. *See, e.g.*, Letter from PhRMA to Board (June 1, 2026); Letter from PhRMA to Board (May 1, 2026); Letter from PhRMA to Board (May 1, 2026); Letter from PhRMA to Board (Mar. 30, 2026); Letter from PhRMA to Board (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 (May 4, 2023); Letter from PhRMA to Board (May 4, 2023); Letter from PhRMA to Board (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.

[3] *See supra* note 1.

I. Lack of Clear, Specific, and Meaningful Standards

PhRMA is concerned that the Draft Regulations lack sufficiently clear, specific, and meaningful standards to guide the Board in determining whether use of a drug creates an affordability challenge. The "circumstances" contemplated in the Draft Regulations are non-exhaustive and rely on vague and undefined terms. For example, the Draft Regulations refer to spending that "makes up a large proportion of the impacted budget" without specifying what constitutes a "large proportion" or indicating whether it relates to gross or net spending.[4] The Draft Regulations also state that "[b]arriers to affordable access for insured patients" include "[a]t a certain percentile, patient out-of-pocket cost in certain markets" that is "disproportionate to the average net cost," but they do not identify the relevant percentile or markets, nor do they define what is meant by "disproportionate."[5] Similarly, the Draft Regulations refer to "disparities in costs or utilization . . . in priority populations," without defining priority populations or explaining how such populations would be identified.[6] These examples illustrate a broader pattern of vague and undefined terms throughout the Draft Regulations.

Compounding PhRMA's concerns, the Draft Regulations also fail to provide objective criteria or a methodology for consistent evaluation and decision-making regarding the circumstances that may create an affordability challenge. Moreover, because the circumstances are non-exhaustive, they neither help stakeholders understand how affordability challenges will be identified nor provide meaningful guardrails on Board discretion. Consistent with PhRMA's comments in prior rulemakings, PhRMA is concerned that the absence of clear standards creates a significant risk of inconsistent application and arbitrary decision-making.[7] This raises concerns under the Maryland Administrative Procedure Act ("APA"), which requires agencies to provide a reasoned basis for—and apply standards consistently in—their decision-making.[8] 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.

II. Circumstances Not Meaningfully Related to "Affordability"

As part of its cost review authority, the Board is charged with identifying and addressing affordability challenges.[9] However, several proposed circumstances do not correlate with affordability—for patients

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[4] Draft Regulations, COMAR §14.01.04.01(B)(1)(a); *see also id.* §14.01.04.01(D)(1), (3) (listing "circumstance[s] under which use of a drug has or will lead to high out-of-pocket costs for patients" to include "[t]he average total out-of-pocket costs for a drug make up a *large proportion* of the average income" and "[a] *large proportion* of patients do not take the drug as prescribed") (emphasis added).

[5] *Id.* §14.01.04.01(B)(4)(d); *see also id.* §14.01.04.01(D)(2) (listing "circumstance[s] under which use of a drug has or will lead to high out-of-pocket costs for patients" to include "[a]t *a certain percentile*, patient out-of-pocket cost in *certain markets* is *disproportionate* to the average net cost paid by payors) (emphasis added).

[6] *Id.* §14.01.04.01(D)(4).

[7] *See, e.g.*, 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.

[8] *See* Md. Code Ann., 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"); *see also, e.g.*, *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).

[9] Md. Code, Health-Gen. § 2C-21-09(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)).

or the State health care system. For example, list prices typically do not reflect the net costs to payers 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 substantially faster than inflation"—do not demonstrate that a drug creates an affordability challenge.[10]

To comply with the PDAB Statute, the circumstances for determining whether use of a drug has led or will lead to affordability challenges must bear a clear and demonstrable relationship to affordability for patients or the State health care system.[11] 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.

III. Mischaracterization of Federal Programs and Lawful Manufacturer Conduct

PhRMA is concerned that the Draft Regulations mischaracterize and undermine longstanding federal frameworks designed to promote innovation, affordability, access, patient safety, and public health. These frameworks—including the federal intellectual property ("IP") framework, Drug Enforcement Administration ("DEA") scheduling, and FDA-approved risk evaluation and mitigation strategies ("REMS")—serve distinct purposes established by Congress. IP protections fuel groundbreaking treatment advances, and federal laws balance the needs for both innovation and competition. DEA scheduling and REMS likewise enable critical medicines to reach patients while also protecting patient safety and public health; neither creates material barriers to generic drug entry or otherwise adversely affect competitive market dynamics. The Draft Regulations fundamentally misrepresent federal frameworks and legal requirements as means to "have the effect of delaying or preventing market competition."[12]

A. Patent and Regulatory Extensions

The Draft Regulations reflect a misunderstanding of the intent and effect of patents, as they appear to target "use of" patents and "regulatory extensions of a government-granted monopoly[.]"[13] Patents, patent term extension, and regulatory exclusivities are core parts of the federal IP framework for medicines. They are rights made available by Congress that manufacturers are expected and entitled to utilize, and help promote the discovery and development of life-saving medicines while fostering a competitive market for generic and biosimilar medicines.[14]

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

[11] *See* Md. Code, Health-Gen. § 2C-21-09(b)(1).

