abbvie

December 2, 2024

VIA ELECTRONIC MAIL TO PDAB.REGS@MARYLAND.GOV

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

Re: Comments on the Proposed Amendments to COMAR 14.01.04.05, "Cost Review Study Process"

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is submitting these comments in response to the Board's proposed amendments to COMAR 14.01.04.05, "Cost Review Study Process," (collectively, the "Proposed Amendments") published in the Maryland Register on November 1, 2024.[1] In multiple respects, the Proposed Amendments and related PDAB actions seek to expand the Board's authority well beyond its statutory mandate in violation of Maryland law, and to introduce vague, open-ended considerations that eviscerate any predictability in cost reviews and invite arbitrary and capricious affordability determinations. And procedurally, in its haste to push through unsupported and ineffective policies, the Board has baselessly attempted to adopt these flawed amendments through "emergency action," bypassing the required notice-and-comment process so important to informed agency decision-making, despite the absence of any conceivable emergency.[2] Due to their extreme substantive and procedural defects, the Board should not adopt the Proposed Amendments.

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie also is a leader in precision medicine, using genetic and molecular data, as well as companion diagnostic tests, to help target medicines to patients who are most likely to respond to and benefit from them. 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.

As we have explained in prior comment letters, the Board's actions have not served the public interest, including, prominently, the needs of patients: pointedly, we believe that the Board has yet to satisfy the statutory directive to consider, in conducting a cost review, patients' out-of-pocket costs—that is, "[t]he average patient copay or other cost–sharing for the prescription drug

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[1] 51:22 Md. R. 957-1028 (Nov. 1, 2024), at https://dsd.maryland.gov/MDRIssues/5122/Assembled.aspx.

[2] Maryland Prescription Drug Affordability Board, Proposed Regulations, "Notice: COMAR 14.01.04, Cost Review Study Process, Emergency Action" at https://pdab.maryland.gov/Pages/proposed-regs.aspx.

product in the State …."[3] The Proposed Amendments provide no further clarity on how, if at all, the Board will consider patient out-of-pocket costs.

Moreover, as a matter of law, the Board's actions have run afoul of Maryland's Administrative Procedure Act ("APA") and the U.S. Constitution, implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause. Among other problems, the Board's opaque cost review process and lack of clear standards for adoption and implementation of an upper payment limit ("UPL"), and lack of transparency regarding its decision-making as to both, is contrary to law and to the public interest and has deprived AbbVie and other impacted stakeholders, including Maryland resident patients, of the ability to effectively and predictably participate in the Board's drug selection and cost review processes.

Indeed, key stakeholders—and even members of the Board's own Stakeholder Council—have expressed grave doubts regarding the Board's activities, including its truncated timelines, inadequate decision-making rationales, lack of transparency, disregard for pharmacist and patient concerns (*e.g.*, impact to medication access), and lack of consideration of information critical to evaluating the actual costs patients pay for drugs (*e.g.*, Pharmacy Benefit Manager ("PBM") and insurance carrier costs).[4] The Proposed Amendments at issue here compound the serious concerns raised repeatedly by AbbVie and other stakeholders regarding the propriety, legality, and implications of the Board's activities and failure to properly consider pharmaceutical cost drivers and the drug supply chain in the United States.

Our comments proceed in three parts. Section I discusses the ways in which the Proposed Amendments and related PDAB actions unlawfully exceed the Board's statutory powers. Section II explains how the Proposed Amendments introduce vague, open-ended standards that jettison any potential predictability in the Board's cost reviews and invite arbitrary affordability determinations. And Section III discusses the Board's baseless and unlawful attempt to evade notice-and-comment procedures by adopting the Proposed Amendments through "emergency action." The Board should pause to consider these and other comments and should not adopt the Proposed Amendments due to their significant flaws.

I. The Proposed Amendments Unlawfully Exceed the Board's Statutory Authority

In multiple respects, the Proposed Amendments and related PDAB actions would vastly expand the Board's authority beyond its statutory mandate in clear violation of Maryland law.

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[3] Md. Health Gen. § 21-2C-09(b)(2)(x).

[4] *See, e.g.*, Kelly Schultz, Commentary, "In Maryland, drug price controls won't help patient affordability," Maryland Matters (October 26, 2024), at https://marylandmatters.org/2024/10/26/in-maryland-drug-price-controls-wont-help-patient-affordability/; *see also* Community Access National Network, Comment, Re: Comment on Proposed Regulations (November 8, 2024) (noting that the Board's truncated comment timelines and use of emergency rulemaking procedures inhibits patient engagement and "degrade[s] public trust in the institution of the Board and staff"); Coalition of State Rheumatology Organizations, Comment, Re: New Chapter – COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 7, 2024) (explaining that the Board's methodology does not account for physician acquisition costs and risks patient access to medications); Healthcare Distribution Alliance, Comment, COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 8, 2024) (explaining that the Board's methodology will create hardships for independent pharmacies and the patients they serve).

Under Maryland's APA, a regulation is invalid if it "exceeds the statutory authority" of the agency.[5] As Maryland's high court has recognized, "it is axiomatic that an administrative regulation must be consistent with the letter and policy of the statute under which the administrative agency acts."[6] "[A] legislatively delegated power to make rules and regulations is administrative in nature, and ***it is not and cannot be the power to make laws***; it is only the power to adopt regulations to carry into effect the will of the legislature as expressed by the statute."[7] An agency accordingly may not adopt "a rule or regulation which is ***inconsistent or out of harmony with, or which alters, adds to, extends or enlarges, subverts, impairs, limits, or restricts*** the act being administered."[8] Courts are "bound to ensure that … agencies act within the confines of their delegated powers."[9] And Maryland courts have not hesitated to declare invalid regulations that exceeded the agency's statutory authority.[10]

The Maryland PDAB statute sets out the legislatively granted scope of the Board's authority. Provided certain preconditions are met, the statute authorizes the Board to:

- Conduct cost reviews to determine whether a prescription drug has created "affordability challenges for the State health care system or high out-of-pocket costs for patients";[11]

- Set an "upper payment limit" for purchases or reimbursements of such a drug by eligible State government entities;[12] and

- Report on cost reviews it conducts and offer "recommendations … on further legislation needed to make prescription drug products more affordable in the State."[13]

Notably, Maryland's PDAB statute does not permit the Board to take other measures, beyond setting UPLs, to address perceived affordability challenges. Nor does the statute permit the Board to apply UPLs to purchases or reimbursements by *commercial* payors or anyone other

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5 Md. Code Ann., State Gov't § 10-125(d)(2).

6 *Ins. Com'r of State of Md. v. Bankers Indep. Ins. Co.*, 326 Md. 617, 606 A.2d 1072 (1992).

7 *Id.*

8 *Id.*

9 *Benson v. State*, 389 Md. 615, 646, 887 A.2d 525, 543 (2005).

