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).

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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.

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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

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.

* * * *

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

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.

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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).

November 8, 2024

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

Via Electronic Correspondence

RE: COMAR 14.01.01.05 (Policy Review, Final Action, and Upper Payment Limits) and COMAR 14.01.01.06 (Hearing Procedures)

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 provide written comments on the Maryland Prescription Drug Affordability Board's draft regulations, COMAR 14.01.01.05 (Policy Review, Final Action, and Upper Payment Limits) and COMAR 14.01.01.06 (Hearing Procedures). In reviewing the regulations, we urge the Board to:

1. **Adopt a patient-center approach in the policy review process;**
2. **Consider a copay accumulator ban in the policy review process;**
3. **Avoid the use of discriminatory cost-effectiveness measures in setting UPLs;**
4. **Adopt a UPL monitoring approach where the Board assumes responsibility, not patients; and**
5. **Remove the authority for the chair or staff designee to limit repetitious testimony from speakers**

I. Adopt a Patient-Centered Approach in the Policy Review Process

The policy review process requires the Board to identify the drivers and market conditions causing affordability challenges and determine which policies may effectively address them. While we appreciate the Board's consideration of alternative, non-UPL policies and its focus on ensuring solutions address affordability drivers, we continue to urge the Board to ensure it adopts a patient-centered approach in its review to ensure that any recommended policies are fully evaluated for their impact on patient affordability of and access to medications.

As the primary beneficiaries of medications, patients offer invaluable insights into challenges that contribute to affordability issues. Their firsthand experiences with disease management, access barriers, treatment preferences, and other factors directly related to medication use provide crucial perspective for understanding the drivers and solutions to high drug costs.[1] By engaging patients, providers, and caregivers, the Board can gain valuable insights essential for conducting a patient-centered policy review that allows for a comprehensive understanding of the most effective policies to address challenges related to prescription drug affordability.

[1] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.

Additionally, in reviewing UPLs as a potential policy recommendation, we strongly urge the Board to proactively identify and assess the access barriers that UPLs could potentially create for patients. While UPL policies intend to reduce costs, they may unintentionally limit patient access to the medications they need, particularly if the UPL results in restrictions on coverage, treatment options, or availability.[2] These unintended consequences must be carefully considered to ensure that any policy aimed at reducing costs does not come at the expense of patient access to essential care.

Furthermore, if the Board decides to recommend the implementation of a UPL, it is crucial that the Board not only assess potential cost savings for payors but also consider how these savings will be passed down to patients. For UPL policies to improve affordability, the benefits must be directed toward reducing out-of-pocket costs for patients. This requires a clear mechanism to ensure that cost savings translate into tangible savings for those who rely on these medications and are directly impacted by high prescription drug costs. Only by fully integrating the patient perspective into its policy analysis can the Board develop policies that truly address the unaffordability of prescription drug while safeguarding access to necessary treatments.

II. Consider Copay Accumulator Ban in the Policy Review Process

In considering policy options, we urge the Board to recommend that Maryland implement a copay accumulator ban. Many patients rely on financial assistance from pharmaceutical manufacturers or other third parties to afford their copays and meet their health plan's cost-sharing obligations for prescription medications. Typically, this third financial assistance is applied toward the patient's deductible and out-of-pocket maximum—unless the health plan has implemented a copay accumulator program.

Under these programs, any third-party assistance is excluded from counting toward the deductible or out-of-pocket maximum, causing patients to face unexpected, additional costs to meet their yearly cost-sharing obligation. This abrupt financial burden can cause significant anxiety and stress and may even force patients to switch medications or discontinue treatment due to unaffordable out-of-pocket expenses once their financial assistance runs out. Consequently, patients may experience worsening of their condition, relapse, and other adverse health outcomes, increasing their overall healthcare needs and costs.

Furthermore, if a patient changes health plans mid-year after exhausting copay assistance under their previous plan, they are unable to access similar assistance through their new plan for the rest of the year. While copay accumulator programs may yield short-term savings for insurers, they ultimately result in higher costs and harm patient well-being over time. Importantly, while health plans may allege that copay accumulators are necessary to mitigate costs, a study by The AIDS Institute found that there was no statistically significant difference in premiums between states that have implemented copay accumulator bans and states that permit the use of copay accumulators. As such, this assistance should be passed directly to consumers to lower their health care costs.

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

To mitigate these issues, 20 states, as well as the District of Columbia and Puerto Rico, have enacted bipartisan laws requiring health plans and pharmacy benefit managers to apply copay assistance toward individuals' deductibles and annual cost-sharing requirements. Therefore, as Maryland evaluates policy options, we strongly encourage the Board to consider a copay accumulator ban as an effective solution to improve affordability and supporting patients across the state.

