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AARP Maryland Praises PDAB's New UPL Regulations

AARP Maryland strongly supports the regulations proposed by the state's Prescription Drug Affordability Board (PDAB) and published this month in the *Maryland Register*. The Board, including its experienced staff and five appointed members, has worked diligently to craft a thorough and fair process aimed at addressing the high and escalating costs of prescription drugs.

The proposed Upper Payment Limit (UPL) process is one of the most comprehensive frameworks developed to date, covering the entire pharmaceutical supply chain and offering much-needed transparency. The Board's unanimous vote to adopt the UPL Action Plan reflects its commitment to tackling affordability challenges, especially in light of significant federal developments, such as Medicare's drug-pricing negotiations under the Inflation Reduction Act.

Currently, the Board is reviewing two drugs included in Medicare's Maximum Fair Price program. By approving the UPL Action Plan, Maryland can align state UPLs with federal rates for certain drugs, a move that could influence prescription drug negotiations for state and local governments, further benefiting Maryland residents.

The UPL Action Plan is the result of a fair and thorough public discussion process, ensuring robust stakeholder participation. It also includes critical safeguards to maintain access to medications under review for UPLs, ensuring Maryland consumers continue to receive the medications they need.

AARP Maryland commends the PDAB for its thoughtful approach and supports the timely implementation of these regulations to help reduce prescription drug costs for all Marylanders.

abbvie

February 10, 2025

VIA ELECTRONIC MAIL TO CHRISTINA.SHAKLEE1@MARYLAND.GOV

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Re: Comments on the Proposed Amendments to COMAR 14.01.01.01 ("Definitions"), New COMAR 14.01.01.06 ("Hearing Procedures"), and New COMAR 14.01.05 ("Policy Review, Final Action, Upper Payment Limits")

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie 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. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review"), a critical step towards the potential future establishment of a UPL by the Board.[1] Accordingly, AbbVie has a significant interest in the Board's rulemaking activities related to these processes.

AbbVie is submitting these comments in response to the Board's proposed amendments to COMAR 14.01.01.01 ("Definitions"), new COMAR 14.01.01.06 ("Hearing Procedures"), and New COMAR 14.01.05 ("Policy Review, Final Action, Upper Payment Limits") (collectively, the

[1] As noted in previous letters submitted by AbbVie, given the value of SKYRIZI® and its affordability to Maryland patients, we do not believe SKYRIZI®'s selection by the Board for cost review was appropriate, and we have serious concerns about the lack of transparency and rationale supporting the Board's selection of the product, particularly when AbbVie still does not have meaningful insight into the methodology, standards, criteria, data, and other information underlying its decision. *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 SKYRIZI® "Therapeutic Alternatives" (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.

"Proposed Regulations") published in the Maryland Register on January 10, 2025.[2] Our comments are intended to supplement our November 8, 2024 comment letter,[3] which we incorporate by reference herein and attach as Exhibit 1, to address the very minimal differences between the draft regulations published by the Board on October 28, 2024 (the "Draft Regulations") (the subject of our November 8 submission) and the Proposed Regulations.

To that end, and as detailed further herein, AbbVie has grave concerns that the Board is not appropriately or sufficiently weighing public feedback on the substance of its rulemakings and is merely rubber stamping its flawed proposals into effect, in violation of Maryland's Administrative Procedure Act ("APA") as well as the statutes authorizing the Board's actions, Md. Code, Health-Gen. §§ 21-2C-01, et seq. Importantly, Maryland law requires agencies to conduct notice-and-comment rulemaking to "give the agency free-flowing information from a broad range of interests[,]"[4] and Maryland courts recognize "an implied limitation upon an administrative board's authority . . . that its decisions be supported by facts and that they be not arbitrary, capricious or unreasonable."[5] An agency's failure to consider a particular argument presented in public comments, or negative consequences of a policy enactment, can provide the basis for arbitrary and capricious review.[6] Most recently, on January 27, 2025, the Board finalized its proposed amendments to COMAR 14.01.04.05 ("Cost Review Study").[7] In the process, the Board only superficially acknowledged the comments it received from stakeholders and generally

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[2] 52:1 Md. R. 1-46 (Jan. 10, 2025), "Notice of Proposed Action (24-221-P), Subtitle 01, Prescription Drug Affordability Board," at https://dsd.maryland.gov/MDRIssues/5201/Assembled.aspx#_Toc187062353.

[3] *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 10/28/2024)," Written Comment Packet, AbbVie Inc. Comment Letter (November 8, 2024), PDF pages 1-23, at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

[4] *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.").

[5] *Heaps v. Cobbs*, 185 Md. 372, 380 (1945); *see also Reese v. Dep't of Health & Mental Hygiene*, 177 Md. App. 102, 144 n.21 (2007) (recognizing that "administrative mandamus . . . creates a right of judicial review of a quasi-judicial order or action of an administrative agency" because Maryland courts have "inherent power . . . to correct abuses of discretion and arbitrary, illegal, capricious[,] or unreasonable acts"). Maryland law defines a "[q]uasi-judicial function" to include "a proceeding before an administrative agency for which Title 7, Chapter 200 of the Maryland Rules would govern judicial review." Md. Code, Gen. § 3-101(i). The Maryland Rules provide for judicial review of "an order or action of an administrative judicial review is authorized by statute." Md. R. Jud. Rev. Cir. Ct. 7-201(a). The Maryland PDAB statute authorizes review of Board decisions. Md. Code, Health-Gen. § 21-2C-15. Thus, final decisions of the Board — such as affordability determinations and adoption of policy recommendations — must be supported by facts or otherwise risk invalidation.

[6] *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (describing one basis of arbitrary and capricious agency action as entirely "fail[ing] to consider an important aspect of the problem" intended to be addressed); 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").

[7] *See* Maryland Prescription Drug Affordability Board, "Amendments to COMAR 14.01.04.05 Cost Review Study" Presentation (January 27, 2025), at https://pdab.maryland.gov/Documents/presentations/2025/Regulations%20Presentation%202025.1.27%20%283%29.pdf.

disregarded serious substantive issues identified in the course of such engagement.[8] For example, AbbVie and others raised significant concerns about the Board's failure to explain how it would ensure that a UPL would not "impact[] statutory or regulatory amounts, such as Medicaid Best Price."[9] The Board has yet to address these concerns in any meaningful way, or offer any methodologies or mechanism by which it could attempt to achieve the aim of its own proposed regulation, even as it progresses through its affordability reviews of selected products. This is particularly concerning because if a UPL were to affect any federal pricing metrics, it would raise significant Constitutional concerns, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect.

Similarly, prior to publishing the Proposed Regulations at issue here in the Maryland Register on January 10, 2025, the Board posted the Draft Regulations to its website on October 28, 2024 and solicited public comment from stakeholders to purportedly "inform[ ] the development of" the Proposed Regulations.[10] In response, the Board received **16** comment letters from a diverse group of stakeholders, including patient groups, health care providers, pharmacies, distributors, and manufacturers.[11] The vast majority of this feedback was highly critical of the Draft Regulations. The stakeholders identified, in detail, significant issues related to the Board's policy positions, as well as numerous substantive and procedural deficiencies in the Draft Regulations and offered suggestions regarding ways the Board could meaningfully consider and/or address such issues.[12] This extensive feedback was further discussed at the Board's November 25, 2024 meeting.[13]

Nevertheless, the Proposed Regulations published two months later in the Maryland Register are nearly identical to the Draft Regulations, compounding the serious concerns raised repeatedly by AbbVie and other stakeholders regarding the propriety, legality, and implications of the Board's activities, including, among other things, the Board's failure to properly consider

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8 *See* Maryland Prescription Drug Affordability Board, "Archived Actions: COMAR 14.01.04 Cost Review Study Process, Written Comment Packet" at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf; Video Recording of January 27, 2025 Maryland Prescription Drug Affordability Board Meeting, at https://www.youtube.com/watch?v=HJb4FasNYxk.

9 *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 10/28/2024)," Written Comment Packet, AbbVie Inc. Comment Letter (November 8, 2024), PDF page 2, at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

10 Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 10/28/2024)," at https://pdab.maryland.gov/Pages/proposed-regs.aspx.

11 Maryland Prescription Drug Affordability Board, "Archived Actions: Draft Proposed Regulations for Comment, Written Comment Packet, at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

12 *See* Maryland Prescription Drug Affordability Stakeholder Council, November 4, 2024 Meeting Minutes, at https://pdab.maryland.gov/Documents/meetings/2024/_2024.11.04%20PDASC%20Meeting%20Minutes%20%281%29.pdf.

13 Maryland Prescription Drug Affordability Board, November 25, 2024 Meeting, Presentation by PDAB Staff , "Draft Regulations (Amend COMAR 14.01.01.01 (Definitions); Add COMAR 14.01.01.06 (Hearing Procedures); Add COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)," at https://pdab.maryland.gov/Documents/presentations/2024.11.25%20PDAB%20Upper%20Payment%20Limit%20and%20Policy%20Review%20Process%20.pdf.

pharmaceutical cost drivers and the drug supply chain in the United States, and the practical implications the Board's policies will have with respect to same, as well as the Board's failure to articulate beyond vague statements how it would even approach implementing such policies in practice. [14] The Board should pause to consider these and other comments and should not adopt the Proposed Regulations due to their significant flaws, of which the Board has been made acutely aware by stakeholders. To instead move forward with haste despite the substantial concerns expressed by a broad range of affected parties would constitute arbitrary and capricious agency action.

Moreover, the Board cannot ignore its obligations under the state's APA. In authorizing the Board to evaluate the necessity of UPLs, the General Assembly plainly envisioned that the Board would act in a quasi-judicial, not a quasi-legislative, capacity.[15] Treating these individualized considerations of particular drugs as quasi-legislative proceedings, rather than quasi-judicial proceedings, would violate the letter and purpose of the governing statute, which directs that the Board engage in individualized factfinding and evaluation of particular drugs.[16] The board therefore must proceed in accordance with the state APA's strictures.

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I. The Board Is Not Meaningfully Considering Public Feedback on the Substance of Its Rulemakings and the Practical Implications of Its Proposals

As we have explained in prior comment letters, the Board's actions have not served the public interest, including, prominently, the needs of patients, and further, that the statute and the Board's implementation and administration of the law is unconstitutional and inconsistent with Maryland's APA, implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause.[17] Among other examples, the Board's opaque cost review

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[14] For example, the Board made no substantive updates to proposed COMAR 14.01.01.06 ("Hearing Procedures"), notwithstanding the fact that, among other issues, stakeholders identified that the text of the Draft Regulations did not adequately address the applicable procedural requirements of Maryland's Open Meetings Act (Md. Code Ann. §§ 3-301-3-501) and valid concerns raised regarding the Board's broad discretion to limit "repetitious testimony from speakers" and timelines associated with stakeholder feedback.

[15] *See, e.g.*, Md. Code, Health-Gen. §§ 21-2C-08(b) (directing the Board to identify whether a particular drug has created affordability challenges); 21-2C-13 (directing the Broad to engage in individualized considerations of a drug's costs).

[16] *See Md. Overpak Corp. v. Mayor & City Council of Balt.*, 395 Md. 16, 33 (2006) (describing how the distinction between a quasi-legislative and quasi-judicial agency action "is guided by two criteria: (1) the act or decision is reached on individual, as opposed to general, grounds, and scrutinizes a single property, and (2) there is a deliberative fact-finding process with testimony and the weighing of evidence" (citations omitted)).

[17] *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

process and implementation of a 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 PDAB's drug selection and affordability review processes. Likewise, the Board's exercise of its prerogative to set UPLs based on policies and standards of its own creation — as opposed to policies and standards annunciated by the General Assembly through the governing statute — implicates the Maryland Constitution's separation-of-powers provision and its incumbent prohibition of improper delegations of lawmaking authority.[18] And by giving itself discretion to choose from several "methodologies" with minimal opportunity for comment on proposed UPLs,[19] the Board is inviting arbitrary decision-making, by putting in place a process for setting UPLs that lacks clear standards, hampers parties from meaningfully participating in the process, and risks arbitrarily treating similarly situated parties differently.[20]

As evidenced by its cursory economic impact review in the Maryland Register for the Proposed Regulations (discussed further in Section II below), including the following excerpt, the Board remains steadfast in its belief that a UPL it establishes for a drug will both decrease total state and local government spending for such product as well as revenues realized by drug's manufacturer:[21]

> **Estimate of Economic Impact**
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> **I. Summary of Economic Impact.** The Board anticipates that implementing COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) will decrease prescription drug expenditures by state and local governments. The regulations establish the procedures for assessing certain cost drivers, and recommending policies to make prescription drugs more affordable, including establishing an upper payment limit. The economic impact of these regulations is difficult to quantify because the impact will vary depending on the number of cost review studies completed, the alternative policies recommended by the Board to redress affordability challenges, and if an upper payment limit is set, the methodologies employed to establish the upper payment limit, the amount of the upper payment limit, utilization of the prescription drug product, the number of upper payment limits in effect, and the implementation of the upper payment limit. Implementation of an upper payment limit is predicted to reduce revenues ultimately realized by pharmaceutical manufacturers.

The Board regularly makes unsupported conclusory statements about these outcomes while ignoring the interconnected market realities of the drug pricing ecosystem and supply chain. Stakeholders have raised critical concerns regarding implementation challenges, risks to patient access, affordability of prescription drugs for patients, the impact on independent pharmacies, provider treatment choices, and other unintended consequences of its actions. With each round of

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(April 23, 2024), at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf.

18 *See* Md. Const. art. 8. ("[T]he Legislative, Executive and Judicial powers of Government ought to be forever separate and distinct from each other."); *Dep't of Transp. v. Armacost*, 311 Md. 64, 77 (1987) (explaining how Maryland law prohibits "a legislative body from delegating its law-making function to any other branch of government or entity"); *Truitt v. Bd. of Pub. Works*, 243 Md. 375, 388 (1966) ("The failure to provide any standards for the exercise of administrative discretion has been held to render the delegation of authority to the agency invalid.").

19 *See* New COMAR § 14.01.05.

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

21 *See, e.g.*, 52:1 Md. R. 1-46 (Jan. 10, 2025), "Notice of Proposed Action (24-221-P), Subtitle 01, Prescription Drug Affordability Board," "Estimate of Economic Impact," "III. Assumptions," at https://dsd.maryland.gov/MDRIssues/5201/Assembled.aspx#_Toc187062353 (emphasis added).

stakeholder comments, the Board's failure to acknowledge and address these realities becomes increasingly unreasonable and arbitrary and capricious.

The Board also appears to believe that a UPL applicable to eligible government entities will somehow operate in a vacuum. Indeed, Executive Director Andrew York's comments on the subject at the November 4, 2024 PDASC meeting illustrate the Board's fundamentally flawed assumptions:

> We don't intend for upper payment limits on eligible governmental entities to change reimbursement on the reimbursement side the way that we plan to implement [it] … we don't have specific guidelines on this so ultimately it's kind of up to the eligible governmental entities on the best way to … do this but the way we are conceiving it we will be working with our governmental entity partners [and] that this all kind of happens on the back end it doesn't adjust any payments out the door … and that's how we're addressing it … again Maryland it's a very specific market for eligible governmental entities so we don't see [impact to independent pharmacies] being an issue and maybe we're kind of misunderstanding how that would happen … for everyone that's not an eligible governmental entity … no one should see anything different for UPLs that are set by the eligible governmental entity.[22]

At a high level, Maryland state-employee health plans are not at all isolated from ways a UPL will shape payer and PBM decision-making for plans' benefit design (*e.g.*, formularies, patient cost sharing). This could include movement into non-preferred tiers, which could have a significant impact on patient access to the product. Any benefit design changes that move drugs into non-preferred or specialty tiers and/or result in removal of a drug from a plan's formulary can increase costs to patients (*e.g.*, increases in cost sharing and coinsurance amounts). Changes to formularies and patient benefit design stemming from UPLs could prompt providers to adjust referral, prescribing, and acquisition patterns for UPL-selected drugs. This could lead to provider pressure to choose specific low-cost medications, not necessarily the product deemed most clinically appropriate for the patient. UPLs could negatively influence patient and provider treatment choices, as they may alter autonomous decision making of treatment pathways by modifying prescribing and supply chain incentives. As UPLs impact how payers and PBMs set benefit designs (*e.g.*, by increasing coinsurance), there could be an increase in need for manufacturer copay assistance, for which Maryland state-employee health plan beneficiaries are generally eligible. In turn, this could increase use of copay adjustment programs, such as copay accumulators and maximizers, which also can alter how patients move through their plan benefits (*e.g.*, reaching their maximum out-of-pocket). Moreover, beneficiaries could lose access to their drugs if pharmacies, who purchase the drugs at wholesale acquisition cost, refuse to sell the drug at a loss.[23] These potential outcomes are not even on the Board's radar years into the process.

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[22] Video Recording November 4, 2024 Maryland Prescription Drug Affordability Stakeholder Council Meeting, at https://www.youtube.com/watch?v=hZArcfdsO68 (A. York comments at 1:22:02-1:23:03).

[23] Pharmacies may choose not to obtain a drug for which they cannot recover the cost. *See* National Association of Chain Drug Stores, Comments on Draft UPL Action Plan (August 20, 2024), https://pdab.maryland.gov/Documents/comments/August%2026%2c%202024%20PDASC%20Comments.pdf. Other supply-chain disruptions may come from an inability to cover costs such as the procuring, storing, preparing,

Specifically with respect to the Proposed Regulations, stakeholders identified, in detail, numerous substantive and procedural deficiencies in the Draft Regulations and offered suggestions regarding ways the Board could address such issues. The PDASC also provided feedback on the Draft Regulations at its November 4, 2024 and December 16, 2024 meetings.[24] The Board has only superficially acknowledged receipt of this extensive input, in some cases dismissing it entirely. For example, at the November 4, 2024 meeting, PDASC members expressed frustration at the Board's lack of a response to stakeholders' repeated requests for hearing procedures that would allow sufficient opportunity for meaningful public comments and stakeholder participation. During its December 16, 2024 meeting, the Board staff cast aside these concerns, claiming that "overly prescriptive" hearing procedures would restrict the Board's activities.

Under Maryland's APA, an agency's decision or action is unlawful if it is "arbitrary and capricious."[25] 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."[26] Agencies must consider relevant information and factors and make their decisions according to objective standards.[27] 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.[28] Maryland courts have consistently held that the

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and handling highly toxic agents. *See* MDCSCO & ASCO Comment (Nov. 7, 2024), *available at* https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

[24] *See* Maryland Prescription Drug Affordability Stakeholder Council, November 4, 2024 Meeting Minutes, at https://pdab.maryland.gov/Documents/meetings/2024/_2024.11.04%20PDASC%20Meeting%20Minutes%20%281%29.pdf.

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

[26] *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").

[27] 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").

[28] *State Dept. of Health v. Walker*, 238 Md. 512, 523, 209 A.2d 555, 561 (1965) (upholding that the Department's ad hoc decision to deny a permit application was arbitrary); *Maryland Real Estate Comm'n v. Garceau*, 234 Md.App. 324, 365, 172 A.3d 496, 521 (finding the Commission's sanction was arbitrary and capricious because it failed to consider exculpatory factors in its decision); see *Cnty. Council of Prince George's Cnty. V. Palmer Road Landfill, Inc.*, 247 Md. App. 403, 419, 236 A.3d 766, (Md. Ct. Sp. App. 2020) (reversing a time limitation that the Council initially "waived and failed to abide themselves" but later sought to enforce); *Forman v. Motor Vehicle Admin.*, 332 Md. 201, 220, 630A.2d 753, 763 (1993) (reversing license revocation because

state's APA requires government entities like the PDAB to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[29] Under this standard, such "[f]indings of fact must [also] be meaningful and cannot simply repeat statutory criteria, broad conclusory statements, or boilerplate resolutions."[30] Many of the Board's policy positions and proposed regulatory provisions simply fail to meet this standard.

II. The Board's Estimate of Economic Impact in the Proposed Regulations is Overly Vague and Based on Flawed Assumptions

In a cursory, conclusory analysis in the Proposed Regulations that exemplifies deficiencies in the Board decision-making discussed in Section I above, the Board assumes "that implementing [the Proposed Regulations] will decrease prescription drug expenditures by state and local governments"[31] but indicates that the "economic impact of [the Proposed Regulations] is difficult to quantify" for various reasons. Section 10-112 of the Maryland State Government Article requires the Board to evaluate the impact of a proposed regulation on various stakeholders before adopting it.[32] Specifically, each proposed regulation published by the Board in the Maryland Register must be accompanied by an estimate of economic impact, in which the agency is expected, whenever practicable, to give actual dollar estimates of the proposal's impact upon the Board itself, regulated parties, other state or local agencies, and the general public.[33] The Board fails to meet this burden by identifying the potential economic impact of the Proposed Regulations as "indeterminable" for each and every relevant stakeholder:

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agency failed to indicate what it found or how it reached the conclusion with respect to material issues); *Dashiell v. Maryland State Dept. of Health and Mental Hygiene*, 327 Md. 130, 137-38 (Md. Ct. App. 1992) (finding the Department's decision to terminate two employees was so unsupported that it renders the determination "essentially arbitrary and capricious").

[29] *Elbert v. Charles Cnty. Plan. Comm 'n,* 259 Md. App. 499, 509 (2023); *see also, e.g., Mortimer v. Howard Research and Development Corp.,* 83 Md. App. 432,442 (1990).

[30] *Bucktail, L.L.C. v. County Council of Talbot County,* 352 Md. 530, 553 (1999).

[31] 52:1 Md. R. 1-46 (Jan. 10, 2025), "Notice of Proposed Action (24-221-P), Subtitle 01, Prescription Drug Affordability Board," "Estimate of Economic Impact," "I. Summary of Economic Impact," at https://dsd.maryland.gov/MDRIssues/5201/Assembled.aspx#_Toc187062353.

[32] MD Code Ann., State Gov't, § 10-112 (2024). *See Fogle v. H & G Restaurant, Inc.*, 337 Md. 441, 461, 654 A.2d 449 (1995) (finding that state agencies conducted "adequate assessment of . . . [the] economic impact and feasibility" of a proposed smoking ban because the agencies "addressed the possible economic impact . . . at two different times during the rule-making process," and included "detailed . . . testimony of a number of witnesses as well as several studies" supporting their conclusion that the proposed regulation would have minimal impact on the private litigants.).

[33] MD Code Ann., State Gov't, § 10-112 (2024).

II. Types of Economic Impact.

Impacted Entity	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE	
B. On other State agencies:		
(1) Department of Budget and Management	(E-)	Indeterminable
(2) Maryland Department of Health	(E-)	Indeterminable
(3) Department of Public Safety & Corrections	(E-)	Indeterminable
C. On local governments:		
(1) County Governments	(E-)	Indeterminable
(2) Municipal Governments	(E-)	Indeterminable
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
PBMs		Indeterminable
Carriers of health benefit plans		Indeterminable
Vendors (government)		Indeterminable
E. On other industries or trade groups:		
Pharmaceutical Manufacturers	(-)	Indeterminable
F. Direct and indirect effects on public:		
public	(+)	Indeterminable

Further, Section 10-124(b)(2)(ii) of the Maryland State Government Article requires the Board to consider "the difficulty of compliance for each class" of regulated businesses when evaluating the economic impact of a proposed regulation, [34] which the Board has also failed to address substantively, merely stating in the Maryland Register that "[t]he proposed action has minimal or no economic impact on small businesses."[35] In fact, the Board has received numerous comments to the contrary identifying ways small businesses would be impacted by the Board's proposal, for example but not limited to the following:

- The Healthcare Distribution Alliance's Comment on New COMAR 14.01.05 dated November 8, 2024 explained 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.[36]

[34] MD Code Ann., State Gov't, § 10-124(b)(2)(ii) (2024).

[35] 52:1 Md. R. 1-46 (Jan. 10, 2025), "Notice of Proposed Action (24-221-P), Subtitle 01, Prescription Drug Affordability Board," "Economic Impact on Small Businesses," at https://dsd.maryland.gov/MDRIssues/5201/Assembled.aspx#_Toc187062353.

[36] Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 10/28/2024)," Written Comment Packet, Healthcare Distribution Alliance Comment Letter (November 8, 2024), PDF pages 46-47, at https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

- The Coalition of State Rheumatology Organizations' Comment on New COMAR 14.01.05 dated November 7, 2024 indicated that the Board's methodology does not account for the acquisition costs of independent medical practices.[37]

- The National Association of Chain Drug Stores' Comment on New COMAR 14.01.05 dated November 8, 2024 noted that the Board's methodology may result in adequate or below-cost reimbursement to community pharmacies.[38]

- The Maryland/District of Columbia Society of Clinical Oncology Comment on New COMAR 14.01.05 dated November 7, 2024 explained that the Board's proposed methodology will impose "a large financial burden" on independent oncology practices.[39]

Indeed, this is not the first time the Board has shortcut these critical analyses required by law. For example, AbbVie flagged the same issue in its comments on the Board's proposed amendments to COMAR 14.01.04.05 ("Cost Review Study Process") dated December 2, 2024.[40]

If the Board has no idea what the practical effect of its activities will be for beneficiaries, taxpayers, and others, or chooses to willfully ignore potential outcomes, even as stakeholders industry wide repeatedly identify specific examples, it cannot continue to forge ahead with implementing its misguided policy initiatives and scrutiny of specific products.

III. Comments on the Amendments to COMAR 14.01.01.01 (Definitions)

- ***The Board's Proposed Definition of "Therapeutic Alternative" (Proposed COMAR 14.0l.0l.0l(B)(63)) Compounds the Lack of Clarity Regarding its Identification and Consideration of "Therapeutic Alternatives"***

The Board proposes to define "therapeutic 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." As we have raised previously, the Board's proposed definition is overly broad, inconsistent with the practice of medicine, and fails to establish clear standards to ensure that only appropriate alternatives are considered, leaving the Board free to identify therapeutic alternatives in a standardless vacuum.[41] This ambiguity and lack of transparency can only serve to

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37 *Id.* at PDF pages 46-47 (Coalition of State Rheumatology Organizations Comment Letter).

38 *Id.* at PDF pages 71-72 (National Association of Chain Drug Stores Comment Letter).

39 *Id.* at PDF pages 69-70 (Maryland/District of Columbia Society of Clinical Oncology Comment Letter).

40 Maryland Prescription Drug Affordability Board, "COMAR 14.01.04 Cost Review Study Process" Written Comment Packet, AbbVie Inc. Comment Letter (December 2, 2024), PDF page 13, at https://pdab.maryland.gov/Documents/comments/2024.12.02-%20Regulations%20Comments%20%281%29.pdf.

41 *See, e.g.*, 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; Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 10/28/2024)," Written Comment Packet, AbbVie Inc. Comment Letter (November 8, 2024), PDF pages 1-23, at

make the process more arbitrary and inconsistent by obscuring the Board's process and leaving unfettered discretion for the Board to group whatever drugs it wishes as therapeutic alternatives, with no standards and no accountability.

Any consideration of 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. The proposed definition fails to accomplish or contribute in a meaningful way to any of these critical objectives. More specifically:

The proposed definition does not adequately consider key product differences and does not serve patient needs: we have concerns that the proposed definition created by the PDAB to identify and compare drug products approved for treatment of the same condition does not account for significant variance in factors among such products, such as safety, efficacy, and clinical outcomes, nor does the definition account for alignment with clinical guidelines. The current definition also does not account for patient specific factors that may need to be considered during treatment selection such as comorbidities and/or contraindications.

The proposed definition does not appropriately consider patient choice and access: determinations resulting from a product's cost review may negatively impact patient access and ultimately patient outcomes. The PDAB must place utmost importance on patients and ensure its actions do not adversely impact patient health. The proposed definition does not account for what patients need and value from these medicines. Each patient presents with a unique set of clinical features; accordingly, treatment decisions are best navigated between trained clinicians specializing in treatments and individual patients.

- ***The Board's Proposed Definitions of "System Net Cost" (Proposed COMAR 14.0l.0l.0l(B)(62)) and "Net Cost" (Proposed COMAR 14.0l.0l.0l(B)(44)) Introduce a Host of Vague and Ill-Defined Considerations That Eliminate Any Potential Predictability in the Board's Policy Review Process and Invite Arbitrary Determinations That Would Not Serve the Public Interest or Address Perceived Drug Affordability Challenges***

The Board proposes to define "system net cost" as "the sum of the 'net cost' and the per unit patient out-of-pocket cost[,]" and "net cost" as the "per-unit cost paid by payors and purchasers of a drug after accounting for all price concessions, discounts, and rebates," but does not further clarify how it will calculate net cost and what information the Board will collect in connection with such calculation. The Board also proposes to use net cost to determine whether a drug poses an affordability challenge and, in turn, whether to set a UPL. If that is the case, we urge the Board instead to consider insurance benefit design as the mechanism to achieve lower out-of-

https://pdab.maryland.gov/Documents/comments/2024.11.08%20UPL%20Regulations%20Comments%20%281%29.pdf.

pocket costs. Insurance plans, not manufacturers, control patient deductibles, copays, and coinsurance. The Board must also consider the utilization management practices used by PBMs and insurers (*e.g.*, prior authorization requirements, step therapy requirements, non-medical switching) that can create barriers to patient access to treatment, beyond a singular focus on out-of-pocket costs alone.

Moreover, the Board does not acknowledge that manufacturers, the subject of the Board's scrutiny regarding drug affordability, (a) do not have control over net cost — a reality the Board even highlighted in its Health-General § 21-2C-09(c) 2024 Annual Report,[42] (b) have only limited insight into patient out-of-pocket cost and utilization; and (c) have extremely limited ability to validate this information, at best.

It is critical, therefore, that the Board does not adopt a strategy that relies on inputs manufacturers do not control, much less have visibility into, unless the Board — at minimum — can guarantee adequate transparency into the data it is using, its calculations, and how it chooses to derive net cost. This information must be made available both upon request and before any hearings in order for stakeholders to meaningfully participate in the administrative process. Currently, for example, the template RFIs for insurers and PBMs, responses to which are voluntary, do not provide a sufficient degree of certainty.[43]

Moreover, if the Board's focus is on net cost and patient out-of-pocket costs as the most significant factors impacting its affordability determination, manufacturers should not be the main target of the Board's cost review. It would be more appropriate for the Board to conduct affordability reviews with respect to PBMs and insurers. Manufacturers' list prices are *not* the main drivers of net costs and out-of-pocket costs, especially with respect to costs to governmental entities and individual patients. By scrutinizing manufacturers above all other entities involved in the purchase and dispense of drugs, the Board fails to consider information critical to evaluating the actual costs patients pay for drugs and the actual costs to the state government.

- ***The Board's Proposed Definitions of "Upper Payment Limit" (Proposed COMAR 14.01.05.01(B)(8)) and "System Net Ingredient Cost" (Proposed COMAR 14.01.05.01(B)(7)) Introduce a Host of Vague and Ill-Defined Considerations That Eliminate Any Potential Predictability in the Board's UPL Setting Process and Invite***

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[42] Maryland Prescription Drug Affordability Board, "Health-General § 21-2C-09(c) 2024 Annual Report (November 2024) 1, 5, at https://pdab.maryland.gov/Documents/reports/2024.11.18.1730.Annual%20Drug%20Pricing%20Trends%20Report%20for%202024%20%281%29.pdf (stating that that "[a]ggregate out-of-pocket costs for all patients increased by 6% in 2023. Out-of-pocket spending increased by $5 billion in 2023 to a total of $91 billion. [] Biopharmaceutical companies provided $23 billion in manufacturer co-pay assistance programs that reduced the out-of-pocket costs to patients.[] However, in spite of these coupons, the out-of-pocket costs still increased by 6%." (Citations omitted.)).

[43] Maryland Prescription Drug Affordability Board, Insurer RFI Submission Template Form, at https://pdab.maryland.gov/Documents/Cost%20Review/2024.07.25.1200.Prompt%20-%20Health%20Insurance%20Carrier%20Requests.pdf; Maryland Prescription Drug Affordability Board, Pharmacy Benefit Manager RFI Submission Template Form, at https://pdab.maryland.gov/Documents/Cost%20Review/2024.07.25.1200.Prompt%20-%20Pharmacy%20Benefit%20Manager%20Requests.pdf.

Arbitrary Affordability Determinations That Would Not Serve the Public Interest or Address Perceived Drug Affordability Challenges

The Board proposes to modify the definition of "upper payment limit" to mean "the amount established by the Board that "represents the system net ingredient cost[,]" and to define "system net ingredient cost" as "the final system cost attributable to or related to the prescription drug product after accounting for all discounts and price concessions, excluding dispensing, administration and direct and indirect remuneration to pharmacies, including patient out-of-pocket costs." As we have raised in prior comment letters, under Maryland law, 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 consider purchases or reimbursements by, and/or costs and other data inputs associated with, commercial payors. Therefore, to not exceed the scope of its statutory authority and violate Maryland's APA, the Board must clarify in the proposed definition of "system net ingredient cost" that it is "the final system cost attributable to or related to ***utilization of*** the prescription drug product ***by eligible government entities*** after accounting for all discounts and price concessions ***applicable to such utilization***, excluding dispensing, administration and direct and indirect remuneration to pharmacies, including patient out-of-pocket costs."

* * * *

Thank you for this opportunity to provide additional comments on the Proposed Regulations, in addition to those prior comments we attach herewith. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

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

Enclosure

Exhibit 1

abbvie

November 8, 2024

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

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

Re: Comments on Proposed Maryland Prescription Drug Affordability Board Regulations Issued October 28, 2024

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie" or "the Company") is submitting comments in response to the proposed regulations published by the Maryland Prescription Drug Affordability Board ("PDAB" or "the Board") on October 28, 2024 (collectively, the "Draft Regulations"), specifically the:

- Amendments to COMAR 14.01.01.01 (Definitions);[1]
- New Regulation COMAR 14.01.01.06 (Hearing Procedures);[2] and
- New Chapter COMAR 14.01.05, *et seq.* (Policy Review, Final Action, Upper Payment Limits).[3]

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. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review"), a critical step towards the potential future establishment of a UPL by the PDAB. Accordingly, AbbVie has a significant interest in the Board's activities generally, and the Draft Regulations specifically.

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[1] Maryland Prescription Drug Affordability Board, Proposed Amendments to COMAR 14.01.01.01 (Definitions) (October 28, 2024), at https://pdab.maryland.gov/Documents/regulations/DRAFT.Amendment%20COMAR%2014.01.01.01%20Definitions.2024.10.28.1200%20%281%29.pdf.

[2] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.01.06 (Hearing Procedures) (October 28, 2024), at https://pdab.maryland.gov/Documents/regulations/DRAFT.2024.10.22.1630.Draft_COMAR%2014.01.01.06%20Hearings%20Procedures.2024.10.28.1200%20%281%29.pdf.