10 *See, e.g.*, *Medstar Health v. Maryland Health Care Comm'n*, 376 Md. 1, 827 A.2d 83 (2003) (declaring invalid a regulation adopted by the Health Care Commission because it was not "consistent with the statutory scheme under which the agency operates"); *Mayor & City Council of Baltimore v. William E. Koons, Inc.*, 270 Md. 231, 310 A.2d 813 (1973) (declaring invalid a regulation that sought to prohibit conduct permitted by the governing statute); *see also Holy Cross Hosp. of Silver Spring, Inc. v. Health Servs. Cost Rev. Comm'n*, 283 Md. 677, 393 A.2d 181 (1978) (finding that Maryland Health Services Cost Review Commission exceeded its statutory authority, which only authorized the Commission to hold public hearings and conduct investigations, when the Commission attempted to review and set fees charged by physicians in certain medical specialties); *Bd. of Liquor License Comm'rs for Baltimore City v. Hollywood Prods., Inc.*, 344 Md. 2, 684 A.2d 837 (1996) (holding that Baltimore Board of Liquor License Commissioners lacked authority to restrict hours of operation of a licensee's establishment because "if the legislature had intended the [Board] to have this authority, it would have incorporated language to that effect in the appropriate provisions").

11 Md. Health Gen. §§ 21–2C–07, 21–2C–08, 21–2C–09.

12 *Id.* § 21–2C–13.

13 *Id.* § 21–2C–09(c).

than the eligible State government entities. The Maryland PDAB statute also does not give the Board any authority to implement or enforce the numerous other State and federal regulatory requirements applicable to prescription drugs. The Board may adopt regulations "to carry out the provisions of" the PDAB statute—not to exceed or expand them.[14]

The Board's recent actions far exceed the scope of this statutory authority in at least three main ways. First, the Board has vaguely introduced, through its UPL Action Plan which the Proposed Amendments incorporate,[15] the notion of "policy options" or alternatives other than setting a UPL upon a finding of affordability challenges.[16] The UPL Action Plan states:

> If the Board determines that a prescription drug product has led or will lead to affordability challenges, the Board may consider, recommend, and implement policies to address those affordability challenges, including establishing an upper payment limit ("UPL") that applies to state and local governments and units . . . . However, because a UPL may not be the preferred policy solution for every affordability challenge, the Board may recommend other policy actions. Board policy actions may include seeking additional legislative authority to implement a policy solution and providing policy recommendations to the legislature, state and local government partners, and others to address the affordability challenges identified in the cost review study.[17]

At its September 10, 2024 meeting, a PDAB member similarly stated that "UPL is one thing we can use [to address a perceived affordability challenge] but we can do other things …."[18]

To the contrary, the Board has no statutory authority to adopt or implement any "policy solution" other than setting a UPL as permitted by the statute. While the Board has acknowledged that a UPL will not be the appropriate policy for many products, and it may make recommendations on possible future legislation, any attempt to pursue non-UPL policy solutions would violate current Maryland law delineating and limiting the scope of the Board's authority. Even the Board's power to make recommendations is limited: the PDAB statute permits the Board to comment generally on "further legislation needed to make prescription drugs more affordable in the State," not to consider or recommend non-UPL options targeting specific drugs.

Second, nothing in the PDAB statute authorizes the Board to make a bifurcated affordability determination—*i.e.*, one for (1) eligible State government entity utilization and a separate one for (2) all other utilization, including payments and reimbursements by commercial payors. The Board is only authorized to evaluate "affordability challenges for the State health care system or high out-of-pocket costs for patients," not affordability challenges for commercial

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14 *Id.* § 21–2C–03(f)(1).

15 As the minutes from the PDAB's September 10, 2024 meeting state, the Proposed Amendments "include … additional amendments to allow for the cost review study process to incorporate the Policy Review Process outlined in the UPL Action Plan." Maryland Prescription Drug Affordability Board, September 10, 2024 Meeting Minutes, at https://pdab.maryland.gov/Documents/meetings/2024/2024.09.10%20Meeting%20Minutes.pdf.

16 UPL Draft Action Plan at 1 (Sep. 10, 2024).

17 *Id.* (emphasis added).

18 Video of September 10, 2024 PDAB Meeting, at https://www.youtube.com/watch?v=Q18vKKSd3_s (starting at 1:02:36).

payors.[19] Similarly, any UPL set by the Board expressly applies only to purchases and reimbursements by eligible State government entities. In this context, there is no basis for the Board to make affordability determinations with respect to purchases or reimbursements by commercial payors, because such affordability determination is the threshold finding required for further Board action. The Board cannot create new categories of "next steps" where the Maryland PDAB statute is silent, and any such affordability determination would exceed the Board's statutory authority in violation of Maryland law.

The Board's apparent intention to conduct bifurcated cost reviews and make bifurcated affordability determinations for government and commercial payors is also procedurally invalid. The PDAB statute expressly requires the Board to "provide the public with the opportunity to provide written comments on pending decisions of the Board."[20] Maryland's APA likewise requires agencies to seek public comment before adopting new substantive policies or regulations.[21] These procedures are designed "to afford fair notice and a meaningful opportunity to comment to all persons who may be affected by the proposed regulation."[22] And Maryland courts have held that, for a regulation to be valid, the agency must act "within the confines of traditional standards of procedural and substantive fair play."[23] If the Board intends to conduct bifurcated cost reviews and make bifurcated affordability determinations—which it presumably does, given its ongoing interest in data and information that is not relevant for a determination of affordability in the context of UPL-eligible utilization—its attempt to do so without notice and comment violates these settled requirements.

Third, the Proposed Amendments state that the Board, in conducting a cost review study, will consider an "[a]nalysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product."[24] This proposed change appears to vastly expand the Board's role to cover compliance with literally *all* federal and state laws relating to prescription drugs the Board is evaluating under cost review—something the Board has no power whatsoever to do, and has established no meaningful framework for doing. Under the PDAB statute, none of the "factors to consider when conducting cost review"[25] could reasonably be read to include "state and federal regulatory and compliance issues" writ large. The Board has provided no foundation as to how this factor could even be linked to affordability challenges for the State health care system or high out-of-pocket costs for patients, nor any guidance for how it would be evaluated and incorporated in any methodology. The PDAB statute does not give the Board anywhere near this breadth of regulatory or investigative mandate. On the contrary, the statute focuses exclusively on aspects of a drug's costs with no mention of regulatory or compliance issues. It also is unclear whether "state and federal regulatory and compliance issues" could encompass issues raised by other regulators or entities but not yet adjudicated. Any attempt by the Board to take action on the basis of such allegations would raise grave due process concerns, in addition to unlawfully

19 Md. Health Gen. § 21–2C–09(b)(1).
20 *Id.* § 21–2C–03(e)(5).
21 Md. State Gov't Code Ann. § 10-111.
22 *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 711 A.2d 158 (1998).
23 *Fogle v. H & G Rest., Inc.*, 337 Md. 441, 654 A.2d 449 (1995).
24 COMAR 14.01.04.05(C)(1)(g)(xiii) (proposed).
25 Md. Health Gen. § 21–2C–09(b).

exceeding the scope of the Board's mandate under the PDAB statute. The Board should strike this factor.

II. The Proposed Amendments Introduce a Host of Vague and Ill-Defined Considerations That Eliminate Any Potential Predictability in Cost Reviews and Invite Arbitrary Affordability Determinations That Would Not Serve the Public Interest

Contrary to the Board's assertion, the Proposed Amendments are more than mere "technical corrections" to the existing cost review regulations.[26] Rather, the Board is proposing substantial changes that introduce multiple vague and open-ended considerations, seemingly authorizing the Board to consider any data or factor it wants in conducting cost reviews. This use of "catchall" considerations eviscerates the purpose of enumerating factors in the PDAB statute and existing cost review regulations. For these reasons, AbbVie urges the Board not to adopt the Proposed Amendments and instead to engage with stakeholders to establish a clear set of considerations and data reviews for cost reviews and meaningful standards to govern the ultimate affordability determinations.