[12] *See* Draft Regulations, COMAR §14.01.04.01(B)(3).

[13] *See id.* §14.01.04.01(B)(3)(a).

[14] The U.S. IP framework and ecosystem provide patients in the United States with access to more innovative medicines than patients in any other countries. Specifically, 88% of new medicines are publicly reimbursed in the United States, compared to an average of 36% in 19 other high-income countries. *See* PhRMA, Access to new medicines in the United States vs. other high-income countries (May 2026), available at https://cdn.aglty.io/phrma/Attachments/NewItems/PhRMA_OnePager_AccessToNewMedicinesReport_8.5x11_v3.2_Print%20(2)_20260512113247.pdf.

The Constitution assigns to Congress—and Congress alone—the responsibility to design and calibrate the balance between innovation incentives and access to patented inventions, including innovative medicines.[15] Congress has exercised that authority by enacting a comprehensive patent framework that allows manufacturers, during the patent term, to price products at market rates, subject to competition and other constraints Congress has chosen to impose.[16] Patent term adjustment and patent term extension similarly reflect federal judgments about how to account and compensate for delays in the patent prosecution and regulatory review processes.[17] Patents do not act as an absolute bar against bringing similar, non-infringing products to market, and once the patent has expired, the invention can be freely used by anyone.

B. DEA Scheduling and REMS

DEA scheduling and REMS are federal legal requirements designed to protect patients and the public from risks associated with use and distribution of a particular medicine and have little connection with competition or affordability. Manufacturers must comply with the federal laws implementing these programs.[18] The Board does not explain why it would treat such compliance as "[c]onduct that delays or prevents market competition" or how it constitutes evidence of an affordability challenge.[19]

C. Preemption Concerns

The Draft Regulations could lead to Board actions that would be preempted by federal law. Each of the federal programs specified in the Draft Regulations—patents, regulatory extensions of "government-granted monopolies[,]" DEA scheduling, and REMS—was created by Congress to achieve a particular objective.[20] Interference with those objectives is inconsistent with the Supremacy Clause, under which federal law is "the supreme Law of the Land."[21]

With respect to patents and regulatory extensions, Congress has adopted a comprehensive federal framework that balances innovation and access. States may not impose burdens on entities that avail themselves of these federal programs. Courts have repeatedly held that a state law that "enters a field of

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[15] U.S. Const. art. I, § 8, cl. 8 (empowering Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"); *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373–74 (Fed. Cir. 2007).

[16] *See* 35 U.S.C. § 1 *et seq.* The Supreme Court has long recognized that "[t]he grant of a patent is the grant of a statutory monopoly." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964).

[17] *See* 35 U.S.C. §§ 154, 156.

[18] Manufacturers of DEA-scheduled products—which are classified based on acceptable medical use and potential for abuse or dependency—are required to comply with the Controlled Substances Act ("CSA"), including with respect to registration, production and procurement quotas, recordkeeping, and reporting. *See* 21 U.S.C. § 812 (schedules of controlled substances); 21 U.S.C. § 821 *et seq.* (registration, quotas, recordkeeping, reporting, etc.); *see also* 21 C.F.R. Parts 1300–1308; DEA, Drug Scheduling (last accessed June 17, 2026), https://www.dea.gov/drug-information/drug-scheduling. REMS likewise are mandatory federal requirements applicable to certain drugs. As directed by Congress, FDA imposes REMS only when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." *See* Federal Food, Drug, and Cosmetic Act ("FDCA") § 505-1(a)(1), 21 U.S.C. § 355-1(a)(1). FDA is not permitted to consider affordability when establishing or modifying a REMS. *See* FDCA § 505-1(a)(1)(A)–(F), 21 U.S.C. § 355-1(a)(1)(A)–(F). Federal law also includes mechanisms to facilitate generic competition, including shared system REMS arrangements between brand name manufacturers and generic manufacturers, or separate REMS in appropriate circumstances. *See* FDCA § 505-1(i)(1), 21 U.S.C. § 355-1(i)(1); FDA, Frequently Asked Questions (FAQs) about REMS (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.