[3] Maryland Prescription Drug Affordability Board, Proposed COMAR 14.01.05, *et seq.* (Policy Review, Final Action, Upper Payment Limits) (October 28, 2024), at https://pdab.maryland.gov/Documents/regulations/DRAFT.14.01.05%20Policy%20Review%20Final%20Action%20and%20UPL.2024.10.28.1220%20%28final%29.pdf.

AbbVie reiterates our view, as communicated in our prior comment letters, that the Board's implementation and administration of the PDAB statute does not serve the public interest, including, prominently, the needs of patients, and further, that the statute and the Board's implementation and administration of the law is unconstitutional and inconsistent with Maryland's Administrative Procedure Act, potentially implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause. Among other examples, the Board's opaque cost review process and implementation of a 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 PDAB's drug selection and affordability review processes.

The Draft Regulations at issue here compound our concerns regarding the propriety and legality of the Board's activities for, but not limited to, the reasons discussed below. Because many of the substantive, legal, and procedural deficiencies in the Board's Draft Regulations have been addressed in our prior comment letters, we incorporate those submissions by reference, including those provided as Exhibit 1 and Exhibit 2, and cite to them where appropriate herein.

As a threshold matter, the Draft Regulations fail to articulate clear and meaningful standards and procedures to adequately guard against the risk of inconsistent and arbitrary decision-making. Under Maryland law, "[a]n agency's decisions must . . . not be so fluid as to become arbitrary or capricious," as occurs if "similarly situated individuals are treated differently without a rational basis for such a deviation."[4] The Draft Regulations, however, do not sufficiently clarify, expand, or otherwise supplement what is already set forth in the PDAB statute or existing implementing regulations.

The lack of clear and concrete standards prevents stakeholders from meaningfully participating in and commenting on the PDAB's processes, and the vagueness of the applicable standards raises inherent concerns about whether the processes addressed in the Draft Regulations (including, among others, the proposed policy review, UPL setting, and hearing procedures) will be appropriately grounded in statutorily relevant factors and consistently applied. Maryland courts have consistently held that the state's Administrative Procedure Act requires government entities like the PDAB to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[5] Under this standard, such "[f]indings of fact must [also] be meaningful and cannot simply repeat statutory criteria, broad conclusory statements, or boilerplate resolutions."[6] Many of the Board's proposed regulatory provisions fail to meet this standard.

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4 *Harvey v. Marshall*, 389 Md. 243, 303, 884 A.2d 1171, 1207 (2005).

5 *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g.*, *Mortimer v. Howard Research and Development Corp.*, 83 Md. App. 432, 442 (1990).

6 *Bucktail, L.L.C. v. County Council of Talbot County*, 352 Md. 530, 553 (1999).

abbvie

Amendments to COMAR 14.01.01.01 (Definitions)

- ***Definition of "Utilization" (Proposed COMAR 14.01.01.01(B)(70))***

The Board proposes to define "utilization" as "information about the use of a drug including the number of units, the number of patients and number of prescriptions or claims." The definition should be revised as follows to specify that it pertains solely to utilization by state and local government entities to which a UPL would apply, and not to utilization in the context of commercial payors and other entities to which a UPL would not apply: "'Utilization' means information about the use of a drug including the number of units, the number of patients and number of prescriptions or claims ***related to Eligible Government Entities, as identified in Health-General Article, §21-2C-14(a), Annotated Code of Maryland***."

A substantial number of the criteria the Board has identified for selecting a drug for affordability review and setting a UPL are derived from drug price and cost metrics associated with commercial utilization. As we have raised in prior comment letters, the Board exceeds the scope of its statutory authority and violates Maryland's Administrative Procedure Act by determining affordability based on data that clearly, erroneously, unreasonably, and disproportionately skews the Board's findings against manufacturers. For example, relative out-of-pocket costs, payor costs, co-pay and cost-sharing amounts, and various spending metrics, among other data elements, are generally higher for a drug in the commercial context as compared to those entities to and contexts in which a UPL will apply in practice. Therefore, it is critical that the PDAB limit the definition of "utilization" to that which can be subject to a UPL implemented by the Board.

New Regulation COMAR 14.01.01.06 (Hearing Procedures)

As a general matter, the types of hearings described in the proposed regulation appear to be in scope of Maryland's Open Meetings Act,[7] but the text of the proposed regulation does not adequately address the associated procedural requirements. For example, as proposed, the notice and recordkeeping provisions are too vague and discretionary, respectively, to meet the law's requirements.[8]

- ***COMAR 14.01.01.06(B)(2)***

We continue to dispute the Board's attempts to characterize various activities it conducts—including, now, hearings it may hold in connection with an affordability review and related actions pertaining to a specific, selected drug—as "quasi-legislative." This characterization is inconsistent with the highly drug- and fact-specific nature of such meetings (including, among other things, that they will be convened for a particular drug and involve a deliberative fact-finding process that weighs data and information that pertains specifically to such product). Further, we are particularly

[7] Md. Code Ann. §§ 3-301-3-501.

[8] Proposed COMAR 14.01.01.06(B), (E), (F).

concerned that the Board's attempts to position its activities as quasi-legislative are not only inconsistent with Maryland legal precedent,[9] but appear to be designed to inhibit judicial review of those activities.

Describing the hearings in scope of this proposed regulation as those held "[t]o gather information from the general public before making recommendations or taking action ***with respect to a policy***; or … [f]or the purpose of receiving technical input, technical information or expert testimony before making recommendations or taking action ***with respect to a policy***"[10] is merely semantic and does not change the fact that, substantively, such "policy" is not broadly applicable and only relates to one specific product. The hearings described in proposed COMAR 14.01.01.06 would not support the process of "making a new law—an enactment of general application prescribing as new plan or policy[,]" but rather would "merely look[] to or facilitate[] the administration, execution, or implementation of a law already in force and effect."[11] This is a key distinction Maryland courts have made between quasi-legislative versus quasi-judicial activities of State agencies. Indeed, the Board's proposed policy review regulations make clear that the policy review process, which includes the hearings described in proposed COMAR 14.01.01.06, will be conducted for a single prescription drug product the Board has determined has led or will lead to an affordability challenge.[12]

New Chapter COMAR 14.01.05, et seq. (Policy Review, Final Action, Upper Payment Limits)

As noted above, many of the concerns we previously expressed in relation to the Board's UPL Action Plan arise again in this proposed new chapter of PDAB regulations, which seeks to codify the UPL Action Plan. We reiterate our overarching concerns in Exhibit 1 and Exhibit 2 that the Board's development of its UPL Action Plan was rushed, with only a superficial focus on critical issues of substance. This is evidenced by the final product, which does not to meaningfully address or even acknowledge much if any of the feedback in the twenty-two public comments the PDAB received on the initial draft UPL Action Plan from providers, pharmacies, trade associations, advocates, and manufacturers (including AbbVie). Significantly, the Draft Regulations fail to meaningfully address any of the "key decisions" for the UPL setting process that the Board itself previously identified—*i.e.*, when UPLs should apply, how the Board will set a UPL, and how the Board will apply a UPL—in the Draft Regulations.[13] The Board has failed in proposed COMAR 14.01.05.03-.05, to, among other things, provide clear and meaningful standards with respect to the following:

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[9] *See, e.g.*, *Md. Bd. of Pub. Works v. K. Hovnanian's Four Seasons at Kent Island, LLC*, 425 Md. 482, 514, 42 A.3d 40, 59 (2012); *Talbot Cnty. v. Miles Point Prop., LLC*, 415 Md. 372, 387, 2 A.3d 344, 353 (2010); *Md. Overpak Corp. v. Mayor of Baltimore*, 395 Md. 16, 33 (2006) (citations omitted).

[10] Proposed COMAR 14.01.01.06(A)(1)-(2).

[11] *Md. Bd. of Pub. Works v. K. Hovnanian's Four Seasons at Kent Island, LLC*, 425 Md. 482, 514, 42 A.3d 40, 59 (2012).

[12] *See, e.g.*, Proposed COMAR 14.01.05.03.

[13] *See* Maryland Prescription Drug Affordability Board, Upper Payment Limits (July 24, 2023), available at: https://pdab.maryland.gov/documents/meetings/2023/pdab_upper_pymt_limits_prst.pdf.

- The Draft Regulations incorporate extensive lists and categories of information and data sources that the Board "may" consider as part of its policy review and UPL setting processes. However, the Draft Regulations lack any specific, concrete, and 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 Draft Regulations fail to provide specific procedures and standards that will govern the Board's determination of whether a UPL is an appropriate "policy option."[14] The Draft Regulations instead merely provide that Board staff may gather and analyze a range of information and "may" analyze "contextual issues" related to the identified affordability challenge.[15] These vague and ambiguous statements fail to establish an ascertainable standard for the Board's decision-making.

- The Draft Regulations fail to establish a specific methodology or sufficiently concrete criteria for establishing a UPL. Instead, the Draft Regulations set forth an extensive list of disparate methodologies with the only requirement that Board staff recommend "at least one" for use in developing a UPL for the product at issue.[16] The Draft Regulations also provide that the Board staff "may recommend certain [types of] contextual information" but does not further clarify how or when one or more methodologies may be selected or how or why one methodology may be prioritized over another.[17]

Additional examples are detailed in Exhibit 1 and Exhibit 2.

- ***Proposed COMAR 14.01.05.02 (Criteria for Setting an Upper Payment Limit)***

    - Proposed COMAR 14.01.05.02(B)(3)

This provision states that the "Board shall **…** [s]et an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences[.]" However, the Board does not further identify or define any particular types of outcomes or consequences of concern that should be minimized, nor does it define what it considers to be an acceptable tolerance threshold for an outcome or consequence to be determined minimal.

As noted above and also addressed in comments submitted by other stakeholders, the setting of a UPL "could inadvertently result in inadequate or below-cost reimbursement to pharmacy providers and pharmacies by failing to reconcile the difference between the UPL and the pharmacy's acquisition cost and cost to dispense the prescribed drug. This outcome could force

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14 Proposed COMAR 14.01.05.02(B)(2).
15 Proposed COMAR 14.01.05.06(A)(2).
16 Proposed COMAR 14.01.05.06(A)(1).
17 *See* Proposed COMAR 14.01.05.06(C).

pharmacies to either operate at a loss, be unable to stock certain medications that a UPL applies to, or worse, potentially close their doors permanently—negatively impacting Marylanders by ultimately worsening patient outcomes[.]"[18] The Board has not meaningfully responded to these concerns in its regulations or proposed any framework for preventing these outcomes. When discussing such concerns, the Board staff alleges no impact on supply chain and references a process of back-end reconciliation through rebates that is not contemplated in statute or any regulations, much less been opened to public comment. Such significant stakeholder concerns merit more robust consideration from the Board.

- Proposed COMAR 14.01.05.02(C)

This provision states that the Board shall not set a UPL if "[u]tilization of the prescription drug product by Eligible Governmental Entities is minimal[,]" but does not further quantify or define what constitutes "minimal utilization." This provision is vague and ambiguous as proposed and, again, the Board offers no clarity regarding what it considers an acceptable tolerance threshold.

- Proposed COMAR 14.01.05.02(D)

This provision prohibits the Board from setting a UPL at an amount that … [i]mpacts statutory or regulatory amounts, such as Medicaid Best Price; or … [i]s lower than the Medicare Maximum Fair Price." The Board has repeatedly acknowledged that it cannot set any UPL that would impact Best Price or other federal pricing metrics. This is for good reason: setting a UPL that affected Best Price or other pricing metrics associated with *federal* healthcare programs would have national impact, affecting transactions that occur entirely outside of Maryland, which raises grave constitutional concerns. Despite repeatedly acknowledging this issue, most recently at the November 4, 2024 PDASC meeting, the Board has yet to provide any explanation of how it intends to mitigate this critical liability. This legal and practical reality cannot be ignored and makes this proposed provision illusory—the Board as a practical matter will be unable to execute it.

Any attempt to address this issue must begin with a solid understanding of the mechanics of the determination of Best Price and how it is reported by manufacturers to, and utilized by, the Centers for Medicare & Medicaid Services ("CMS"). We have discussed in prior submissions how transactions impacted by a UPL set by the PDAB will be Best Price-eligible (*i.e.*, there is no applicable legal exclusion for these transactions).[19] Therefore, in order to prevent a UPL from setting a new Best Price for the affected drug, the Board must have a process in place to ensure that, in every single calendar quarter, the UPL is not lower than the drug's Best Price. But critically,

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[18] National Association of Chain Drug Stores, Comments on Draft UPL Action Plan (August 20, 2024), at https://pdab.maryland.gov/Documents/comments/August%2026%2c%202024%20PDASC%20Comments.pdf.

[19] Md. Health Gen. § 21-2C-14(a) ("If [the UPL Action Plan] is approved . . . the Board may set upper payment limits for prescription drug products that are: (1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including: (i) State or county correctional facilities; (ii) State hospitals; and (iii) Health clinics at State institutions of higher education; (2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or (3) Purchased for or paid for by the Maryland State Medical Assistance Program.").

the Board is legally prohibited from accessing the exact data it needs to ensure there will be no such effect.

Indeed, a manufacturer's Best Price data (among other federal pricing metrics to which the Board would require access to ensure a UPL does not impact a statutory or regulatory price) is confidential under federal law.[20] **Short of attempting to compel a manufacturer to provide Best Price data to the Board, which would be preempted by such federal statutory protections, the Board cannot actually verify whether a UPL does in fact impact Best Price.** It is therefore far from apparent how the Board could know or verify whether a UPL for a particular drug impacts the drug's Best Price, either at the outset when a UPL is implemented or in any future quarter.

If a UPL were to affect any federal pricing metrics, it would raise significant constitutional infirmities, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect, but it needs access to Best Price data it does not and cannot have to do so. So far, we have not seen any attempt by the Board or Board staff to meaningfully grapple with this significant issue.

Additionally, Best Price is reported quarterly at the NDC-9 level. The Board has identified multiple NDC-9s in scope of its cost review for all of the selected drugs, which presumably means that all of the in-scope NDC-9s would be subject to a UPL if implemented by the Board for a product.[21] Each NDC-9 can have a different Best Price and the UPL could theoretically affect some NDC-9s but not others. This means that the Board would not only need to track Best Price impact on a quarterly basis, but do so for each NDC-9 to which a UPL applies. This is only one example of a statutory or regulatory pricing metric that a UPL could affect and by itself is a massive undertaking for which the Board neither has the essential data it needs to execute the task nor the resources to undertake it in the first instance. There is no practical solution to this critical flaw, which left unattended creates an outcome that contravenes Constitutional law.

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[20] *See* 42 U.S.C. §1396r–8(b)(3)(d) ("Confidentiality of information").

[21] Maryland Prescription Drug Affordability Board, "Board Selected Drugs and Any Applicable Information," at https://pdab.maryland.gov/Pages/board-selected-da-info.aspx.

abbvie

Thank you for this opportunity to provide written comments on the Draft Regulations. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

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

Enclosures

Exhibit 1 to AbbVie's November 8, 2024 Comment Letter

abbvie

August 26, 2024

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

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

Re: Comments on Draft Upper Payment Limit Action Plan

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie" or "the Company") is submitting comments in response to the "Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits" ("Draft UPL Action Plan") that the Maryland Prescription Drug Affordability Board ("PDAB" or "the Board") published on August 9, 2024.[1]

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 a threshold matter, AbbVie believes that the Maryland PDAB statute is bad public policy that will not result in improving patient affordability. Moreover, we believe that the Board's implementation of the PDAB statute is unconstitutional, potentially implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause. Additionally, as expressed in our prior comment letters, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's Administrative Procedure Act ("APA"). Among other examples, the Board's lack of transparency regarding its decision-making is contrary to the public interest and has deprived AbbVie of the ability to effectively and predictably participate in the PDAB's drug selection process.

The Draft UPL Action Plan further compounds our concerns regarding the legality of the Board's activities for, but not limited to, the following reasons:

[1] Maryland Prescription Drug Affordability Board, "Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits" (August 9, 2024), at https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf.

- **The Board incorrectly characterizes the UPL setting process as a quasi-legislative action.** The Board states several times in the Draft UPL Action Plan that "setting a UPL is a quasi-legislative action," and that the cost review study and setting of a UPL are part of a "quasi-legislative process."[2] First, the PDAB's repeated, out-of-context references to a key aspect of Maryland's judicial standard applicable to the review of agency action is unusual and suggests the Board recognizes that the deficiencies of its flawed PDAB policies and processes will be challenged by impacted stakeholders in court. Second, characterizing its cost review study and setting of a UPL as "quasi-legislative" is wholly inconsistent with the highly drug- and fact-specific nature of those activities (including, among other things, that both are determined with respect to a particular drug following a deliberative fact-finding process that weighs data and information that pertains specifically to such product),[3] inconsistent with Maryland legal precedent,[4] and appears to be designed to discourage judicial review of those activities.

- **The Board fails to explain how it will ensure that a UPL would not "impact[] statutory or regulatory amounts, such as Medicaid Best Price."[5]** AbbVie supports the Board's position that a UPL "shall not . . . impact statutory or regulatory amounts, such as Best Price."[6] Indeed, if a UPL were to affect any federal pricing metrics, it would raise significant Constitutional concerns, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect. The Board must identify specifically which statutory or regulatory amounts a UPL shall not impact and explain how the Board will overcome significant implementation challenges to comply with this requirement in practice, the costs of which could reasonably exceed any perceived savings generated by setting a UPL. For example, statutory and regulatory pricing metrics like Medicaid Average Manufacturer Price and Best Price and Medicare Part B Average Sales Price continually change, and the Board's standard would therefore require constant monitoring. Also, to ensure there is no impact, the Board would need to obtain confidential information which the PDAB and, more broadly, the State of Maryland, may not possess just to know whether and how a particular UPL might affect "statutory or regulatory amounts." In many cases such information is protected from disclosure to a state or other third party by federal

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2 Draft UPL Action Plan at 2.

3 *See, e.g.,* COMAR 14.01.04.02 ("Identifying Drugs Eligible for Cost Review"); COMAR 14.01.04.03 ("Selecting Drugs for Cost Review"); COMAR 14.01.04.04 ("Request for Information for Cost Review"); COMAR 14.01.04.05 ("Cost Review Study"); MD Code, Health - General, § 21-2C-08 ("Identifying prescription drug products that create affordability challenges for State health care system and patients"); MD Code, Health - General, § 21-2C-09 ("Cost review of prescription drug products identified in § 21-2C-08"); MD Code, Health - General, § 21-2C-13 ("Process for setting upper payment limits for prescription drug products that lead to affordability challenges"); MD Code, Health - General, § 21-2C-14 ("Upper payment limits"); Maryland Prescription Drug Affordability Board, "Requests for Information," at https://pdab.maryland.gov/Pages/Request-for-Information.aspx.

4 *See, e.g.*, *Md. Bd. of Pub. Works v. K. Hovnanian's Four Seasons at Kent Island, LLC*, 425 Md. 482, 514, 42 A.3d 40, 59 (2012); *Talbot Cnty. v. Miles Point Prop., LLC*, 415 Md. 372, 387, 2 A.3d 344, 353 (2010); Md. Overpak Corp. v. Mayor of Baltimore, 395 Md. 16, 33 (2006) (citations omitted).

5 Draft UPL Action Plan at 3.

6 *Id.*

law,[7] and the Board lacks authority to compel disclosure of the information in contravention of such federal protections.

- **The Draft UPL Action Plan lacks clear and meaningful standards and procedures to adequately guard against the risk of inconsistent and arbitrary decision-making.** Under Maryland law, "[a]n agency's decisions must . . . not be so fluid as to become arbitrary or capricious," as occurs if "similarly situated individuals are treated differently without a rational basis for such a deviation."[8] The Draft UPL Action Plan, however, merely reiterates the categories of potential information that it may consider, as already identified in statute and regulation. Significantly, none of the "key decisions" for a UPL action plan the Board itself previously identified—*i.e.*, when UPLs should apply, how the Board will set a UPL, and how the Board will apply a UPL—are meaningfully addressed in the Draft UPL Action Plan.[9] The lack of clear and concrete standards prevents stakeholders from meaningfully participating in and commenting on the PDAB's processes, and the vagueness of the applicable standards raises inherent concerns about whether the policy review and/or UPL setting processes will be appropriately grounded in statutorily relevant factors and consistently applied. AbbVie has identified below several such areas for which the Board has failed to provide clear and meaningful standards:

    - The Draft UPL Action Plan incorporates extensive lists and categories of information and data sources that the Board "may" consider as part of its policy review and UPL setting processes.[10] However, the Draft UPL Action Plan lacks any specific, concrete, and 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 Draft UPL Action Plan fails to provide specific procedures and standards that will govern the Board's determination of whether a UPL is an "appropriate policy solution" or an "appropriate tool."[11] The Draft UPL Action Plan instead merely provides that Board staff "may" analyze "contextual issues" related to the identified affordability challenge. These vague and ambiguous statements fail to establish an ascertainable standard for the Board's decision-making.

    - The Draft UPL Action Plan fails to establish a specific methodology or sufficiently concrete criteria for establishing a UPL. Instead, the Draft UPL Action Plan sets forth an extensive list of disparate methodologies that the Board staff "may"

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[7] *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3)(D) (protecting from disclosure pricing information, including Best Price and Non-FAMP, submitted by a manufacturer to the Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs).

[8] *Harvey v. Marshall*, 389 Md. 243, 303, 884 A.2d 1171, 1207 (2005).

[9] *See* Maryland Prescription Drug Affordability Board, Upper Payment Limits (July 24, 2023), available at: https://pdab.maryland.gov/documents/meetings/2023/pdab_upper_pymt_limits_prst.pdf.

[10] Draft UPL Action Plan at 6-7.

[11] Draft UPL Action Plan at 3, 8.

recommend and asserts that Board staff "may" recommend the Board consider "certain factors" that provide "additional context" to the listed methodologies.[12] The Board states it "may select or prioritize one or more of the methodologies and factors" without clarifying how the Board will select a methodology or how one methodology may be "prioritize[d]" over another.[13] The following are examples of the myriad deficiencies in the PDAB's proposed methodologies:

- The Board proposes a "Therapeutic Class Reference Upper Payment Limit" that would consider "competitor products that have similar chemical structures and act through similar pathways to treat the same conditions" but has not established clear standards to ensure that only appropriate alternatives are considered, leaving the Board free to identify therapeutic alternatives in a standardless vacuum. This ambiguity and lack of transparency can only serve to make the process more arbitrary and inconsistent by obscuring the Board's process and leaving unfettered discretion for the Board to group whatever drugs it wishes as therapeutic alternatives, with no standards and no accountability. Any consideration of 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.

- The Board proposes a "Cost Effectiveness Analysis" as another potential methodology for setting a UPL but acknowledges not only that it has not developed any clear and consistent standards for this methodology, but that such analysis will vary significantly by product "[g]iven the variety of drugs" that could undergo review. The PDAB states only "that the policy review process will help guide the determination of the appropriate health outcome for the drug, and thus, the appropriate threshold." Again, this vague principle of a methodology seems to allow the Board unfettered discretion to design and conduct such analyses in a standardless vacuum with inconsistent principles applied on a drug-by-drug basis.

- The Board proposes a "Budget Impact-Based Upper Payment Limit" methodology for setting a UPL, but merely describes the principle of a methodology in a single sentence and provides no further details or standards for any such approach.

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12 Draft UPL Action Plan at 8-11.

13 Draft UPL Action Plan at 8.

- **The Board should determine "affordability" solely as to state and local government entities to which a UPL would apply and should not consider "affordability" as to commercial payors and other entities to which a UPL would not apply.** A substantial number of the criteria for setting a UPL identified in the Draft UPL Action Plan are derived from drug price and cost metrics associated with commercial utilization of the products the Board will have deemed unaffordable. The Board exceeds the scope of its statutory authority and violates Maryland's APA by determining affordability based on data that clearly, erroneously, unreasonably, and disproportionately skews the Board's findings against manufacturers. For example, relative out-of-pocket costs, payor costs, co-pay and cost-sharing amounts, and various spending metrics, among other data elements, are generally higher for a drug in the commercial context as compared to those entities to and contexts in which a UPL will apply in practice.

- **The Board should not use an "International Reference Upper Payment Limit" as a potential methodology to set a UPL.** The Board proposes an "International Reference Upper Payment Limit" as a potential methodology to set a UPL for a drug it determines to be unaffordable.[14] The Board states in the Draft UPL Action Plan that if it "uses the international reference UPL as the method for setting the UPL, the Board may set the UPL to be the lowest price among those paid in the United Kingdom, Germany, France, and Canada, converted to U.S. dollars."[15] 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 Constitutional concerns. For example, Canadian and many other countries' prices are governed by price controls that are based on the use of quality-adjusted life years ("QALYs"). The U.S. federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability.[16] Indeed, a bill that would prohibit the use of QALYs and other similar discriminatory measures in all federal programs passed in the U.S. House of Representatives earlier this year and is now being considered by the Senate.[17]

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[14] Draft UPL Action Plan at 10.

[15] Draft UPL Action Plan at 10.

[16] In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern." National Council on Disability, "Quality-Adjusted Life Years and the Devaluation of Life with Disability" (November 6, 2019), at https://ncd.gov/newsroom/2019/federal-study-finds-certain-health-care-cost-effectiveness-measuresdiscriminate.

[17] H.R. 485 would prohibit the use of QALYs and other similar discriminatory measures in all federal programs, an expansion from the current prohibition that only applies in a limited fashion to the Medicare program. *See* H.R.485, "Protecting Health Care for All Patients Act of 2023," at https://www.congress.gov/bill/118th-congress/house-bill/485. Note also that the Inflation Reduction Act of 2022, which established the Medicare Drug Price Negotiation Program ("DPNP"), explicitly prohibits use of QALYs as factors for consideration in determining the offers and counteroffers in the DPNP. Social Security Act § 1194(e)(2) ("the Secretary shall not use evidence from comparative clinical

- **The Board should focus on identifying drugs with high out-of-pocket costs for patients and work with *insurers* to lower those out-of-pocket costs.** As part of its proposed criteria for setting a UPL, the Board seeks to prioritize drugs that have a high proportion of out-of-pocket costs for patients compared to the net cost of the drug.[18] If that is the case, we urge the Board to instead consider insurance benefit design as the mechanism to achieve lower out-of-pocket costs. Insurance plans, not manufacturers, control patient deductibles, copays, and coinsurance. The Board must also consider the utilization management practices used by pharmacy benefit managers and insurers (e.g., prior authorization requirements, step therapy requirements, non-medical switching) that can create barriers to patient access to treatment, beyond a singular focus on out-of-pocket costs alone.

- **The Board should clarify several aspects of the UPL setting process, including, without limitation, the term of a UPL, whether a UPL will be set through a formal rulemaking process, and the expert testimony process.** First, other than stating that a UPL should be suspended if it leads to a drug shortage, the Draft UPL Action Plan does not provide any indication of the term of a UPL. Given the highly dynamic nature of drug pricing, there must be, at minimum, adjustment for inflation, which is standard in government pricing, but also, for example and not limited to, consideration of changed circumstances and a process for terminating a UPL. AbbVie requests that the Board clarify how long a drug's UPL will apply and provide its justification for a currently indefinite price control. Second, the Draft UPL Action Plan states that "the procedures in this plan provide for the setting of a UPL by adopting a regulation through notice and comment rulemaking provisions of the Maryland Administrative Procedure Act.[19] The Board has given no indication of whether it intends to pursue notice and comment rulemaking to codify the UPL process proposed in the Draft UPL Action Plan. We urge the Board to clarify whether it intends to initiate formal rulemaking now or in the future. Third, as part of the policy review process, the Board proposes to convene expert testimony hearings. Specifically, the Draft UPL Action Plan states "the Board may convene a hearing for the purpose of receiving expert testimony and soliciting testimony from persons with specific knowledge, skills or expertise."[20] While AbbVie supports the Board's interest in seeking expert input, we are concerned the Board will not be providing sufficient transparency with respect to the feedback it collects and how such feedback will be considered in its approach. The PDAB must provide further information on this opaque proposed expert testimony process. Specifically, among other things, the Board must clarify how experts will be selected for testimony and who will lead this selection process, the criteria for their presentations, how often these hearings will be convened, the process for stakeholder input, and opportunities for manufacturers to select their own experts. The PDAB should also consider seeking testimony, in a transparent manner, from healthcare provider advisory boards that fairly reflect the treating community and can provide input as to what drugs

effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.").

[18] Draft UPL Action Plan at 3.

[19] Draft UPL Action Plan at 2.

[20] Draft UPL Action Plan at 7.

truly should be considered as therapeutic alternatives. It should also identify the sources it is relying on and allow manufacturers a meaningful opportunity to engage in discussion on the input.

- **We continue to have, and reiterate, our concerns regarding the reliability of information sources used by the Board.** The Draft UPL Action Plan contemplates the Board considering and using data and information from a variety of sources.[21] The PDAB also proposes that it may consider additional information beyond those sources identified in the Draft UPL Action Plan.[22] However, the Board fails to articulate how it will appropriately consider and weigh the accuracy, reliability, and validity of these varied sources and how the Board will limit its consideration of data and information from such sources to the factors listed in statute and implementing regulations. The PDAB's decision-making can be only as accurate as the data and information the Board relies upon, so we request that the Board identify with greater specificity the processes it will implement to help reduce the risk that the Board's analyses may rely on erroneous, incomplete, dated, or otherwise misleading and/or deficient datasets or analyses.

- **We continue to have, and reiterate, our concerns about the adequacy of the Board's safeguards for ensuring the confidentiality of all trade secret, confidential, or proprietary information used in association with the activities of the Board, and for preventing the unlawful and unconstitutional disclosure of such information.** Regulations promulgated by the Board state the Board "may . . . determine that information it has received is confidential, trade secret, or proprietary."[23] We believe this is inconsistent with the plain reading of the PDAB statute, which states that "all information and data obtained by the Board under the subtitle, that is not otherwise publicly available: (1) Is considered to be a trade secret and confidential and proprietary information; and (2) Is not subject to disclosure under the Public Information Act."[24] The statute thus does not grant the Board authority to "determine" whether information is confidential, and thus, protected. That authority rests with those submitting data to the Board and the individual certifying that information is designated as protected information. If data is not otherwise publicly available, then its status under the statute is unambiguously protected information and the Board should recognize it as so. Those making decisions as to what data they will submit, and in what format, should have transparency as the procedures and protection for such statutorily protected trade secret and confidential and proprietary information so that they are able to meaningfully participate in the requested data submission process.

- **We continue to have, and reiterate, our concerns regarding deficiencies in the Board's drug selection process.** As the manufacturer of a drug selected for cost review, AbbVie has serious concerns about the Board's drug selection process and as noted above, the quality of available data to the Board. Selecting drugs for cost review requires a transparent and consistent process, but the Board has not publicly adopted or applied such a process.

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21 Draft UPL Action Plan at 6-7.

22 *Id.*

23 Md. Code Regs. 14.01.01.04.

24 Md. Code Ann., Health-Gen. § 21-2C-10 (emphasis added).

Among other things, we are concerned that the Board's selections may not reflect drugs that pose actual affordability challenges to Maryland patients. With respect to data the Board considered during the drug selection process, the Board has only provided a limited subset of data in a public dashboard[25] which lacks context and complete source information. Moreover, as discussed above, such data considered by the PDAB largely pertains to commercial utilization of SKYRIZI®. If the Board had obtained and evaluated more complete and accurate data during the selection process, it would have been found that SKYRIZI results in overall savings compared to other medicines and greatly improves patient outcomes, and that the vast majority of patients, whether or not insured, can access SKYRIZI for little or no cost. The lack of consistency and transparency regarding the Board's decision-making in selecting drugs for cost review is contrary to the public interest, raises questions under Maryland's APA, and has critically deprived AbbVie of the ability to effectively participate in the Board's selection process.

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Thank you for this opportunity to provide our comments on the Draft UPL Action Plan. Please contact Helen Fitzpatrick at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

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

[25] *See* Maryland PDAB, "Drugs Referred to the Stakeholder Council- Dashboard," at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

Exhibit 2 to AbbVie's November 8, 2024 Comment Letter

October 18, 2024

VIA ELECTRONIC MAIL TO RYANE.NECESSARY@MLIS.STATE.MD.US AND DANA.TAGALICOD@MLIS.STATE.MD.US

The Honorable Bill Ferguson, Co-Chair
The Honorable Adrienne A. Jones, Co-Chair
Members of the Legislative Policy Committee
Department of Legislative Services
Legislative Services Building, Room 200B
90 State Circle, Annapolis, MD 21401

Re: Written Testimony Explaining Why the Legislative Policy Committee Cannot Approve the Maryland Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Dear Hon. Ferguson, Hon. Jones, and Members of the Legislative Policy Committee:

AbbVie Inc. ("AbbVie" or "the Company") is pleased to submit this written testimony in advance of the Legislative Policy Committee's ("LPC's") October 22, 2024 hearing on the "Health General Article § 21-2C-13(d) Prescription Drug Affordability Board Upper Payment Limit Action Plan" ("UPL Action Plan") that the Maryland Prescription Drug Affordability Board ("PDAB" or "the Board") approved on September 10, 2024. ***For the reasons discussed herein, the LPC cannot approve the UPL Action Plan.***

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.

AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review"), a critical step towards the potential future establishment of a UPL by the PDAB. Accordingly, AbbVie has a significant interest in the Board's activities generally, and the UPL Action Plan specifically. Since the Board's formation, AbbVie has actively participated in the PDAB's administrative processes — that is, when the Board has presented opportunities to do so. As a directly impacted stakeholder, we have attempted to meaningfully engage with the Board through, among other things, our submission of numerous public comments on various topics, as well as multiple requests to the Board under Maryland's

Public Information Act seeking basic but critical information the Board — in stark contrast to other state PDABs — has not made publicly available.[1]

SKYRIZI® is approved by the U.S. Food and Drug Administration for the treatment of three (3) different conditions: (1) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; (2) active psoriatic arthritis in adults; and (3) moderately to severely active Crohn's disease in adults.[2] The product has clear and well-defined clinical and economic value to patients and payors alike supported by an extensive body of data, information, and health care provider and patient accounts, among other relevant information we have provided directly to the Board during its PDAB review and selection processes. Of particular concern to AbbVie, the Board has never even explained how or why SKYRIZI® was chosen for affordability review, notwithstanding all the compelling information to the contrary.

As a threshold matter, AbbVie has significant concerns with the Maryland PDAB statute and the Board's implementation of the law, including but not limited to its adoption of the UPL Action Plan. The Maryland PDAB statute is flawed public policy that will not result in improving patient affordability. Moreover, the Board's implementation of the law is unconstitutional, potentially implicating the U.S. Constitution's Dormant Commerce Clause, Supremacy Clause, Takings Clause, and Due Process Clause, among other issues. Additionally, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's Administrative Procedure Act. Among other examples, the Board's lack of transparency regarding its decision-making is contrary to the public interest and has deprived AbbVie and all other impacted stakeholders, including Maryland resident patients, of the ability to effectively and predictably participate in the PDAB's drug selection and review processes.