A. The Board Proposes to Add Vague Factors Without Meaningful Standards

Under Maryland's APA, an agency's decision or action is unlawful if it is "arbitrary and capricious."[27] This requires agencies to engage in reasoned decision-making, and an agency acts arbitrarily and capriciously "when decisions are made impulsively, at random, or according to individual preference ***rather than motivated by a relevant or applicable set of norms***."[28] Agencies must consider relevant information and factors and make their decisions according to objective standards.[29] Courts have invalidated agency decisions and actions where the agency considered irrelevant factors, failed to identify the factors guiding its determination, or failed to identify objective standards governing its decisions.[30]

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[26] Maryland Register, Emergency Action on Regulations, Document No. 24-136-E (Filed with AELR Committee on September 16, 2024), at https://mgaleg.maryland.gov/pubs/committee/AELR/24-108E-Regulation.pdf.

[27] Md. Code, State Gov't §§ 10-222(h)(3)(vi).

[28] *Harvey v. Marshall*, 389 Md. 243, 299, 884 A.2d 1171, 1205 (2005) (emphasis added); *see also id.* (stating that agency actions must be "reasonable [and] rationally motivated"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that agency action is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise").

[29] *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").

[30] *Walker*, 238 Md. 512, 523, 209 A.2d 555, 561 (upholding that the Department's *ad hoc* decision to deny a permit application was arbitrary); *Maryland Real Estate Comm'n v. Garceau*, 234 Md.App. 324, 365, 172 A.3d 496,

By introducing multiple vague and open-ended considerations in the cost review process (as detailed below), the Proposed Amendments eliminate any potential predictability in this process and invite arbitrary and capricious affordability determinations.

1. Proposed COMAR 14.01.04.05(B)(2)(f), "Analyses and Data Compilation" is vague, unpredictable and lacks accountability.

Under the current Cost Review Study Process regulations, the Board may consider "data and analyses" that are "[d]erived from the [Maryland Claims Data Base (MCDB], any claims set of the MCDB, and other databases."[31] The Proposed Amendments would broaden this clause to include "*any* other database *containing relevant information*."[32] This is an example of the type of vague new language that appears designed to remove any limitation of the data sources the Board may consider. If there are data sources the Board wants to consider that are outside the scope of the existing regulation, the Board should identify them and revise the regulation to cover them specifically. As currently drafted, there do not seem to be any limits on what additional information the Board is proposing to consider—"any" database with "relevant" information does not enable any meaningful standards or guardrails.

2. Proposed COMAR 14.01.04.05(B)(2)(h), "Analyses and Data Compilation" is vague, unpredictable and lacks accountability.

As detailed in our prior comment letters,[33] AbbVie already has serious concerns about the veracity of the data and information the PDAB relied upon to select SKYRIZI® for cost review. Allowing the Board broader latitude to consider data and analyses "[d]erived from quantitative and qualitative data collected by Board staff[]" further exacerbates these concerns. Again, "quantitative and qualitative data" is vague and open-ended, and the absence of any specificity seems to give the Board carte blanche to consider any data it wants. The Board should identify and explain the sources of "quantitative and qualitative data" that Board staff will collect, and that the

521 (finding the Commission's sanction was arbitrary and capricious because it failed to consider exculpatory factors in its decision); *see Cnty. Council of Prince George's Cnty. V. Palmer Road Landfill, Inc,* 247 Md. App. 403, 419, 236 A.3d 766, (Md. Ct. Sp. App. 2020) (reversing a time limitation that the Council initially "waived and failed to abide themselves" but later sought to enforce); *Forman v. Motor Vehicle Admin.*, 332 Md. 201, 220, 630A.2d 753, 763 (1993) (reversing license revocation because agency failed to indicate what it found or how it reached the conclusion with respect to material issues); *Dashiell v. Maryland State Dept. of Health and Mental Hygiene*, 327 Md. 130, 137-38 (Md. Ct. App. 1992) (finding the Department's decision to terminate two employees were so unsupported that it renders the determination "essentially arbitrary and capricious").

[31] COMAR 14.01.04.05(B)(2)(f).

[32] COMAR 14.01.04.05(B)(2)(f) (proposed new text in italics).

[33] *See, e.g.*, *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf; AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf; AbbVie's Comments on the Board's List of "Therapeutic Alternatives" for SKYRIZI® (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf; AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf.

Board may consider in its cost reviews. The Board also should explain what it means by "qualitative" in this context.

Illustrating the problem, the Board has yet to provide any verifiable, objective information for its selection of SKYRIZI® for cost review, and it should not be granted even broader flexibility to consider unspecified "quantitative and qualitative data" from unidentified sources. Indeed, this excerpt from an opinion piece published by Board member Gerard Anderson, Ph.D., on October 22, 2024 exemplifies why the factors and data evaluated by the PDAB in connection with its cost reviews must be subject to meaningful guardrails:[34]

> The board selected the first six drugs based on multiple criteria, but one of the most important was the cost of the drug. There are six drugs on the initial list. These are all very expensive drugs that you see being advertised in newspapers, on TV and in social media every day. The data shows they have high out-of-pocket costs for each individual patient and for all patients. The data I reviewed as a member of the Maryland PDAB shows that the Medicaid program is paying significant amounts for each of these six drugs and the state is paying a large amount for each of these drugs to provide health insurance for state and county employees.

This Board member's views highlight several issues we have repeatedly raised with respect to the Board's activities, as well as why the vague and undefined proposed new regulations will not result in proper implementation of the statute. These conclusory statements ignore actual SKYRIZI® data AbbVie submitted to the Board well before publication of this opinion piece demonstrating that the product is affordable for patients, including patients in Maryland.[35] It is unclear how or why the Board selected SKYRIZI® for cost review despite this data, or even what standard the Board applied in making that determination. The Proposed Amendments make the situation even less clear.

3. Proposed COMAR 14.01.04.05.C(1)(g)(xv), "Factors Considered in Cost Review Study, Additional Board Factors" is vague, unpredictable and lacks accountability.

The Proposed Amendments would also allow the Board to review the "[i]mpact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks[.]"[36] This factor is vague and overly broad. What "public budgets" and "relevant benchmarks" is this referring to? The Board provides no further clarification. The Board should not proceed with finalizing any such regulation

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[34] Gerard F. Anderson, Commentary, "Cost cannot be ignored by drug board – just ask the patients who can't afford prescriptions," Maryland Matters (October 22, 2024), at https://marylandmatters.org/2024/10/22/cost-cannot-be-ignored-by-drug-board-just-ask-the-patients-who-cant-afford-prescriptions/.

[35] *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf.

[36] COMAR 14.01.04.05 (C)(1)(g)(xv) (proposed).

without providing more clarity as to which benchmarks will be evaluated, and then allowing for appropriate notice and comment to inform that consideration, which is anything but "technical."

4. Proposed COMAR 14.01.04.05(B)(2)(g), "Analyses and Data Compilation" is vague, unpredictable and lacks accountability.

Under the current regulation, the Board may consider data "[d]erived from reports generated by U.S. governmental entities, foreign governmental and quasi-governmental agencies, and U.S. and foreign non-profit organizations."[37] A proposed amendment would allow the Board also to consider "reports generated by . . . State governmental entities."[38] It is unclear whether this includes other States besides Maryland, and if so which ones. As stated in our prior comment letters to the Board, AbbVie believes that the Board should determine "affordability" solely as to Maryland state and local governmental entities to which a UPL would apply. The Board should not consider "affordability" in any other jurisdiction or as to any entities to which a UPL would not apply.