III. Avoid the Use of Discriminatory Cost-effectiveness Measures in Setting UPLs

Under the proposed rules, UPLs may be set "using 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." Cost-effectiveness frameworks can restrict patient access to care by assigning a fixed value to medications, failing to account for individual circumstances or needs. For example, quality-adjusted life years (QALYs) are a cost-effective measurement that combines a person's quality of life with their life expectancy to assess the value of health care interventions.[3]

The use of certain cost-effective measures, like QALYs, to assess the value of any prescription drug treatment raises significant ethical issues because they assign a monetary value to human life based solely on diagnosis, implying that individuals with chronic or rare conditions are less valuable than those with more common conditions. This approach effectively discriminates against individuals with chronic or rare diseases in favor of those with more common or less costly conditions. We strongly urge that the Board abstain from using discriminatory cost-effectiveness frameworks, such as QALYs, when setting UPLs, as they could unintentionally exacerbate disparities and limit access to care for vulnerable patient populations.

IV. 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 UPL is effectively monitored. If the Board does move forward with imposing a UPL, we believe it is essential for the responsibility of 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.

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

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[3] Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS, 1-8 (Jan. 15, 2024).

Lastly, 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 an informal hearing. It is essential to respect the time and commitment of individuals 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.

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 can overlook critical insights that may 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 stronger stakeholder engagement and ensure that policy decisions are based on a comprehensive understanding of the issues.

VI. Conclusion

In conclusion, we urge the Board to revise its rules to prioritize patients by: (1) prioritizing a patient-centered approach throughout the policy review process; (2) considering a copay accumulator ban in the policy review process; (3) refraining from using discriminatory cost-effectiveness measures when setting UPLs; (4) adopting a UPL monitoring approach that places the responsibility on the Board rather than patients; and (5) removing the authority for the chair or staff designee to limit repetitious testimony.

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

November 11, 2024

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

Re: Upper Payment Limit Action Plan

Dear Members of the PDAB:

On behalf of the Alliance for Patient Access (AfPA), I am writing to provide comment on the recent approval of the Upper Payment Limit Action Plan. Health care costs, including prescription drug costs, are a concern for health care payers, providers and patients. As you are considering next steps, we want to ensure that policies do not negatively impact patient access to the treatments they need.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision making, promote personalized care and protect the clinician-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials.

Recent discussions surrounding the UPL Action Plan have raised questions regarding transparency in how this program will operate. AfPA is concerned that despite a finalized UPL Action Plan and approval from the General Assembly's Legislative Policy Committee there is a lack of clarity on how the UPL will be operationalized, particularly in regard to the backend rebate reconciliation.

In addition, a backend rebate reconciliation would expand the scope of the PDAB beyond its original purview. AfPA is concerned implementation of a backend rebate will negatively impact both physicians who administer treatments and pharmacists. Further, this policy could have a downstream effect that will limit patient access to certain therapies.

Finally, as mentioned during the LPC Meeting on 10/22, there is not a clear mechanism to allow for savings to be passed on to patients. AfPA believes that ensuring patient affordability is critical to access.

AfPA supports making treatments more affordable for patients. We encourage you to incorporate the perspective of patients and providers as these policies are being considered. We recognize the complexity of issues that come with this policy and thank you for the opportunity to comment. If you have any questions or would like further information, please contact Casey McPherson at cmcpherson@allianceforpatientaccess.org.

Sincerely,

Josie Cooper
Executive Director
Alliance for Patient Access

ARTHRITIS AND RHEUMATISM ASSOCIATES, P.C.

November 7, 2024

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

RE: New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Dear PDAB Members,

Arthritis and Rheumatism Associates, P.C. appreciates the opportunity to comment on the Draft regulations regarding "policy review, final action, upper payment limits."

ARA PC is the largest practice group of rheumatologists in the Mid-Atlantic area. We are dedicated to the diagnosis and treatment of people with disorders of the joints, muscles, tendons, and other connective tissue. Our practice integrates excellent medical care with comprehensive services. We maintain a full-service laboratory, x-ray facilities, a physical therapy division, seven centers for the diagnosis and treatment of osteoporosis and seven infusion centers. We take care of over 30,000 patients a year at 5 of our centers located in Maryland.