The Board's development of its UPL Action Plan has been rushed, with only a superficial focus on critical issues of substance, as evidenced by the final product now before the LPC for review. Indeed, we seriously question whether the Board actually considered any of the feedback in the **twenty-two** public comments it received on the initial draft UPL action plan from providers, pharmacies, trade associations, advocates, and manufacturers (including AbbVie) given the following timeline, and the few revisions made to the final version adopted by the PDAB now before the LPC:

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[1] *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.

[2] SKYRIZI®, Full Prescribing Information, at https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

- **Friday, August 9, 2024:** Board publishes initial draft of UPL Action Plan.
- **Monday, August 26, 2024:** Deadline to submit public comments on draft UPL Action Plan.
- **Monday, August 26, 2024:** Date of the Maryland Prescription Drug Affordability Stakeholder Council ("PDASC" or "Stakeholder Council") meeting during which the PDASC — the purpose of which is to represent impacted stakeholders[3] — provided feedback to the Board on the draft UPL Action Plan. It seems inconceivable that before it met that day, the Stakeholder Council could have read and considered each and every one of the twenty-two comments submitted by that **same day**, betraying a lack of any intent by the PDAB to provide an opportunity for meaningful public engagement.
- **Friday, August 30, 2024:** Board issues revised draft UPL Action Plan on the Friday of Labor Day Weekend.[4]
- **Tuesday, September 10, 2024:** PDAB meeting during which the Board approves the minimally revised draft UPL Action Plan.[5]

Maryland courts have consistently held that the state's Administrative Procedure Act requires government entities like the PDAB to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[6] Under this reasoned analysis standard, such "[f]indings of fact must [also] be meaningful and cannot simply repeat statutory criteria, broad conclusory statements, or boilerplate resolutions."[7] This is exactly what we see in the UPL Action Plan, however. The timing of the Board's approval of the UPL Action Plan relative to the number of comments the PDAB received from the public, together with the lack of quality of the final document, unequivocally demonstrate the Board's efforts fail to satisfy applicable standards and compounds our concerns regarding the legality and propriety of the Board's activities. **We respectfully request that the LPC consider the enclosed comment letter, which summarizes AbbVie's main objections to an earlier draft of the UPL Action Plan (which, as noted above, was largely unchanged in the final version now before the LPC).** Because the Board failed to address our concerns in the current draft, the UPL Action Plan that the LPC is considering suffers from the same flaws and cannot be approved.

Beyond the aforementioned failures in proper conduct by the Board, we bring to your attention a critical constitutional concern that the Board has publicly acknowledged but has

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[3] Maryland Prescription Drug Affordability Board, "Prescription Drug Affordability Stakeholder Council, 2022 Stakeholder Council Meeting," at https://pdab.maryland.gov/pdab_stakeholder_2022.html ("The purpose of the Prescription Drug Affordability Stakeholder Council is to provide stakeholder input to assist the PDAB in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system").

[4] Maryland Prescription Drug Affordability Board, "Maryland Prescription Drug Affordability Board Upper Payment Limit Action Plan (August 30, 2024)," at https://pdab.maryland.gov/Documents/UPL%20Action%20Plan.2024.08.30.1745.pdf.

[5] Maryland Prescription Drug Affordability Board, "PDAB Meeting: Upper Payment Limit Action Plan (September 10, 2024)," at https://pdab.maryland.gov/Documents/meetings/2024/FINAL%202024.09.10%20Presentation%20UPL%20.pdf.

[6] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g.*, *Mortimer v. Howard Research and Development Corp.*, 83 Md. App. 432, 442 (1990).

[7] *Bucktail, L.L.C. v. County Council of Talbot County*, 352 Md. 530, 553 (1999).

not addressed in the UPL Action Plan or other work product — that a Maryland UPL could reasonably have far-reaching impacts on federal pricing metrics that determine drug reimbursement amounts across the United States, including purchases under *federal* and other healthcare programs that occur entirely outside of Maryland. This legal and practical reality cannot be ignored.

As background, drugs that are dispensed or administered in federal healthcare programs – such as Medicaid and Medicare Part B – may be reimbursed based on metrics that consider a manufacturer's sales outside of that federal program. For example, in the Medicaid Drug Rebate Program, manufacturers of covered outpatient drugs are required to pay rebates to state Medicaid programs that generally are based on a drug's "Best Price" to an eligible entity.[8] In enacting this provision, Congress intended that the Medicaid program would get the "Best Price" offered to other commercial customers.[9] Thus, a manufacturer's sale of a drug to an eligible customer is excluded from Best Price *only* if it falls under an exclusion that is explicitly enumerated in the federal Medicaid statute. For example, prices offered under certain federal healthcare programs are excluded (e.g., Indian Health Service, Department of Veterans Affairs, Medicare Part D), as well as prices used in a State pharmaceutical assistance program.[10] However, there is no exclusion from Best Price that appears to exclude a future Maryland UPL – which would apply to certain purchases and reimbursements under Maryland state programs.[11]

If a UPL were to affect any federal pricing metrics, it would raise significant Constitutional infirmities, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect. In recognition of this serious legal obstacle, the UPL Action Plan states that a UPL "shall not . . . impact statutory or regulatory amounts, such as Best Price."[12] In our enclosed comments to the Board, we supported the Board's statement that any UPL should not impact Best Price or any other federal pricing metrics, for the reasons summarized above, but asked the Board to explain how it would effectuate this position in practice in light of significant implementation challenges which we outlined. We are troubled that the Board has not further addressed this issue.

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8 42 U.S.C. § 1396r-8(c)(1)(C)(i) ("The term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," subject to enumerated exclusions.).

9 136 Cong. Rec. E2813 (1990) (Sep. 12, 1990) (statement of Senator Ron Wyden) ("There is simply no logical reason why the Medicaid Program . . . should have to pay prices for drugs which average 40 to 70 percent more than those prices paid by other large purchasers.").

10 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I-VI).

11 Md. Health Gen. § 21-2C-14(a) ("If [the UPL Action Plan] is approved . . . the Board may set upper payment limits for prescription drug products that are: (1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including: (i) State or county correctional facilities; (ii) State hospitals; and (iii) Health clinics at State institutions of higher education; (2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or (3) Purchased for or paid for by the Maryland State Medical Assistance Program.").

12 UPL Action Plan at 3.

abbvie

Fundamentally, a state administrative body (such as the Maryland PDAB) cannot unilaterally exclude a given purchase from Best Price. Only the U.S. Congress can add exclusions to the federal Best Price statute. Additionally, statutory and regulatory pricing metrics like Best Price (and Medicaid Average Manufacturer Price and Medicare Part B Average Sales Price) are calculated on a quarterly basis and continually change;[13] therefore, the Board's standard would therefore require constant monitoring. Also, to ensure there is no impact, the Board would need to obtain confidential information which the PDAB and, more broadly, the State of Maryland, may not possess just to know whether and how a particular UPL might affect "statutory or regulatory amounts." In many cases such information is protected from disclosure to a state or other third party by federal law,[14] and the Board lacks authority to compel disclosure of the information in contravention of such federal protections.

The intent of Maryland's PDAB law is "to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products."[15] If the Board does not provide meaningful information regarding how it determines whether a drug will lead to an affordability challenge, or how it will develop a UPL if the Bord determines a drug is "unaffordable," AbbVie and the broader public have no way to determine whether the Board is acting consistently with its charge. Given that the UPL Action Plan not only fails to meet this statutory threshold, but further, also raises significant constitutional concerns, the LPC cannot approve the UPL Action Plan.

* * * *

Thank you for this opportunity to provide written testimony on the LPC's consideration of the UPL Action Plan. Please contact Helen Fitzpatrick at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

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

Enclosure

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[13] 42 U.S.C. § 1396r-8(b)(3)(A) (requiring manufacturers to report to the Centers for Medicare & Medicaid Services their Best Price and Average Manufacturer Price every calendar quarter); 42 U.S.C. § 1395w-3a (Average Sales Price is calculated each calendar quarter).

[14] *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3)(D) (protecting from disclosure pricing information, including Best Price and Non-FAMP, submitted by a manufacturer to the Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs).

[15] Md. Code Ann., Health-Gen. § 21-2C-02(b).

February 10, 2025

Christina Shaklee
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
christina.shaklee1@maryland.gov

Via Electronic Correspondence

RE: COMAR 14.01.01 (General Provisions) and COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Dear Maryland Prescription Drug Affordability Board,

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We are writing to comment on the Maryland Prescription Drug Affordability Board's draft regulations, COMAR 14.01.01 (General Provisions) and COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits). In reviewing the regulations, Aimed Alliance urges the Board to:

(1) Consider out-of-pocket costs for patients;
(2) Adopt a UPL monitoring approach where the Board assumes responsibility, not patients;
(3) Remove the authority for the chair or staff designee to limit repetitious testimony from speakers; and
(4) Prohibit the use of QALYs in PDAB assessments.

I. Consider Out-of-Pocket Costs for Patients

The purpose of the PDAB "is to protect *State residents,* State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products" (emphasis added). [1] However, when outlining the methodology for establishing an upper payment limit (UPL), the draft rules only consider total out-of-pocket costs for state health plans, county, bicounty, and municipal health plans, and Medicaid. They do not consider the direct patient costs. As such, Aimed Alliance urges the Board to incorporate patient out-of-pocket costs, including copayments, deductibles, and other associated costs, when determining a UPL. This would ensure a more patient-centered approach that fully considers the UPL's impact on patient affordability. This more comprehensive assessment would also provide a clearer picture of the economic burden patients face and help the Board fulfill its mission of protecting State residents from the high costs of prescription drugs.

[1] Md. Code, Health-Gen. § 21-2C-02.

II. Adopt a UPL Monitoring Approach Where the Board Assumes Responsibility, Not Patients

We appreciate the Board's commitment to ensuring that any potential imposition of a UPL is monitored. If the Board does move forward with imposing a UPL, we believe it is essential for the responsibility of any ongoing monitoring to rest with the PDAB itself. Patients already face substantial burdens in managing their health, personal lives, and careers, and it is unrealistic to expect them to proactively follow complex regulatory changes or the intricacies of UPL implementation. To facilitate effective monitoring, we suggest that the Board actively engage trusted stakeholders within relevant disease communities. These stakeholders can provide critical feedback and share experiences regarding access, out-of-pocket costs, and overall impact of UPLs on patients. By regularly consulting these community leaders, the Board will be better equipped to respond to patient concerns and ensure that any unintended consequences of UPL policies are promptly addressed.

III. Remove the Authority for the Chair or Staff Designee to Limit Repetitious Testimony from Speakers

The proposed rules authorize the Chair or staff designee to limit repetitious testimony. However, it is essential to respect the time and commitment of individuals, especially patients, who volunteer to speak at these hearings. When stakeholders sign up to participate, they invest their time and perspectives, and their contributions should be heard with respect. Limiting repeated testimony may inadvertently silence important concerns of patients and caregivers. Therefore, we urge the Board to remove the language providing the Chair or staff designee the authority to limit repetitious testimony from speakers in the procedures for conducting informal hearings.

Moreover, when a particular issue or concern is repeatedly raised by multiple individuals, it may signal a broader and potentially significant issue that warrants additional attention and discussion. Dismissing or limiting these repeated comments may overlook critical insights that could shape more informed and effective decisions. Thus, we urge the Board to remove the language providing the authority for the chair or staff designee to limit repetitious testimony to foster a positive environment that encourages stakeholder engagement and ensure that policy decisions are based on a comprehensive understanding of the issues.

IV. Prohibit the Use of QALYs in PDAB Assessments

Under the proposed rules, the Board may use a "cost-effectiveness analysis" when setting the UPL for a prescription drug. This entails modelling how much health benefit is gained per dollar of additional spending when using a drug product compared to an alternative. These frameworks, however, can limit patient access to care by assigning a fixed value to a medication, without considering individual needs or circumstances. For example, quality adjusted life years (QALYs) aim to quantify the health benefits of medical interventions or healthcare programs that are often used in decision-making to ration healthcare resources. The use of QALY measures raises significant ethical concerns, as these measures effectively place a monetary value of human life based solely on a diagnosis, suggesting that individuals with chronic, debilitating, and rare conditions are less valuable than those with common conditions. These types of approaches treat

individuals' lives and health as a commodity and ignores patients' and practitioners' individualized perception of the value of a specific treatment. Aimed Alliance reiterates its longstanding position against using QALYs to evaluate any treatment and urges the Board to prohibit the use of QALYs throughout the UPL-setting process and in any cost effectiveness analysis.

V. Conclusion

In conclusion, we urge the Board to revise its rules to prioritize patients by (1) considering the total out-of-pocket costs for patients; (2) adopting a UPL monitoring approach where the Board assumes responsibility, not patients; (3) removing the authority for the chair or staff designee to limit repetitious testimony from speakers; and (4) prohibiting the use of QALYs in PDAB assessments.

We appreciate the opportunity to provide written comments. If you have any questions or would like to further discuss our concerns. Please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance

VIA Electronic Delivery February 10, 2025

Christina Shaklee

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

Re: Maryland Prescription Drug Affordability Board Notice of Proposed Action: COMAR 14.01.01 General Provisions and COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits

Dear Ms. Shaklee:

The Biotechnology Innovation Organization (BIO) and Maryland Tech Council (MTC) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s Notice of Proposed Action: COMAR 14.01.01 General Provisions and COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits.

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.

The MTC is Maryland's largest association of life sciences and technology companies. MTC has over 800 Maryland member companies that span the full range of the technology sector. Our vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the nation. We bring our members together and build Maryland's innovation economy through advocacy, networking, and education.

With respect to this Notice of Proposed Action, BIO and MTC's comments in this letter address edits to Maryland's proposed amendments and regulations made since December 2, 2024. For more detailed recommendations on COMAR 14.01.01-14.01.09, we ask that the Board reference BIO's previous comments submitted on November 8, 2024.

Please note our recommendations do not resolve the more fundamental issues of UPL effectuation and our positioning remains that UPLs should not be enacted.

Estimate of Economic Impact

BIO and MTC are concerned that the Economic Impact chart does not provide sufficient context or supporting information on how "negative" or "positive" impact indications were determined. It is challenging for stakeholders to derive meaningful information from the chart without explanation or supporting data and documentation. As the Board completes its

analysis to finalize this section, BIO and MTC urges the Board to thoroughly examine the potential negative impacts of a UPL for all parties, including the impact to pharmacies and providers, whose costs to acquire supply of a drug subject to a Maryland UPL may exceed the UPL-based reimbursement from Maryland state & local governments. A 2024 study by Avalere predicts that providers may change referral, prescribing, and acquisition patterns for drugs subject to UPLs. Patients who visit small provider practices and specialty providers may be disproportionately harmed if those providers cannot, or will not, access these drugs anymore because reimbursement for associated services is limited.[1] In addition, the study suggests that plans and PBMs may reform their benefit designs for drugs subject to UPL, in such that those drugs may be shifted onto higher formulary tiers or be removed from the plan's formulary altogether, which would significantly harm patient access to those products and even increase patient out-of-pocket costs. It is evident that establishing a UPL has profound negative implications, and a thorough analysis is necessary for the Board to carefully weigh and mitigate any unintended consequences before proceeding with this rulemaking.

***

BIO and MTC appreciate the opportunity to provide feedback to the Maryland PDAB through these draft regulations. We look forward to continuing to work with the Board to ensure 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.

Sincerely,

/s/

Melody Calkins
Director
Healthcare Policy
BIO

Kelly Schulz
Chief Executive Officer
Maryland Tech Council

[1] Upper Payment Limits on Drugs Could Alter Patient Access. Avalere. April 8, 2024. Retrieved: https://avalere.com/insights/upper-payment-limits-on-drugs-could-alter-patient-access

Kimberly Y. Robinson
Vice President
State Government Affairs

CareFirst BlueCross BlueShield
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Baltimore, MD 21224-5744
Tel. 410-528-2221

February 10, 2025

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

Submitted via email to christina.shaklee1@maryland.gov

RE: Notice of Proposed Action

Dear Ms. Shaklee:

CareFirst BlueCross Blue Shield (CareFirst) appreciates the opportunity to again submit comments to inform development of regulations for the Maryland Prescription Drug Affordability Board (PDAB or the Board).

In our 87th year of service, CareFirst is one of the nation's largest not-for-profit healthcare companies that provides a comprehensive portfolio of health insurance products and administrative services to more than 3.5 million individuals and employers in the District of Columbia, Maryland, and Northern Virginia. As part of our mission, CareFirst is committed to driving transformation of the healthcare experience with and for our members and the communities we serve. CareFirst believes everyone should be able to get the medications they need at an affordable price. Therefore, we applaud the Board's efforts to curb prescription drug costs and improve healthcare affordability for Maryland residents.

We continue to strongly support the Maryland PDAB and advocate for PDAB legislation in the District of Columbia and Virginia. We appreciate some of the changes the Board has already made to previously proposed regulations. However, in reviewing the latest draft of proposed regulations, CareFirst continues to believe there are some opportunities to strengthen the language, particularly where it is ambiguous and could lead to affordability objectives not being fully achieved. We offer the following recommendations to support effective implementation of upper payment limits (UPL) and welcome continued engagement with the Board to ensure any regulations meaningfully help control prescription drug costs and ensure access to drugs that are currently unaffordable for some Marylanders.

We appreciate the Board removing the proposal to not set a UPL if utilization of the prescription drug by an eligible governmental entity is "minimal," given the ambiguity of such language. Additionally, we applaud the Board for defining the term "system net cost" to mean the sum of "net cost" previously defined and the per unit patient out-of-pocket (OOP) cost. We note the revised regulations direct the Board to prioritize drugs for UPLs that have a high proportion of OOP costs compared to the newly defined term, "system net cost." As we stated previously,

including the OOP costs paid by patients more accurately reflects the total spend on drugs selected for UPLs. Refining the UPL criteria to consider the OOP costs of consumers improves the selection criteria for drugs potentially subject to a UPL. The Board should also consider using this new definition in its methodology for setting the UPL, for example by looking at the lowest *system* net cost, rather than net cost, among competitor products in the therapeutic class. Cost-sharing, plan design, and other factors impacting "competitor" products could shift the calculation of the UPL. Finally, in Medicare Part D, net cost includes beneficiary cost-sharing in addition to those already listed in the Board's proposed definition (i.e., price concessions, discounts, and rebates). For these reasons, we recommend "system net cost," which includes patient cost-sharing amounts, be used where appropriate throughout the regulations.

We continue to support the Board's decision to not set a UPL for products with a generic and sufficient therapeutic equivalents on the market; however, we recommend the Board further clarify its decision to set the therapeutic equivalent threshold at nine or more. Very few, if any, prescription drugs would be expected to have nine or more therapeutic equivalents, effectively making any drug product selectable for a UPL. Furthermore, research has shown that the entry of four generic competitor products can reduce prices by more than 70%,[1] suggesting a lower threshold may be sufficient.

The Board proposes to not set a UPL that impacts statutory or regulatory amounts, such as the Medicaid Best Price. We remain concerned about how this may be implemented and recommend the Board clarify how this provision will be operationalized, particularly with respect to Medicaid Best Price, which requires drug manufacturers to offer state Medicaid programs the best price given to any other purchaser. Based on this requirement, establishing a UPL would seem to drive down the Medicaid Best Price, which should benefit the Medicaid program.

Finally, we continue to believe that additional clarity is needed around the enforcement and monitoring procedures that will be used by the Board to ensure the UPL is being offered. The Board states that it will "work with eligible governmental entities to develop the best method for implementing the UPL for the entity and a prospective effective date that provides sufficient time for implementation," but we believe additional clarity on how the Board will hold the eligible governmental entities accountable for the UPL is necessary.

Once again, CareFirst applauds the Board for moving forward with establishing UPLs for high-cost drugs. We look forward to continued collaboration and partnership with you to ensure these UPLs are developed as intended to help address affordability challenges for Maryland residents.

Sincerely,

Kimberly Y. Robinson

[1] U.S. Food and Drug Administration. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. December 2019.

EACH PIC COALITION

February 10, 2025

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

Comments on Proposed PDAB Regulation COMAR 14.01.05

Dear Members of the Board, Stakeholder Council, and Staff:

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.

On behalf of the organizations below, we would like to submit feedback on COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) which defines the process for establishing an Upper Payment Limit by the board.

.04 Policy Review - Information Gathering

We urge the board to put significant emphasis on gathering input from patients during the information gathering process of establishing a UPL. This will ensure that the board is appropriately identifying and addressing real patient problems and that patients' lived experiences are addressed by board proposed policy solutions.

To foster more robust patient input into the UPL process, the board should consider setting minimum thresholds for patient input. Additionally, the board should be required to hold meetings, focus groups, or other scheduled events at varied times and locations to ensure members of the public are given adequate opportunity to attend. Also, focus groups and surveys should have basic parameters for both structure and participant numbers to be considered representative of the viewpoints of the public.

Further, we recommend that the board work directly with patient organizations to better understand and attain patient perspectives. There are many proven methods patient organizations have used to collect meaningful, unaltered data from patients (including discussion sessions, surveys, etc.) that we could facilitate, acting as a bridge to enable more voices to be heard. We could combine these efforts with those conducted by the board, in a transparent way that ensures the raw patient data is untouched, thus increasing real-world evidence without any perceived bias of data submission.

.05 Policy Review—Preliminary Policy Recommendations

We applaud continued discussions and emphasis by the board and stakeholder council to consider alternative policy solutions along with UPLs. However, we continue to urge the board to seek authority to implement policy alternatives before proceeding with the UPL process.

The board currently has no authority to implement alternative policies nor has it outlined any alternatives under consideration. Proceeding with the UPL process without taking these important steps increases the likelihood that the board will resort to implementing UPLs simply because other policy solutions have not been explored and are therefore not available to implement.

Currently, the board simply does not have enough tools to address patient needs and lower drug costs. Therefore, we urge the board to suspend its ongoing cost reviews and dedicate board meetings and time to exploring other potential policy options.

.06. Policy Review – Process for Establishing a UPL

We urge the board to proceed with extreme caution when considering implementing reference prices within a therapeutic class of drugs. We fear that lowering prices for only some drugs within a therapeutic class could incentivize payers to implement utilization management or adverse tiering for some or all the drugs in the class. As a result, patients could face non-medical switching of their medications, increased costs, or decreased access to their preferred medication.

Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered. For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

.08 Establishing and Monitoring a UPL

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. We appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these changes after the UPL has been implemented.

Patients will bear the consequences of these policies and are at risk of immediate harm during the monitoring process, let alone the time it would take the PDAB to take any action to mitigate the actions.

Instead, we urge the board to work with the state legislature to put in place safeguards for patients prior to moving forward with UPL policies to protect patients from increased utilization management, compromised access to drugs under review, and other unintended consequences of the board's actions. Further we believe that monitoring for utilization management for only the drug subject to review will be inadequate and suggest interventions be put in place across all drugs in the class.

We look forward to continuing to engage with staff on the specifics of board policies and to provide testimony during board meetings. We invite any and all opportunities to speak directly with any board member who would be interested in more detailed perspectives from our national network of patient organizations and allied groups.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

Advocates for Compassionate Therapy Now
AiArthritis
Aimed Alliance
Arthritis Foundation
Biomarker Collaborative
Caring Ambassadors Program
CF United
Chronic Care Policy Alliance
Community Liver Alliance
Crohn's & Colitis Foundation
Exon 20 Group
Global Healthy Living Foundation
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
Infusion Access Foundation
Looms For Lupus
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MET Crusaders
Multiple Sclerosis Foundation
National Bleeding Disorders Foundation
National Infusion Center Association
Partnership to Improve Patient Care
Patients Rising
PD-L1 Amplifieds
Pharmacists United for Truth and Transparency
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February 4, 2025

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
Sent via email to: christina.shaklee1@maryland.gov

RE: Comment to Notice of Proposed Action, [24-221-P]

Dear Board,

Our organization, the Global Healthy Living Foundation (GHLF), represents chronically ill patients across the country. These patients rely on various therapies to live the most fulfilling lives they can. As such, our organization has taken a keen interest in the work of Prescription Drug Affordability Boards (PDABs or Boards) in various states and the potential impact to our patients' accessibility to necessary drugs.

We write to comment on your Proposed Action [24-221-P] as to the amendment of existing regulations and adoption of new regulations under COMAR Section 14.01. When considering costs related to drug usage, we implore you to listen to the concerns of patients. The treatment of chronically ill patients – who rely regularly on medications to live – should be of paramount importance. The cost relative to *patients* should be afforded greater weight than cost savings to institutions.

In the Summary of Economic Impact, it notes that the implementation of Upper Payment Limits for important drugs will "decrease drug expenditures by state and local governments." This is an obvious statement! If a government board were to propose an upper payment limit on the costs of gasoline for fire vehicles, it would lead to reduced expenditures (for gasoline) for local governments. But this would not necessarily lead to an overall reduction in expenditures for local governments! Less funding for local fire departments could lead to more uncontained fires, leading to larger costs later.

Similarly, the costs "saved" by local governments via an upper payment limit may save short term costs but lead to devasting costs down the road for local governments required to covered health care needs for patients requiring surgeries, hospitalizations, and more because they were denied access to medications that had kept these patients stabilized.

Beyond the costs to the local governments, we urge you to look at the costs to patients directly.

People in the United States pay more for medicine than people living in many other parts of the world simply because our system allows for secret negotiations between drug manufacturers, pharmacy benefit managers, and health insurers that artificially inflate drug prices through complex contracts that include rebates and discounts. Yet, these savings never trickle down to patients. When assessing drug costs the Board should review extensively the role of pharmacy benefit managers (PBMs) in rising patient costs.

The statement in Section III (Assumptions) that "the proposed action has no impact on individuals with disabilities" is nothing short of tone deaf.

Patients often spend years trying different medications before they can find one that leads to stabilization of their condition. Disruptions in the marketplace could have devastating consequences for these patients. Just in terms of costs: the cost to an individual who ceases to be stable could include lost income, increased childcare costs associated with the inability to rear their children, and medical expenses not covered by existing plans. Beyond the fiscal costs are the human ones: to through chaos into the system can destabilize chronically ill patients leading to mental health ailments that can take years to remedy.

We thank you for your time, and again, hope that you will consider the patient voices as you deliberate on the costs of drugs.

Sincerely,

Steven Newmark
Chief Policy Officer
Global Healthy Living Foundation

February 10, 2025

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

We welcome the opportunity to provide public comment in support of the proposed regulations under **COMAR 14.01.05, *Policy Review, Final Action, Upper Payment Limits.*** We appreciate the thoughtful consideration the Staff, Board, and Stakeholder Council Members have given this important work, and look forward to how Maryland can continue to remain a leader in establishing processes for Prescription Drug Affordability Boards around the nation.

The October approval of the Board's Upper Payment Limit Action Plan by the Legislative Policy Committee was an important demonstration of trust in the Upper Payment Limit (UPL) process for state and local government entities. As one of the few policy solutions to review, engage, and apply to the entirety of the supply chain, a UPL offers increased transparency and a balanced approach between the revenue needs of industry members and affordability needs of our state and local governments.

The proposed regulations that detail the procedural processes of UPL determinations are comprehensive and transparent, and we thank you for the continued opportunity to engage with the Board and Stakeholder Council on these matters. For increased patient accessibility, we would encourage the Board and its Staff to consider ways in which patient and consumer input that applies to a specific prescription drug product be made available for Board and Stakeholder Council consideration each time said product is being considered for selection, affordability review, and final UPL determination, without requiring resubmittal during each open public comment period.

Should the Board and Staff wish to speak with Maryland patients regarding accessibility to meetings and public comment submittal, we would be happy to connect you with consumers willing to provide feedback. Thank you for your work.

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www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-9000

Eli Lilly and Company

Lilly USA
Lilly Corporate Center
Indianapolis, IN 46285
USA

February 10, 2025

By Electronic Submission

Christina Shaklee
Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
christina.shaklee1@maryland.gov

Re: Proposed Regulations – COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) [24-221-P]

Dear Ms. Shaklee and Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments on the Board's Policy Review, Final Action, and Upper Payment Limits ("UPLs") Proposed Regulations (the "Proposed Regulations") published in the Maryland Register on January 10, 2025.[1]

The Proposed Regulations are identical to the Draft Regulations previously published by the Board and, like the Draft Regulations, would effectively codify the Board's UPL Action Plan in regulations with only slight modifications.[2] Lilly therefore reasserts and incorporates by reference, its prior comments on the Draft Regulations and UPL Action Plan.[3] Below, we summarize these prior comments and highlight recent Board activities that exemplify our concerns.

Lilly continues to believe price controls, like UPLs, are bad policy that harm patients. Price controls harm patients both by limiting access to medicines and by suppressing the development of new and potentially transformative treatments. The Board should consider establishing price controls only after determining that non-UPL policy options could not address a given

[1] *See* Notice of Proposed Action, 52 Md. Reg. 1–46 (Jan. 10, 2025), available here.
[2] *See* Draft Regulations (Nov. 18, 2024), available here; Action Plan (Sept. 10, 2024), available here.
[3] Letter from Lilly to Board (Nov. 8, 2024); Letter from Lilly to Board (Aug. 26, 2024). Copies of Lilly's prior comments are enclosed for reference.

prescription drug's affordability challenge or high out-of-pocket costs, and only after evaluating and mitigating any potential obstacles for patients to access their medicine.

Lilly also continues to have concerns about the lack of procedural safeguards included in the proposed UPL-setting procedures. In particular, the Board should take related actions sequentially, at separate Board meetings, to ensure rational and methodical decision-making. At the Board's recent January 27, 2025 meeting, it approved amendments to the cost review regulations and then presented a report conducted under the same regulations. Lilly remains concerned that combining multiple decisions into a single meeting risks producing arbitrary decision-making that fails to fulfill the Board's obligations under the PDAB statute and the Maryland Administrative Procedure Act ("APA").

Additionally, Lilly is troubled by the Board's failure to address the substantial public feedback on the UPL-setting process.[4] The APA requires the Board to consider the feedback it receives and explain its reasoning for declining to make the recommended changes, and the Board has not done so, to-date.

I. Inadequate Procedural Safeguards

The Proposed Regulations fail to provide the procedural protections needed to facilitate sound and APA-compliant decision-making. Consistent with our prior comments, Lilly is particularly concerned that the Proposed Regulations do not guarantee meaningful comment opportunities, including by permitting the Board to act through a combined decision-making process.[5]

Each Step of the PDAB's Process Must Be Separately and Sequentially Completed

Lilly continues to have serious concerns about the Board's ability to act through a combined decision-making process. Specifically, the Proposed Regulations would permit the Board to finalize determinations about whether a medicine has or will lead to an affordability challenge or high-out-of-pocket costs, whether UPL or non-UPL measures are appropriate policy solutions, and the most appropriate UPL amount *all in the same Board meeting*.[6] Lilly strongly urges the Board to revise the Proposed Regulations to explicitly prohibit such combined decision-making, which contravenes both law and logic for the reasons discussed in Lilly's prior comments and summarized below:

- First, the PDAB statute prohibits a combined decision-making process that permits concurrent performance of cost reviews, policy reviews, and UPL calculations.[7] By its express terms, the statute requires the Board to first determine whether use of a medicine

[4] *See* Draft Regulations; *Reports*, Md. Prescription Drug Affordability Bd., https://pdab.maryland.gov/Pages/reports.aspx (last visited Jan. 27, 2025) (reflecting multiple drafts of the UPL Action Plan).
[5] *See* Letter from Lilly to Board at 2–4 (Nov. 8, 2024); Letter from Lilly to Board at 2–3 (Aug. 26, 2024).
[6] *See* Proposed Regulations § 14.01.05.07B(3)(b) ("[T]he adoption of the final cost review study report, non-UPL policy recommendations, and proposed regulations setting a UPL amount . . . [m]ay be taken at the same Board meeting.").
[7] *See* Letter from Lilly to Board at 3 (Nov. 8, 2024).

selected for cost review "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients," and only after completing this step may the Board set UPLs "for prescription drug products *that have led or will lead to an affordability challenge*."[8]

- Second, the Maryland APA requires the Board to render decisions at each stage of the statutory process at *separate* meetings with *separate* opportunities for public comment to ensure there are adequate opportunities for stakeholder input.[9] Merging these steps would compromise the integrity of the Board's decision-making by denying stakeholders an opportunity to fully and meaningfully engage, thereby producing rushed conclusions that fail to account for the full range of stakeholder feedback.[10]

- Third, the Proposed Regulations should be revised to require the Board to formally adopt a recommendation of a UPL as the appropriate policy solution for a particular affordability challenge before selecting a methodology and developing a UPL amount for a particular medicine. Without such formal determination, the Board risks presupposing that a UPL is the appropriate policy measure and investing significant resources into calculating a UPL amount before ever actually making that predicate determination—and before stakeholders have a designated opportunity to weigh in on whether a UPL is suitable in the first place. As drafted, the Proposed Regulations do not direct the Board to specifically determine that a UPL is the appropriate policy measure for a particular medicine until it decides to adopt proposed regulations setting the UPL, at which point the Board already would have evaluated and selected one or more UPL methodologies and developed UPL amounts.[11]

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[8] Md. Code, Health-Gen. §§ 21-2C-09(b)(1), 21-2C-13(b)(1) (emphasis added).

[9] For example, the Maryland APA requires that any substantive change to a proposed regulation requires that the regulation be "proposed anew" and adopted only after notice-and-comment—indicating the intent that the public be able to comment on each stage the agency decision-making. Md. Code, State Gov't § 10-113(b); *see also* 75 Op. Atty Gen. Md. at 43 (Jan. 23, 1990) (describing "public notice and hearing procedures" as at "the heart" of the APA, and noting that such comment processes are "[d]esigned to assure fairness and mature consideration of rules of general application" and therefore "serve the important twin functions of safeguarding public rights and educating the administrative lawmakers"), available here.

[10] *See* Letter from Lilly to Board at 3 (Nov. 8, 2024) (explaining that combining these steps also "undermines the purpose of the comment periods and public hearings that precede the Board's key UPL-related decisions").

[11] The Proposed Regulations never explicitly require the Board to consider both UPL and non-UPL policy options before specifically determining that a UPL is the most appropriate policy solution. Instead, the Proposed Regulations merely provide that the Board "may" adopt "non-UPL policy recommendations" and "may pursue development of a UPL as a policy option," without ever directing the Board to weigh UPL and non-UPL policies against one another. Proposed Regulations § 14.01.05.05B(2), C(4). However, the Proposed Regulations contemplate that the Board would propose regulations to establish a UPL, and such rulemaking must reflect the Board's belief that the proposed UPL is the most suitable policy. *Id.* § 14.01.05.08A. *See generally FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009); Board, Supply Chain Report at 121 (Sept. 10, 2024), available here ("[F]or drugs that the Board has determined have led to an affordability challenge as a result of the Cost Review process, the Board will affirmatively determine

Lilly is particularly concerned about these risks given the Board's history of combined decision-making, as illustrated by the following non-exhaustive, recent examples:

- At the recent January 27, 2025 Board meeting, the Board approved amendments to the cost review regulations and then presented a report conducted under the same regulations.