In addition, it would be inappropriate for the Board to consider data derived from other states' price transparency laws during Maryland's cost review process. Differing state laws requiring manufacturers to report pricing information have different underlying legal standards, and different instructions or reporting requirements. When a manufacturer submits information to another state to comply with that state's law, that compilation of information is tailored to address that specific state law, in response to that state's specific questions. Moreover, state price transparency laws also have different jurisdiction-specific confidentiality standards and restrictions to protect confidential, proprietary, and trade secret information. It would be inconsistent with those state laws for the Board to access or consider such information.

Finally, we reiterate that it is wholly inappropriate for the Board to consider drug prices outside the United States when conducting a cost review (or setting the UPL). As we have stated in our prior comments to the Board, other countries have pricing and reimbursement regimes that are not market-based or governed by U.S. healthcare laws, and their healthcare systems and policies do not match those found in the U.S. or any individual state or territory. These prices are not a relevant consideration for pricing in the U.S. and using them to set a UPL would raise significant Constitutional concerns.

B. The Proposed Amendments Compound the Lack of Clarity Regarding the Board's Identification and Consideration of "Therapeutic Alternatives"

As expressed in our prior comment letters, AbbVie continues to have concerns with the Board's consideration of therapeutic alternatives. There is a lack of clear standards on how the Board would determine alternatives and the lack of transparency as to the information and input the Board is considering when making such determinations. Proposed COMAR 14.01.04.05(C)(1)(c)(iii) would compound existing issues by adding reference to "[t]he utilization, costs, and out-of-pocket costs for therapeutic alternatives." The PDAB, however, has yet to establish clear standards to ensure that only appropriate alternatives are considered, leaving the Board free to identify therapeutic alternatives in a standardless vacuum. Any consideration of

[37] COMAR 14.01.04.05(B)(2)(g).
[38] COMAR 14.01.04.05(B)(2)(g) (proposed).

therapeutic alternatives should be based exclusively on clinical appropriateness within the same class and mechanism of action and should not consider the costs of therapy of other drugs. The Board should consider whether a potential therapeutic alternative is medically appropriate for the same group of patients as the selected drug, as supported by widely accepted and updated clinical guidelines, real-world practice, and evidence-based medicine. Likewise, the Board should clarify, and be transparent about, the data, information, and resources it uses to select therapeutic alternatives, which it should do from within appropriate drug classes.

As AbbVie has expressed in prior comment letters, the Board's methodology with respect to rulemaking, the cost review process, and the UPL-setting process has lacked transparency at every step. Any such lack of transparency would be extremely concerning as the Board's selection of therapeutic alternatives. The Board has no justification for not sharing pertinent information about how it will select therapeutic alternatives, including what sources were used, what experts were consulted, and why it looked outside the relevant drug class, if indeed it did. Any methodology the Board is applying should be transparently communicated to the public during the Board's review process and should be open for comment to ensure reasoned decision-making informed by robust and balanced information. Moreover, stakeholders should be able to provide input and ask questions about the Board's consideration of therapeutic alternatives. The Proposed Regulations do not allow for such participation, seemingly resulting in further opacity for AbbVie and other manufacturers.

C. The Proposed Amendments Do Not Explain How Data Will Be Weighted in Cost Reviews or Provide for Adequate Consideration of Patient Out-of-Pocket Costs

Beyond their introduction of vague, unspecified new data sources, the Proposed Amendments still are silent on how any data the Board considers will be weighted during the cost review process. Both the existing and proposed Cost Review Study Process regulations lack any specific, concrete, or meaningful procedures and standards that explain how the Board intends to make use of the information it obtains from these disparate sources, including how information will be weighed, compared, and considered both independently and relative to other information and factors considered by the Board. The opacity raises significant concerns about whether the cost review will be consistently applied across different products and different manufacturers, and whether it is appropriately grounded in the statutory factors. AbbVie requests that the Board establish a consistent and transparent cost review process, allowing manufacturers and other stakeholders a clear understanding of the process and the standards that will govern the Board's ultimate determination of whether a drug poses affordability challenges.

Lastly, we repeat our concern stated above that the Board still has not satisfied the statutory directive to consider, in conduct a cost review, patients' out-of-pocket costs—that is, "[t]he average patient copay or other cost–sharing for the prescription drug product in the State …."[39] The Proposed Amendments provide no further clarity on how, if at all, the Board will consider patient out-of-pocket costs.

[39] Md. Health Gen. § 21-2C-09(b)(2)(x).

III. The Board's Attempt to Adopt the Proposed Amendments Through "Emergency Action" Is Baseless and Unlawful Because There Is No Plausible Emergency

In addition to the Proposed Amendments' serious substantive flaws, the Board's attempt to adopt them through "emergency action" illustrates its disregard for proper process and informed decision-making. Emergency action is only appropriate when there is an emergency or exigency, and the Board has failed to adequately explain what conceivable emergency justifies such haste here. In fact, over four years since the Board was established, there is no plausible emergency and thus no legitimate basis for emergency action. The Board should follow ordinary procedures that allow full public participation and agency deliberation and should thus withdraw its request for emergency approval of these Proposed Amendments from the General Assembly's Joint Committee on Administrative, Executive & Legislative Review (the "AELR Committee").

During an October 28, 2024 meeting, PDAB staff stated that the Board was seeking emergency approval from the AELR Committee so that the Board could utilize these new cost review procedures at its next meeting, which was scheduled for November 25, 2024. During the October 28, 2024 meeting, certain Board members appeared to express concern with this process, and discomfort with the pace, as well as the lack of clear information on the timing of the regulations. The Board's concern with this process is correct—rushing through emergency rulemaking, when there are no exigent circumstances, is inconsistent with the Maryland APA and the public's interest in proper notice-and-comment rulemaking.

In general, Maryland law requires agencies to conduct notice-and-comment rulemaking to "give the agency free-flowing information from a broad range of interests."[40] Administrative law recognizes both the centrality of the comment process to an agency's activities and the necessity of providing members of the public with the information they need to meaningfully comment.[41] Under the Maryland APA, agencies may take emergency action to bypass the notice-and-comment process in very limited circumstances. An agency may adopt a regulation "immediately" only if the agency: (i) "declares that the emergency adoption is necessary"; (ii) "submits the proposed regulation to the [AELR Committee] and the Department of Legislative Services," together with a fiscal impact statement; and (iii) "has the approval of the [AELR Committee] for the emergency adoption."[42]

The Act details the process for the AELR Committee to approve an emergency regulation.[43] As the AELR has explained, emergency regulations are appropriate only if there are "exigent circumstances." The AELR's Regulation Review Process document states: "Emergency

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40 *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc*., 350 Md. 104, 123 (1998).

41 *See* 75 Op. Atty Gen. Md. at 43 (Jan. 23, 1990) ("[T]he heart of an APA's rulemaking requirements is its public notice and comment procedures. Designed to assure fairness and mature consideration of rules of general application, these significant provisions serve the important twin functions of safeguarding public rights and educating the administrative lawmakers."); *Conn. Light and Power Co. v. Nuclear Reg. Com'n*, 673 F. 2d 525, 530–31 (D.C. Cir. 1982) (construing the federal Administrative Procedure Act, 5 U.S.C. § 553(b)(3)) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."); Md. Bar Ass'n, Practice Manual for the Maryland Lawyer, ch. 3, Administrative Law § 5 (6th Ed. 2023) (Maryland courts generally "seek to harmonize Maryland common administrative law and Maryland APA interpretation with federal administrative law").