[19] *See* Draft Regulations, COMAR §14.01.04.01(B)(3).

[20] *See* Draft Regulations, COMAR §14.01.04.01(B)(3)(a).

[21] U.S. Const. art. VI, cl. 2; *see Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479 (2013) ("[I]t has long been settled that state laws that conflict with federal laws are without effect") (citations omitted).

regulation which the patent laws have reserved to Congress" is preempted.[22] Similar considerations apply to regulatory extensions, DEA scheduling, and REMS. In each case, Congress imposed a "comprehensive scheme of federal control" with which Maryland now seeks to interfere.[23] As discussed above, Congress enacted a comprehensive regime governing both the regulation of controlled substances under the Controlled Substances Act ("CSA") and FDA's regulation of drugs subject to a REMS under the Federal Food, Drug, and Cosmetic Act ("FDCA").[24] If the Board were to penalize manufacturers as a result of these federal frameworks and their compliance with federal requirements, such action could "stand[] as an obstacle to the accomplishment of the full purposes and objectives of Congress" by burdening and potentially penalizing manufacturers for simply complying with federal law.[25]

IV. 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.[26] Specifically, the Draft 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.[27]

As PhRMA has previously explained, some therapies that could be identified as therapeutic alternatives under the Board's definitions are not appropriate for all patients and may not be considered comparable treatments.[28] 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.[29] Accordingly, PhRMA reiterates its request that, before finalizing the Draft 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.[30]

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[22] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 143, 167 (1989); *see also Amgen, Inc. v. Sandoz, Inc.*, 877 F.3d 1315 (Fed. Cir. 2017); *see also Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373–74 (Fed. Cir. 2007) (held that a D.C. law that regulated only patented drug prices was preempted because "[b]y . . . limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.")

[23] *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 629 (1973).

[24] *See* 21 U.S.C. § 812; FDCA § 505-1, 21 U.S.C. § 355-1.

[25] *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

[26] *See* COMAR § 14.01.01.01(B)(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 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.

[27] Draft Regulations, COMAR § 14.01.04.01(B)(2)(b), (c).

[28] *See, e.g.*, Letter from PhRMA to Board (June 1, 2026) at 8-9; Letter from PhRMA to Board (Mar. 30, 2026) at 4.

[29] *See e.g.*, Letter from PhRMA to Board (July 16, 2024) at 4-5; Letter from PhRMA to Board (May 10, 2024) at 4.

[30] *See* 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.

Further, the Draft 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. Patients in these groups in particular may respond differently to treatments and be limited to one specific drug therapy for their condition.[31] The Draft 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.

V. Procedural Concerns

PhRMA is concerned that the Draft Regulations lack sufficient procedural clarity and do not provide stakeholders with adequate notice of how certain provisions may be applied. Specifically, the Draft Regulations include broad, undefined "catch-all" provisions that would allow the Board to find that a drug creates an affordability challenge based on "any other circumstance" not already listed.[32] 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.[33] As Maryland courts have found, agency action must be supported by reasoned analysis.[34]

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.[35] Without such explanation, stakeholders cannot meaningfully assess or comment on the Board's decisions. The Draft Regulations should clearly establish opportunities for stakeholder comment on the Board's analysis and determinations before the Board renders a preliminary affordability determination, particularly if a "catch-all" provision is invoked.[36]

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

Many of the circumstances in the Draft Regulations are driven by factors and market dynamics other than drug pricing. For example, lack of coverage, coverage that "is not coextensive with FDA-approved indications," "[h]igh occurrence of required prior authorization or high claims rejection rate," and "patient out-of-pocket cost in certain markets is disproportionate to the average net cost paid by payors" are largely the result of decisions made by insurers and pharmacy benefit managers ("PBMs").[37] Indeed, utilization

[31] *See* Letter from PhRMA to Board (May 10, 2024) at 4-5.
[32] *See* Draft Regulations, COMAR § 14.01.04.01B(5), D(5).
[33] *See* Letter from PhRMA (Aug. 26, 2024) at 2; *see also 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).
[34] *See, e.g.*, *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); *see also 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").
[35] *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.").
[36] *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").
[37] Draft Regulations, COMAR § 14.01.04.01B(4).