- At the September 10, 2024 Board meeting, the Board approved the final Supply Chain Report and then approved the final UPL Action Plan which relied heavily upon the findings in the Supply Chain Report.[12]

These procedural and substantive concerns raise serious questions about arbitrary and capricious agency action. The Proposed Regulations create unnecessary and excessive risk that the Board would impose a UPL without fully evaluating the propriety of such a price control,[13] threatening the health and lives of patients in Maryland. For all these reasons, the Board should not—*and lawfully cannot*—prematurely commit to a UPL before completing the cost review, which must include adequate time for stakeholder review and input.

The Board Must Provide Consistent and Meaningful Opportunities for Comment

In addition to separately and sequentially completing each step of its process, the Board must also consistently provide a *meaningful* opportunity for public comment at *every* such step.[14] The Proposed Regulations nominally contemplate comment periods at certain steps, but there is no minimum comment period, no requirement for the Board to disclose its reasoning, and no requirement that the Board consider and respond to the comments it receives—such that no *meaningful* opportunities for public input are guaranteed.[15] To comport with APA principles and

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that an upper payment limit is the appropriate policy tool to improve access to–and affordability of–the prescription drug[.]").

[12] *See* Board, Meeting Minutes (Sept. 10, 2024), available here.

[13] Proposed Regulations §§ 14.01.05.03A, .04C ("If the Board makes a ***preliminary determination*** that use of the prescription drug product has led or will lead to an affordability challenge, the Board shall commence the policy review process . . . , including the ***consideration and setting of a UPL***." (emphasis added)).

[14] The Proposed Regulations provide opportunities for public comment at some steps of the Board's review process, but the Board does not expressly propose comment periods at *each* step of the Board's review—and, furthermore, no minimum comment periods or genuine Board consideration are guaranteed. *See, e.g.*, Proposed Regulations §§ 14.01.05.06D(4) (requiring Board staff to publicly post UPL values and staff recommendations for proposed UPL amounts), 14.01.05.06F (requiring a public comment opportunity for any modification or amendment of UPL values). The Proposed Regulations also generally provide for comment on "any decision pending before the Board," but these catch-all provisions are distinct from specific comment requirements, do not guarantee meaningful comment periods, and violate the Maryland APA. *See* Proposed Regulations §§ 14.01.05.05B(4), 14.01.05.05C(5), 14.01.05.07A(3), 14.01.05.07B(2).

[15] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998) (noting that the Maryland APA notice-and-comment procedures are designed "to afford fair notice and a *meaningful* opportunity comment to all persons who may be affected by the proposed regulation" (emphasis added)); *Fogle v. H & G Restaurant, Inc.*, 337 Md. 441, 462–63 (Md. Ct. App. 1995) (finding comment opportunity was meaningful and compliance with Maryland APA because "[s]everal public hearings were held," "[a] multitude of documentary evidence was submitted," and the published decision "set[] forth [the

promote consistent, reasoned decision-making, the Board should revise the Proposed Regulations to secure the following basic procedural protections:

- **Separate Comment Opportunities at Every Stage of Decision-making.** Each step of the Board's process is critical to fully understanding a product's affordability landscape and assessing the most suitable policy measures to be address any identified affordability challenges. As such, it is crucial that the public be afforded a separate comment opportunity for each step of the Board's review. In their current form, the Proposed Regulations are inconsistent and incoherent as to the provision of comment periods. The Proposed Regulations explicitly provide for comment opportunities at certain steps of the UPL-setting process but not for others,[16] and they generally provide for public comment on "any decision pending before the Board" but fail to set forth any specific procedures or standards for such comment.[17] The Maryland APA requires at least 30 days of public comment during rulemaking and imposes a new comment period if the proposed regulation changes "substantively"—and, as discussed below, all Board policies of general application must be established through rulemaking.[18] Lilly urges the Board to clarify its procedures by expressly adopting discrete comment requirements for each decision point in the UPL development process.

- **Disclosure of Bases for Board Determinations.** The Board must revise its Proposed Regulations to make clear that, where opportunities for public comment are provided, the Board will disclose the underlying data and information relied on to reach its preliminary conclusions, to the extent such data are not confidential. Courts have long emphasized that the failure to reveal the technical bases behind a proposal constitutes a "serious procedural error" because it prevents stakeholders from providing meaningful comment on an agency's proposal.[19] Maryland courts recognize "an implied limitation upon an administrative board's authority . . . that its decisions be supported by facts and that they

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Commissioner's] explanation for the choices that he made in promulgating [the regulation] in light of the evidence presented to him throughout the rule-making process").

[16] *Compare* Proposed Regulations § 14.01.05.06A(3) (requiring Board staff to publish their UPL methodology recommendations and request public comment), *with id.* § 14.01.05.05 (omitting express comment requirements for Board staff's policy recommendations).

[17] *See id.* §§ 14.01.05.05B(4), .05C(5), .07A(3), .07B(2) ("The public may provide oral and written comments concerning any agenda item of the Board or any decision pending before the Board in accordance with the procedures and timelines in COMAR 14.01.01.05A and B(2)."); *see also* COMAR §§ 14.01.01.05A, .05B(2) (providing that written comments and written notice of oral comments should be provided at least "2 work days before the scheduled Board meeting" but not providing for any minimum comment period).

[18] Md. Code, State Gov't §§ 10-111, 10-113.

[19] *See, e.g.*, *Conn. Light & Power v. NRC*, 673 F. 2d 525, 531 (D.C. Cir. 1982) (federal APA rulemaking context); 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").

be not arbitrary, capricious or unreasonable."[20] To ensure that the contemplated comment opportunities are robust and meaningful, Lilly strongly urges the Board to revise its Proposed Regulations to make clear that the Board will publicly disclose all non-confidential information and data it relies upon in developing its preliminary conclusions, including those related to affordability, appropriate policy options, and UPL development.

- **Rulemaking for All Agency Policies.** The Proposed Regulations are inconsistent as to what the Board intends to promulgate through future rulemaking. Like the Action Plan and Draft Regulations, the Proposed Regulations refer to using a "proposed regulation" for setting a UPL *amount*, but they do not mandate use of "regulation" (i.e., rulemaking) to complete other steps of the process *prior* to the setting of a UPL amount. The Board cannot simply adopt the UPL amount via rulemaking without subjecting the predicate processes that lead to the setting of that UPL amount (i.e., the policy review and UPL development) to the rulemaking process as well. Under Maryland law, all agency policies "of general application" must be established through rulemaking."[21] As Maryland courts have long explained, "where an agency statement of general applicability implements, interprets or prescribes law or policy, it is a rule which *must* comply with the APA," including by adopting legislative rules via notice-and-comment rulemaking and abiding by all timelines and processes required by the APA.[22]

II. Vagueness and Lack of Clear Methodologies

Lilly reiterates its concerns that the Proposed Regulations leave core definitions, standards, and procedures undefined or addressed only at a cursory level.[23] The notable absence of clear or detailed standards inhibits meaningful stakeholder input and needlessly amplifies the risk that the Board will ultimately apply its policies in an arbitrary and inconsistent manner in violation of the APA.[24]

Lilly highlights the following non-exhaustive examples of the lack of clear standards in the Proposed Regulations:

- **Preliminary Determinations Regarding Affordability Challenges.** Despite the critical gatekeeping role of the preliminary determination, the Proposed Regulations conspicuously lack *any* processes or standards to guide the Board's preliminary decision-

[20] *Heaps v. Cobbs*, 185 Md. 372, 380 (1945); *see also Reese v. Dep't of Health & Mental Hygiene*, 177 Md. App. 102, 144 n.21 (2007).
[21] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009); *see also* Md. Code, State Gov't, tit. 10, subtit. 1, pt. III. This requirement applies not only to legislative rules that establish substantive standards and requirements but also to "organizational rules, procedural rules, interpretive rules and statements of policy." *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003).
[22] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986).
[23] *See* Letter from Lilly to Board at 5–9 (Nov. 8, 2024); Letter from Lilly to Board at 5–12 (Aug. 26, 2024).
[24] *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.").

making.[25] To avoid the risk of arbitrary decision-making, the Board should revise the Proposed Regulations to set forth a clear methodology governing preliminary determinations regarding affordability to avoid the risk of arbitrary decision-making.[26] In doing so, Lilly reiterates the following specific recommendations:

- First, Lilly urges the Board to revise its proposed definition of "affordability challenge."[27] As Lilly noted in prior comments, a clear definition of "affordability challenge" is foundational to providing a workable and meaningful standard for affordability determinations—determinations at the center of the entire PDAB regime—and to ensure compliance with the PDAB statute.[28] Although the Proposed Regulations purport to define "affordability challenge," the proposed definition merely restates statutory language in a circular and ultimately standardless fashion.[29] Lilly recommends that the Board define "affordability challenge" so as to require consideration of the net price at which State health care system entities currently access the medicine, the level of purchases and utilization by such entities, and the actual out-of-pocket costs incurred by their patients.[30]

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[25] The Proposed Regulations do not include even the high-level description of the preliminary determination process included in the Action Plan. *See* Action Plan, at 4. The Board's cost review regulations set forth factors the Board "may" consider in conducting a cost review study, but those regulations do not address how the Board would determine that use of a drug under review has led or will lead to "[a]ffordability challenges to the State health care system" or "high out-of-pocket costs for patients." COMAR 14.01.04.05A.

[26] Lilly also urges the Board similarly to adopt a consistent methodology for rendering final determinations on affordability.

[27] *See* Proposed Regulations § 14.01.05.01C.

[28] Letter from Lilly to Board at 6 (Nov. 8, 2024); Letter from Lilly to Board at 5–6 (Aug. 26, 2024).

[29] Proposed Regulations § 14.01.05.01C ("For the purpose of this chapter, 'affordability challenge' refers to either (a) high out-of-pocket costs for patients or (b) an affordability challenge for the State health care system."); Md. Code, Health-Gen. § 21-2C-09(b)(1) ("If the Board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients.").

[30] Lilly understands the reference to the "State health care system" to mean the specific State entities that could be subject to a UPL, i.e., state or county correctional facilities and their patients, state hospitals and their patients, health clinics at state institutions of higher education and their patients, health benefit plans making payments on behalf of a unit of State or local government and enrollees thereof, and (to the extent legally permissible) the Maryland State Medical Assistance Program and Medicaid enrollees. *See* Md. Code, Health-Gen. § 21-2C-14(a) (authorizing the Board to set UPLs for prescription drug products that are "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, . . . [p]aid for through a health benefit plan on behalf of a unit of State or local government, . . . [or] [p]urchased for or paid for by the Maryland State Medical Assistance Program"). As Lilly explained in its prior letters, it would not be logical or consistent with the PDAB statute to evaluate affordability from the perspective of other entities, such as private health plans or other private purchasers for which a UPL would have no bearing. *See* Letter from Lilly to Board at 6 (Nov. 8, 2024); Letter from Lilly to Board at 5–6 (Aug. 26, 2024).

- Second, Lilly asks the Board to define "high out-of-pocket costs for patients" as that term is used in the definition of "affordability challenge."[31] All consideration of out-of-pocket costs should also take account of the fact that out-of-pocket costs are the byproduct of benefit design choices made by independent health plans and pharmacy benefit managers (PBMs), which are outside of the control of manufacturers and others in the pharmaceutical supply chain.[32]

- **Policy Recommendations.** Under the Proposed Regulations, once the Board determines, under an unknown standard, that a medicine has led or will lead to an affordability challenge, the Board would proceed to weigh multiple complex policy options in a similarly standardless manner. Lilly reiterates several recommendations to address the lack of clear processes outlined in the Proposed Regulations for identifying, evaluating, and recommending policy options:

  - First, Lilly asks the Board to more clearly identify the information and analyses that will support the development of policy recommendations. As drafted, the Proposed Regulations state that the Board "may" consider various factors—for example, "drivers" of high out-of-pocket costs or other affordability challenges, how the policy would address a driver, and strengths and weaknesses—but fail to operationalize any of these factors. Lilly recommends that the Board elaborate upon these factors by specifying how they will be measured and assessed with respect to the patients and State health care system entities within the PDAB statute's scope.

  - Second, Lilly urges the Board to ensure parity between the proposed procedures for considering UPL and non-UPL policy options. As noted in Lilly's prior comments, the Board appears to propose different standards for the preliminary policy recommendation based on whether a UPL is the proposed solution. For example, the Proposed Regulations provide for evaluation of the strengths and weaknesses of non-UPL solutions without establishing a corresponding requirement when evaluating the appropriateness of a UPL.[33] This raises concerns under the Maryland APA, which, as noted, requires similarly situated circumstances to be treated in a

[31] *See* Proposed Regulations § 14.01.05.01C.
[32] *See* Board, Supply Chain Report at 34–36 (Sept. 10, 2024), available here.
[33] *Compare* Proposed Regulations § 14.01.05.05B(2) (setting forth criteria the Board "may analyze" when recommending non-UPL policy options: "(a) Drivers of the affordability challenge; (b) How the policy addresses a driver; (c) Strengths and weaknesses of the policy; (d) Possible implementation of the policy; and (e) Potential impacts of the policy")), *with id.* § 14.01.05.05C(2) (setting forth criteria the Board "may analyze" when "recommending a UPL as a policy option," including "(a) The drivers and market conditions causing the affordability challenge phenomena; (b) Ability of a UPL to address these issues; (c) Relevant regulatory criteria under Regulation .02 of this chapter; and (d) Use of the drug by eligible governmental entities")).

similar fashion absent some reasoned basis for differentiation.[34] These diverging approaches also raise overarching concerns about whether the review of potential policy solutions will be biased in favor of UPL-based options.

- Third, Lilly recommends that the Board be required, by express regulation, to consider all relevant factors when evaluating policy options. The Proposed Regulations state that the Board "may" analyze factors like the "drivers of the affordability challenge" and "how the policy addresses a driver" when recommending policy options, but the Board is not required to consider *any* particular factors.[35] Under APA principles, an agency's failure to consider statutorily relevant factors or otherwise fail to supply a reasoned basis for the decision made is an additional basis for deeming agency action arbitrary or capricious.[36] The Board patently could not, consistent with these APA principles, adopt a particular policy recommendation without considering factors like the "drivers" of the identified affordability challenges and "how" the recommended policy action would address such drivers. [37]

- **Criteria for Setting UPLs.** Lilly reiterates that the proposed criteria for setting UPLs are both underdeveloped and incomplete. In particular, Lilly recommends the Board revise the Proposed Regulations as follows:

  - First, Lilly urges the Board to provide clear, workable standards for operationalizing the UPL-setting criteria. As Lilly noted with respect to the Draft Regulations, the Proposed Regulations largely recite the criteria for setting UPLs in its Action Plan without explaining how the Board will specifically define or apply those criteria.[38] For example, the Board says it will "set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences," but does not actually propose a framework to allow it to systematically evaluate if it is doing so in a rational and non-arbitrary way.[39]

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[34] *See* Letter from Lilly to Board 7 (Nov. 8, 2024); Letter from Lilly to Board 7 (Aug. 26, 2024); *see, e.g.*, *Harvey*, 389 Md. at 303–04 ("Just as actions that are inconsistent with prior administrative precedents may be deemed 'arbitrary' or 'capricious,' an agency action also may be deemed 'arbitrary or capricious' if similarly situated individuals are treated differently without a rational basis for such a deviation." (citing *Social Workers v. Chertkov*, 121 Md. App. 574, 589 (Md. Ct. Spec. App. 1998)).

[35] Proposed Regulations § 14.01.05.05B(2).

[36] *Md. Dep't of the Env't v. Assateague Coastal Trust*, 484 Md. 399, 450 n.41 (2023) (applying standard from *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)).

[37] *See State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (describing one basis of arbitrary and capricious agency action as entirely "fail[ing] to consider an important aspect of the problem" intended to be addressed).

[38] As discussed above, this does not allow stakeholders to meaningfully comment on the proposed process and raises concerns about arbitrary agency action.

[39] Proposed Regulations § 14.01.05.02B(3). As another example, the Board proposes to "consider the cost of administering [a] drug and delivering the drug to consumers, as well as other relevant administrative

- Second, Lilly urges the Board to adopt an additional criterion that would consider the potential impact on patient access before implementing a UPL. As recommended in prior comments, such additional criterion would prevent the Board from establishing a UPL (or setting a particular UPL amount) without first making an evidence-based determination that the UPL (or UPL amount) will not negatively affect patient access in the state.[40] In the absence of such a requirement, there is a serious risk that a UPL could have meaningful unintended negative consequences, including significantly impairing patient access.[41]

- **Establishing a UPL.** The Proposed Regulations again largely recite the UPL-setting process outlined in the Action Plan without meaningful additional detail. Lilly therefore refers the Board to its prior comments regarding the proposed UPL methodologies and summarizes these comments below:

  - First, Lilly asks the Board to provide important details regarding each contemplated UPL methodology. Consistent with Lilly's prior comments, the Proposed Regulations do not describe the UPL methodologies in sufficient detail for stakeholders to meaningfully comment on the various methodologies.[42] For example, with respect to the "Cost Effectiveness Analysis" approach, the Board still has not described the type of cost effectiveness analyses it intends to use, whether the Board intends to conducts its own independent cost effectiveness analyses or rely on third-party analysis, or what controls the Board will put into place to prevent cherry-picking of data (e.g., if the Board is relying on third-party analyses, it is unclear how the Board will choose among cost effectiveness analysis performed by different third-party institutions).[43]

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costs" but does not define how it will operationalize these considerations to ensure consistent comparisons between products. Proposed Regulations § 14.01.05.02B(1).

[40] The Proposed Regulations direct the Board to assess a UPL's impact on drug access in the event that the Board decides to *reconsider* a UPL, but there is no similar requirement that the Board specifically consider a UPL's likely impact on access prior to adopting proposed UPL regulations. *See* Proposed Regulations § 14.01.05.09B(1)(d)(iv); *see also* Letter from Lilly to Board at 8 (Nov. 8, 2024); Letter from Lilly to Board at 7–8 (Aug. 26, 2024).

[41] *See* Letter from Lilly to Board at 8 (Nov. 8, 2024) ("As the Board itself has acknowledged, 'the pharmaceutical supply chain is complex,' and 'the unintended consequences of regulations and policies may cause higher prices over time.' An evidence-based criterion focused on patient access also would help safeguard against arbitrary decision-making, as it would work to ensure that the Board lays out both its reasoning and the factual basis in support of that reasoning should it determine to impose a UPL or any specific UPL amount. (first citing Board, Supply Chain Report at 15, 66; and then citing Md. Code, Health-Gen. § 21-2C-07(1)(ii) (implicitly acknowledging that UPLs are not the right solution for every affordability challenge by requiring study of other policy options))).

[42] *See* Letter from Lilly to Board at 10–12 (Aug. 26, 2024).

[43] *See* Proposed Regulations § 14.01.05.06B(1); Letter from Lilly to Board at 10 (Aug. 26, 2024) (explaining that the lack of detail on the proposed approach "raises serious concerns because there are a wide range of different types of cost effectiveness analyses, all of which have differing levels of reliability,

- Second, Lilly reasserts its request that the Board ensure its methodologies adequately account for relevant supply chain complexities that impact both the implementation of the methodologies and their suitability.[44] For example, Lilly reiterates that any domestic reference UPL must consider the context in which the reference price is provided and, therefore, should account for any performance requirements that must be met for that domestic reference UPL to be available to other U.S.-based entities.[45]

- Third, Lilly urges the Board to establish consistent criteria that it must consider when deciding which UPL methodologies to adopt, as the Proposed Regulations currently lack any standards whatsoever for that decision point.[46]

- **Reconsideration of a UPL.** Because the Proposed Regulations are identical to the Draft Regulations, they similarly lack important details in the proposed process for reconsideration of a UPL, including the proposals for implementing the statutory requirement that the Board reconsider whether a UPL should be suspended or altered in the event of a shortage of the medicine.[47] Lilly reiterates the following specific recommendations:

  - First, consistent with other comments above, Lilly urges the Board to establish standards and processes for determining the circumstances under which a UPL suspension could appropriately be lifted or the period of suspension.[48] The Board cannot, consistent with the Maryland APA, make the decision to re-impose a UPL in an ad hoc and standardless fashion. For example, once a product is no longer in shortage, a UPL may no longer be an appropriate policy measure or the medicine may no longer present an affordability challenge. The Board must establish clear procedures for determining that re-imposing a UPL is the appropriate policy measure to address an affordability challenge without compromising patient access.

  - Second, Lilly recommends that the Board to revise the Proposed Regulations to require no less frequent than monthly checks of the FDA website to determine if a

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validity, and robustness," and that "some types of cost-effectiveness analyses raise serious concerns, such as Quality-Adjusted Life Year ('QALY') analyses, which have been shown to discriminate against the sick, elderly, and historically under-represented minority populations").

[44] Letter from Lilly to Board at 10–12 (Aug. 26, 2024) (discussing concerns with specific proposed UPL methodologies: cost effectiveness analysis, therapeutic class reference UPL, domestic reference UPL, international reference UPL, "market basket" UPLs; also discussing concerns with use of state expenditure data to develop UPL amounts and with the application of different methodologies to different drugs).

[45] *Id.* at 11; *see* Proposed Regulations § 14.01.05.06B(5).

[46] *See* Proposed Regulations § 14.01.05.06D.

[47] Md. Code, Health-Gen. § 21-2C-14(c)(ii); Proposed Regulations § 14.01.05.09A(2).

[48] Proposed Regulations § 14.01.05.09A(4)(c).

medicine subject to a UPL is in shortage, to suspend the UPL promptly upon such a finding, and to require a new affordability review that complies with the framework established by the PDAB statute before reinstating any UPL.

- Third, consistent with Lilly's comments above, we urge the Board to ensure that any decision to reinstate a UPL also includes careful consideration of the impact of such price control on patient access.[49]

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Lilly appreciates the opportunity to comment on the Board's Proposed Regulations and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or need clarifications.

Sincerely,

Cynthia Ransom

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Lilly USA

[49] *See* Letter from Lilly to Board at 9 (Nov. 8, 2024).

November 8, 2024

By Electronic Submission

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Re: Draft Regulations – COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

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

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments on the Board's Policy Review, Final Action, and Upper Payment Limits ("UPLs") Draft Regulations (the "Draft Regulations").[1]

If finalized, the Draft Regulations would effectively codify the Board's UPL Action Plan (the "Plan") in regulations with only slight modifications.[2] Lilly is concerned that the Draft Regulations fail to address the many concerns previously raised by stakeholders about the Action Plan, including prior comments from Lilly.[3] In addition to these prior comments, which we incorporate by reference, below, we offer specific comments on the Draft Regulations.

To start, Lilly continues to have overarching concerns about the propriety of price controls. UPLs and other price controls harm patients both by reducing access to medicines and stifling the development of new and potentially transformative treatments. Lilly urges the Board to consider establishment of price controls only after carefully assessing whether non-UPL policy options could address a given prescription drug's affordability challenge or high out-of-pocket costs.

Lilly also continues to have concerns with the timing and deadlines of the Board's implementation process to date. Notably, the Board released the Draft Regulations on Monday, October 28th and requires comments be submitted just two weeks later. Ten business days is not nearly enough time for stakeholders to meaningfully review and comment on proposals across a range of areas that will be critical to the Board's operationalization of the PDAB statute, including the Board's procedures for setting a UPL under any circumstances.

Lilly acknowledges that the Draft Regulations may reflect the Board's desire to allow for stakeholder feedback *before* the provisions are formally proposed in the Maryland Register but emphasizes that the highly abbreviated nature of the comment period on the Draft Regulations

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[1] *See* Draft Regulations, available here.
[2] *See* Action Plan, available here.
[3] Letter from Lilly to Board (Aug. 26, 2024).

inhibits the meaningfulness of such comment period and is inconsistent with the Maryland Administrative Procedure Act ("APA"). These deficiencies are only further compounded by the significant lack of detail in the Board's current draft, which makes it impossible for stakeholders to fully comment on many aspects of the Board's current draft. For all these reasons, Lilly strongly urges the Board to extend the time for commenting on the Draft Regulations by at least 30 days. We also urge the Board to revise the substance of its Draft Regulations consistent with our comments below. Finally, when the Board issues a formal Proposed Rule in the Maryland Register, we emphasize that the Board must comply with all timeline and processes required under the Maryland APA).

I. Inadequate Procedural Safeguards

The Draft Regulations fail to provide for adequate procedural protections needed to facilitate sound and APA-compliant decision-making. Although the Draft Regulations nominally contemplate comment periods at certain steps, there is no minimum comment period, no requirement for the Board to disclose its reasoning, and no requirement that the Board consider and respond to the comments it receives—such that no *meaningful* opportunities for public input are guaranteed.[4]

Each Step of the PDAB's Process Must be Separately and Sequentially Completed

Consistent with our prior comments, Lilly is concerned that the Draft Regulations would permit the Board to act through a combined decision-making process. Specifically, the Draft Regulations permit the Board to finalize determinations about whether a drug has or will lead to an affordability challenge or high-out-of-pocket costs, whether UPL vs. non-UPL measures are appropriate policy solutions, and the most appropriate UPL amount *all in the same Board meeting.*[5] We strongly urge

[4] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998) (noting that the Maryland APA notice-and-comment procedures are designed "to afford fair notice and a *meaningful* opportunity comment to all persons who may be affected by the proposed regulation" (emphasis added)); *Fogle v. H & G Restaurant, Inc.*, 337 Md. 441, 462–63 (Md. Ct. App. 1995) (finding comment opportunity was meaningful and compliance with Maryland APA because "[s]everal public hearings were held," "[a] multitude of documentary evidence was submitted," and the published decision "set[] forth [the Commissioner's] explanation for the choices that he made in promulgating [the regulation] in light of the evidence presented to him throughout the rule-making process").

[5] Lilly interprets the Draft Regulations to require a public comment opportunity for "any decision pending before the Board," including decisions related to UPL-setting that do not come with explicit comment requirements. For example, the public would be able to comment on the Board's decisions to "pursue development of a UPL as a policy option and direct Board staff to provide recommendations concerning the methodologies and contextual information that may be used to set a UPL." Draft Regulations § 14.01.05.05C(4). Likewise, there would be a comment opportunity before a Board decides to "[s]elect one or more [UPL] methodologies" or "[d]irect staff to use the selected and identified methodologies and contextual information to perform analyses and calculations to obtain UPLs," and such comment opportunity would be distinct from the required comment opportunity on Board staff's UPL methodology recommendations. Draft Regulations §§ 14.01.05.06A(3) (providing for comment on Board staff's

the Board to revise its Draft Regulations to expressly prohibit such combined decision-making, as such an approach would be inconsistent with law and logically incoherent for the reasons stated below:

- First, it would violate the PDAB Statute for the Board to engage in a combined decision-making process that permits concurrent review of the cost review, policy review, and UPL calculation processes. Under Section 21-2C-09, if the Board decides to engage in a cost review for a prescription drug, it must determine "whether use of the prescription drug product . . . has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients."[6] Only after the Board has completed this step may the Board set UPLs "for prescription drug products *that have led or will lead to an affordability challenge*."[7]
- Second, consistent with the Maryland APA, the Board's decisions at each stage of the statutory process should be rendered in *separate* meetings with a *separate* opportunity for public comment to ensure there are adequate opportunities for stakeholder input.[8] Combining these steps will impair the integrity of the Board's decision-making, as it would fail to allow stakeholders an opportunity to fully and meaningfully engage, may result in rushed conclusions that do not account for the full range of stakeholder feedback, and undermines the purpose of the comment periods and public hearings that precede the Board's key UPL-related decisions.
- Third, the Draft Regulations should be revised to require the Board to formally adopt a recommendation of a UPL as the appropriate policy solution before selecting a methodology and developing a UPL amount for a particular drug. Under the Draft Regulations, the Board does not specifically determine that a UPL is the appropriate policy measure for a particular drug until it decides to adopt proposed regulations setting the UPL.[9] By that point, the Board would have already evaluated and selected one or more

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recommended methodology and contextual information), .06D(4) (providing for comment before Board decisions to select methodologies and direct staff to develop UPL values). If the Board does not intend for its Draft Regulations to be interpreted in this manner, Lilly urges the Board to adopt express comment requirements for each decision point in the UPL development process.

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

[7] *Id.* § 21-2C-13(b)(1).

[8] For example, the Maryland APA requires that any substantive change to a proposed regulation requires that the regulation be "proposed anew" and adopted only after notice-and-comment—indicating the intent that the public be able to comment on each stage the agency decision-making. Md. Code, State Gov't § 10-113(b); *see also* 75 Op. Atty Gen. Md. at 43 (Jan. 23, 1990) (describing "public notice and hearing procedures" as at "the heart" of the APA, and noting that such comment processes are "[d]esigned to assure fairness and mature consideration of rules of general application" and therefore "serve the important twin functions of safeguarding public rights and educating the administrative lawmakers"), available here.

[9] The Draft Regulations never explicitly require the Board to consider both UPL and non-UPL policy options and specifically adopt a determination that a UPL is the most appropriate policy solution. However, the Draft Regulations contemplate that the Board would propose regulations to establish a UPL, and such rulemaking must reflect the Board's belief that the proposed UPL is the most suitable policy. *See generally*

UPL methodologies and developed UPL amounts, expending not insignificant public resources to do so—and all before stakeholders have a designated opportunity to weigh in on whether a UPL is suitable in the first place.

The totality of the above procedural and substantive concerns create serious questions about arbitrary and capricious agency action. The Draft Regulations create undue risk that the Board would impose a UPL without fully evaluating the appropriateness of such a price control,[10] creating potentially dire consequences for Maryland residents. For all these reasons, the Board should not—*and lawfully cannot*—prematurely commit to a UPL before completing the cost review, which must include adequate time for stakeholder review and input.

The Board Must Provide Consistent and Meaningful Opportunities for Comment

In addition to needing to separately and sequentially complete each step of its process, the Board should also consistently provide an opportunity for public comment at *every* such step.[11] Each step of the Board's process is critical to building a full picture of a product's affordability landscape and evaluating the most appropriate policy actions to be taken in response to any identified affordability challenges. As such, it is critical that there be a separate comment opportunity for each step of the Board's review.

In addition, the Board must revise its Draft Regulations to make clear that, where opportunities for public comment are provided, the Board will disclose the underlying data and information relied on to reach its preliminary conclusions, to the extent such data are not confidential. Courts have long emphasized that the failure to reveal the technical bases behind a proposal constitutes a "serious procedural error" because it prevents stakeholders from providing meaningful comment on an agency's proposal.[12] Maryland courts recognize "an implied limitation upon an administrative board's authority . . . that its decisions be supported by facts and that they be not

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FCC v. Fox Television Stations, Inc., 556 U.S. 502 (2009); Board, Supply Chain Report at 121 ("[F]or drugs that the Board has determined have led to an affordability challenge as a result of the Cost Review process, the Board will affirmatively determine that an upper payment limit is the appropriate policy tool to improve access to–and affordability of–the prescription drug[.]").

[10] Draft Regulations §§ 14.01.05.03A, .04C ("If the Board makes a ***preliminary determination*** that use of the prescription drug product has led or will lead to an affordability challenge, the Board shall commence the policy review process . . . , including the ***consideration and setting of a UPL***." (emphasis added)).

[11] Relative to the Action Plan, the Draft Regulations provide new opportunities for public comment at some of the steps of the Board's review process, but the Board does not expressly propose comment periods at each step of the Board's review. As noted, *supra* note 5, the Draft Regulations do generally provide for comment on "any decision pending before the Board," but these are distinct from specific comment requirements and do not guarantee meaningful comment periods.

[12] *See, e.g.*, *Conn. Light & Power v. NRC*, 673 F. 2d 525, 531 (D.C. Cir. 1982) (federal APA rulemaking context); 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").

arbitrary, capricious or unreasonable."[13] To ensure that the contemplated comment opportunities are robust and meaningful, Lilly strongly urges the Board to revise its Draft Regulations to make clear that the Board will publicly disclose all non-confidential information and data it relies upon in developing its preliminary conclusions, including those related to affordability, appropriate policy options, and UPL development.

The Board Must Comply with the Procedural Requirements of the Maryland APA

The Draft Regulations are ambiguous as to what the Board intends to promulgate through future rulemaking. Like the Action Plan, the Draft Regulations refer to using a "proposed regulation" for setting a UPL *amount*, but do not mandate use of "regulation" (i.e., rulemaking) to complete other steps of the process *prior* to the setting of a UPL amount. The Board cannot simply adopt the UPL amount via rulemaking without subjecting the predicate processes that lead to the setting of that UPL amount (i.e., the policy review and UPL development) to the rulemaking process as well. Under Maryland law, all agency policies "of general application" must be established through rulemaking."[14] As Maryland courts have long explained, "where an agency statement of general applicability implements, interprets or prescribes law or policy, it is a rule which *must* comply with the APA," including by adopting legislative rules via notice-and-comment rulemaking and abiding by all timelines and processes required by the APA.[15]

II. Vagueness and Lack of Clear Methodologies

Throughout the Draft Regulations, core definitions, standards, and procedures are either left undefined or are addressed only at a cursory level. The striking absence of clear or detailed standards inhibits meaningful comment and creates an undue risk that the Board will ultimately apply its policies in an arbitrary and inconsistent manner in violation of the APA.[16]

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[13] *Heaps v. Cobbs*, 185 Md. 372, 380 (1945); *see also Reese v. Dep't of Health & Mental Hygiene*, 177 Md. App. 102, 144 n.21 (2007) (recognizing that "administrative mandamus . . . creates a right of judicial review of a quasi-judicial order or action of an administrative agency" because Maryland courts have "inherent power . . . to correct abuses of discretion and arbitrary, illegal, capricious or unreasonable acts"). Maryland law defines a "[q]uasi-judicial function" to include "a proceeding before an administrative agency for which Title 7, Chapter 200 of the Maryland Rules would govern judicial review." Md. Code, Gen. § 3-101(i). The Maryland Rules provide for judicial review of "an order or action of an administrative judicial review is authorized by statute." Md. R. Jud. Rev. Cir. Ct. 7-201(a). The Maryland PDAB statute authorizes review of Board decisions. Md. Code, Health-Gen. § 21-2C-15. Thus, final decisions of the Board—such as affordability determinations and adoption of policy recommendations—must be supported by facts or otherwise risk invalidation.

[14] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009); *see also* Md. Code, State Gov't, tit. 10, subtit. 1, pt. III. This requirement applies not only to legislative rules that establish substantive standards and requirements but also to "organizational rules, procedural rules, interpretive rules and statements of policy." *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003).

[15] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986).

[16] *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.").