42 Md. Code Ann. § 10-111(b)(1).

43 Md. Code Ann. § 10-111(b)(2)-(3).

regulations, which bypass the normal public notice and comment period, remain in effect for a limited period of time – not to exceed 180 days – to meet ***exigent circumstances***."[44] The AELR Committee shall impose, as part of its approval, a time limit not to exceed 180 days on each request for emergency status.[45] If the agency proposing the emergency regulation does not adopt the regulation (through normal procedures) during this 180 day period, the regulation reverts to its status before the emergency adoption.

Although the Department of Legislative Services has analyzed the Board's request for emergency action on the proposed amendments to the Cost Review Regulations, neither the Board nor the Department have adequately explained why emergency action is warranted here. In its September 16, 2024 request for emergency action, the Board explained the reason it was invoking emergency action as follows:

> "Six drugs are subject to study under the existing cost review study procedures. The Board seeks to amend COMAR 14.01.04.05 on an emergency basis to make certain technical corrections, and to authorize the Board to consider certain information relevant to the completion of the cost review studies. The amendments also establish procedures for a preliminary affordability challenge determination and report, with an opportunity for public comment, that aligns with the proposed policy review and upper payment limit procedures. Emergency approval of these amendments, which are also submitted as a proposed action for notice and comment, will allow the Board to continue to work expeditiously through the cost review study procedures."[46]

The Board has requested the AELR Committee approve the Board' request for emergency action on the proposed amendment to the Cost Review Regulations, with emergency status beginning on October 1, 2024 and expiring March 30, 2025.[47] In its analysis, the Department of Legislative Services repeats the Board's stated reasons for pursuing emergency action, but does not explain why this justification constitutes an exigency. In relevant part, the Department of Legislative Services analysis states:

> The board requests emergency status beginning October 1, 2024 and expiring March 30, 2025. This emergency period is within the normal time frames approved by the Joint Committee on Administrative, Executive, and Legislative Review. The board indicates the emergency status is necessary to make certain technical corrections and to authorize the board to consider certain information relevant to the completion of the cost review studies of the six drugs currently subject to study. The regulation also establishes procedures for a preliminary affordability challenge determination and report, with an opportunity for public comment, that aligns with

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[44] Maryland General Assembly, Department of Legislative Services, "AELR Regulation Review Process, at https://mgaleg.maryland.gov/pubs-current/aelr/AELR-Regulation-Review-Process.pdf (emphasis added).

[45] Md. Code Ann. § 10-111(b)(4)(ii).

[46] Maryland General Assembly, Department of Legislative Services, Emergency Action on Regulations, Document No. 24-136-E (September 16, 2024), at https://mgaleg.maryland.gov/pubs/committee/AELR/24-108E-Regulation.pdf.

[47] Maryland General Assembly, Department of Legislative Services, Emergency/Proposed Regulation Analysis DLS Control No. 24-108, at https://mgaleg.maryland.gov/pubs/committee/AELR/24-108E-Analysis.pdf.

> the proposed policy review and upper payment limit procedures. The board advises that emergency approval of the regulation will allow the board to continue to work expeditiously through the cost review study procedures.[48]

In a cursory, conclusory analysis, the Department of Legislative Services also expressed the view that the Proposed Amendments "present[] no legal issues of concern."[49] As these comments make clear, that statement is incorrect; the Proposed Amendments present multiple legal issues of significant concern. The Department's assertion that the Proposed Amendments have "minimal or no impact on small businesses in the State" is similarly conclusory and highlights the critical need for the Board to receive input on proposed regulations *before* they are adopted.[50]

None of the proffered rationales can justify emergency action here. For one, the Board's stated desire to "work expeditiously" is an insufficient and unjustified basis for seeking to take emergency action. While Maryland courts have not addressed attempts to invoke emergency regulations based solely on a desire to act "expeditiously," the Maryland federal district court ruled against precisely this rationale in rejecting a federal agency's attempt to bypass notice-and-comment procedures and adopt a proposed regulation immediately.[51] In 2020, amidst the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Studies (CMS) sought to rush through an "emergency" rule regarding drug pricing.[52] The court held that no "good cause" justified emergency action, rejecting the agency's argument that "the rising cost of drug prices and the economic consequences of the COVID-19 pandemic" justified "dispensing with the required procedures."[53] As the court explained, notice-and-comment procedures are "essential to ensuring civic participation in the rulemaking process as well as informed agency decisionmaking."[54] And,

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[48] Maryland General Assembly, Department of Legislative Services, Emergency/Proposed Regulation Analysis DLS Control No. 24-108, at https://mgaleg.maryland.gov/pubs/committee/AELR/24-108E-Analysis.pdf.

[49] Maryland General Assembly, Department of Legislative Services, Emergency/Proposed Regulation Analysis DLS Control No. 24-108, at https://mgaleg.maryland.gov/pubs/committee/AELR/24-108E-Analysis.pdf.

[50] *See, e.g.*, Coalition of State Rheumatology Organizations, Comment, Re: New Chapter – COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 7, 2024) (explaining that the Board's methodology does not account for the acquisition costs of independent medical practices); Healthcare Distribution Alliance, Comment, COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 8, 2024) (explaining that the Board's methodology will reduce the ability of independent pharmacies to maintain overhead and will likely lead to consolidation or closures within the pharmacy community); National Association of Chain Drug Stores, Comment, Re: COMAR 14.01.05 (November 8, 2024) (noting that the Board's methodology may result in adequate or below-cost reimbursement to community pharmacies); Maryland/District of Columbia Society of Clinical Oncology, Comment, Re: Draft Proposed Regulation COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (November 7, 2024) (explaining that the Board's proposed methodology will impose "a large financial burden" on independent oncology practices). *See also* Julie A. Patterson, et al., *Unanswered Questions And Unintended Consequences Of State Prescription Drug Affordability Boards*, Health Affs. (June 5, 2024), https://www.healthaffairs.org/content/forefront/unanswered-questions-and-unintended-consequences-state-prescription-drug-affordability ("Provider reimbursements would likely decline and potentially lead to reimbursements below acquisition costs if UPLs are set below ASP, which may disproportionately impact smaller practices and contribute to existing trends in practice consolidation or shifts to higher reimbursed treatments.").

[51] Maryland courts generally "seek to harmonize Maryland common administrative law and Maryland APA interpretation with federal administrative law." Md. Bar Ass'n, Practice Manual for the Maryland Lawyer, ch. 3, Administrative Law § 5 (6th Ed. 2023).

[52] 85 Fed. Reg. 76180.

[53] *Association of Community Cancer Centers v. Azar*, Case No. 1:20-cv-03531-CCB, at 3 (D. Md. Dec. 23, 2020).

[54] *Id.* at 29.

the court found, "an agency may not dispense with notice and comment procedures ***merely because it wishes to implement what it sees as a beneficial regulation immediately***. Agencies presumably always believe their regulations will benefit the public. If an urgent desire to promulgate beneficial regulations could always satisfy the requirements of the good cause exception, the exception would swallow the rule and render notice and comment a dead letter."[55] The same is true here. Allowing emergency regulations whenever an agency wants to "work expeditiously" would trample the rights of impacted stakeholders and undermine informed agency decision-making.