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.[38] PhRMA has also noted that such factors can significantly increase patient out-of-pocket costs, even where net prices are stable or declining.[39] Adherence issues (e.g., "large proportion of patients do not take the drug as prescribed") may also result from insurers' benefit design choices.[40] UPLs do not address these underlying drivers of affordability challenges and may exacerbate access barriers. PhRMA urges the Board to consider non-UPL policy measures that do instead.

* * *

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

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director – Law

[38] *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, HealthGen. § 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").

[39] *See, e.g.*, Letter from PhRMA to Board (May 1, 2023) at 3-4; Letter from PhRMA to Board (Sept. 12, 2022) at 2.

[40] Adherence issues may also result from non-cost factors like side effects, contraindications, clinical considerations, or patient preference.

Value of Care Coalition

June 25, 2026

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

RE: Comments on Proposed Amendments to COMAR 14.01.04.01 — Circumstances Under Which Use of a Drug May Create an Affordability Challenge

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

The Value of Care Coalition appreciates the opportunity to comment on the proposed amendments to COMAR 14.01.04.01 regarding the circumstances under which use of a drug may create an affordability challenge for Maryland's health care system and patients.

The Coalition supports efforts to improve patient affordability and address barriers that prevent Marylanders from accessing medically necessary treatments. We offer the following comments in that spirit.

Public Reporting

We are opposed to the removal of the existing public reporting process. Patients and caregivers are uniquely positioned to identify affordability and access challenges that may not be visible through claims data, spending analyses, or utilization metrics. Eliminating this mechanism reduces transparency and narrows opportunities for meaningful patient engagement. We urge the Board to retain the public reporting process or establish a comparable avenue for direct patient and caregiver input.

High Spending as an Affordability Indicator

Spending levels alone are an incomplete proxy for affordability challenges. Spending levels are often a result of high usage rather than high list price. High or growing utilization of a therapy often reflects expanding access to effective treatment — itself a positive policy outcome — rather than evidence of a pricing problem. The Board's cost review work to date has acknowledged that aggregate spending growth is driven in significant part by increased utilization. The criteria in this section do not account for that distinction, and a determination of affordability challenge that follows from utilization growth risks penalizing therapies that patients and providers rely on precisely because they work.

Sufficient Value to the Health Care System

The Coalition has longstanding concern about how value is assessed in the context of cost review. Value is not best measured by a system-level price-to-outcomes comparison. It is primarily determined by the patients who benefit from effective therapy and the clinicians who rely on a range of treatment options to make individualized care decisions. A drug that addresses a patient's specific comorbidities, that a patient has stabilized on after prior treatment failures, or that a prescriber selects because of a distinct clinical profile may provide substantial value that aggregate or comparative analyses are structurally unable to capture.

We also note that the Board's cost review work to date has not demonstrated meaningful consideration of the downstream positive effects tied to treatment adherence and continuity, including patient stability, avoidance of complications, reduced hospitalizations, and related costs to the health care system. Whether or not those factors are incorporated into a formal value framework, their absence from affordability determinations leaves the analysis incomplete.

Open-Ended Board Authority

The proposed regulation grants the Board authority to identify "any other circumstance" it determines may constitute an affordability challenge, without corresponding standards or limiting principles. This open-ended authority creates significant uncertainty for stakeholders and provides no meaningful check on the scope of Board action. The Coalition objects to this provision as drafted.

Access Barriers and the Limits of Available Remedies

The Coalition agrees that barriers to affordable access including prior authorization requirements, high claims rejection rates, coverage gaps, and disproportionate patient cost-sharing are appropriate considerations in any affordability review framework. These factors directly affect patients' ability to obtain and adhere to prescribed treatments.

However, it bears noting that these barriers are primarily caused by insurer benefit design, not drug pricing alone. Upper payment limits, the Board's principal enforcement tool, operate on the payer side and do not reach the coverage and cost-sharing decisions that health plans make. A finding that access barriers exist, or that patient out-of-pocket costs are disproportionate to net payer costs, would not be resolved by an UPL. Recognizing these criteria as relevant to affordability is appropriate; concluding that the Board's available remedies are adequate to address them is not.

We have consistently urged the Board to examine how benefit design choices by health plans shape patient affordability outcomes. These regulations present another opportunity to ensure that relationship remains visible in the Board's work.

Conclusion

The Value of Care Coalition remains committed to advancing policies that improve affordability for patients while preserving access to innovative and medically necessary treatments. We encourage the Board to apply these criteria with transparency, clear evidentiary standards, and consistent attention to patient access and clinical value, and to resist interpretations that would expand the scope of affordability review beyond what the evidence and the Board's available remedies can support.

Sincerely,

Derek Flowers
Value of Care Coalition