Preliminary Determinations Regarding Affordability Challenges

Despite the important gatekeeping role of the preliminary determination, the Draft Regulations do not set forth *any* processes or standards to guide the Board's preliminary decision-making.[17] The Draft Regulations do not include even the high-level description of the preliminary determination process included in the Action Plan.[18] The Board should revise its Draft Regulations to propose a clear methodology governing preliminary determinations of affordability to avoid the risk of arbitrary decision-making.[19] In doing so, Lilly specifically urges implementation of the following:

- First, Lilly urges the Board to revise its draft definition of "affordability challenge." As Lilly noted in its comments regarding the Action Plan, a definition of "affordability challenge" is critical to providing a meaningful standard for affordability determinations and to ensure compliance with the PDAB statute. While the Draft Regulations do purport to define "affordability challenge," in reality, the definition merely restates statutory language in a circular and ultimately standardless fashion.[20] Lilly recommends that the Board define "affordability challenge" in a manner that requires consideration of both the net price at which state health care system entities currently access the drug and the level of purchases and utilization by those entities.[21]
- Second, Lilly asks the Board to define "high out-of-pocket costs for patients" as that term is used in the definition of "affordability challenge." All consideration of out-of-pocket costs should also take account of the fact that out-of-pocket costs are the byproduct of benefit design choices made by independent health plans and pharmacy benefit managers

[17] The Board's cost review regulations set forth factors the Board "may" consider in conducting a cost review study, but those regulations do not address how the Board would determine that use of a drug under review has led or will lead to "[a]ffordability challenges to the State health care system" or "high out-of-pocket costs for patients." COMAR 14.01.04.05A.

[18] Action Plan, at 4.

[19] Lilly also urges the Board similarly to adopt a consistent methodology for rendering final determinations on affordability.

[20] Draft Regulations § 14.01.05.01C ("For the purpose of this Regulation, "affordability challenge" refers to either (a) high out-of-pocket costs for patients or (b) an affordability challenge for the State health care system."); Md. Code, Health-Gen. § 21-2C-09(b)(1) ("If the Board conducts a review of the cost of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients.").

[21] Lilly understands the reference to "State health care system" to mean the State entities that could be subject to a UPL. *See* Md. Code, Health-Gen. § 21-2C-14(a) (authorizing the Board to set UPLs for prescription drug products that are "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, . . . [p]aid for through a health benefit plan on behalf of a unit of State or local government, . . . [or] [p]urchased for or paid for by the Maryland State Medical Assistance Program"). As Lilly explained in its prior letter, it would not be logical or consistent with the PDAB statute to evaluate affordability from the perspective of other entities, such as private health plans or other private purchasers for which a UPL would have no bearing.

(PBMs), which are outside of the control of manufacturers and others in the pharmaceutical supply chain.[22]

Policy Recommendations

Lilly has the several concerns about the lack of clear processes outlined in the Draft Regulations for identifying, evaluating, and recommending policy options:

- First, the Draft Regulations state that the Board "may" consider various factors—for example, "drivers" of high out-of-pocket costs or other affordability challenges, how the policy would address a driver, and strengths and weaknesses—but do not operationalize any of these factors. The Board should revise the Draft Regulations to more clearly identify the information and analyses that will support the development of policy recommendations. Lilly recommends that the Board elaborate upon these factors by specifying how they will be measured and assessed with respect to the patients and state health care system entities within the PDAB statute's scope.
- Second, as noted in Lilly's prior letter, the Board appears to propose different standards for the preliminary policy recommendation based on whether a UPL is the proposed solution. For example, the Draft Regulations provide for evaluation of the strengths and weaknesses of non-UPL solutions without establishing a corresponding requirement when evaluating the appropriateness of a UPL.[23] This raises concerns under the Maryland APA, which, as noted, requires similarly situated circumstances to be treated in a similar fashion absent some reasoned basis for differentiation. It also raises overarching concerns about whether the review of potential policy solutions will be biased in favor of UPL-based options.
- Third, while the Draft Regulations state that the Board "may" analyze factors like the "drivers of the affordability challenge" and "how the policy addresses a driver" when recommending policy options, the Board is not required to consider *any* particular factors.[24] Under APA principles, failing to consider statutorily relevant factors or otherwise failing to supply a reasoned basis for the decision made is an additional basis for finding agency action to be arbitrary and capricious.[25] It would be patently arbitrary if the Board adopted a particular policy recommendation without considering factors like the "drivers" of the identified affordability challenges and "how" the recommended policy action would address such drivers. [26]

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[22] *See* Board, Supply Chain Report at 34–36 (Sept. 10, 2024), available here.
[23] *Compare* Draft Regulations §§ 14.01.05.05
[24] Draft Regulations § 14.01.05.05B(2).
[25] *Md. Dep't of the Env't v. Assateague Coastal Trust*, 484 Md. 399, 450 n.41 (2023) (applying standard from *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)).
[26] *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (describing one basis of arbitrary and capricious agency action as entirely "fail[ing] to consider an important aspect of the problem" intended to be addressed).

Criteria for Setting UPLs

In the Draft Regulations, the Board largely recites the criteria for setting UPLs in its Action Plan without explaining how those criteria will be applied or specifically defined. As discussed above, this does not allow stakeholders to meaningfully comment on the proposed process and raises concerns about arbitrary agency action.[27] For example, the Board says it will "set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences," but does not actually propose a framework to allow it to systematically evaluate if it is doing so in a rational and non-arbitrary way.[28]

Notably, the listed criteria also do not direct the Board to consider the potential impact on patient access before implementing a UPL. As noted in prior comments, Lilly urges the Board to add an additional criterion that prevents the Board from establishing a UPL (or setting a particular UPL amount) unless there is an evidence-based determination by the Board that the UPL (or UPL amount) will not negatively affect patient access in the state.[29] In the absence of such a requirement, there is a serious risk that a UPL could have meaningful unintended negative consequences, including significantly impairing patient access. As the Board itself has acknowledged, "the pharmaceutical supply chain is complex," and "the unintended consequences of regulations and policies may cause higher prices over time."[30] An evidence-based criterion focused on patient access also would help safeguard against arbitrary decision-making, as it would work to ensure that the Board lays out both its reasoning and the factual basis in support of that reasoning should it determine to impose a UPL or any specific UPL amount.[31]

Establishing a UPL

The Draft Regulations again largely recite the UPL-setting process outlined in the Action Plan without meaningful additional detail. Lilly therefore refers the Board to its prior comments regarding the lack of sufficient detail for stakeholders to meaningfully comment on the various UPL methodologies. Lilly also reasserts its previously raised concerns regarding the specific proposed UPL methodologies, including Lilly's general and overarching concern that the Board ensure that its methodologies adequately account for relevant supply chain complexities that

[27] For example, the Board proposes to "consider the cost of administering [a] drug and delivering the drug to consumers, as well as other relevant administrative costs" but does not define how it will operationalize these considerations to ensure consistent comparisons between products. Draft Regulations § 14.01.05.02B(1).

[28] *Id.*

[29] The Draft Regulations direct the Board to assess a UPL's impact on drug access in the event that the Board decides to *reconsider* a UPL, but there is no similar requirement that the Board specifically consider a UPL's likely impact on access prior to adopting proposed UPL regulations. *See* Draft Regulations § 14.01.05.09B(1)(d)(iv).

[30] Board, Supply Chain Report at 15, 66.

[31] Md. Code, Health-Gen. § 21-2C-07(1)(ii) (implicitly acknowledging that UPLs are not the right solution for every affordability challenge by requiring study of other policy options).

impact both the implementation of the methodologies and their appropriateness.[32] Additionally, in line with the comments above, the Board should establish consistent criteria that it must consider when deciding which UPL methodologies to adopt, as there are currently no standards for that decision point.

Reconsideration of a UPL

The Draft Regulations propose a process for reconsideration of a UPL, including proposing to implement the statutory requirement that the Board reconsider whether a UPL should be suspended or altered in the event of a shortage of the prescription drug.[33] Under the Draft Regulations, suspension is for "a specified period," but the Draft Regulations otherwise provide no standards or process for determining the circumstances under which a UPL suspension could appropriately be lifted or the period of suspension.[34] Lilly does not believe that the legislature intended the decision to re-impose a UPL to be implemented in an ad hoc and standardless manner. The PDAB statute does not specify a time period for any shortage-related UPL suspension, and, manifestly, the statute's objectives would not be served by simply reimposing the UPL as soon as a shortage technically ends, only for shortage to reoccur. Furthermore, a shortage may continue for a substantial period of time, at which point a UPL may no longer be an appropriate policy or the drug may no longer present an affordability challenge. We urge the Board to revise the Draft Regulations to require no less frequent than monthly checks of the FDA website to determine if a drug subject to a UPL is in shortage, to suspend the UPL promptly upon such a finding, and to require a new affordability review that complies with the framework established by the PDAB statute before reinstating any UPL. Consistent with Lilly's comments above, any decision to reinstate a UPL must also include careful consideration of the impact of such price control on patient access.

* * *

Lilly appreciates the opportunity to comment on the Board's Draft Regulations and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or clarifications.

Sincerely,

Cynthia Ransom

Cynthia Ransom
Sr. Director, Government Strategy, Lilly USA

[32] Letter from Lilly to Board (Aug. 26, 2024), at 10–12.
[33] Md. Code, Health-Gen. § 21-2C-14(c)(ii); Draft Regulations § 14.01.05.09A(2).
[34] Draft Regulations § 14.01.05.09A(4)(c).

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August 26, 2024

By Electronic Submission

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

Re: Draft Outline Upper Payment Limit Action Plan

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

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments on the Board's Draft Outline Upper Payment Limit ("UPL") Action Plan (the "Plan").[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly offers the following comments notwithstanding its grave concerns about the constitutionality of the State of Maryland's attempt to authorize the PDAB to impose UPLs, including the application of UPLs to patented drug products. The Supreme Court has long explained that patents confer a statutory period of market exclusivity on patent holders, during which manufacturers are permitted to charge market prices for their drugs.[2] State price control laws like UPLs fundamentally disrupt the intent of the federal patent laws and federal drug exclusivity periods, and thus are preempted under the Supremacy Clause of the United States Constitution.[3] Lilly also believes that any application of a UPL to the Maryland Medicaid Program is precluded by the Social Security Act. Lilly expressly reserves all available arguments regarding the legality of the

[1] *See* Draft Plan, available here.
[2] *See Sears, Roebuck & Co. v. Stiffel Co*., 376 U.S. 225, 229 (1964).
[3] *See Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1363, 1373 (Fed. Cir. 2003).

PDAB statute and its implementation, and we urge the Board to revise the Plan consistent with our comments below.

The Board Must Complete Cost Reviews, Policy Reviews to Consider Potential UPL and Non-UPL Options, and Calculations of UPLs at Separate Meetings with Sufficient Time at Each Step for Meaningful Stakeholder Input and Board Responses to Such Input

Lilly is concerned that the Board proposes to adopt a process that enables it to finalize its determination that an affordability challenge exists, determine that the adoption of a UPL is an appropriate policy solution, and adopt a UPL amount *all in the same Board meeting*. This means that the Board would be calculating UPL amounts *before* reaching a final decision on whether a drug actually presents an affordability challenge and *before* the Board determines that a UPL is an appropriate policy solution. Such an approach is neither consistent with the requirements of the PDAB statute, nor logically coherent.

First, the proposed consolidated timeline and process in the Plan violates the PDAB statute. Under Section 21-2C-09, if the Board decides to engage in a cost review for a prescription drug, it must determine "whether use of the prescription drug product . . . has led or will lead to affordability challenges for the State health care system or [whether] high out–of–pocket costs for patients are associated with affordability challenges."[4] Only after the Board has completed this step may the Board set UPLs "for prescription drug products *that have led or will lead to an affordability challenge.*" This statutory language necessarily requires a final determination of an affordability challenge, through the cost review process, *before* the Board evaluates possible policy solutions, including the potential imposition of a UPL.[5] In fact, under Section 21-2C-13, the Board must consider certain statutory factors when creating a UPL, including some of the very same cost data the Board must evaluate in making the final determination of whether an affordability challenge exists. The Plan fails to comply with these statutory requirements and deprives stakeholders—including patients and manufacturers—of the procedural safeguards imposed by the legislature.

Second, the Board's decisions at each stage of the statutory process should be rendered in *separate* meetings with a *separate* opportunity for public comment to ensure there are adequate opportunities for stakeholder input. As noted, the Plan contemplates that the final cost review report, policy recommendations, and proposed UPL amounts could be adopted sequentially, in a nod to the statutory requirements, but nevertheless at the same Board meeting.[6] Stakeholders should have the opportunity to comment on and engage in each of these processes separately, and the Board must meaningfully respond to those comments before proceeding onto the next step. Combining these steps would impair the integrity of the Board's decision-making, encouraging rushed conclusions that do not fully account for the full range of stakeholder feedback and perspectives relevant to each distinct decision. Abbreviating and consolidating the different steps

[4] Md. Code Ann., Health-Gen. § 21-2C-09.
[5] *Id.* § 21–2C–14.
[6] Draft Plan at 5.

of the Board's decision-making into a single meeting subverts these objectives and undermines the purpose of the comment periods and public hearings that precede the Board's key UPL-related decisions.

Third, the Plan does not require disclosure of the reasoning that led to the Board's preliminary affordability determinations, and merely says that the Board's *staff* "may" include such information to inform the Board's thinking. Given the absence of any clear requirement for the Board to memorialize its reasoning, disclose its reasoning to stakeholders at each step of the process, and engage substantively with comments, the Board's proposal to allow one-stop decision-making risks ignoring potential qualitative and quantitative changes that may occur as the affordability review moves from the preliminary to the final determination.

The totality of these procedural and substantive concerns create serious questions about arbitrary and capricious agency action, as the Plan suggests that the Board will pre-judge the outcome of its reviews through the development of UPLs before it is finally determined that a UPL is appropriate in the first instance, and before consideration of all the information and public comments provided during the review process.[7] Ultimately, this creates undue risk that the Board would impose a UPL without fully evaluating the appropriateness of such a price control, which risks dire consequences for patients by incentivizing rushed judgments that may fail to fully consider the potential negative repercussions of a UPL on patient access across the state. For all these reasons, the Board should not—*and lawfully cannot*—prematurely commit to a UPL before completing the cost review, and the Board must ensure adequate time for stakeholder review and input, and thoughtfully respond to such input.

The Board Must Comply with the Procedural Requirements of the Maryland Administrative Procedure Act ("APA")

[7] *Id.* at 6 ("The ***preliminary determination*** that the drug has led or will lead to affordability challenges is a predicate for the Board to start the policy review process to study and assess what, if any, policy tools are ***best suited to redress the identified affordability challenges, including whether a UPL is an appropriate policy solution***.") (emphasis added).

The Plan acknowledges that "setting a UPL is a quasi-legislative action"[8] and states that "the procedures in this action plan provide for the setting of a UPL by adopting a regulation through the notice and comment rulemaking provisions of the Maryland Administrative Procedure Act."[9] While Lilly agrees that the setting of any UPL must be adopted through rulemaking, Lilly believes that the Board must also clarify that the policies of general application summarized in the Plan itself must also undergo a rulemaking meeting the requirements of the Maryland APA *before* the Plan is finalized and sent to the Legislative Policy Committee for approval.[10]

The Plan is unclear as to what the Board intends to promulgate through future rulemaking. The Board cannot simply adopt the UPL amount in a subsequent regulation via rulemaking without subjecting the processes that lead to the setting of that UPL amount (i.e., the Plan) to the rulemaking process as well. Under Maryland law, all agency policies "of general application" must be established through rulemaking.[11] This requirement applies not only to legislative rules that establish substantive standards and requirements but also to "organizational rules, procedural rules, interpretive rules and statements of policy."[12] As Maryland courts have long explained, "where an agency statement of general applicability implements, interprets or prescribes law or policy, it is a rule which *must* comply with the APA."[13]

Simply put, the Board cannot use the Plan as a mechanism to evade the requirements of the APA.[14] The Plan represents a policy of general applicability because it describes the approach the Board will apply going forward in reviewing drugs for purposes of deciding whether to impose UPLs and set UPL amounts. As with any other statement that "implements, interprets, or prescribes law or policy" and will be applied to future proceedings, the Board *must* undertake a notice-and-comment rulemaking with respect to the Plan itself and *must* ensure that such rulemaking complies with the APA.[15]

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[8] Lilly also requests that the Board clarify how it is defining what constitutes a quasi-legislative action. Maryland courts often refer to "quasi-legislative" action to refer to any agency action that involves creating or changing a rule of "general application," which prescribes a new plan or policy rather than merely facilitating the administration of an existing law. *Kor-Ko Ltd v. Md. Dep't of the Env't*, 451 Md. 401, 409 (2017). It is unclear to Lilly if the Board is using the term "quasi-legislative" action in this sense, or if the Board has adopted some alternative understanding of the term.

[9] Draft Plan at 2. The Board also suggests that certain activities like Expert Testimony Hearings are "quasi-legislative *hearings*" for which the Board must adopt subsequent regulations. *See, e.g.*, *id.* at 7 (emphasis added).

[10] Md. Code, Health-Gen. § 21-2C-13.

[11] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009); *see also* Md. Code Ann., State Gov't, tit. 10, subtit. 1, pt. III.

[12] *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003) ("Under the Maryland APA, an agency's organizational rules, procedural rules, interpretive rules and statements of policy all must go through the same procedures as required for legislative rules").

[13] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986) (emphasis added).

[14] *See* Md. Code, Health-Gen. § 21-2C-13 (no exemption from APA requirements in provision authorizing the Board to submit its plan of action).

[15] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986).

Lilly is deeply concerned that, to date, the Board's processes have failed to abide by the APA's requirements. The APA requires that rules of general applicability (like the Plan) be proposed and published in the Maryland Register,[16] as well as the Board's website,[17] with "at least 30 days" opportunity for public comment, and cannot be finalized until "at least 45 days after [] first publication in the Register."[18] Notably, the Board released the Plan after the close of business on Friday, August 9th, never published it in the Maryland Register, and requires comments be submitted just two weeks later. Fourteen days is less than ***half*** the time required under the APA, and not nearly enough time for stakeholders to meaningfully review and comment on the Board's plan to operationalize key aspects of the PDAB statute, including the Board's blueprint for setting a UPL. Manufacturers and other members of the public are entitled to the full protection of the APA's requirements, including a full opportunity to comment.[19]

Lilly also emphasizes that the Plan fails to address critical details about the substance of the Board's newly proposed processes, which as noted above, also must be implemented through notice-and-comment rulemaking. As explained in more detail below, critical definitions, standards, and procedures are either left undefined or only addressed at a summary level without providing key details about how they will be operationalized in practice.

Definitions

Lilly is concerned that the Board has not provided clear and practical definitions for a number of key terms in the Plan. The lack of transparency in how these terms will be interpreted and applied hinders stakeholders' ability to effectively engage with the Board. Further, the absence of clear definitions may lead to arbitrary and inconsistent application in the UPL setting process and other unintended consequences. Lilly urges the Board to adopt the following recommendations with respect to certain key terms and their definitions:

- Affordability challenge: The Board should define the term "affordability challenge" to be limited to "state health care system entities"[20] and their patients. In particular, affordability should be analyzed with reference to the specific governmental entities that can be subject to UPLs as enumerated in the PDAB statute and their patients—meaning state or county correctional facilities and their patients; state hospitals and their patients; health clinics at state institutions of higher education and their patients; health benefit plans making

[16] Md. Code Ann., State Gov't § 10-112.
[17] *Id.* § 10-112.1.
[18] *Id.* § 10-111.
[19] Lilly is similarly concerned that the Board's acceleration of the date on which it plans to approve the Plan—from September 23 to September 10—further limiting the time allowed for stakeholders and the Board to consider the implications of the Plan. The irregular nature of these proceedings raises serious questions about whether stakeholder comments will be seriously considered by the Board.
[20] Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).

payments on behalf of a unit of state or local government and enrollees thereof, and (to the extent legally permissible) the Maryland State Medical Assistance Program and Medicaid enrollees.[21] Because the PDAB statute makes clear that these are the only entities that could be subject to a UPL established by the Board, it would not be logical or consistent with the statute to evaluate affordability from the perspective of other entities, such as private health plans or other private purchasers for which a UPL would have no bearing.[22] Rather, the statute dictates that affordability be analyzed from the perspective of these entities and their patients. Lilly also recommends that the Board define "affordability challenge" in a manner that requires consideration of both the net price at which state health care system entities currently access the drug and the level of purchases and utilization by those entities.[23]

- High out-of-pocket costs: The Board should similarly ensure that "high out-of-pocket costs" is defined and that such definition is specific to patients of the state health care system entities that could be subject to a UPL. Just as the PDAB statute contemplates that "affordability challenges" be defined by reference to state health care system entities, so too does the statute contemplate "high out-of-pocket costs" be analyzed from the perspective of the patients of those state health care systems. Otherwise, the Board's UPL analysis would be of patient populations that have no bearing to the scope of the UPL as defined under the statute. Further, a more expansive definition could risk incorporating factors that are not directly relevant to the patients that would benefit from the UPL, potentially leading to unintended consequences in setting the UPL. As discussed in more detail below, all consideration of out-of-pocket costs should also take account of the fact that out-of-pocket costs are the byproduct of benefit design choices made by independent health plans and pharmacy benefit managers (PBMs), which are outside of the control of manufacturers and others in the pharmaceutical supply chain.[24]

- Therapeutic class: Lilly recognizes that the Board has defined the term "therapeutic class" in regulation to mean, "a group of drugs containing active moieties that share scientifically documented properties and are defined on the basis of any combination of three attributes: mechanism of action, physiologic effect, and chemical structure."[25] Lilly is concerned that use of this unduly broad definition, especially in the UPL setting process, would result in prices being set based on invalid comparisons between materially distinct products.[26] We urge the Board to adopt a different definition of therapeutic class that focuses instead on

[21] *Id.* § 21-2C-14(a). As noted above, Lilly reserves its argument that UPLs cannot be imposed with respect to the Maryland State Medical Assistance Program. However, we refer to the state Medicaid program and its enrollees in the above list to maintain consistency with the language in the PDAB statute.
[22] *See id.* § 21-2C-14(a)(1)–(3) (limiting UPLs to transactions involving certain state or local government entities).
[23] *See* Board, Draft Supply Chain Report at 21–23, (Dec. 12, 2023), available here.
[24] *Id.* at 39–41, 96–97.
[25] COMAR 14.01.01.01(62).
[26] Lilly also has concerns about this existing definition in the context of cost reviews, but focuses its comments on the UPL setting process because it is the focus of the Draft Plan.

therapeutic alternatives, and specifically therapeutic alternatives available to state health care system entities consistent with the statutory scope of UPLs under the PDAB statute.

While Lilly believes a focus on therapeutic alternatives is far more appropriate for all of the above reasons, to the extent the Board continues to adopt a broader approach, the Board should at least establish a definition of therapeutic class that avoids arbitrary comparisons between dissimilarly situated products and accounts for clinical and practical distinctions between disparate products.[27] Different products that are sometimes colloquially described as belonging to the same class can still have material distinctions including chemical formula, mechanism of action, mode of administration, and safety and effectiveness. These differences can translate into significant differences in whether they are an appropriate choice for a given patient, given their individualized circumstances and needs.

Preliminary Recommendation Process

The Board appears to have established different standards for the Preliminary Recommendation based on whether a UPL is the proposed solution. For example, the Board only proposes to require evaluation of the strengths and weaknesses of non-UPL solutions without establishing a corresponding requirement when evaluating the appropriateness of a UPL.[28]

This raises concerns under the Maryland APA, which requires similarly situated circumstances to be treated in a similar fashion absent some reasoned basis for differentiation.[29] It also raises overarching concerns about whether the review of potential policy solutions will be biased in favor of UPL-based options.

Criteria and Requirements Related to Setting a Upper Payment Limit

Lilly recommends refinements to the criteria that the Board intends to apply when determining whether a UPL is appropriate and when setting a UPL amount.[30] In principle, Lilly agrees that specific criteria should be adopted to guide the Board's discretion in determining whether to impose a UPL (as well as the amount of any such UPL). Lilly is concerned, however, that the criteria in the Plan disregard important details that bear on how they would be implemented, and that the Plan also fails to mandate consideration of other important factors that should be included as mandatory criteria.

First, Lilly urges the Board to add an additional criterion that prevents the Board from establishing a UPL (or setting a particular UPL amount) unless there is an evidence-based determination by the Board that the UPL (or UPL amount) will not negatively affect patient access in the state.

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[27] Lilly further addresses its concerns with the Therapeutic Class UPL methodology below.
[28] *Id.* at 7–8.
[29] *Md. State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998).
[30] *See* Draft Plan at 3.

As the Board itself has acknowledged, the decision to impose a UPL requires the balancing of "many competing interests."[31] While the Board asserts that if a UPL could simulate a "perfectively competitive [market] equilibrium," it could "in theory" address potential market failures, it has also acknowledged that "the pharmaceutical supply chain is complex and imperfect competition exists at multiple levels."[32] As a consequence, there is a serious risk that a UPL could have meaningful unintended negative consequences, including significantly impairing patient access. The Board should be attentive to this risk and thoroughly analyze the threat to patient access posed by a given UPL to ensure that UPLs are only imposed where they do not risk impairing patient access.[33]

An evidence-based criterion focused on patient access also would help safeguard against arbitrary decision-making, as it would work to ensure that the Board lays out both its reasoning and the factual basis in support of that reasoning should it determine to impose a UPL or any specific UPL amount. Reliance on such an evidence-based criterion would also be consistent with the intent of the legislature, which was to target use of UPLs only where most appropriate.[34] As the Board itself has stated, "there is no single approach that will address" all problems of affordability, and the Board should limit its use of UPLs to situations where it can confirm that these price controls will not have negative repercussions for patient access.[35] The Board should also commit to disclosing such a determination to the public and providing a meaningful opportunity for comment.

Second, Lilly provides the following additional comments on the current criteria set forth in the Plan:

- Costs to be considered in setting a UPL. The PDAB statute does not limit the cost categories the Board may consider in setting a UPL, and therefore the Board should not limit itself to consideration of only those three categories of costs identified in statute: the cost of administering the drug, the cost of delivering the drug to consumers, and other relevant administrative costs related to the drug.[36] As part of the cost review process, the Board may obtain a range of different information related to whether a drug may create affordability challenges (e.g., patient out-of-pocket cost data, expenditures by the statutorily-specified state purchasers and payers subject to any UPL) from public sources and other stakeholders, and the Board should thoughtfully consider the reliable and relevant information used in the cost review process in deciding whether to impose a UPL and the most appropriate UPL amount.

[31] Board, Draft Supply Chain Report at 65.
[32] *Id.* at 52.
[33] Such analysis would necessarily need to account for the unique patient population characteristics and supply chain issues relevant to the specific drug at issue.
[34] Md. Code Ann., Health-Gen. § 21-2C-07(1)(ii) (implicitly acknowledging that UPLs are not the right solution for *every* affordability challenge by requiring study of other policy options).
[35] Board, Draft Supply Chain Report at 49.
[36] Md. Code Ann., Health-Gen. § 21-2C-13(b).

- UPLs shall not impact statutory or regulatory amounts, such as Medicaid Best Price. Lilly agrees that UPLs should not impact statutory or regulatory amounts like Medicaid Best Price. A UPL that alters Best Price would be preempted by the Medicaid Drug Rebate Program ("MDRP") statute, as it would fundamentally disrupt the MDRP's complex and interlocking scheme of federal coverage and pricing for the Medicaid program. Specifically, under the MDRP, Congress intended to strike a "grand bargain" under which manufacturers must agree to provide rebates to states in exchange for coverage and payment of their products under Medicaid and Medicare Part B. A UPL that alters Best Price would fundamentally disrupt this carefully negotiated regulatory scheme, and stand as an obstacle to the "accomplishment and execution of the full purposes and objectives of Congress," which would render it preempted under the Supremacy Clause of the United States Constitution.[37] The same arguments apply to other federal price points, such as the Part B Average Sales Price (ASP) and the federal 340B ceiling price, both of which are also set with reference to transactions considered in the Medicaid Best Price calculation.

- A UPL shall not be set lower than the Medicare Maximum Fair Price ("MFP"). Lilly agrees that a UPL should not be set below the MFP, but also stresses that a UPL should not be set at the MFP itself. When Congress enacted the Inflation Reduction Act ("IRA"), it expressly chose to limit the scope of the MFP to the Medicare population, which differs significantly in demographics, age, and diversity from the Maryland patients that would be affected by a UPL. Expansion of the MFP by states to non-Medicare populations would fundamentally disrupt the careful balance that Congress struck in enacting the IRA, jeopardizing patient access to and hindering innovation of new and potentially life-saving medicines. In addition to being unsound public policy, use of the MFP would raise serious preemption concerns by expanding the reach of the MFP beyond what Congress ever intended, thereby fundamentally disrupting the structure of the federal scheme and creating increasing disincentives to participation in the Medicare program.

- Prioritization of drugs with high proportion of out-of-pocket costs as compared to net cost. Lilly requests that the Board clarify how this criterion will be implemented and applied. Among other things, it is not clear "when" this criterion will be applied by the Board, much less "how" it will be operationalized. Specific details are needed for stakeholders to meaningfully comment on whether the Board's proposal is a reasonable one or if the criterion should be eliminated. For example, the Board's proposal raises a number of operational questions, as it is not clear how the Board would define "net cost," verify the data relied upon in calculating the ratio of net cost to out-of-pocket cost, or determine what constitutes an unacceptably "high" proportional difference. Stakeholders therefore need more specific information and a new opportunity to comment to be able to meaningfully address this proposal.

[37] *Crosby v.* NFTC, 530 U.S. 363, 372–73 (2000); *see also Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Methodologies and Factors to Establish UPLs

Lilly has a number of questions and concerns about the different proposed methodologies laid out for calculating UPL amounts. In general, Lilly is concerned that the methodologies lack sufficient detail for stakeholders to fully understand and comment on them.

First, certain of the proposed methodologies raise significant concerns even based on the high-level summaries provided in the Plan. Lilly highlights the following specific concerns about the methodologies described in the Draft Plan:

- Cost effectiveness analysis. Lilly believes that any cost effectiveness analysis used in determining a UPL must account for net price available to State health care system entities and patients, not the list price. Lilly is also concerned that the description of this methodology in the Plan suffers from an overriding lack of clarity and specificity. Among other things, the Board has not described the type of cost effectiveness analyses it intends to use. This raises serious concerns because there are a wide range of different types of cost effectiveness analyses, all of which have differing levels of reliability, validity, and robustness. For example, some types of cost effectiveness analyses raise serious concerns, such as Quality-Adjusted Life Year ("QALY") analyses, which have been shown to discriminate against the sick, elderly, and historically under-represented minority populations.[38] Further, it is not clear whether the Board intends to conduct its own independent cost effectiveness analyses or rely on third party analyses. It is also unclear what controls the Board will put into place to prevent cherry-picking of data (e.g., if the Board is relying on third party analyses, it is not clear how the Board will choose among cost effectiveness analyses performed by different third party institutions).

- Therapeutic class reference UPL. Consistent with our comments above regarding the definition of "therapeutic class," the Board should ensure that, any therapeutic class UPL setting process should focus on products that are therapeutic alternatives to the product at issue. The therapeutic alternatives must also be available to state health care system entities and their patients (e.g., they must be products currently commercially available for purchase by the state health care system entities subject to UPLs for use with the entities' patients)—because the statutory focus of any UPL established by the Board should be the patients of certain state health care system entities.[39] Consideration should also be given to meaningful distinctions between different products, even if they are considered to share the same therapeutic class or be a therapeutic alternative. The Board should not rely on an unduly expansive understanding of therapeutic class to establish a reference UPL that ultimately results in prices being set based on arbitrary comparisons between materially,

[38] *See, e.g.*, P. Schneider, The QALY is ableist: on the unethical implications of health states worse than dead, 31 Qual. Life Res. 1545 (2021).
[39] *See* Md. Code Ann., Health-Gen. § 21-2C-14(a)(1)–(3).

clinically, or practically distinct products, as this could harm patients by distorting market incentives in a manner that discourages access to a more clinically appropriate therapy.

- Domestic reference UPL. Any domestic reference UPL should account for any performance requirements that are a condition of that domestic reference UPL being made available to other US-based entities. Otherwise, using such a reference UPL could result in apples-to-oranges comparisons that fail to consider the context in which the reference price is being provided. In other words, a non-arbitrary domestic UPL reference price should focus on similarly situated entities to those state and local government entities that will be the target of UPLs under the PDAB statute. Accordingly, domestic reference UPLs should focus on the net price paid by other governmental purchasers and payers—not commercial or non-governmental payers that are materially different situated than the types of entities that will be subject to the Maryland UPL. Moreover, when referring to the net price paid, the Board should also consider the underlying factors that contributed to that price, such as a drug's placement on a preferred formulary tier or minimal utilization requirements that facilitated its availability.

- International reference UPL. Lilly recommends that this reference price methodology be eliminated. UPLs based on international reference are inappropriate. There are fundamental differences in the United States marketplace versus the market landscape in ex-U.S. countries, including with respect to market sizes and conditions, national income, regulatory structure, supply chain distribution structure, and a host of other factors. This prevents non-arbitrary comparisons of pricing levels between different countries, as it is virtually impossible to control for these diverse variables. International reference pricing also does not account for the fact that patients in other countries often face delays in accessing new medications compared to patients in the U.S., making comparisons to these prices misleading and potentially harmful.[40] Therefore, Lilly urges the Board to remove any consideration of international pricing in the UPL setting process.

Second, Lilly also has comments about several other aspects of the Board's proposed UPL process, including as follows:

- Calculation of "market basket" of UPLs. Lilly requests clarification on how the Board intends to calculate and use the proposed "market basket" of UPL values. The Plan indicates that Board staff would develop a "'market basket' of UPL amounts consistent with certain regulatory criteria," and that the Board would consider the "market basket" in selecting a proposed UPL amount.[41] Lilly believes more detail is needed to understand

[40] *See, e.g.*, PhRMA, New Analysis Shows that More Medicines Worldwide Are Available to U.S. Patients (June 5, 2018), available here (finding that from 2012-2017, "90 percent of [220] newly launched medicines were available in the United States, compared to just two-thirds in the United Kingdom, half in Canada and France, and one-third in Australia.").
[41] Draft Plan at 3; *see also id.* at 11–12.

what the Board means. Additional clarity is also needed as to how the Board will use the market basket and the overarching purpose of the market basket. Absent such clarifications (with an opportunity for subsequent comment), Lilly does not believe it is possible to meaningfully comment on the proposal, and such proposal should be removed.