Nor does the Board's characterization of the Proposed Amendments as a mere "technical correction" justify emergency action. Even if agencies could bypass notice-and-comment procedures to make purported technical corrections to existing regulations (which the Maryland APA does not allow), the proposed changes to the Board's existing cost review regulation are far from mere technical corrections. As explained above, the proposed changes would vastly expand the scope of the Board's statutory authority in violation of Maryland law, and they introduce a host of vague factors that lack meaningful standards for the Board to apply in conducting cost reviews.

In sum, there is no basis to adopt these Proposed Amendments through emergency action, and the Board should withdraw its request to the AELR Committee for emergency approval. It is critical that the Board take the time to consider stakeholders' views before establishing its cost review and UPL-setting policies.

* * * *

Thank you for this opportunity to provide comments on the Proposed Amendments to the Cost Review Regulations. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

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

[55] *Id.* at 19 (emphasis added).

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VIA Electronic Delivery

December 2, 2024

Mr. Van Mitchell, Chair

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

Re: Maryland Prescription Drug Affordability Board Draft Proposed Regulations- COMAR 14.01.04 Cost Review Study Process, Emergency Action

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 Proposed Regulations- COMAR 14.01.04 Cost Review Study Process, Emergency Action (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.

As we have stated in previous comments, BIO remains concerned that the data and information used to inform the Board's cost review process does not accurately reflect the prices that patients pay for drugs, nor do they encompass the continuously evolving dynamics within the supply chain. It is problematic that the Board continues to rely on misguided and often inappropriate factors in the cost review study, including data from international reports. While the Board continues to inform on its stated goal of examining "affordability challenges for the State health care system or high out-of-pocket costs for patients," it is evident that manufacturers do not have visibility to patient costs for purchasers or payors. BIO continues to urge the Board to ensure that the cost review process is accurate and transparent so that the Board's decisions are fair, evidenced-based, and aligned with the realities faced by patients to support their access to necessary therapies.

Analyses and Data Compilation

The Draft Regulation states that data and analyses used in the cost review study "may be derived from the MCDB, and any other databases containing relevant information" as well as "any quantitative and qualitative data collected by Board staff." BIO is concerned about the

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Board's potential use of the MCDB, which calculates net costs using pharmacy allowable cost reported, rather than true net plan costs. Using the MCDB would therefore result in a flawed and inaccurate reflection of net costs. Similarly, it is concerning that this overly broad language does not provide any definitions or guardrails around what is considered "quantitative" or "qualitative data." Without a clear distinction of the types of information that will be used, the language gives the Board carte blanche to consider any information, which could result in arbitrary and capricious findings. It is critical that appropriate guidelines and stakeholder input be considered in lieu of unrestricted data selection, which could otherwise result in the Board utilizing incomplete, outdated, or inaccurate information to support the Board's predetermined outcomes.

The Draft Regulation also states that data and analyses may be derived from reports generated by "foreign governmental and quasi-governmental agencies" and "foreign non-profit organizations." As BIO has stated in previous comments, international drug markets are extremely different than the United States, with different overall healthcare systems, market sizes and conditions, such as purchasing power, competition or negotiation practices, healthcare expenditures, cost of living, currency exchange rate fluctuations, and other differences in pricing structures. Further, most countries outside the United States use discriminatory measures of value, such as QALY analysis, to assist in price setting. It is evident that using data and analyses from foreign sources for the cost review ignores the stark differences between healthcare systems and puts America's innovative medicine pipeline at risk.

Factors Considered in Cost Review Study

Within the factors considered in the cost review study, the Draft Regulation states that the Board will consider "the average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives," However, the Board does not provide any source as to where they will receive this payer discount information, potentially resulting in the use of incomplete or inaccurate data rather than true net costs. Without a complete and accurate account of net cost, a drug could potentially be triggered for selection solely based on high utilization, even if the drug is highly discounted. Further, the Draft Regulation references potential metrics including "WAC, AWP, NADAC, SSAC, ASP, and FSS at which each therapeutic alternative has been sold in the State." BIO is concerned that these metrics are significantly misleading and would provide the Board with an inaccurate interpretation of pricing data. The National Average Drug Acquisition Cost, or NADAC, and the State Actual Acquisition Cost, or SSAC, both measure pharmacy acquisition costs and are based on incomplete surveys of participating pharmacies. These metrics evidently reflect pharmacy purchases rather than manufacturer pricing and are therefore inappropriate for the Board to consider.

BIO also opposes the use of Average Wholesale Price, or AWP, within the cost review, as it overlooks patient OOP costs and the negotiated discounts, rebates, and other price adjustments within the supply chain. BIO is concerned that utilizing AWP would not account for the complexities of market dynamics, potentially leading to flawed assessments that could devalue a drug's importance and fail to acknowledge key patient access

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considerations. Similarly, BIO is concerned that the use of Federal Supply Schedule or FSS as a metric may result in pervasive under-reimbursement and discouraging utilization.

Finally, BIO urges the Board to consider the use of cost offsets within its factors for consideration in the cost review study, including long-term savings for individual patients, their families, and the broad healthcare system. It is disheartening that the Board's consideration of "affordability challenges" has not considered the societal burden of living with a rare disease, including but not limited to missed school and work for the patient and caregivers. Meanwhile, a drug's potential unprecedented benefits to patients include improved overall physical and psychological well-being, improved functional abilities, the ability to return to productive and fulfilling lives, the eliminated or reduced need for chronic therapy, the relieving of caregiver burden, and other clinical and secondary impacts, which may translate to long term cost offsets. The value of therapies may span a lifetime and result in significant cost offsets such as reducing hospitalization and other healthcare utilization, productivity gains, and even savings from non-medical costs associated with early retirement, caregivers, underemployment, and other situations. Even entities such as the Congressional Budget Office have long recognized and utilized cost offsets in their scoring methods. BIO strongly encourages the Board to add cost offsets under (g) Additional Board Factors, to appropriately value the benefits received by patients of a given drug.

***

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.

/s/

Melody Calkins
Director
Health Policy and Reimbursement

PhRMA
RESEARCH • PROGRESS • HOPE

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By Electronic Submission

December 2, 2024
Maryland Prescription Drug Affordability Board
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comments.pdab@maryland.gov

RE: Proposed Regulation – Amendments to COMAR § 14.01.04.05 (Cost Review Study Process)

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the proposed amendments to Code of Maryland Regulations ("COMAR") § 14.01.04.05 (the "Proposed Regulation"), which were published in the Maryland Register on November 1, 2024.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser 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 recognizes the Board's ongoing work to carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA continues to have concerns, however, about the Board's implementation of the PDAB Statute, including the additional processes and considerations described in the Proposed Regulation.[3] PhRMA addresses its specific questions and concerns regarding the Proposed

[1] *See* Proposed Regulation at COMAR 14.01.04.05 (Cost Review Study), *available at* https://pdab.maryland.gov/Documents/regulations/14.01.04.05%20Amended_Cost_Review_Study_Corrected_Final_Emergency.pdf.

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

[3] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the constitutionality of the Maryland PDAB statute and all other legal arguments regarding the PDAB statute and its implementation. 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* Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter – COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 2022).