- State expenditure data. Lilly agrees that use of state expenditure data is an important starting point in considering the appropriateness of a UPL or UPL amount. Such data are important in determining whether an affordability challenge has or will exist because the PDAB statute contemplates that reviews of affordability must focus on costs for specifically referenced entities to the State health care system.[42] Accordingly, Lilly emphasizes that the state expenditure data that the Board relies upon must be appropriately tailored to the statutory objectives of the PDAB statute. This means that the only state expenditure data relevant to the Board's consideration is the expenditure data of the *specific* state and local government entities that are the subject of UPLs under the Maryland PDAB statute.[43] Also, given the attenuated distribution, payment, and reimbursement relationships in the prescription drug market, it is essential that "expenditures" be defined as "net expenditures," not "gross expenditures" and the state should expressly commit to this principle. As the Board itself has acknowledged, "it is important to differentiate between the payments and flow of money on the product side[,] . . . which results in the gross spend on the drug, and on the payment side (PBM payment to the pharmacy, manufacturer rebates to PBM), which results in the net cost of the drug *to the health system and patient*."[44]

- Application of different methodologies to different drugs. The Plan states that the Board "may select or prioritize one or more of the methodologies and factors, and direct staff to use those methodologies and any other methodology identified by the Board, to conduct analyses and calculations to obtain upper payment limit amounts."[45] Lilly is concerned that this proposal would allow for the improper, arbitrary, and unexplained application of different methodologies to different drugs, leading to inconsistencies in how these products are evaluated. As noted above, Maryland courts have consistently held that agency actions are arbitrary and capricious where they treat similarly situated entities or products differently without a reasonable justification for such differential treatment, or where there are unexplained inconsistencies with prior agency decisions.[46] To avoid setting UPLs in an arbitrary and capricious manner, the Board should revise the Plan to ensure that it applies its methodologies consistently across similarly situated products and provides a clear rationale for the methodologies used for each specific case.

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[42] *See* Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).
[43] *See id.* § 21-2C-14(a)(1)–(3) (enumerating the entities subject to UPLs).
[44] Board, Draft Supply Chain Report at 21 (emphasis added).
[45] Draft Plan at 8.
[46] *See, e.g.*, *Christopher v. Montgomery County Dep't of Health & Human Servs.*, 381 Md. 188, 215 (2004); *Md. State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998).

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Lilly appreciates the opportunity to comment on the Board's Plan and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or clarifications.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

To: The Maryland Prescription Drug Affordability BoaRD

My name is Paul Schwartz and I am the Region II Vice President of The National Active & Retired Federal Employees Association, NARFE. We strongly support the regulations proposed by the state's Prescription Drug Affordability Board (PDAB) and published this month in the *Maryland Register*. The Board, including its experienced staff and five appointed members, has worked diligently to craft a thorough and fair process aimed at addressing the high and escalating costs of prescription drugs.

The proposed Upper Payment Limit (UPL) process is one of the most comprehensive frameworks developed to date, covering the entire pharmaceutical supply chain and offering much-needed transparency. The Board's unanimous vote to adopt the UPL Action Plan reflects its commitment to tackling affordability challenges, especially in light of significant federal developments, such as Medicare's drug-pricing negotiations under the Inflation Reduction Act.

Currently, the Board is reviewing two drugs included in Medicare's Maximum Fair Price program. By approving the UPL Action Plan, Maryland can align state UPLs with federal rates for certain drugs, a move that could influence prescription drug negotiations for state and local governments, further benefiting Maryland residents.

The UPL Action Plan is the result of a fair and thorough public discussion process, ensuring robust stakeholder participation. It also includes critical safeguards to maintain access to medications under review for UPLs, ensuring Maryland consumers continue to receive the medications they need.

I wholeheartedly commend the PDAB for its thoughtful approach and supports the timely implementation of these regulations to help reduce prescription drug costs for all Marylanders.

Remember, since Maryland can no longer rely on the federal government to provide oversight of pharmaceutical pricing to keep prices affordable, the role of the PDAB takes on greater importance for Marylanders.

Sincerely,

Paul K. Schwartz

Region II Vice President

National Active & Retired Federal Employees

240 838-2200

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PIPC Partnership to Improve Patient Care

February 6, 2025

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

Dear Ms. Shaklee:

I am writing again to share the strong concerns from patients and people with disabilities about the methodology proposed by the Maryland Prescription Drug Affordability Board to set Upper Payment Limits (UPLs) for selected drugs. As an original author and sponsor of the Americans with Disabilities Act (ADA), it is a high priority to me and the disability community that discriminatory value assessments have no place in the U.S. health care system. Yet, the Board's proposed methodology for establishing UPLs explicitly calls for use of cost effectiveness analysis and international prices from countries known to use quality-adjusted life years (QALYs) and similar measures barred by federal law and regulations. The Board has failed to include any safeguards in the proposed rulemaking that would protect people with disabilities and serious chronic conditions from decisions made in reliance on discriminatory value assessments.

Additionally, the Board does not describe how comparative effectiveness research (CER) may be used in decisions related to therapeutic alternatives, where treatments often impact patients very differently. For example, when Congress created the Patient-Centered Outcomes Research Institute, CER was a defined term that acknowledged differential impacts among subpopulations and sought to protect against its use to define effectiveness as averages, with legal protections against its use as a sole source for coverage decisions. Patients and people with disabilities are not average. No such protections exist in the Maryland proposed rule.

PIPC and others have consistently argued against policies that drive discrimination and increased barriers to accessing personalized care prescribed by doctors in consultation with their patients. We urge the Board to focus its efforts on making health care more affordable for patients and people with disabilities, such as addressing the utilization management strategies imposed by payers to make care less accessible and affordable. We are hopeful for a response to our concerns, described at length in prior letters attached.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

August 26, 2024

Mr. Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Chair Mitchel and Board members:

As organizations representing patients and people with disabilities, we strongly urge the Maryland Prescription Drug Affordability Board (PDAB) to prioritize the perspectives of people whose care may be impacted by your decisions as it works to finalize a Plan of Action for Implementing the Process for Setting Upper Payment Limits. Therefore, we would like to provide the following recommendations:

- Develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments.
- Improve the Board's patient engagement practices and use of survey data.
- Avoid the use of discriminatory value assessments.
- Avoid reference to drug prices in other countries.

We are deeply concerned with recommendations from academia to states implementing PDABs that are not centered on helping patients gain affordable access to the drugs that patients and doctors determine to be the most effective treatment.[1,2] Patients and people with disabilities have consistently expressed opposition to policies advancing use of discriminatory value assessments, closed formularies, utilization management strategies in which a drug must fail before patients can access a drug that works, non-medical switching to "therapeutic alternatives" as determined by a payer based on cost considerations, and formulary exclusions. Ultimately, we urge the Board to advance policies that support high-quality shared decision-making between patients and providers, ensuring patients can access the care that will have the most optimal impact on their quality of life and health outcomes. Adopting the recommendations below will be a strong start to protecting people with disabilities and serious chronic conditions in Maryland.

Develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments.

[1] NASHP Toolkit to PDABs https://nashp.org/prescription-drug-affordability-board-toolkit/
[2] https://pdab.maryland.gov/documents/stakeholders/2023/havard_med_brigm_prst.pdf

We appreciate that the statute governing the Board's activities calls for cost reviews that determine whether a treatment "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." It is our hope that the Board is first and foremost seeking to protect patients and people with disabilities seeking to access the treatment that is recommended by their providers and most effective for the patient. By now, the Board is aware that affordability challenges are often associated with placement on formularies, utilization management strategies imposed by payers to restrict access to certain drugs, and outright denials that force patients to pay out-of-pocket for access to the drug on which they are most stable. It does patients and people with disabilities little good to lower the price of a drug if the outcome is to make it harder to access that drug or an alternative drug that may be more effective for the patient but is no longer on a preferred tier or is subject to a fail first policy.

The Board has significant latitude to determine whether an Upper Payment Limit (UPL) is the policy solution for an affordability challenge. What many patients know to be true is getting the drug they need is often difficult and burdensome. Meaningful policies to genuinely help patients address their out-of-pocket costs must mitigate the use of discriminatory value assessments by payers to justify restricting access to care for people with disabilities and serious chronic conditions, as well as older adults. Addressing affordability starts with policies that support shared decision-making between patients and providers and ensure affordable coverage of the treatment plan that patients and providers determine to be most effective.

Therefore, we urge the Board to develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments, which could increase patient costs and impede physicians' judgment about the best care for individual patients. The draft plan states the Board will set UPLs in a way to minimize adverse outcomes and minimize the risk of unintended consequences, as well as monitor availability of prescription drugs subject to a UPL to protect against shortages. We hope the Board will go further to ensure patients and people with disabilities are not losing access due to coverage denials, step therapy, prior authorization, etc. We appreciate that the Board proposes to reconsider or suspend UPL's where they find selected drugs to be unavailable and propose the Board adopt the same policy to respond to payers that restrict access to selected drugs or other alternatives.

Improve the Board's patient engagement practices and use of survey data.

The Board states in its draft UPL plan that its process is transparent and offers multiple opportunities for public engagement and input. Yet, it is not clear to stakeholders how information submitted by patients is used by the Board to make decisions. We would urge the Board to review the work of experts in patient engagement such as the patient-Centered Outcomes Research Institute (PCORI), National Health Council, the University of Maryland, AcademyHealth and the Innovation and Value Initiative on how to best engage the patient community in its work. For meaningful engagement on the factors listed for consideration by

the Board – including therapeutic alternatives, patient access, comparative clinical effectiveness research, cost sharing, clinical information and disease burden – we recommend the Board:

- Develop a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels.
- Use patient insights to clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.
- Solicit input from diverse communities to ensure representation of the diversity of the patients and communities affected by the topic.
- Ensure that opportunities for patient engagement are accessible.
- To gauge both successes and challenges, establish a structured process for continuous review and assessment of its engagement strategy.
- Avoid one-size fits all value metrics.[3]

The Board has received substantial comments about the factors that drive affordability challenges for patients and people with disabilities, yet the Board continues to focus its work on establishing UPLs without addressing the economic burdens that patients too often face, whether it be transportation, caregiving, utilization management strategies blocking coverage of prescribed care, etc. Entities such as the Patient-Centered Outcomes Research Institute (PCORI) have invested significant resources in engaging patients to identify the full range of clinical and patient-centered outcomes, including the potential burdens and economic impacts of health care services[4,5]. Additionally, a patient-developed survey is now available to help the Board determine the many factors that can lead to affordability and access challenges for patients, led by the Patient Inclusion Council, also known as the PIC.[6] We urge the Board to use these resources to better understand the burdens facing patients and to develop patient-centered strategies for improving access to care.

Avoid the use of discriminatory value assessments.

The Board highlights in the draft that it may consider many different factors part of a cost review, including cost effectiveness analyses. Yet, on May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving federal financial assistance against the use of discriminatory value assessments also known as cost effectiveness analyses.[7] The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting

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[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_recommendations_for_patient_engagement_final.pdf

[4] https://www.pcori.org/sites/default/files/PCORI-Out-of-Pocket-Cost-Taxonomy-Scoping-Review-Sept-2023.pdf

[5] https://www.pcori.org/sites/default/files/PCORI-Assigning-Costs-to-Healthcare-Utilization-Report-March-2023.pdf

[6] https://www.surveymonkey.com/r/PatientDrugAffordability

[7] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG) that are most common methodologies for calculating cost effectiveness. The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating recipient obligations under the rule are broader than section 1182 of the Affordable Care Act. Section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. Therefore, it is important for the Board to avoid the use of cost effectiveness analyses to make decisions that affect reimbursement and coverage of prescription drugs to remain aligned with federal law and regulations barring discrimination.

It is now widely recognized that traditional methods and metrics of value assessment – even beyond the QALY – have significant shortcomings. Well-intentioned development of other measures and approaches that developers assert to be nondiscriminatory and more patient-centered come with tradeoffs, need for improvement, and inherent methodological flaws. We urge the Board to avoid the use of cost effectiveness analyses that at worst violate federal nondiscrimination laws and regulations and at best force tradeoffs such as whether to value life extension or quality of life improvement. No patient is average, and no measure of value should assume so.[8]

Avoid reference to drug prices in other countries.

The Board's draft plan also proposes use of an international reference upper payment limit using drug prices in other countries. Referencing other countries is similarly contrary to federal laws governing disability discrimination due to their reliance on discriminatory value assessments, including QALYs. The Board's proposed policy would import those discriminatory standards from other countries and lead directly to lack of access to needed treatments for many Americans.[9] While Germany is often raised, we encourage the Board to review the German system, including its limited use of evidence, inappropriate comparators and endpoints, exclusion of health outcomes that are important to patients, and failure to capture heterogeneity of patient populations.[10] In Canada, the current coverage and reimbursement process for new drugs impedes access to care due to its reliance on QALY-based assessments conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH).[11] In the United Kingdom, medicines exceeding the National Institute for Health and Care Excellence (NICE) cost-per-QALY threshold are not deemed cost effective, leading to a high rate of

[8] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf
[9] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf
[10] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf
[11] Guidelines for the Economic Evaluation of Health Technologies: Canada. July 2017

rejections denying patients access to new medicines.[12] Ireland similarly denies patients care based on QALY thresholds.[13]

We encourage the Board to reference the work of the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, which has consistently recommended against referencing foreign prices in comments related to a proposed international pricing index,[14] Most Favored Nation policy,[15] and federal legislation.[16] The NCD's recommendations against reliance on cost effectiveness are largely reflected in the new federal Section 504 regulations, providing increased clarity on the prohibited use of discriminatory value assessments.

Thank you for the opportunity to comment on the draft UPL plan. We look forward to revisions that prioritize policies centered on access to care for patients and people with disabilities. Please reach out to sara@pipcpatients.org with any questions.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association of Kidney Patients (AAKP)
Asthma and Allergy Foundation of America
Biomarker Collaborative
Cancer*Care*
Caring Ambassadors Program
Coalition of State Rheumatology Organizations (CSRO)
Color of Gastrointestinal lllnesses
Cystic Fibrosis Research Institute
Derma Care Access Network
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Equity Collaborative
Epilepsy Foundation
Exon 20 Group
Familia Unida Living with MS
GO2 for Lung Cancer

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[12] Drummond, M. and Sorenson, C. Nasty or Nice? A Perspective on the Use of Health Technology Assessment in the United Kingdom. Value in
Health 2009; 12(S2).
[13] National Centre for Pharmacoenomics (NCPE). http://www.ncpe.ie/about/
[14] https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/
[15] https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/
[16] https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/

Headache and Migraine Policy Forum
Health Hats
HealthHIV
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
MET Crusaders
MLD Foundation
Monica Weldon Consulting, LLC
National Infusion Center Association (NICA)
National Infusion Center Association (NICA)
Partnership to Fight Chronic Disease (PFCD)
Partnership to Improve Patient Care
Patients for Patient Safety - US
PD-L1 Amplifieds
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The IMAGE Center for People with Disabilities

cc: Stakeholder Council

PIPC Partnership to Improve Patient Care

May 13, 2024

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

Dear Mr. York:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Maryland Prescription Drug Affordability Board's ongoing Cost Review Study process. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment.[1] We are writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving federal financial assistance.[2] In response to the proposed rule last year, the Partnership to Improve Patient Care (PIPC) joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.[3]

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals

[1] https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[2] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov
[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf

with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment." As you may be aware, section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. PIPC was pleased that the final rules governing Section 504 would be interpreted as broader than the section 1182 statute.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[4] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

Alternatively, we would encourage the Board to engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.[5,6,7,8] We are also concerned about the transparency of the decision-making process by the Board and hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

[4] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.
[5] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[6] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[7] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[8] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

PIPC Partnership to Improve Patient Care

May 2, 2023

Andrew York
Executive Director
Maryland Prescription Drug Affordability Board 4160 Patterson Avenue
Baltimore, MD 21215

comments.pdab@maryland.gov

Dear Mr. York:

The Partnership to Improve Patient Care (PIPC) is pleased to provide comments on the draft proposed regulations issued by the Maryland Prescription Drug Affordability Board, specifically related to the concerns of patients and people with disabilities related to the Board's potential use of cost effectiveness analyses. These comments follow the letter sent to the Board on August 3, 2021, from 38 organizations urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment. As you know, the organizations offered to be resources to the Board as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.[1]

We are concerned that the draft regulations ignore the letter referenced above, instead specifically calling for information on cost effectiveness "derived from health economics and outcomes research" which is known to rely on biased and discriminatory measures such as QALYs. By devaluing people with disabilities, whether in terms of their life extension or quality of life, cost effectiveness analyses relying on QALYs and similar measures have no place in our health care system.

Recently, 56 organizations sent a letter to the Centers for Medicare and Medicaid Services (CMS) related to their initial guidance for implementing the Medicare Drug Price Negotiation Program. Their comments centered on three pillars: 1) creating additional procedures to meaningfully engage with patients and ensure that the evidence CMS relies on is transparent; 2) establishing patient-centered standards and outcomes; and 3) more definitively rejecting the use of Quality-Adjusted Life Years (QALYs) and other discriminatory cost-effectiveness standards. Their recommendations to CMS may also be useful to the Maryland Prescription Drug Affordability Board in its efforts to develop evidentiary standards and engagement practices that ensure patient benefits are central to decision-making. The letter is also attached as an appendix.[2] I hope that the Board will take into consideration each of its recommendations.

[1] https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[2] http://www.pipcpatients.org/uploads/1/2/9/0/12902828/joint_comment_to_cms_on_negotiation.pdf

We strongly support standards for the research used to make judgements about therapeutic impacts of drugs, assuring it is centered on value to patients and people with disabilities and inclusive of real-world evidence.[3] The same sentiment applies here to the Board's work if it is to truly be centered on patients and people with disabilities. Its decision-making process should be publicly transparent and avoid discriminatory research using QALYs or similar methods steeped in stigma in favor of measures that encourage treatments valued by patients and people with disabilities. The Board should begin by recognizing the historic discrimination from use of biased cost effectiveness measures such as QALYs to make decisions related to health care, instead of focusing on outcomes that matter to patients and people with disabilities.[4]

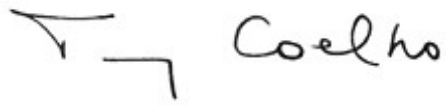
Therefore, we urge the Board to abandon its proposal to rely on cost effectiveness measures that are known to disproportionately impact care access for subpopulations already experiencing substandard health care, especially for people that too often experience discrimination doubly by virtue of being Black, Indigenous, or people of color and having a disability or chronic condition.[5] We urge the Board to incorporate the recommendation of the National Council on Disability, an independent federal agency, calling for a blanket prohibition on QALYs, whether used directly or by reference to a third party, as part of its Health Equity Framework.[6]

We were particularly disappointed that the draft proposed regulations did not outline a robust process for engaging patients and people with disabilities. As outlined in the letter to CMS referenced above, engagement should happen early and often, including roundtables with affected patients and people with disabilities related to the treatments being considered by the Board, and concerted efforts to engage with diverse communities, especially those not represented in the data. We urge the Board to reference the best practices of the Patient-Centered Outcomes Research Institute (PCORI) outlined in its Patient Engagement Rubric,[7] Compensation Framework,[8] recommendations for Budgeting for Engagement Activities,[9] and its Equity and Inclusion Guiding Principles[10] providing insights on bringing diverse voices to the table. Robust patient engagement goes beyond public comment periods at a Board meeting and will require much more effort to capture outcomes that are valued by people living with the condition.

[3] https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-avoid-metrics-steeped-stigma
[4] https://www.ajmc.com/view/is-the-qaly-fit-for-purpose-
[5] https://www.thevalueinitiative.org/wp-content/uploads/2022/10/IVI_Sick-Cells_Equity-in-Value_2022.pdf
[6] https://www.ncd.gov/sites/default/files/NCD_Health_Equity_Framework.pdf (Recommendation #8 on page 10)
[7] https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
[8] https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf
[9] https://www.pcori.org/sites/default/files/PCORI-Budgeting-for-Engagement-Activities.pdf
[10] https://www.pcori.org/sites/default/files/Equity-and-Inclusion-Guiding-Engagement-Principles.pdf

Thank you for your consideration. I hope that the Board will strike reference to cost effectiveness measures in its final regulations and pursue robust engagement strategies with patients and people with disabilities.

Sincerely,



Tony Coelho, Chairman
Partnership to Improve Patient Care

August 3, 2021

Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. York:

We understand that the rising cost of healthcare is a concerning issue that requires real solutions. As organizations representing patients and people with disabilities, the affordability of health care is a significant priority, and we look forward to working with state policymakers to manage health costs in a manner centered on meeting the health care needs of people with disabilities and chronic conditions. In doing so, we urge the state to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment.

We are aware that the Maryland Prescription Drug Affordability Board (PDAB) is tasked with addressing high-cost prescription drug products and engaging diverse stakeholders in that process. As created by statute, the Board consists of five members who possess expertise in the fields of either health care economics or clinical medicine, thereby missing the critical voices of patients and people with disabilities. Therefore, it is essential that people with disabilities and chronic conditions, those who would be most impacted by these policies, are able to have a robust voice in this discussion. The undersigned organizations representing patients and people with disabilities would like to be resources to the PDAB as it strives to make balanced decisions and avoid unintended consequences for patient access to needed care.[1]

We are writing to share information with the Board about QALYs. As you may be aware, other states that have recently enacted similar legislation to create a Prescription Drug Affordability Board have included a bar on the use of metrics that discriminate such as QALYs.[2] As the Maryland PDAB initiates its work, we are hopeful that the entity will similarly take a stand against incorporating the use of QALYs in its deliberations. Recently, the Institute for Clinical and Economic Review (ICER), an entity that relies on QALYs in its value assessment studies and calls QALYs the "gold standard",[3] presented to the PDAB on how its work could be leveraged by the PDAB.[4]

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[1] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports
[2] Colorado Senate Bill 21-175, 10-16-1407(4)(a) and Oregon Senate Bill 844 A
[3] https://icer.org/news-insights/press-releases/icer-describes-qaly/
[4] https://pdab.maryland.gov/2021_board_meeting.html

As background. referencing discriminatory metrics such as QALYs can potentially violate existing civil and disability rights laws. QALY-based assessments assign a financial value to health improvements provided by a treatment that do not account for outcomes that matter to people living with the relevant health condition and that attribute a lower value to life lived with a disability. When applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. We encourage you to review the report from the National Council on Disability, an independent federal agency, recommending that policymakers avoid referencing the QALY, clarifying that its use in public programs would be contrary to United States civil rights and disability policy.[5] Most recently, the National Council on Disability initiated work to review "State's use of QALY-Based Cost-Effectiveness Reports to Inform Medicaid Coverage for Prescription Drugs" which is anticipated to provide information on how QALYs are being used and their implications for restricting access to care.[6]

The United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.[7] Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.[8] Based on the ADA's passage in 1990, in 1992 HHS rejected a state waiver application because its reliance on QALYs and cost effectiveness standards would have violated the ADA and lead to discrimination against people with disabilities in determining the state's prioritized list of services.[9]

In 2010, the Affordable Care Act (ACA) stated that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services "solely on the basis of comparative effectiveness research" nor to use such research in a manner that would attribute a lower value to extending the lives of older adults, people with disabilities or people with a terminal illness.[10] Additionally, the ACA specifically prohibits QALYs and similar metrics from being used by HHS as a threshold to establish what type of health care is cost effective or recommended, as well as prohibiting their use as a threshold in Medicare to determine what is covered, reimbursed or

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[5] National Council on Disability. (November 16, 2019). Quality-Adjusted Life Years and the Devaluation of Life with Disability. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[6] https://ncd.gov/newsroom/2021/NFO-state-use-qaly-based-cost-effectiveness-reports
[7] 29 USC Sec 794, 2017. Accessed November 30, 2020.
[8] 42 USC Sec 12131, 2017. Accessed November 30, 2020.
[9] Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. The New York Times.
[10] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.

incentivized.[11] Most recently, HHS reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in VBP arrangements.[12]

We hope that you will engage patients and people with disabilities in your current process and bear in mind these legal protections under health and civil rights laws as you work on policies to reduce the cost of care for beneficiaries. We appreciate the important work you are doing and stand ready to work with you on appropriate policies that do not discriminate or limit access to needed care and treatment. We would be happy to speak with the members of the Maryland PDAB about our concerns and the experiences of patients and people with disabilities. Please reach out to Sara van Geertruyden at sara@pipcpatients.org if you would like to discuss in more depth.

Sincerely,

Allergy & Asthma Network

Alliance for Aging Research

Alliance for Patient Access

ALS Association

American Association on Health & Disability

American Autoimmune Related Diseases Association

Autistic Self Advocacy Network

Axis Advocacy

Boomer Esiason Foundation

Cancer*Care*

Center for Autism and Related Disorders

Color of Crohn's and Chronic Illness

Cystic Fibrosis Research Institute

Davis Phinney Foundation

[11] 42 USC Sec 1320e, 2017. Accessed November 30, 2020.
[12] https://www.federalregister.gov/d/2020-12970

Diabetes Leadership Council

Diabetes Patient Advocacy Coalition

Epilepsy Foundation Maryland

Global Liver Institute

GO2 Foundation for Lung Cancer

Health Hats

ICAN, International Cancer Advocacy Network

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Lupus and Allied Diseases Association, Inc.

Lupus Foundation of America

Maryland Center for Developmental Disabilities at Kennedy Krieger Institute

Men's Health Network

MLD Foundation

Not Dead Yet

Partnership to Improve Patient Care

Rare New England

SYNGAP1 Foundation

The Bonnell Foundation: Living with cystic fibrosis

The Coelho Center for Disability Law, Policy and Innovation

TSC Alliance

United Spinal Association

VHL Alliance

Whistleblowers of America

ZERO - The End of Prostate Cancer

670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

By Electronic Submission

February 10, 2025

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

christina.shaklee1@maryland.gov

RE: Proposed Rules – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Dear Ms. Shaklee and 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 Board's proposed amended regulations for Code of Maryland Regulations ("COMAR") section 14.01.01.01 (Definitions), proposed new regulations for section 14.01.01.06 (Hearing Procedures), and proposed new chapter 14.01.05 (Policy Review, Final Action, Upper Payment Limits ("UPLs")) (collectively, the "Proposed Rules").[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 implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA has expressed in detail its concerns regarding the Board's implementation of the PDAB Statute,[3] as well as the regulatory amendments contemplated in the

[1] *See* Notice of Proposed Action 24-221-P, 25:1 Md. R. (Jan. 10, 2025), https://dsd.maryland.gov/MDRIssues/5201/Assembled.aspx#_Toc187062353.

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

[3] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the constitutionality of the Maryland 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* Letter from PhRMA to Board Regarding Proposed Regulation – Amendments to COMAR § 14.01.04.05 (Cost Review Study Process) (Dec. 2, 2024); Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade-Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding

Proposed Rules.[4] PhRMA encourages the Board to consider these previously submitted comments, including those in the non-exhaustive discussion below:

A. Procedural Safeguard and Protection for Confidential, Trade Secret, and Proprietary Information

PhRMA remains concerned that the Board has not expressly incorporated the procedural protections afforded by the Maryland Administrative Procedure Act ("APA") and that, in some instances, the Proposed Rules are not consistent with the requirements of the APA.[5] PhRMA requests that the Board revise the Proposed Rules to comply with and incorporate the APA's requirements.

PhRMA remains similarly concerned that that the Board has not addressed how it will implement statutory confidentiality protections and protect that confidential, trade secret, and propriety information against public disclosure.[6] Prior to finalizing the Proposed Rules, PhRMA asks the Board to amend the Proposed Rules to include express protections for such sensitive information, including in publicly posted versions of UPLs and staff recommendations.

B. Lack of Clear and Meaningful Standards

PhRMA refers the Board to its previous comments for more comprehensive discussion of areas in the Board's hearing procedures and regulatory definitions that, as amended under the Proposed Rules, would continue to lack clear and meaningful standards to guide the Board's actions and may lead the Board to arbitrary decision making.[7] To address these issues, PhRMA renews its request that the Board establish specific and reasonable timelines[8] for public notice of Board hearings—and for publication of any agendas or materials related to those hearings—to provide stakeholders with adequate opportunities to engage in the Board's decision-making process. In addition to formalizing specific notification and publication standards, PhRMA requests that the Board require all public meetings to be recorded and made accessible on the Board's website within forty-eight hours thereafter, strike the provision giving the Board Chair or staff designee the power to subjectively "limit repetitious testimony,"[9] and require that publicly disclosable[10] testimony and materials from technical hearings be made available for stakeholder review and written comment.

Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 12, 2022).

[4] *See, e.g.*, Letter from PhRMA to Board (Nov. 8, 2024).

[5] *See, e.g. See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 2; Letter from PhRMA to Board (Aug. 26, 2024) at 2.

[6] *See, e.g.,* Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 6 at 13.

[7] *See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 2-4.

[8] PhRMA recommends posting notices of hearings to the Board's website no less than two weeks prior to a hearing and posting any agendas or other materials to the Board's website no less than one week prior to the hearing.

[9] Draft COMAR § 14.01.01.06(C)(2)(b) ("The Chair or staff designee shall give all persons who register to speak an opportunity to do so but may limit repetitious testimony.").

[10] *See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 3 (requesting that testimony and materials be published "subject to protections for confidential, trade secret, and proprietary information").

PhRMA also reasserts its concerns that certain terms in the Board's Proposed Rules lack a clear and concrete definition.[11] In addition to clarifying these terms, PhRMA urges the Board to clarify the meaning of the new defined term, "system net cost."[12] This term appears to rely on the definition of "net cost," about which PhRMA has expressed concern, and PhRMA asks the Board to provide additional transparency regarding how it intends to calculate this metric.[13]

C. UPL and Non-UPL Analyses and Determinations

PhRMA urges the Board to address—among other previously cited concerns[14]—the lack of clear standards, uniformity, opportunities for public comment, and confidentiality protections in the proposed regulations on UPLs.[15]

PhRMA reiterates its concern that the procedures and considerations for recommending a UPL materially differ from those for non-UPL policy options—with non-UPL options seemingly requiring greater analysis and scrutiny.[16] Without clear standards for evaluating UPL and non-UPL policy options and objective metrics by which to evaluate them, there are few, if any, guardrails against arbitrary and capricious decision-making. To create a uniform process and provide protections against bias, PhRMA asks the Board to adopt parallel procedures and timelines for consideration of UPL and non-UPL policy options and that those procedures require materially identical consideration of the potential impacts on patient affordability and out-of-pocket costs.[17]

PhRMA also remains concerned that the Proposed Rules lack meaningful standards to guide the staff research and analysis underlying the Board's recommendations and decisions. PhRMA refers the Board to its prior comments for more comprehensive discussion, including its concerns with proposed UPL methodologies and the methodology selection process.[18] To address these concerns, PhRMA urges the Board to incorporate explicit guardrails against inconsistent application of analytical methods and considerations across different drugs.[19] Further, PhRMA requests that the Board amend the Proposed Rules to set forth standards for monitoring availability of UPL drugs, making drug shortage determinations, and reconsidering or suspending a UPL in the event of a shortage.[20]

Additionally, PhRMA reasserts its request that the Board incorporate opportunities for stakeholder comment at each step of the decision-making process, including, but not limited to, soliciting public comment at each stage and requiring both informational and technical hearings.[21] To this end, PhRMA

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[11] *See, e.g., id.* at 4-6.
[12] *See supra* note 1 (proposing to amend COMAR § 14.01.01.01(B)(62) to add "system net cost" as a defined term).
[13] *See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 4 (expressing concerns regarding determination and validation of "net cost").
[14] *See id.* at 4-12.
[15] *See supra* note 1 (proposing new chapter, "Policy Review, Final Action, Upper Payment Limits," to be codified at COMAR §§ 14.01.05.01–.09).
[16] *See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 7-8.
[17] *See supra* note 1 (proposing to codify in, COMAR § 14.01.05.01(C), "high out-of-pocket costs for patients" as a focus in assessing "affordability challenge").
[18] *See, e.g.,* Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 6 at 3-7.
[19] *See supra* note 4 at 8-11.
[20] *See* Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 4 at 7.
[21] *See id.* at 3-4.

requests that the Board set reasonable minimum comment periods and clear timelines for the Board to incorporate and address feedback. To provide decision-makers with necessary context, PhRMA further requests that the Board adopt provisions granting manufacturers the opportunity to inspect any data considered—and engage with the Board about that data—before the Board reaches a preliminary determination that use of a prescription drug has led or will lead to an "Affordability Challenge."

* * *

We thank you again for the opportunity to provide comments and feedback on the Board's Proposed Rules and for your consideration of our questions, concerns, and requests for clarification. Although PhRMA remains concerned with some provisions of the Proposed Rules, we continue to welcome opportunities for constructive dialogue. If PhRMA can provide additional information or technical assistance, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

Attachments:

PhRMA Comments on MD Draft Regulations (November 2024)
PhRMA Comments on MD PDAB Draft UPL Action Plan (August 26, 2024)

PhRMA
RESEARCH • PROGRESS • HOPE

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By Electronic Submission

November 8, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

comments.pdab@maryland.gov

RE: 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)

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 Board's draft amended regulations for Code of Maryland Regulations § 14.01.01.01 (Definitions), and draft new regulations for § 14.01.01.06 (Hearing Procedures), and ch. 14.01.05 (Policy Review, Final Action, Upper Payment Limits ("UPLs")) (collectively, "Draft Regulations").[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 implement and 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 through the processes outlined under the Draft Regulations.[3] PhRMA addresses its

[1] *See* Draft Amendments to COMAR 14.01.01.01 (Definitions), *available at* https://pdab.maryland.gov/Documents/regulations/DRAFT.Amendment%20COMAR%2014.01.01.01%20Definitions.2024.10.28.1200%20%281%29.pdf; Draft New Regulation COMAR 14.01.01.06 (Hearing Procedures), *available at* https://pdab.maryland.gov/Documents/regulations/DRAFT.2024.10.22.1630.Draft_COMAR%2014.01.01.06%20Hearings%20Procedures.2024.10.28.1200%20%281%29.pdf; Draft New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits), *available at* https://pdab.maryland.gov/Documents/regulations/DRAFT.14.01.05%20Policy%20Review%20Final%20Action%20and%20UPL.2024.10.28.1220%20%28final%29.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. 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 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

specific questions and concerns regarding the Draft Regulations below.

I. Draft New Regulations COMAR § 14.01.01.06 (Hearing Procedures)

PhRMA has significant concerns regarding the Board's Draft Regulations on hearing procedures. Overall, the Draft Regulations lack protections critical to providing stakeholders with opportunities to have their voices heard throughout the Cost Review and Upper Payment Limit setting processes. Below, PhRMA provides a non-exhaustive list of examples of areas where the Board should revise the Draft Regulations to require that stakeholder input is given due consideration, as required under the PDAB Statute.[4]

A. Lack of Required Procedural Protections

The Draft Regulations do not provide for the required protections for manufacturers under the Maryland Administrative Procedure Act ("APA"). As PhRMA has previously stated,[5] under the Maryland APA, agency hearings implicating a statutory (or constitutional) right, duty, entitlement, or privilege are considered contested cases[6] and are subject to various procedural requirements, including rights to a hearing conducted by an agency head or Administrative Law Judge;[7] reasonable notice of the agency's action and the hearing;[8] trial-like protections for the hearing process;[9] and judicial review.[10] Further, the nature of the hearings will implicate the Maryland protections for "quasi-judicial" hearings, as they will involve consideration of the particular facts of the drug under consideration. Where a hearing concerns more "property-specific" facts than "general, 'legislative facts,'" Maryland courts have stated that the protections for quasi-judicial hearings apply.[11] The Draft Regulations contain none of the protections for quasi-judicial hearings and therefore conflict with the APA. Instead, the Draft Regulations only contemplate protections for what is required for "quasi-legislative" hearings.[12] These protections conflict with what is required for hearings implicating a statutory right, by, for example, allowing the Board Chair to delegate conducting the hearing to "a staff member designated by a chair"[13] and stating that the right of cross-examination and the rules of evidence do not apply to the hearings.[14] PhRMA requests that the Board revise the Draft Regulations to comply with what is required under the Maryland APA for quasi-judicial contested case hearings.

B. Lack of Clear Notice Requirements

In addition, the Draft Regulations do not provide a specific timeline for when the Board will give stakeholders the hearing notice contemplated under the draft. Rather, the Draft Regulations only state that "[t]he Board shall

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Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 2022).

[4] Md. Code Ann., Health-Gen. § 21-2C-03(e)(4), (5).

[5] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 7 (Aug. 26, 2024).

[6] Md. Code Ann., State Gov't, § 10-201(d)(i).

[7] *Id.* at § 10-205(a)(1).

[8] *Id.* at § 10-207(a).

[9] *Id*. at § 10-213.

[10] *Id.* § 10-222.

[11] "The greater a decisionmaker's reliance on general, 'legislative facts,' the more likely it is that an action is legislative in nature. Likewise, the greater a decision-maker's reliance on property-specific, 'adjudicative facts,' the more reasonable it is to term the action adjudicatory in nature." *Talbot Cnty. v. Miles Point Prop., LLC*, 415 Md. 372, 387, 2 A.3d 344, 353 (2010).

[12] Draft COMAR § 14.01.01.06(B)(2).

[13] *Id.* § 14.01.01.06(B)(2)(a)(ii).

[14] *Id.* § 14.01.01.06(B)(2)(d).

publish a notice of the hearing on the Board's website."[15] As PhRMA has previously recommended, we ask that the Board revise its Draft Regulations to provide clear timelines for publication of its agenda and materials for consideration ahead of the Board's meetings, with specific standards for how far in advance of the meeting such publication will occur.[16] Further, notices for hearings should be posted no less than two weeks prior to a scheduled hearing and all materials should be posted to the website no less than one week prior to the hearing. Advance publication of the Board's agenda and materials gives stakeholders a more fair opportunity to review them and prepare adequate comment. Failure to provide such advance publication impedes the ability of stakeholders to provide relevant information for the Board's consideration, restricting the ability of members of the public to participate in the Board's deliberations, and limiting the value of the public comment process.

C. Recordings of Meetings

The Draft Regulations do not require that the Board record all public hearings, only providing for recordings of quasi-legislative hearings "[a]t the Board's discretion."[17] While PhRMA recognizes that the Board has publicly posted the recording of its last four Board meetings, PhRMA reiterates its request that the Board codify this practice in the Draft Regulations to clarify that it will post *all* of its past and future public meetings, and that such recordings be promptly posted (or linked) on the Board's website within 48 hours of each meeting.[18] This will provide a critical opportunity for stakeholders who are unable to attend the Board's meetings to be able to review information that informs the Board's decision-making.

D. Restrictions on Testimony

The Draft Regulations would allow the Board to subjectively limit stakeholder testimony by giving the Board Chair or staff designee the option to "limit repetitious testimony."[19] The Board should revise the Draft Regulations to remove this provision. The Board should not have the subjective discretion to decide that testimony is "repetitious" and should give all interested parties an opportunity to fully testify. Further, it is not clear how the Board would determine which testimony it considers "repetitious" without discriminating based on the viewpoint of the person who is seeking to testify.[20] The decisions made by the Board have significant implications for Maryland residents and it is crucial that all who desire to testify can do so without interference.

E. Technical Hearing Testimony

The Draft Regulations' provision on technical hearings only provides for "public notice" of technical hearings, but does not require the Board to provide transparency regarding how the Board intends to conduct its technical hearings.[21] PhRMA requests that, subject to protections for confidential, trade secret, and proprietary information, the Board provide the public with testimony provided at technical hearings upon receipt, as well as any technical data, methodologies, or similar materials provided to the Board. Manufacturers and other stakeholders should have the opportunity to review and comment on all of the non-confidential materials that inform the Board's

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[15] *Id.* § 14.01.01.06(B)(1)(a).
[16] *See* Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act at 1–2 (May 4, 2023).
[17] Draft COMAR § 14.01.01.06(E)(1).
[18] Letter from PhRMA to Board Regarding Selected Drug List at 2 (July 16, 2024).
[19] Draft COMAR § 14.01.01.06(C)(2)(b) ("The Chair or staff designee shall give all persons who register to speak an opportunity to do so but may limit repetitious testimony.").
[20] See, e.g., *Child Evangelism Fellowship of S.C. v. Anderson School Dist. Five*, 470 F.3d 1,062, 1,067 (4th Cir. 2006) ("It is axiomatic … that the government may not regulate speech based on its substantive content or the message it conveys.") (quoting *Rosenberger v. Rector & Visits of Univ. of Va.*, 515 U.S. 819, 828 (1995)).
[21] *Id.* § 14.01.01.06(D)(1)(b).

decision-making. The regulations should also make clear that, in addition to written testimony, written comments will be solicited from stakeholder and members of the public for any technical hearing.

II. Amendments to COMAR § 14.01.01.01 (Definitions)

PhRMA is concerned with the draft amendments to the Board's definitions and provides the following non-exhaustive list of issues for Board consideration. We ask that the Board further refine these definitions in the Draft Rule:

- **"Net Cost."** The Board's latest draft proposal would revise the definition of Net Cost to add consideration of the per-unit cost paid by "purchasers."[22] PhRMA continues to have concerns regarding how the Board will determine net costs as part of the cost review process. The Board has not detailed how it will validate net cost information, as PhRMA has previously requested.[23] Due to the multi-layered structure of the supply chain, manufacturers typically do not have access to net cost information and may be unable to validate such per unit costs. PhRMA emphasizes that various other sources of cost information may also be unreliable or only offer an incomplete portion of the full picture relevant to the Board's assessment. Use of erroneous data would impact the reliability of the Board's assessments and could ultimately result in erroneous evaluations regarding a drug's affordability.

- **"Purchaser."** PhRMA requests that the Board clarify the specific persons and entities that the Board is attempting to capture as part of the contemplated new definition of "purchaser".[24] As currently worded, the scope of the draft definition of "purchasers" could be broader than intended by the Board: for instance, family members who are responsible for paying a patient's deductibles or cost-sharing on the patient's behalf. PhRMA urges the Board to clarify the specific persons and entities it is intending to capture with this definition, and to specifically enumerate which supply chain entities – for example, wholesalers, hospitals, pharmacies, and physician offices, may or may not be included.

- **"Therapeutic Alternative**." The Board's Draft Regulations would revise the definition of therapeutic alternative to mean "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."[25] PhRMA reiterates its request that the Board set forth a detailed process to identify therapeutic alternatives to reduce the risk of certain therapies being identified as therapeutic alternatives that are not appropriate for all patients using the therapy.[26] Such process should include meaningful engagement with manufacturers on potential therapeutic alternatives and reference to clinical guidance and widely recognized scientific resources to identify therapeutic alternatives.[27] The Board should provide additional details on how it will identify therapeutic alternatives before moving forward with the cost review processes.

III. New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

PhRMA is deeply concerned that the Draft Regulations on policy reviews, final action, and UPLs fail to account for the significant complexities and challenges inherent in the UPL consideration and implementation process. PhRMA

[22] *Id.* § 14.01.01.01(B)(44).
[23] *See* Letter from PhRMA to Board Regarding Request For Information Draft Forms at 3 (July 12, 2024).
[24] Draft COMAR § 14.01.01.01(56).
[25] *Id.* § 14.01.01.01(62) (emphasis added to show revision).
[26] *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process at 11-12 (May 1, 2023).
[27] *See* Letter from PhRMA to Board Regarding Selected Drug List at 4 (July 16, 2024).

has repeatedly emphasized the need for clear, well-defined processes, as well as opportunities for stakeholder engagement, as part of the cost review and UPL-setting processes, and these elements remain unaddressed or insufficiently addressed in Draft Regulations. Further, as we have emphasized previously, clear and meaningful standards are necessary to prevent inconsistent decision-making in violation of the requirement that the Board treat similarly situated drugs in a similar manner, absent a reasoned basis for any departure.[28] The lack of clear and meaningful standards in the Draft Regulations would create the distinct possibility for inconsistent decision-making by the Board, raising serious concerns under the Maryland APA. PhRMA details these issues below and emphasizes that the Draft Regulations should be substantially revised before the Board moves forward with a formal proposed rule.

A. Lack of Clear Standards

PhRMA provides below a non-exhaustive list of examples of areas where the Draft Regulations lack adequately clear standards and should be revised to provide greater specificity.

- **"Affordability Challenge" Definition.** The Draft Regulations contemplate a circular definition of affordability challenge that would lead to inconsistent affordability determinations across drugs.[29] Specifically, the draft definition of "affordability challenge" states that it includes "*an affordability challenge* for the State health care system."[30] PhRMA asks that the Board revise its proposed definition by incorporating specific criteria and a concrete methodology that can be applied consistently across drugs as part of the cost review and UPL determination processes. Without such specificity, PhRMA is concerned about the distinct possibility of unexplained inconsistencies across the Board's decision-making for various drugs, leading to arbitrary and capricious decision-making.[31]

- **Opportunities for Stakeholder Comment.** At several places in the Draft Regulations, the Board either does not state whether it will provide for public comment, nor (where a comment period is contemplated) does it specify the length of time that will be provided for public comment.[32] The lack of consistent opportunities for stakeholder comments is concerning given the importance of the Board's deliberations and decisions, which carry significant clinical, economic, and policy ramifications. Likewise, where a comment period is provided, the Board should specify in the Draft Regulations the length of time provided for comments and provide an adequate period for stakeholders to provide meaningful feedback. This period should accounts for the fact that stakeholders will need to evaluate voluminous information to sufficiently respond to pending decisions before the Board. Stakeholders should be given no less than 60 days to provide comments.

  Accordingly, the Board should specify that it will provide opportunities for comment on each distinct step in the Board's decision-making processes, including the Board's preliminary determination that use of the

[28] *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). *See also* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024).

[29] "For the purpose of this Regulation, 'affordability challenge' refers to either (a) high out-of-pocket costs for patients or (b) *an affordability challenge* for the State health care system." Draft COMAR § 14.01.05.01(C) (emphasis added).

[30] *Id.* (emphasis added).

[31] *See*, *supra*, note 27.

[32] *See*, *e.g.*, Draft COMAR § 14.01.05.03(A) (not providing a comment period for the Preliminary Determination) and *Id.* § 14.01.05.06(A)(3)(A) (not specifying the comment period length when the Board Staff recommends a UPL).

prescription drug product has led or will lead to an affordability challenge.[33] Where the Draft Regulations contemplate a comment period, the Board should also specify a minimum period of comment that gives stakeholders adequate time to review and respond. The Board should revise the Draft Regulations to provide a specific and adequate time period for comment regarding (1) the recommendation by Board Staff of whether to impose a UPL,[34] (2) the proposed UPL value,[35] (3) the amendment of recommendations and UPL value,[36] and (4) the materials posted ahead of Board meetings, including the agenda and any supporting documents.[37] PhRMA also emphasizes that the specific timeline for comment should be adequate to allow for stakeholders to provide meaningful feedback. We request that the Board provide sufficient time for public comment, as well as clear timelines and steps for the Board to incorporate and address feedback in a manner that is clear and transparent.

- **Hearings.** The Draft Regulations would give the Board discretion regarding whether to hold both informational and technical hearings as part of the various processes it contemplates, including as part of the information gathering process,[38] setting of UPL value,[39] and UPL reconsiderations.[40] PhRMA requests that the Board revise the Draft Regulations to provide that the Board "must" hold both an informational and technical hearing at each of these steps and seek public comment to require that the Board appropriately obtain feedback from technical experts and other key stakeholders.

- **Minimal Utilization.** The Draft Regulations would prohibit the Board from setting a UPL on a particular drug if "[u]tilization of the prescription drug product by Eligible Governmental Entities is minimal."[41] PhRMA requests that the Board clarify in the Draft Regulations what constitutes "minimal" utilization, so that a clear and consistent standard can be applied across all prescription drugs.

- **Adverse Outcomes.** The Draft Regulations' criteria for setting a UPL state that the Board shall "[s]et an upper payment limit in a way to minimize *adverse outcomes* and minimize the risk of unintended consequences."[42] To require that the Board's evaluation is consistent across the similarly situated drugs it considers, PhRMA urges the Board to adopt a definition of "adverse outcomes" and objective metrics for evaluating whether adverse outcomes may have occurred.

- **Data Sources Transparency.** The Draft Regulations include "Board Staff Research and Analysis" as part of the information gathering process conducted when performing policy reviews or considering options to address affordability challenges.[43] PhRMA is concerned that the Board has set forth no meaningful standards about what may be entailed by such staff research and analysis. The absence of specific standards and methodologies governing that process could lead to inconsistent consideration of data between drugs, use of unreliable data sources, or the improper generalization of data that are not specific to the drug under consideration. It also raises serious APA concerns, given the APA's requirement that all agency decision-making must be based on "factors which [the legislature] ... intended it to consider," and

[33] *Id.* § 14.01.05.03(A).
[34] *Id.* § 14.01.05.06(A)(3)(A).
[35] *Id.* § 14.01.05.06(D)(3)(C).
[36] *Id.* § 14.01.05.06(F)(3).
[37] *Id.* § 14.01.05.04(B)(4). The Board should also add specific comment periods where it institutes additional opportunities for public comment.
[38] *Id.* § 14.01.05.04(1), (3).
[39] *Id.* § 14.01.05.06(E).
[40] *Id.* § 14.01.05.09(1)(B).
[41] *Id.* § 14.01.05.02(C)(1).
[42] *Id.* § 14.01.05.02(B)(3) (emphasis added).
[43] Draft COMAR § 14.01.05.04(D)(4).

grounded in statutorily relevant criteria and considerations.[44] Accordingly, the Board should revise the Draft Regulations to specify the data sources that Board staff may utilize as part of their research and analysis, and require disclosure to the manufacturer of the drug in question as well as public disclosure of the non-confidential reports and data sources relied upon by the Board and its staff, so that such information can be validated by stakeholders.

Consistent with our prior comment letters, PhRMA also requests that the Board provide manufacturers with additional mechanisms for engagement regarding the data the Board intends to use.[45] The processes contemplated in the Draft Regulations require compilation of voluminous data from diverse sources, and there is an inherent risk that some of the data may be inaccurate, incomplete, or misleading. PhRMA therefore requests that the Board provide manufacturers an opportunity, subject to confidentiality protections, to review, evaluate, comment on, and meet with the Board about the data it is relying on before the Board renders any final decisions on based on that data. We also specifically ask that the Board provide such an opportunity to manufacturers before the Board makes a preliminary determination that use of the prescription drug product has led or will lead to an affordability challenge.

- **Recommendation of UPL or Other Policy Action.** The Draft Regulations set forth two different lists of considerations that are to be applied depending on whether Board Staff are analyzing whether to (1) recommend policy action other than a UPL or (2) recommend a UPL.[46] PhRMA requests that the Board provide for a *uniform* process that applies regardless of whether Board staff are analyzing whether to recommend a policy action other than a UPL, or recommend a UPL. As currently constituted, the Draft Regulations appear to contemplate more analysis and scrutiny of non-UPL policy actions, than for UPLs. For example, the analysis of non-UPL policy actions would involve the analysis of the "[s]trengths and weaknesses of the policy," where there is no similar analysis of a potential UPL.[47] Under the Draft Regulations, the impact of a UPL on patient affordability and ability of the UPL to address patient out-of-pocket costs may also go unaddressed in the staff's analysis.[48] PhRMA requests that the Board adopt the same procedures for consideration of UPLs and non-UPL policy options, and that both processes expressly require materially identical consideration of potential policies' impacts on patient affordability and patient out-of-pocket costs.

  PhRMA also requests that the Board revise the Draft Regulations to specifically state that Board staff must consider patient out-of-pocket costs and how, if at all the proposed non-UPL or UPL policy action would impact these costs. As the Draft Regulations are currently worded, there is no mention of patient out-of-pocket costs as part of the policy recommendation process for either non-UPL or UPL recommendations.[49] Given that out-of-pocket costs are specifically identified as a focus area in the definition of "affordability challenge," PhRMA requests that they be given due consideration in the policy recommendation process.[50]

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[44] *Maryland Dep't of Env't v. Anacostia Riverkeeper*, 447 Md. 88, 121 (2016) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

[45] *See* Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024).

[46] Draft COMAR. § 14.01.05.05(B)(2) (in the case of considering a non-UPL policy action, analyzing "(a) [d]rivers of the affordability challenge; (b) [h]ow the policy addresses a driver; (c) Strengths and weaknesses of the policy; (d) [p]ossible implementation of the policy; and (e) [p]otential impacts of the policy"); *id.* § 14.01.05.05(C)(2) (in the case of considering a UPL as a policy action, analyzing "(a) [t]he drivers and market conditions causing the affordability challenge phenomena; (b) [a]bility of a UPL to address these issues; (c) [r]elevant regulatory criteria under Regulation .02 of this Chapter; and (d) [u]se of the drug by eligible governmental entities").

[47] *Id.* § 14.01.05.05(B)(2)(c).

[48] *See id.* § 14.01.05.05(C).

[49] *Id.* § 14.01.05.05.

[50] *Id.* § 14.01.05.01(C).

Additionally, the Draft Regulations lack clear standards for how the Board will go about determining its ultimate policy action of proceeding with a UPL or recommending a non-UPL action. There Draft Regulations provide no requirements for what metrics the Board will use to decide what policy to enact. For example, the Draft Regulations state that the Board's staff will provide recommendations on the "extent to which a UPL may address the drivers [of the affordability challenges]," but do not state how that "extent" will be measured for a specific policy.[51] PhRMA requests that the Board provide additional detail for how the impact of policy recommendations are to be evaluated and measured by the Board's staff.

Finally, when Board staff recommend a UPL as a policy option, the Draft Regulations state that the Board "*may analyze*" the four listed factors.[52] PhRMA requests that this draft language be changed to "must analyze." PhRMA believes that consideration of the enumerated factors should be mandatory, because the factors address considerations that are essential to providing a non-arbitrary justification for the Board's policy choice. For example, the factors include criteria like the "drivers" of an identified affordability challenge and the "extent to which" a policy solution actually addresses such drivers. The Board could not ignore such factors without completely "failing to consider an important aspect of the problem" it is seeking to address, which would be inherently arbitrary and capricious.[53] Further, consistent consideration of all of enumerated factors would guide the Board toward treating similarly situated drugs in a similar manner, as required under the APA.[54]

- **Selecting UPL Methodology.** PhRMA addresses the potential UPL methodologies identified in the Draft Regulations below, but we also emphasize our overarching concern with the lack of details for how the Board's staff will decide which methodology to recommend and how the Board will decide on a particular methodology. The Draft Regulations require Board staff to "recommend at least one methodology ... for use in developing a UPL for the subject prescription drug product,"[55] but contains no guidelines for how the Board staff will decide between the eight potential methodologies contemplated under the Draft Regulations or for requiring that the decision-making process for selecting a methodology will be conducted consistently across drugs that the Board considers. PhRMA requests that the Board revise its Draft Regulations to provide specific criteria for how Board staff will make their recommendations, as well as to guide the Board's discretion in rendering an ultimate determination as to the UPL methodology applied to a particular drug.

  Additionally, the Draft Regulations allow the Board to "identify another methodology" to calculate a UPL, other than the eight potential methodologies identified in the Draft Regulations.[56] Implementing a novel methodology on an ad hoc basis would lead to inconsistent and arbitrary decision-making. If the Board wants to develop an additional methodology, it must be adopted via notice and comment rulemaking, such that stakeholders are given a fair opportunity to comment on the specific contours of the new methodology before it is applied by the Board.[57]

[51] *Id.* § 14.01.05.05(C)(3)(a).
[52] *Id.* § 14.01.05.05(C)(2)(a)-(d) (emphasis added).
[53] *GenOn Mid-Atl., LLC v. Maryland Dep't of the Env't*, 248 Md. App. 253, 268, 241 A.3d 40, 49 (2020).
[54] *See*, *supra*, note 27.
[55] Draft COMAR § 14.01.05.06(A).
[56] *Id.* § 14.01.05.06(D)(1)(b).
[57] *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."), *available at* https://www.marylandattorneygeneral.gov/Opinions%20Documents/Volume75_1990.pdf.

- **Public Version of UPL.** The Draft Regulations direct the Board staff, as part of calculating a UPL, to "post a public version of [t]he UPL values developed through analysis" and the "[s]taff's recommendation for a proposed UPL amount with a description of the calculation and analyses and relevant underlying assumptions used in the analysis such as health outcome or threshold."[58] The Draft Regulations do not, however, specify what the "public version" would entails or indicate that confidential information will be safeguarded as against public disclosure. PhRMA requests additional clarity on what exactly Board Staff will publicly post and requests that the Board expressly clarify in the Draft Regulations that this process will be subject to statutorily required confidentiality protections.[59] We also ask that, prior to posting the "public version," that the Board provide an opportunity for manufacturers to review and, subject to protections for confidential, trade secret, and proprietary information, provide comments on these values to Board.

- **UPL Monitoring.** The Draft Regulations state that the Board "shall develop a program for monitoring the availability of any prescription drug product for which it sets a UPL" and that "[i]f monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL."[60] The PDAB Statute requires this monitoring to be an element of any UPL-setting process; further, it requires the Board to "reconsider or suspend" a UPL in the event of a shortage.[61] The Draft Regulations do not provide enough information to effectively evaluate this draft proposal, nor do they appear to be consistent with the requirements of the PDAB Statute. PhRMA requests that the Board revise the Draft Regulations to specify how it will monitor this information and how it will determine whether "shortage" exists for a UPL drug.

B. Proposed UPL Methodologies

In the Draft Regulations, the Board sets forth eight methodologies for Board staff to select from in recommending how a UPL will be calculated for a given drug.[62] Most of these methodologies were previously described as part of the Draft Action Plan released by the Board in August. PhRMA refers the Board to the comments in our letter on the Draft Action Plan for a comprehensive discussion of the draft methodologies and briefly reiterates the main points in the comments below.[63]

- **Cost Effectiveness Analysis.** As part of the cost effectiveness analysis methodology, the Board would use "a cost-effectiveness analysis to model how much additional health outcome is gained per dollar of additional spending when using a drug product compared to an alternative."[64] PhRMA reiterates its prior concerns about the use of certain types of cost effectiveness analyses, including the use of Quality Adjusted Life Years ("QALYs") or other metrics like "equal value of life year gained" ("evLYG") would raise especially significant equity concerns, as these metrics have been shown to discriminate against people with disabilities, the elderly, and communities of color by placing lower value on their lives and the

[58] Draft COMAR § 14.01.05.06(D)(3)(a)–(b).
[59] Md. Code Ann., Health-Gen. § 21-2C-10(a).
[60] Draft COMAR § 14.01.05.08(B)(1)–(2).
[61] Md. Code Ann., Health-Gen. § 21-2C-13(c)(2).
[62] *Id.* § 14.01.06(B).
[63] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 10–12 (Aug. 26, 2024).
[64] Draft COMAR § 14.01.06(B)(1)(a)(i).

preservation of life.[65] PhRMA urges the Board to revise the Draft Regulations to specify that it will not use these types of cost-effective analyses for this methodology.

- **Therapeutic Class Reference Upper Payment Limit.** PhRMA reiterates our discussion above and in our comment letter on the Draft Action Plan regarding the use of therapeutic alternatives. Reliance on a therapeutic alternative based methodology risks leading to inappropriate comparisons and pricing based on erroneous assumptions that, among other things, would not account for patient needs or provider expertise.[66]

- **Launch Price-Based Upper Payment Limit.** Under this methodology, the Board would set UPLs based on launch price information as adjusted using the Consumer Price Index for All Urban Consumers (CPI-U).[67] As we stated when we commented on this proposal in the Draft Action Plan, general inflation measures like CPI-U are not necessarily aligned with what is happening in health care, as medical inflation typically is higher than general inflation.[68] Further, PhRMA questions the reliability of this methodology more broadly. Rather than setting UPLs based on pricing decisions made years ago, the Board should focus on patient-centric drug pricing reforms that lower patient out-of-pocket costs for medicines today.

- **Same Molecule Reference Upper Payment Limit.** PhRMA reiterates its concern about setting a UPL by comparing a prescription drug product to other products based only on shared characteristics, for example other products with "the same active ingredient and [that are] approved for one or more of the same or similar indications as the product under review."[69] Such an approach is likely to result in broad and misleading comparisons that could result in products being improperly grouped together. Such improper groupings could lead to UPLs being proposed or established in an arbitrary and capricious manner and stifle innovation.

- **Domestic Reference Upper Payment Limit.** This methodology raises a number of questions and concerns. Among other things, PhRMA remains concerned about the potential use of the Medicare Maximum Fair Price ("MFP") to set UPLs. Use of the MFP as a reference price is premature, as the impact of the MFP on patient affordability and access under the Medicare Drug Price Negotiation Program is not yet known. Further, the focus of the MFP is on a different patient population (Medicare beneficiaries) than the patient population the Board is considering (Maryland residents), and expanding the MFP to such a disparate new population could create new and significant risks.[70] Additionally, where the Board considers domestic references based on "estimated net costs," PhRMA requests additional information on how the Board will determine the "estimated net cost of a prescription drug product to other purchasers and payors for the same prescription drug product within the United States or the net price received by the manufacturer."[71] As stated above, manufacturers may not have access to net cost information and should have the opportunity to validate these figures.

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[65] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 9–10 (Aug. 26, 2024).
[66] *See id.* at 10.
[67] Draft COMAR § 14.01.06(B)(3)(b).
[68] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 10 (Aug. 26, 2024).
[69] Draft COMAR § 14.01.06(B)(4)(b). *See id.* at 11.
[70] *See id.*
[71] Draft COMAR § 14.01.06(B)(5)(a).

- **International Reference Upper Payment Limit.** Consistent with our prior comments, PhRMA emphasizes that a comparison between U.S. prescription drug prices and international drug prices would be an improper apples-to-oranges comparison that would ignore the many downsides of prices in other (ex-US) countries.[72] The pricing in the countries cited in the Draft International Reference Price UPL Regulations are the result of government price setting that have been shown to significantly limit patient access to new drugs. In considering the appropriateness of this methodology, PhRMA urges the Board to consider the context of pricing decisions in other countries and the demonstrated negative effect that price setting in non-US countries has on patient access.

- **Budget Impact-Based Upper Payment Limits.** The Draft Regulations on the budget impact-based UPLs states that "[u]nder the budget impact-based UPL methodology, a UPL value may be set so that spending on the drug does not exceed a certain percentage *of a budget* as specified by the Board or have a disproportionate impact *on that budget*."[73] As described in our prior comments, PhRMA remains unable to provide detailed comment on the budget impact-based UPL as the Board has not specified the budget on which this methodology will be based.[74] PhRMA encourages the Board to provide more specific details about this potential methodology, including specifying the budget that would be used and detailing how the percentage threshold would be calculated.[75]

- **Blend of Multiple Methodologies.** The Draft Regulations incorporates an option to use a "blend of methodologies."[76] It is unclear what this methodology would entail, and PhRMA requests additional details, including the rationale for why the Board would choose to blend methodologies, the circumstances under which the Board would consider implementing such blending, and the criteria that the Board would apply in deciding whether to use a blend of multiple methodologies. PhRMA is concerned that blending methodologies may lead to inconsistent decision-making by the Boad and would inhibit the ability of stakeholders to comment on how the UPL value was determined.

C. Process Timelines

PhRMA remains deeply concerned about the sequencing of the processes detailed in the Draft Regulations, which PhRMA believes risk biasing the Board's decision-making in favor of a finding of an affordability challenge.[77] As contemplated under the Draft Regulations, the policy review process would commence if the Board makes a preliminary determination that use of the prescription drug product has led or will lead to an affordability challenge.[78] Beginning the policy review process to evaluate policies to address an affordability challenge *before* the Board has finalized its determination of whether an affordability challenge exists is administratively deficient and presupposes a finding of an affordability challenge. Additionally, beginning the policy review process and devoting significant resources to such review could bias the Board in favor of finalizing its preliminary determination, even if stakeholders provide compelling evidence to refute the Board's preliminary assessment.

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[72] *Id.* § 14.01.06(B)(6). *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 11–12 (Aug. 26, 2024).
[73] Draft COMAR § 14.01.06(B)(7)(a) (emphasis added).
[74] *Id.* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 12 (Aug. 26, 2024).
[75] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 12 (Aug. 26, 2024).
[76] Draft COMAR § 14.01.06(B)(8).
[77] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 7–9 (Aug. 26, 2024).
[78] "If the Board makes a preliminary determination that use of the prescription drug product has led or will lead to an affordability challenge, the Board shall commence the policy review process." Draft COMAR § 14.01.03(A).

Consistent with our comments on the Draft Action Plan, PhRMA urges the Board to revise the Draft Regulations to require that the Board begin the policy review process only *after* the affordability challenge determination has been finalized.[79]

D. Confidentiality Protections

PhRMA requests that the Board revise the Draft Regulations provide details on how it will integrate confidentiality protections in its UPL-setting processes. The Board's processes are subject to statutory confidentiality protections, but the Draft Regulations do not address how these protections will be afforded for confidential, trade secret, and proprietary information that stakeholders may provide to the Board.[80] As we have stated in our prior comment letters, PhRMA emphasizes the importance of the Board safeguarding all such sensitive information from unlawful disclosure consistent with the requirements of the PDAB Statute and other state and federal laws.[81] PhRMA requests that, consistent with its statutory obligation, the Board revise its Draft Regulations to provide protections for confidential information as part of these processes.

* * *

We thank you again for this opportunity to provide comments and feedback on the Board's Draft Regulations and for your consideration of our questions, concerns, and requests for clarifications. Although PhRMA has concerns with the Draft Regulations, 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 plan is further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[79] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 7–9 (Aug. 26, 2024).
[80] Md. Code Ann., Health-Gen. § 21-2C-10(a).
[81] *See* Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document at 13 (Aug. 26, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms at 4 (July 12, 2024); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process at 2 (May 1, 2023).

PhRMA
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By Electronic Submission

August 26, 2024
Maryland Prescription Drug Affordability Board
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RE: Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document

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 Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document ("Draft Action Plan") drafted by the Board as part of implementing its upper payment limit ("UPL") setting process.[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.

PhRMA recognizes the Board's ongoing work to implement and 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 through the processes outlined under the Draft Action Plan.[3] PhRMA addresses its specific questions and concerns regarding the Draft Action Plan below.

I. Lack of Clear and Meaningful Standards

PhRMA is concerned that the Draft Action Plan lacks sufficiently clear and meaningful definitions, standards, and processes. As detailed below, if the Draft Action Plan is finalized and approved, the Board

[1] *See* Draft Action Plan, *available at* https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.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. 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 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).

must establish clear and specific rules governing the new processes outlined in the draft plan prior to beginning its UPL-setting processes. Not only does the Maryland Administrative Procedure Act ("APA") require such standards be established through separate rulemaking, but such clear and specific standards are a necessary safeguard against arbitrary and inconsistent agency decision-making.[4]

The lack of clear and specific standards in the Draft Action Plan also impacts the ability of stakeholders to fully and meaningfully comment on the plan. This issue is further compounded by the limited time window provided for comment, as the two-week comment period provided for the Draft Action Plan does not allow for full or meaningful stakeholder participation. Key stakeholders in the UPL process may not be able to provide written feedback given the short timeline. Going forward, we request that the Board provide multiple opportunities for stakeholder feedback (written or verbal), sufficient time for public comment (at least 60 days), as well as timelines and steps for the Board to incorporate and address feedback are clear and transparent.

A. Need for Subsequent Rulemaking

PhRMA emphasizes that, if the Draft Action Plan is finalized and approved by the Legislative Policy Committee of the General Assembly (or the Governor and Attorney General),[5] the Maryland APA nonetheless requires that separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern the UPL processes outlined in the Draft Action Plan.[6] Specifically, under the Maryland APA, all policies "of general application ... must be accomplished by rulemaking."[7] This includes both legislative rules that establish substantive standards and requirements, as well as "organizational rules, procedural rules, interpretive rules and statements of policy."[8] Further, the Maryland APA establishes clear processes and timelines that govern the proposal and finalization of new rules.[9] The Board must, consistent with these requirements, adopt comprehensive regulations governing each procedural step, factor, and methodology described in the Draft Action Plan through notice and comment rulemaking.

Further, to be consistent with due process requirements, regulations implementing the UPL Action Plan must do more than repeat the broad descriptions in the Draft Action Plan or the PDAB Statute. Rather, the Board's rules must set forth the *specific definitions, processes, guidelines, and standards* that the Board proposes to apply to the UPL process. As courts have explained, agencies must establish clear and specific processes that give certainty "in advance to persons dealing with the agency" as to the rules of the road

[4] *See 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.").
[5] Md. Code Ann., Health-Gen. § 21-2C-13(d).
[6] *See* Md. Code Ann., State Gov't, tit. 10, substit. 1, pt. III. As the Board notes, formally setting UPLs also requires the adoption of "a regulation through notice and comment rulemaking." Draft Action Plan 2. PhRMA understands the Draft Action Plan to be acknowledging that the Board will undertake a separate rulemaking for setting UPLs, with a distinct notice and comment period that complies with the requirements of the Maryland APA. PhRMA urges the Board to set forth clear timelines for such subsequent rulemaking to help ensure the adequacy of the notice and comment process associated with it.
[7] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009).
[8] *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003) ("Under the Maryland APA, an agency's organizational rules, procedural rules, interpretive rules and statements of policy all must go through the same procedures as required for legislative rules").
[9] *See* Md. Code Ann., State Gov't, tit. 10, subtit. 1, pt. III. *See also Kor-Ko Ltd v. Md. Dep't of Env't*, 451 Md. 401, 409 (2017) (rules "of general application prescribing a new plan or policy [as opposed to] one which merely looks to or facilitates the administration, execution, or implementation of a law already in force and effect," require adoption through notice and comment rulemaking.)

that will be applied.[10] "Only then can there be some assurance against arbitrary and capricious conduct on the part of the agency."[11] Likewise, the agency's substantive rules should not merely reproduce statutory language.[12] Just as agencies cannot "simply [] parrot general statutory requirements or rest on broad conclusory statements" when rendering findings, the agency's substantive rules cannot either and should establish sufficiently clear and specific standards to guide the agency's discretion and limit arbitrary and inconsistent, ad hoc determinations.[13] PhRMA therefore urges the Board to establish clear and specific definitions, processes, and standards in its regulations governing the UPL-setting process that allow for consistent decision-making across the various areas identified in the Draft Action Plan. The Board should also clarify how it intends to specifically define and weigh the various criteria and factors it describes in the Draft Action Plan.