Regulation below.[4]

I. Board Determinations

PhRMA is concerned that the Proposed Regulation lacks specificity on how the Board will determine affordability challenges, as well as and a concrete and specific methodology for how those determinations will be made in a consistent manner. We provide below the following non-exhaustive list of issues for the Board's consideration.[5] We ask that the Board revise and re-issue its Proposed Regulation:

- **Consideration of Out-of-Pocket Costs.** The Proposed Regulation would add that, as part of the determinations made in the cost review study process, the Board may "*[i]dentify the circumstances under which the prescription drug product has or will lead to ... high out-of-pocket costs to patients under §A(1) of this regulation*."[6] Consistent with our recommendations in prior comment letters,[7] PhRMA emphasizes that the Proposed Regulation should be revised to require the Board to consider all factors that are driving high out-of-pocket costs, specifically including benefit design choices and fees, rebates, and other price concessions paid by drug manufacturers to pharmacy benefit managers ("PBMs") and plans that are not shared directly with patients.[8] These factors are outside of the manufacturers control and can be significant contributors to patients' out-of-pocket costs; they should be given appropriate consideration in the cost review process, as they directly bear issues on patient affordability. Additionally, PhRMA remains concerned with any potential comparison of net costs and out-of-pocket costs before taking rebates or other discounts into consideration.[9] Out-of-pocket costs are impacted by benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment, and copay maximizer programs) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance carriers that are not shared directly with patients. PhRMA requests that the Proposed Regulation be revised to require the Board to take the impact of benefit design on out-of-pocket costs into consideration, and that the Board identify a specific methodology for verifying the accuracy of this information.[10]

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[4] As previously stated, PhRMA reiterates concerns that the Proposed Regulation do not provide the "quasi-judicial" protections that are required under the Maryland Administrative Procedure Act ("APA"). Under the Maryland APA, agency hearings implicating a statutory (or constitutional) right, duty, entitlement, or privilege are considered contested cases and are subject to various procedural requirements, including rights to a hearing conducted by an agency head or Administrative Law Judge; reasonable notice of the agency's action and the hearing; trial-like protections for the hearing process; and judicial review. *See* Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024). Additionally, PhRMA remains concerned with the sequences of addressing affordability challenges and calculating Upper Payment Limit ("UPL") amounts before a final decision is made that a prescription drug has or will lead to affordability challenges. *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024).

[5] Proposed COMAR § 14.01.04.05(A).

[6] *Id.* § 14.01.04.05(A)(3) (added text in the Proposed Regulation is italicized).

[7] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023).

[8] *See id.*

[9] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023).

[10] PhRMA asks that any revisions to the Proposed Regulation be subject to additional notice-and-comment rulemaking, in order to provide stakeholders with an opportunity to review and comment on any further process or methodology elements that the Board may propose.

- **Determination of Future Affordability Challenges.** As part of the cost review study process, the Board also proposes that it may "*[i]dentify the circumstances under which the prescription drug product has or will lead to an affordability challenge*."[11] PhRMA recommends that the Proposed Regulation be revised to provide details on how the Board would make these determinations and the data that the Board would use, particularly with respect to circumstances that the Board determines "*will lead*" to an affordability challenge. The Board should revise its Proposed Regulation to provide specifics on how the Board will make these determinations, especially with respect to drugs that the Board believes "will lead" to an affordability challenge at some point in the future.[12] In the absence of clearer standards, PhRMA is concerned that identification of affordability challenges that may occur in the future will be speculative and could result in arbitrary determinations by the Board.

- **Data Review Process.** As PhRMA has noted in its prior letters, the Board's cost review process requires voluminous data from different sources, which could result in data being inaccurate, incomplete, or misleading.[13] PhRMA recommends that the Board revise its Proposed Regulation to add a process that allow manufacturers an opportunity to review, evaluate, confirm, and confer with the Board about the data that it is relying on before the Board renders any final decisions on the basis of that data. Consistent with PhRMA's prior comment letters, we also ask that such review protect confidential, proprietary, and trade secret information as required by federal and state law.[14]

II. Analyses and Data Compilation

PhRMA is concerned that the additional "Analyses and Data Compilation" described in the Proposed Regulation does not provide specific processes and methodology for how such data will be compiled and analyzed. Among other things, the Proposed Regulation does not specify the data sources the Board intends to make use of, or the specific methodologies for using that data, making it unclear how the Board intends to verify the accuracy of the information it relies.[15] PhRMA provides the following non-exhaustive list of specific issues and asks that the Board revise its Proposed Regulation to address our concerns:

- **Databases Containing Relevant Information.** The Proposed Regulation would add language allowing the Board staff to assemble "data and analyses" for the Board's consideration from "*any other* databases *containing relevant information*."[16] PhRMA is concerned that this language does not provide any clear indication of which specific databases the Board staff may draw from, and could provide the Board with undue discretion in the data sources it uses.[17] PhRMA asks that the Board revise the Proposed Regulation be to identify the specific data or databases that may be considered and that stakeholders.

[11] Proposed COMAR § 14.01.04.05(A)(3).
[12] *Id.*
[13] *See* Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024).
[14] *See* Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024).
[15] Proposed COMAR § 14.01.04.05(B).
[16] *Id.* § 14.01.04.05(B)(2)(f).
[17] *See generally Landover Books, Inc. v. Prince George's Cnty.*, 81 Md. App. 54, 81 (1989) (noting it is arbitrary for an agency to vest itself with unlimited discretion).

- **Data Derived from Reports by State Governmental Entities.** The Proposed Regulation would also add language allowing the Board to utilize data and analyses from reports by "*state governmental entities*."[18] Reports from other states do not reflect the specific patient populations in Maryland, and the PDAB statute is very clear that the Board's purpose is to "protect State residents, State and local governments ... from the high costs of prescription drug products."[19] It would be inappropriate for the Board to potentially rely on reports Data from other states, as such reports would not specifically address the affordability challenges that may be face by Maryland residents face.
- **Quantitative and Qualitative Data.** PhRMA is concerned by language in the Proposed Rule that would allow the Board to review data and perform analyses "*[d]erived from quantitative and qualitative data collected by Board staff.*"[20] This proposal does not provide the specific data sources that the Board intends to rely on for that "*quantitative and qualitative data*," and PhRMA is concerned that, without proper clarity, there would be an undue risk that the Board could collect information from unknown and inappropriate data sources.[21] PhRMA requests that the Board revise its Proposed Regulation to set forth clear and specific data sources regarding the referenced "*quantitative and qualitative data"* and add clear processes for how the Board proposes to collect and use such data.

III. Factors Considered in Cost Review Study Process

PhRMA is also concerned with the proposed amendments to the factors the Board may consider during the cost review study process. As detailed below, the Proposed Regulation would add various factors for the Board's consideration but does not indicate how the Board will utilize these additional factors or provide sufficient standards and parameters around their use. We provide the following non-exhaustive list of issues for Board consideration, and ask the Board to revise its Proposed Regulation in a manner consistent with our recommendations:

- **Drug-Specific Patient Access Programs.** As part of the cost review study process, the Proposed Regulation would permit the Board to consider "[t]he current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer *for the drug product under review and the policies surrounding and implementing such programs*."[22] The Board should revise its Proposed Regulation to clarify its standards surrounding consideration of such information. Currently, the Board provides no meaningful details around how the Board intends to gather information regarding such patient access programs or the weight such information will be given in the Board's analyses. As PhRMA has previously explained, patient access programs are essential and have various patient benefits.[23] Over the last several years, commercial health plans have shifted the burden of prescription drug costs to patients exposing them to higher deductibles