B. Examples of Lack of Clear Standards

PhRMA provides below a non-exhaustive list of examples of areas where greater clarity and specificity should be provided in the Board's plan and subsequent regulations:

- **Policy Review**. The Draft Action Plan outlines the Board's contemplated policy review process, but does not provide clear standards and processes for how it will be implemented in a manner that provides clear and consistent decision making. PhRMA is concerned that the Policy Review process would give unduly broad discretion to Board staff, including with respect to the categories of information gathered, the processes employed in gathering information, and the sources considered. Such broad discretion would likely result in inconsistent and ad hoc application of the process for evaluating different drugs, which could result in such reviews being conducted in a manner that is arbitrary and capricious.[14] Maryland courts have long held that agency action can be found to be arbitrary and capricious if similarly situated entities or products are treated differently without a rational basis for such differential treatment,[15] and have likewise struck down decisions that have unexplained inconsistencies with prior agency decisions.[16]

  PhRMA is also concerned that the Draft Action Plan does not require the Board to provide transparency to manufacturers or other stakeholders in how it conducts its policy reviews. Rather, the Draft Action Plan only states that the Board "may" convene informational hearings, "may" make public specific questions or topics in advance, and "may" provide the Board with summaries of the testimony and staff recommendations.[17]

[10] *Calvert Cnty. Plan. Comm'n v. Howlin Realty Mgmt., Inc.*, 364 Md. 301, 322 (2001).
[11] *Id.*
[12] *See, e.g.*, Hanah Metchis Volokh, *The Anti-Parroting Canon*, 6 NYU J.L. & Liberty 290, 293 (2011).
[13] *Rodriguez v. Prince George's Cnty.*, 79 Md. App. 537, 550, 558 A.2d 742, 748 (1989); *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").
[14] *Harvey*, 389 Md. at 302.
[15] *Maryland State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998). As further discussed below, while the Draft Action Plan refers to certain elements of the UPL-setting process as "quasi-legislative" in nature, these processes should also incorporate procedural protections consistent with the requirements for contested cases under the Maryland APA. *See* below, pp. 8-9.
[16] *See, e.g.*, *Christopher v. Montgomery Cnty. Dep't of Health & Human Servs.*, 381 Md. 188, 215 (2004).
[17] Draft Action Plan at 6-7.

In addition, the Board's Draft Action Plan permits the Board to make "other (non-UPL) policy recommendations" in lieu of or in addition to implementing a UPL.[18] The Draft Action Plan, however, does not *require* the Board to consider or review non-UPL policy recommendations. PhRMA recommends that the Board establish regulations governing consideration of UPL alternatives that include a requirement the Board provide a written, public explanation as to which alternative policies were considered and why the Board does or does not adopt alternative policy recommendations provided by the Board or the Board's staff.

- **Regulatory Price Impact**: PhRMA acknowledges the Board's efforts to limit the impact of UPLs on other regulatory drug pricing programs, but is concerned about the lack of detail as to how the Board intends to operationalize the prohibition on setting a UPL amount that "impacts statutory or regulatory amounts, such as Medicaid Best Price."[19] PhRMA requests that the Board provide greater detail as to how the Board envisions this limitation being implemented as well as the scope of regulatory prices that the Board considers impacted by this approach. As the Board knows, statutory and regulatory amounts are not static, may not be publicly available, and can be impacted by criteria established under other laws. For example, Medicaid Best Price is calculated quarterly.[20] Thus, while a particular UPL may not impact Best Price at the time it is put in place, that may change as Best Price fluctuates over time. We encourage the Board to further detail this requirement and allow for stakeholder comment on this concept.

- **Statutory Requirements for Establishing UPL**: The Draft Action Plan is silent on several statutory requirements for setting UPLs and monitoring UPLs that are put into place.[21] The Board should ensure it addresses *all* statutory requirements for setting UPLs, including the Board's plan for monitoring a UPL after it is set.[22]

- **Out-of-Pocket Costs**: The Draft Action Plan's criteria for setting UPLs contemplates that the Board "shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug."[23] As PhRMA has emphasized in prior comments, any consideration of high out-of-pocket costs should account for the full range of factors driving such costs.[24] This includes 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.[25] These factors are outside of the control of manufacturers and can be significant contributors to patients' out-of-pocket costs, and should be given appropriate consideration, as they directly bear on issues of patient affordability, but are the result of the decisions of independent third parties, namely health insurance carriers and PBMs

[18] *Id.* at 12.
[19] *See id.* at 3.
[20] *See generally* 42 C.F.R. § 447.505.
[21] As an example, the Draft Action Plan does not address that "[the] process for setting upper payment limits [submitted to the legislature] shall" require the Board to "[m]onitor the availability of any prescription drug product for which it sets an upper payment limit" and "[i]f there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit." Md. Code Ann., Health-Gen. § 21-2C-13(c)(2). The PDAB Statute specifically requires the Board to provide a "plan of action for implementing" the UPL-setting process to which the monitoring requirement would apply. *See id.* 21-2C-13(a).
[22] *See id.* 21-2C-13(c).
[23] Draft Action Plan at 3.
[24] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 3-4 (May 1, 2023).
[25] *See id.*

PhRMA is especially concerned that simply comparing net cost and out-of-pocket costs for particular drugs would be misleading. It would not account for the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of health plans and PBMs. Consistent with our prior comments, PhRMA also reiterates its request that the Board clarify how it will determine that the information it receives provides adequate detail about the formulary and benefit design that is applicable to the specific prescription drug product (e.g., complex tiering mechanisms and utilization management applicable to the drug).[26] The Board should also clarify that out-of-pocket costs will appropriately account for the full range of factors driving such out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment[27] and copay maximizer programs[28]) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance carriers that are not shared directly with patients at the point of sale. Failing to do so could result in misleading cost calculations that are arbitrary and capricious, and not reflective of the actual costs to Maryland patients. For additional context, the Board should also consider the impact of PBMs requiring the use of PBM-owned specialty pharmacies and retail pharmacies has on patient out-of-pocket costs.

- **Board Technical Hearing**: The Draft Action Plan states that the Board "may" convene a hearing to receive technical input and testimony as part of the process of establishing a UPL amount, and states that the Board will adopt regulations governing these quasi-legislative hearings.[29] Given the complexity of UPL-setting analyses and calculations, it would be inappropriate for the Board to set a UPL without first holding a technical hearing to consider stakeholder testimony on the proposed UPL amount and other UPL considerations. In order to provide for sufficient stakeholder input as well as transparency into its UPL processes, the Board should adopt provisions in its Draft Action Plan and subsequent implementing regulations that make these technical hearings mandatory. Requiring a technical hearing will also give stakeholders an opportunity to provide the Board with additional information and technical feedback on how a proposed UPL will affect Maryland patients' access to drugs before a UPL is put in place.

- **Cost of Drug Administration**: The Draft Action Plan states that "[t]he criteria for setting a UPL shall include consideration of the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs."[30] PhRMA seeks clarification on how the Board intends to implement this criterion, specifically on how this factor would be considered in setting any UPL amounts, as these costs reflect the charging practices of independent third parties in the pharmaceutical supply chain. As noted in our prior comment letters, health insurance carriers and PBMs determine the out-of-pocket costs for patients, so considering their impact on the cost of administration of the drug is imperative.[31]

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[26] *See* Letter from PhRMA to Board Regarding Request For Information Draft Forms 3-4 (July 12, 2024).

[27] Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.

[28] Copay maximizer programs are insurance benefit designs that generally restructure patients' cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits.

[29] Draft Action Plan at 12. *See* further discussion of the UPL-setting process as a quasi-legislative process below, pp. 8-9.

[30] *Id.* at 2.

[31] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 3-4 (May 1, 2023).

- **Regulatory Criteria for Determining the Appropriateness of a UPL**: The Draft Action Plan refers to "certain regulatory criteria" that will be considered to determine if the UPL is an appropriate policy to address an affordability challenge.[32] However, the Draft Action Plan does not include the specific regulatory criteria that the Board will assess or utilize. PhRMA recommends that the Board clarify the specific criteria that will be assessed and utilized to determine if the UPL is the appropriate solution, and solicit comment on these proposed criteria consistent with the requirements of the Maryland APA.

- **Blend of Multiple Methodologies**: The Board's plan suggests that "Board staff may provide recommendations on the potential values for the UPL" under a "[b]lend of [m]ultiple [m]ethodologies."[33] PhRMA requests that the Board clarify its intent for how and when its staff may blend multiple methodologies, as this may lead to inconsistent recommendations.

- **Factors for Additional Context for Setting a UPL**: The Draft Action Plan would allow Board staff to recommend methodologies and factors to establish a UPL to the Board.[34] PhRMA asks that the Board revise the Draft Action Plan to provide specific factors that will be considered when establishing a UPL instead of authorizing subsequent staff recommendations. The Board should subsequently propose regulations specifying how these additional factors will be considered and weighed. Considering the importance of the information included as additional factors in the Draft Action Plan, it is critical that the Board have clear criteria and guidelines for the operationalization, use, and weighting of these factors.

- **UPL Calculation Data**: The Draft Action Plan permits the Board staff to use "[a]ny information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information" as a factor for providing "additional context for setting a UPL."[35] PhRMA is concerned that this additional factor is unduly broad and vague. We reiterate that the Board's UPL decision-making must be based on "factors which [the legislature] ... intended it to consider," and grounded in statutorily relevant criteria and considerations.[36] It would therefore be inappropriate for the Board to operate in a manner that permits it to adopt additional extra-statutory considerations, or modify the ways it uses and considers data, on an ad hoc, case-by-case basis. PhRMA recommends the Board create guardrails around the information that can be considered and utilized to establish a UPL. Additionally, PhRMA recommends that the Board make publicly available the calculations or other data operations used in its processes. Except where protected against disclosure due to confidential or proprietary information, such data should be available to the public to allow stakeholders to understand the basis of the Board's determinations and provide feedback where the Board's data operations appear inappropriate or based on erroneous data assumptions.

- **Market Basket**. The Board's Draft Action Plan refers to staff calculation of a "market basket of UPL values."[37] However, the Draft Action Plan does not include a clear definition of "market basket,"

[32] *Id.* at 3.
[33] Draft Action Plan at 10.
[34] *Id.* at 8.
[35] *Id.* at 11.
[36] *Maryland Dep't of Env't v. Anacostia Riverkeeper*, 447 Md. 88, 121 (2016) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).
[37] Draft Action Plan at 11.

or meaningful details on what will be included in a "market basket." PhRMA recommends that the Board clarify the definition of "market basket" and how it will inform the determination of UPL amounts. Absent more clarity on how the Board defines and intends to use the "market basket," stakeholders cannot meaningfully comment on the Board's proposal.

- **Quasi-Legislative Hearings:** The Draft Action Plan includes three references to "quasi-legislative hearings" related to expert testimony, informational, and Board technical hearings.[38] As the Board itself appears to acknowledge,[39] it must establish through regulations detailed processes governing all such quasi-legislative hearings.

  Further, under the Maryland APA, agency hearings implicating a statutory (or constitutional) right, duty, entitlement, or privilege are considered contested cases[40] and are subject to various procedural requirements, including rights to a hearing conducted by an agency head or Administrative Law Judge;[41] reasonable notice of the agency's action and the hearing;[42] trial-like protections for the hearing process;[43] and judicial review.[44] PhRMA urges the Board to adopt procedural protections for stakeholders impacted by a UPL-setting process that are consistent with the requirements of the Maryland APA.

  The Draft Action Plan and subsequent regulations should also provide additional details as to how these hearings will be operationalized. For example, provisions governing the Board's use of expert testimony should include details as to how decisions are made on whether expert testimony is needed and how individuals are chosen to deliver such testimony. The Draft Action Plan and subsequent regulations should also address how conflict of interest disclosure and recusal procedures will be implemented to require that any testimony given as part of these hearings is unbiased. The definition of conflict of interest that the Board adopts should be consistent with the statutory definition of conflict of interest for members of the Board.[45] The conflict of interest procedures should also cover relationships with all entities in the prescription drug supply chain (e.g., payers, distributors, PBMs, and associated trade associations).

II. Sequence of Cost Reviews, Policy Reviews, and UPL Calculation

PhRMA is concerned that the Draft Action Plan proposes to begin addressing affordability challenges and calculating UPL amounts *before* a final decision is made that the drug at issue has or will lead to affordability challenges. Such sequencing is not consistent with the process described in the PDAB Statute.

The PDAB Statute contemplates the cost review and UPL determinations be separate and distinct processes conducted in sequence. First, Section 21-2C-09 of the PDAB Statute says that a cost review must

[38] Draft Action Plan at 7, 12.
[39] For example, the Draft Action Plan says that the information gathering process described in the Draft Action Plan includes the potential convening of "expert testimony hearings," and states that the Board will adopt regulations to govern these hearings.
[40] Md. Code Ann., State Gov't, tit. 10, subtit. 2, pt. II.
[41] *Id.* at pt. V.
[42] *Id.* at pt. VII-VIII.
[43] *Id.* at pt. XIII.
[44] *Id.* at pt. XXII. We note that the PDAB Statute at § 21-2C-15 also explicitly provides for appeal rights, including judicial review, for any "person aggrieved by an upper payment limit set by the Board."
[45] "Any conflict of interest, including whether the individual has an association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision." Md. Code Ann., Health-Gen. § 21-2C-03(a)(5).

be conducted to determine if certain products are associated with affordability challenges.[46] Then, in Section 21-2C-14 of the PDAB Statute, the legislature states that UPLs may only be set "for prescription drug products that have led or will lead to an affordability challenge,"[47] as determined through cost reviews. By codifying cost reviews and UPL-setting as separate and distinct procedural steps under separate sections of the law, the legislature demonstrated its intent that only drugs for which a cost review process has been completed, and which have been determined to be associated with affordability challenges, may be eligible for a UPL.[48] In other words, the law intends for the two processes to be distinct and sequential, not parallel and combined, as the Draft Action Plan contemplates.

Further, PhRMA is concerned that the Board's combined sequencing may bias the Board's final decision as to affordability in a manner that would be arbitrary and capricious. Until the cost review is finalized, the Board has not made a determination that a drug raises affordability challenges, much less determined that UPLs are the appropriate recourse. Prematurely beginning the UPL determination process risks prejudicing the outcome of the cost review process. It also signals that the Board may presume that a UPL is the only appropriate solution if an affordability challenge is identified, and limits the opportunities for stakeholders to provide information for the Board's consideration. The legislature specifically recognized that UPLs are not the only policy option that can be appropriate to address affordability challenges,[49] and the Board should not appear to prejudge the appropriateness of a UPL before making a final determination that affordability challenges exist with respect to a given drug.

PhRMA is especially concerned about this risk because the wording of the Draft Action Plan appears to presume that the Board will ultimately decide a given drug is unaffordable and that a UPL should be implemented.[50] While the Draft Action Plan states that there will be a public comment period after the preliminary affordability determination is made, and that the preliminary affordability decision is "non-final and subject to revision and modification," the sequencing of processes contemplated under the Draft Action Plan creates the appearance of bias or (at worst) even suggests that the final affordability determination would be *a fait accompli*.[51]

For these reasons, PhRMA asks that the Board revise its Draft Action Plan to make clear that the cost review will be finalized *before* the Board initiates its policy review, which could lead to the initiation of the UPL-setting process. Additionally, PhRMA requests that the Board clarify that it will separately consider other policy options before determining whether to set a UPL. As the Draft Action Plan itself correctly acknowledges, a UPL may not be the appropriate policy solution for every affordability challenge.[52] As such, it is unclear why the Board would devote resources to the technical development of a potential UPL before the Board has even determined whether a UPL is the proper tool to address affordability concerns.

In addition, PhRMA is concerned about the language in the Draft Action Plan that would allow the adoption of the final cost review report, policy recommendations, and proposed UPL amounts at the same Board meeting. Stakeholders should have the opportunity to separately comment on and participate in each of

[46] *Id.* § 21-2C-09.
[47] *Id.* § 21-2C-14.
[48] *Compare id.* § 21-2C-09 *with* § 21-2C-14.
[49] *See id.* § 21-2C-07(2).
[50] "The *preliminary determination* that the drug has led or will lead to affordability challenges is a predicate for the Board to start the policy review process to study and assess what, if any, policy tools are *best suited to redress the identified affordability challenges, including whether a UPL is an appropriate policy solution*." Draft Action Plan at 6 (emphasis added).
[51] *Id.* at 4.
[52] *See, e.g.*, Draft Action Plan 3, 6.

these processes independent of one another. Joining these processes together would not allow for meaningful stakeholder participation, and would undermine the fidelity of the Board's processes by encouraging rushed decision-making that does not incorporate the full range of stakeholder feedback, information, and perspectives that bear on each of these distinct decision points.

In sum, the Board should revise the Draft Action Plan to require that the Board, in sequence: finalize the cost review; then (if a drug is determined to raise affordability challenges) consider multiple policy options before determining whether a setting a UPL is appropriate; and only then (if the Board decides to institute a UPL and provides justification of why another solution was not appropriate) conduct its methodology to determine the UPL amount. These decisions should be made in separate meetings, with separate opportunities for comment on each distinct procedural step.[53]

III. Cost Effectiveness Analysis

PhRMA remains concerned with the proposed consideration of cost effectiveness analyses ("CEA") as part of the factors used in determining UPL amounts. While the Draft Action Plan does not specify the types of CEA the Board contemplates relying on, PhRMA reiterates its prior concerns about the use of certain types of cost effectiveness analyses.[54] As explained in more detail in our prior comments, use of Quality Adjusted Life Years ("QALYs") or other metrics like "equal value of life year gained" ("evLYG") would raise especially significant equity concerns, as these metrics have been shown to discriminate against people with disabilities, the elderly, and communities of color by placing lower value on their lives and the preservation of life.[55]

More broadly, policies, including UPLs, that are based on cost-effectiveness determinations can prevent patients from accessing the treatments that best meet their personal needs and preferences, and override physician judgment in making individualized treatment decisions. By combining average study results into a single numeric judgment of value, CEAs overlook the significant differences in the needs of individual patients, many of whom do not fit the average. As one patient group has noted, "It is widely acknowledged that a summary measure such as [those used in CEAs] will never be able to adequately capture the vast differences in individual preferences and values."[56] It has also been widely noted by stakeholders that CEA discriminates against individuals with disabilities and chronic illnesses by undervaluing their lives.[57] Experts in the field of CEA recently acknowledged that "the problem of whether CEA unjustly discriminates against the disabled remains a deep and unresolved difficulty for the use of CEA."[58]

Cost-effectiveness analysis may also contribute to perpetuating longstanding inequities in health care and health outcomes. The assumptions used in CEA disadvantage marginalized populations through use of

[53] As above, PhRMA also urges the Board to establish regulations specifically defining the processes that will govern each of these decisions.

[54] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 12–13 (May 1, 2023).

[55] National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability 3 (Nov. 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf; Broder, M., Ortendahl, J., *Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research* (2021), *available at* https://blogsite.healtheconomics.com/2021/08/is-cost-effectiveness-analysis-racist/.

[56] Partnership to Improve Patient Care. "Measuring Value in Medicine: Uses and Misuses of QALYs." 2017. Available at: http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_white_paper_-_measuring_value_in_medicine_-_uses_and_misuses_of_the_qaly.pdf.

[57] *Id.*

[58] P Neumann, G Sanders, et al. Cost Effectiveness in Health and Medicine, Second Edition. 2017.

QALYs, health care costs, as well as assumptions around lost productivity. [59] These assumptions undermine health interventions that may improve health for marginalized populations and favor interventions that will further the status quo of inequity. PhRMA urges the PDAB to reconsider its use of CEA as "systematic underestimation of cost-effectiveness for marginalized populations can contribute to further entrenchment of health inequities."

IV. Upper Payment Limit Calculation Options

The Draft Action Plan lists several potential methods to calculate UPLs. PhRMA addresses its feedback and concern for these potential options below based on the descriptions contained in the Draft Action Plan.[60]

Therapeutic Class Reference UPL: PhRMA is concerned that the Board has not fully explained how it will identify whether drugs fall into the same "therapeutic class." As drafted, the contemplated "Therapeutic Class Reference" UPL method appears to define a therapeutic class by reference to "competitor products that have similar chemical structures and act through similar pathways to treat the same conditions."[61] Similar to concerns raised by PhRMA about the Board's unduly broad definition of therapeutic alternative, this approach could lead to certain therapies being identified as within the same therapeutic class that are not appropriate for all patients using the therapies and should not be compared for the purposes of determining a UPL.[62] PhRMA urges the Board to refine this calculation method to establish a more specific and nuanced definition of therapeutic class that avoids misleading comparisons between meaningfully distinct products. Specifically, the Board should establish through regulation a consistent process that each drug must be evaluated under for purposes of this UPL pathway to determine whether it can be appropriately considered to be in the same "therapeutic class." The process should include:

- Meaningful engagement with the manufacturer and local medical professionals on potential therapeutic class members;
- Review of clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource; and
- Review of other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic class members.

- **Launch Price-Based UPL:** The Draft Action Plan contemplates setting a UPL tied to "launch price adjusted for inflation."[63] PhRMA asks the Board to provide additional details regarding this methodology, including how it intends to adjust launch prices for inflation and specifically which inflation measures it intends to use for this purpose. Inflation measures are not necessarily aligned with what is happening in health care, as medical inflation typically is higher than general inflation. Rather than setting UPLs based on pricing decisions made years ago, the Board should focus on patient-centric drug pricing reforms that lower patient out-of-pocket costs for medicines today.

[59] The Risk Of Perpetuating Health Disparities Through Cost-Effectiveness Analyses, Sanjay Basu, Atheendar S. Venkataramani, and Dean Schillinger, Health Affairs 2024 43:8, 1165-1171.
[60] The Board has not provided detailed information about the different UPL options or provided specific definitions, standards, or processes that will govern the calculation of UPLs under each option. As explained in more detail above, if the Draft Action Plan is finalized and approved, more specific processes and standards must be outlined through a separate rulemaking consistent with the requirements of the Maryland APA.
[61] Board, Draft Action Plan at 9.
[62] *See* Md. Code Regs. 14.01.01.01(B)(61) (defining "[t]herapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug").
[63] Draft Action Plan at 9-10.

- **Same Molecule Reference:** The Draft Action Plan contemplates that the Board may set "a UPL based on the prices of other products with the same active ingredients with the same indications for use."[64] The products considered under this methodology range from generics, biosimilars, brand name drugs approved under 505(b)(2), products approved under an original New Drug Application ("NDA"), or authorized generics.[65] PhRMA is concerned that reliance on the same active ingredient to identify drugs subject to the same UPL is likely to result in broad and misleading comparisons that could result in products being improperly grouped together. Such improper groupings could lead to UPLs being proposed or established in an arbitrary and capricious manner and stifle innovation. Post-approval research and development often leads to new drugs and biological products with the same active ingredient providing meaningful treatment advances for patients.[66] For example, long-acting injectable formulations of antipsychotics have significantly improved patient adherence and treatment outcomes.[67]

- **Domestic Reference UPL:** In setting the domestic reference UPL, the Draft Action Plan would allow the Board to consider the Medicare Maximum Fair Price.[68] The Maximum Fair Prices recently released by the Centers for Medicare and Medicare Services do not go into effect until 2026, and as such, PhRMA reiterates that consideration of any part of the Medicare Drug Price Negotiation Program is premature.[69] The Program is in its infancy, and it will take years to understand its effect on patient affordability and access. Additionally, the Negotiation Program considers prices for the Medicare population, which is completely different in key respects (including demographics, age, and diversity) from the Maryland patient population that may be considered for UPLs.[70] PhRMA encourages the Board to limit its focus to data relevant to the patient populations targeted under the PDAB Statute for UPLs, as well as to approaches that have been proven to not restrict patient access to drugs and for which there is a demonstrated understanding of impact on patient affordability.

- **International Reference UPL:** PhRMA continues to be concerned with the Board's contemplated use of international pricing data.[71] The Draft Action Plan states that the Board may set a UPL at

[64] Draft Action Plan at 10.
[65] *Id.*
[66] *See Anacostia Riverkeeper*, 447 Md. at 121 (agency decisions cannot be based on consideration of impermissible factors, run counter to the evidence before the agency, fail to consider important aspects of the issue being addressed, or be based on an implausible view of the evidence).
[67] Long-acting injectable (LAI) anti-psychotics improved medication adherence and patient outcomes leading to lower odds of hospitalization and fewer emergency room visits. Among Medicaid beneficiaries with schizophrenia, improved adherence due to LAI antipsychotics generated annual net savings of up to $3.3 billion, or $1,580 per patient per year, driven by lower hospitalizations, outpatient care, and criminal justice system involvement. Predmore Z.S., Mattke S., Horvitz-Lennon M. (April 1, 2015). Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States. Psychiatric Services. Available at: https://pubmed.ncbi.nlm.nih.gov/25555222/; Bera R., Offord S., Zubek D., et al. (February 2014). Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy. Journal of Clinical Psychopharmacology. Available at: https://pubmed.ncbi.nlm.nih.gov/24135840/.
[68] Draft Action Plan at 10.
[69] Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process 5-6 (Apr. 24, 2024).
[70] *See* Md. Code Ann., Health-Gen. § 21-2C-14(a).
[71] Draft Action Plan at 10. PhRMA has provided detailed discussion of its concerns regarding international pricing information in its prior comments to the Board. *See, e.g.*, Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); 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).

the lowest price among a sub-set of countries. This risks relying on this data without proper context. Among other things, the prices in these countries are the result of government price setting that has been shown to significantly limit patient access to new drugs. While 85 percent of all new medicines launched between 2012 and 2021 are reimbursed in the Medicare and Medicaid programs, only 61 percent of new medicines are reimbursed in Germany, 48 percent in the United Kingdom, 43 percent in France, and 21 percent in Canada.[72]

Further, the Draft Action Plan lacks significant details on the source of the international pricing data. To the extent the Board intends to rely on public or proprietary sources for such data, it should be aware that there are numerous issues with international pricing data, including that international pricing data is generally collected at different levels in each country. For example, in some countries data is collected at the hospital level, while in other countries it is collected only at a higher level such as the wholesale level. International pricing data aggregator(s) often then use proprietary methods to estimate whole-country sales volumes and prices. As such, the data represents proprietary and non-transparent ***estimates*** of drug sales and volume and is not reflective of actual transaction or volume information. These proprietary estimates would not be appropriate to use as a method to establish an upper payment limit. Secondly, many sources of international pricing data are licensed on a confidential basis to subscribers for their internal use, and it is unclear how the Board's proposal would plan to use the data to establish an upper payment limit with such restrictions.

Finally, international reference pricing raises the same issues with cost-effectiveness analysis discussed above. Several of the countries that Maryland proposes to reference rely on rigid CEA standards to determine coverage and payment, resulting in patients in those countries facing significant restrictions on access to treatments. Patients who have diseases such as cancer, diabetes and rare diseases, have faced access restrictions based on cost-effectiveness determinations. Recent analysis noted that these types of CEAs and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of patients.[73]

- **Budget Impact-Based UPL:** The Draft Action Plan gives minimal detail or guidance on how a budget impact-based UPL would operate, so it is difficult to provide meaningful comment on this option. PhRMA requests that the Board more fully develop this option prior to finalizing the Draft Action Plan and address, among other things, how the Board will determine whether a product impacts the budget; what constitutes a "disproportionate" impact on the budget; and how the Board will determine what percentage or threshold of the budget that a particular drug cannot exceed. The Draft Action Plan's brief description of this option also raises a host of other significant questions (e.g., who determines the threshold or percentage of the budget a drug cannot exceed; whether the threshold will vary by drug category or therapeutic area), but lacks sufficient detail to fully explain how the Board intends to implement this option, which inhibits the ability of PhRMA to provide more detailed comments.

[72] *See* PhRMA analysis of IQVIA MIDAS and country regulatory data, October 2022 (Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021). A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where the medicine is reimbursed by the public plan. A medicine is considered publicly reimbursed in the United Kingdom if the medicine is recommended by England's National Institute for Health and Care Excellence (NICE) for funding by England's National Health Services (NHS).

[73] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.

V. Confidentiality

The Draft Action Plan does not address the protections that will be afforded for confidential, trade secret, and proprietary information that stakeholders may be asked to provide as part of the new processes outlined in the plan. Consistent with our prior comment letters, PhRMA emphasizes the importance of the Board safeguarding this information from unlawful disclosure as part of its processes, as described and required by the PDAB statute and regulations consistent with state and federal law.[74] PhRMA requests that the Board provide greater detail as to how the Board and its staff members will identify and protect manufacturers' confidential, trade secret, and proprietary information. PhRMA is particularly concerned because the Board's current regulations governing confidentiality elide many critical details, and it is not clear that they will adequately protect the sensitive information provided as part of the new processes outlined in the Draft Action Plan.[75]

* * *

We thank you again for this opportunity to provide comments and feedback on the Board's Draft Action Plan and for your consideration of our questions, concerns, and requests for clarifications. Although PhRMA has concerns with the Draft Action Plan, 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 plan is further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[74] *See* Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 2 (May 1, 2023).
[75] *See* Md. Code Regs. 14.01.01.04.

February 10, 2025

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VIA email: christina.shaklee1@maryland.gov

Supply Chain Coalition Comments
COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Dear Chair Mitchell, Members of the Board, and Staff:

On behalf of the undersigned organizations, representing diverse stakeholders in the healthcare supply chain who ensure access to critical medications in Maryland, we would like to express our collective feedback and concerns regarding the Maryland PDAB's final proposed regulations COMAR 14.01.05 Policy Review, Final Action, Upper Payment Limits.

While the Healthcare Distribution Alliance (HDA), National Association of Chain Drug Stores (NACDS), and the National Community Pharmacy Association (NCPA) support the state's goal in addressing the affordability of prescription drugs, our organizations have individually expressed concerns within previous comment letters regarding the significant impact these Upper Payment Limit (UPL) proposals could have on the availability and accessibility of identified prescription drugs. These proposals also fail to reflect how drugs are bought and sold in the United States and fail to ensure fair and adequate reimbursement levels for pharmacies.

State-level UPLs do not align with how prescription drugs are bought and paid for in the United States. If the Maryland PDAB chooses to establish a cap on the price for prescription drugs, the price at which these drugs are bought and sold for nationally will remain unchanged. Because many Maryland providers purchase drugs in out-of-state transactions that would not be subject to the limitations of a state-level UPL, our in-state distributors and providers will purchase drugs at a national price and then be subject to in-state price caps. Providers will then have to choose whether to purchase drugs for more than they can be reimbursed or to stop purchasing some drugs altogether. This, in turn, could drive some patients to out-of-state retail and mail order pharmacies, further deepening the impact on our healthcare infrastructure. Additionally, even if the UPL allowed for a nominal dispensing fee, it would be unlikely that the pharmacy or healthcare provider would be able to recoup costs for dispensing the drug; this could leave many local pharmacies, already under immense and continued financial pressure, unable to stock these medications for Marylanders.

A provider such as a pharmacy, hospital, or clinic that dispenses or administers drugs to patients must first purchase the physical product and float the cost until after they dispense the product and receive subsequent reimbursement from the insurer. The complex drug purchasing and distribution system -- from manufacturer to wholesaler, then to the pharmacy or healthcare provider, and, finally, to the patient --- involves numerous data and financial transactions between each entity. In addition, there are parallel and simultaneous permissions and transactions with insurance companies, pharmacy benefit managers, and government payers. At each step along the way, transactions are subject to private negotiations and involve complicated discount and rebate arrangements that often take place at the national level and are not state specific, thus leaving pharmacies, hospitals, and clinics often reimbursed below their costs to acquire and subsequently dispense drugs.

For example, as you know and have recognized, pharmacy reimbursement should be comprised of two

parts: 1) the product cost; and 2) a professional dispensing fee across payer markets (e.g., Medicaid, Medicare, commercial) to help ensure reasonable reimbursement at a level that allows pharmacies to serve patients. The dispensing fee is typically calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient counseling, and other cost elements necessary to provide quality patient care.[1] Maryland Medicaid performed a cost of dispensing (COD) study in 2020 that found it costs $13.72 pharmacies to Maryland's pharmacies to dispense most medications[2]. In the Maryland PDAB plan of action, staff are directed to consider the "cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs" when setting a UPL. In order to maintain pharmacy availability and access for Marylanders, it is imperative that the PDAB account for both the product cost of the drug and a professional dispensing fee.

We appreciate that the Board has limited the definition of Upper Payment Limit to the ingredient cost for a prescription drug product after all price concessions, discounts, and rebates. However, COMAR14.01.05 is silent on a professional dispensing fee. The Board noted during their September 10, 2024, meeting that the UPL methodology should not impact stakeholders in the supply chain, including pharmacies[3]. In an effort to ensure pharmacies are not reimbursed below their costs to acquire and dispense the drug, we respectfully request that the PDAB provide written guidance that specifically states that the UPL will include a professional dispensing fee. Additionally, stakeholders need to know how the PDAB plans to control Pharmacy Benefit Manager clawbacks and fees that significantly reduce pharmacy reimbursements but are not publicly transparent. Finally, we do not believe the rules contain adequate provisions for monitoring drug shortages to protect Marylanders – Shortages that could be exacerbated by the UPLs.

In conclusion, we oppose the rules as written and encourage the PDAB to strongly consider other methods to reduce drug costs outside of setting a UPL. However, if the PDAB moves forward with seeking to establish a UPL, we urge the Board to incorporate language in the Rule that guarantees that pharmacies will be made whole for their costs to acquire and dispense drugs subject to a UPL. Without this, UPLs could inadvertently threaten Marylanders' access to the medications they need.

Sincerely,

Healthcare Distribution Alliance (HDA)

National Association of Chain Drug Stores (NACDS)

National Community Pharmacists Association (NCPA)

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[1] CMS defines the professional dispensing fee at 42 CFR § 447.502, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.502

[2] Maryland Department of Health Survey of the Average Cost of Dispensing a Prescription to Fee-For-Service Maryland Medicaid Participants, https://health.maryland.gov/mmcp/pap/docs/MD_2018_COD_Report_final_report%20Jan%202020.pdf

[3] PDAB Board Meeting, September 10th, https://www.youtube.com/watch?v=Q18vKKSd3_s at 57 minutes and 1 second.