[18] Proposed COMAR § 14.01.04.05(B)(2)(g).
[19] Md. Code Ann., Health-Gen. § 21-2C-02(b).
[20] Proposed COMAR § 14.01.04.05(B)(2)(h).
[21] PhRMA continues to be concerned that performing cost reviews without sufficient guidelines in place for the Board's procedures and methodologies risks arbitrary and capricious determinations by the Board. *See, e.g.*, *Harvey v. Marshall*, 389 Md. 243, 302 (2005) ("[A]n agency action nonetheless may be 'arbitrary or capricious' if it is irrationally inconsistent with previous agency decisions."); *Hines v. Petukhov*, No. 0594, Sept. term, 2020, 2021 WL 4428781, at *8 (Md. Ct. Spec. App. Sept. 27, 2021) (holding it arbitrary and capricious where an agency "applied different standards and drew irreconcilable and inconsistent conclusions" in its review of a second licensing request, relative to the review of the first request).
[22] Proposed COMAR § 14.01.04.05(C)(1)(d)(iii).
[23] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023).

and to coinsurance as opposed to copays.[24] Coinsurance is based on the undiscounted price of the medicine, which results in higher out-of-pocket costs for patients. These commercial health insurance companies are paying the negotiated rate, which reflects the manufacturer discounts, but are not passing the discounts on to the patient at the pharmacy counter. To enhance patient access to the medicines they need, manufacturers have created patient access or assistance programs. These programs, or cost-sharing assistance, have been associated with improved patient adherence to medicines, with the share of patients staying on treatment for one year increasing by up to 47%.[25]

PhRMA is also concerned with the language in the Proposed Regulation that would give the Board the ability to request "*policies surrounding and implementing such [patient access] program[s].*"[26] Manufacturers' internal policies, and associated decisions made related to patient assistance programs, may include proprietary and trade secret information. We are concerned that unnecessary collection of this information could risk such confidential information from improper disclosure.[27] PhRMA requests that the Proposed Regulation be revised to clarify the specific policies that the Board intends to review and how the Board will consider this information.

- **Product Hopping.** PhRMA is concerned with the Proposed Regulation's inclusion of "product [] *hopping*" in the list of factors that may be considered in the cost review study process.[28] The proposed "product hopping" factor utilizes a term that inaccurately characterizes the way American Intellectual Property ("IP") laws work. Biomedical research and development is critical for finding ways to improve upon existing treatments, whether by reducing side effects, improving product quality, finding new diseases a medicine can treat, or making medicines more convenient for patients to take. Penalizing companies for introducing improved products into the market by labeling them as "product hopping" would essentially freeze these innovations. IP laws recognize the critical role of these improvements in advancing medical innovation, and require that all patented products be new, useful, and non-obvious.[29] PhRMA requests that the Board remove reference to "product hopping," as inclusion of such factor suggests a concerning bias against certain technologies protected under federal IP law and reflects a fundamental misunderstanding about how medical science advances and the significant benefits of encouraging new medical innovations for patients.

- **Additional Board Factors.** The Proposed Regulation would adopt five additional factors that the Board may consider in the cost review process, but does not provide any specific methodology for how information on these factors may be gathered or considered by the Board.[30] Given the

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[24] *See* Rae, M.; Copeland, R.; Cox, C.; Peterson Center on Healthcare and Kaiser Family Foundation, *Tracking the rise in premium contributions and cost-sharing for families with large employer coverage: Peterson-KFF Health System Tracker* (Aug. 14, 2019), https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage.

[25] Hung, A. B., D.V.; Miller, J.; McDermott, J.; Wessler, H.; Oakes, M.M.; Reed, S.D.; Bosworth, H.B.; Zullig, L.L.; *Impact of Financial Medication Assistance on Medication Adherence: A Systematic Review*, 27 Journal of Managed Care & Specialty Pharmacy 924-35 (2021).

[26] Proposed COMAR § 14.01.04.05(C)(1)(d)(iii).

[27] Md. Code Ann., Health-Gen. § 21-2C-10 (explaining that any data obtained by the Board that is not publicly available is a trade secret, confidential, and proprietary information and should not be disclosed to the public).

[28] Proposed COMAR § 14.01.04.05(C)(1)(g)(xi).

[29] 35 U.S.C. §§ 101-103.

[30] Proposed COMAR § 14.01.04.05(C)(1)(g)(xii)–(xvi).

complexity of these factors,[31] PhRMA asks that the Board provide additional specificity around how the factors will be implemented. In particular, PhRMA seeks clarification on the "*regulatory and compliance issues,*"[32] "*relevant benchmarks,*"[33] and "*market* context"[34] factors. Stakeholders cannot meaningfully evaluate and comment on these factors without greater specificity about what information they are meant to encompass and how that information will impact the Board's consideration (e.g., what constitutes "compliance issues," what "relevant" benchmarks would be, and the intended interpretation for "market context"). Adopting these factors without promulgating clear, specific, and appropriately tailored definitions and methodologies for them could result in inconsistent treatment of similarly situated products, which raise concerns of arbitrary and capricious decision-making by the Board.[35]

The Proposed Regulation also allow the Board to conduct "*[a]nalyses and research including literature review by Board staff in response to information submitted by an entity*."[36] PhRMA is concerned that this process would potentially provide the Board staff with an opportunity to ghather additional information in order to refute the information submitted by stakeholders, without allowing stakeholders an opportunity to respond. In order to provide stakeholders an opportunity to address any erroneous or incomplete data sources relied upon by the Board as part of such a response, PhRMA requests that the Board revise its Proposed Regulation to provide stakeholders an opportunity to respond to any additional analyses or research that the Board staff may conduct in response to stakeholder submissions.

IV. Preliminary Determinations

The Proposed Regulation include an additional procedure for publishing the Board's "preliminary determinations" regarding a prescription drug products' potential for raising affordability challenges.[37] PhRMA urges the Board to revise this procedure to establish more specific processes surrounding how this preliminary determination will be rendered, in order to provide a more consistent approach to reporting the results of its considerations.[38] The Proposed Regulation also states that the public would be given an opportunity to comment on the preliminary determination's cost review study report, but provides no minimum comment period.[39] PhRMA requests that the Board revise its Proposed Regulation to give the public a comment period of at least 60 days. PhRMA believes that a minimum of 60 days is necessary to allow stakeholders sufficient time to adequately review any preliminary report and provide comments, given the complexity of the analyses anticipated to be incorporated into the preliminary reports and the time-consuming nature of evaluating the data sources and information the Board is expected to rely upon in drafting such reports for purposes of developing responsive comments.

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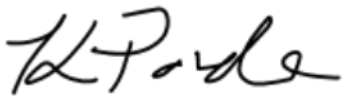
[31] For example, these factors include "Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product [and] Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks;"). *Id.*
[32] *Id.* § 14.01.04.05(C)(1)(g)(xiii).
[33] *Id.* § 14.01.04.05(C)(1)(g)(xv).
[34] *Id.* § 14.01.04.05(C)(1)(g)(xi).
[35] *See Harvey*, 389 Md. at 303-04.
[36] Proposed COMAR § 14.01.04.05(C)(1)(g)(xvi).
[37] *Id.* § 14.01.04.05(F)(1).
[38] *See Harvey*, 389 Md. at 303-04.
[39] Proposed COMAR § 14.01.04.05(F)(3)(b).

We thank you again for this opportunity to provide comments and feedback on the Board's Proposed Regulation and for your consideration of our questions, concerns, and requests for clarifications. Although PhRMA has concerns with the Proposed Regulation, we are ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as the regulations are further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,



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