We wish to highlight and expand the comments presented in an October 23rd letter authored by the Coalition of State Rheumatology Organizations (CSRO) and directed to the Legislative Policy Committee of the Maryland General Assembly:

> "We appreciate that the Board has recognized the importance of considering "the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs" when establishing an upper payment limit (UPL). This is critically important to healthcare providers who directly administer medications to their patients, as the UPL places these providers at significant risk if they are not able to cover acquisition costs for these medications.
>
> As currently drafted, the UPL caps provider reimbursement for a prescription drug consistent with the rate determined by the Board. It does not, however, require that providers acquire the medication at a rate sufficiently below the UPL to account for acquisition costs to the provider. This is highly problematic for healthcare providers who administer medications directly to patients in outpatient settings.

If UPL measures don't account for the acquisition costs to outpatient practices, then the consequences for the patient can be dire. Access to appropriate medication is critical for the short term and long term health of our patients.

Specifically, we offer the following language:

Amendment #1: Page 1 - .01 Definitions, B(6) after "rebates." INSERT

"THE UPL SHALL BE INCLUSIVE OF THE COSTS BORNE BY PROVIDERS FOR THE ACQUISITION, AND STORAGE OF THESE DRUGS."

(6) "Upper payment limit" or "UPL" means the amount established by the Board that an eligible governmental entity may not exceed when purchasing or paying for the ingredient cost for a prescription drug product after all price concessions, discounts, and rebates. **THE UPL SHALL BE INCLUSIVE OF THE COSTS BORNE BY PROVIDERS FOR THE ACQUISITION AND STORAGE OF THESE DRUGS.**

Healthcare practices, such as ours, that directly administer medications on an outpatient basis, pre-purchase drugs and bill a payer for reimbursement once the medication is administered to a patient. Margins for practices engaged in this patient care modality are thin. Administering drugs in these settings are often more cost-effective settings for the payer and safer for immunocompromised patients when compared to hospital-based infusion centers. Moreover, reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance.

Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices and their patients at risk. To be clear, not every practice has the capacity to provide these services, but patients who are treated in practices that do find it to be an invaluable link to better health and efficient care. Should those practices be forced underwater, patients will be cut off and left without the treatment they rely on. Stopgap measures that would be required to transition patients into a new care setting or other patient modality would have long lasting impacts to their short- and long-term care.

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

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

Financial cost is an ever-present factor in modern day health care delivery, but as physicians we must weigh the physical and emotional costs our patients endure every single day. We appreciate the opportunity to provide this input to the Board. If we can be of further assistance, please call Dr Angus Worthing at 301-942-7600.

November 8, 2024

MD Prescription Drug Affordability Board
Department of Insurance
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the MD Prescription Drug Affordability Board:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and over 1 million Maryland residents living with doctor-diagnosed arthritis, we appreciate the opportunity to submit comments to the Maryland Prescription Drug Affordability Board (PDAB) on "Title 14, Independent Agencies; Subtitle .01 Prescription Drug Affordability Board; Chapter .05 Policy Review, Final Action, Upper Payment Limits."

We appreciate the inclusion of several provisions in this document, including:

- Ensuring that the PDAB "shall (2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product; (3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences." This reflects a thoughtful approach to the complexities of the drug supply chain in addition to comments the patient community has made around the need to consider unintended consequences.
- Taking into account factors like Medicaid Best Price and Maximum Fair Price in UPL calculations. The interconnected pricing algorithms across payers are critical to the consideration of any UPL-setting methodology and ensuring that a UPL cannot go below these thresholds recognizes some of those operational challenges.
- Ensuring public comment opportunities throughout the processes of affordability reviews, policy determinations, and UPL-setting.
- Ensuring the Board can reconsider and repeal a UPL for any reason. This is important for maintaining the ability to act quickly in the event problems arise.

We urge the Board to continue working with patients and patient groups through the Information Gathering process and recommend this be explicitly stated in the policy review document. For example, "Public Informational Hearings" and/or "Board Staff Research and Analysis" could include explicit mention of collecting structured qualitative patient data in the form of surveys, patient journey maps, and focus groups. Formal mechanisms exist for each of these data collection methods and are invaluable for informing the broader context around key variables like therapeutic alternatives and utilization management.

Under "Methodologies, Cost Effectiveness Analysis" within the "Process for Setting a UPL," we urge the Board to include a requirement to use multi-criteria decision analysis or to perform cost-effective analyses using multiple methodologies. Each cost-effectiveness analysis methodology has distinct limitations, and relying on or allowing for one single methodology could lead to a result that is not truly representative or accurate.

Also within "Methodologies," we caution against using International Reference Pricing as a potential methodology, as each country has its own unique pricing and reimbursement system and the factors internationally may not be germane or transferrable domestically.

If a UPL is established, we urge the Board to include in the criteria for monitoring a UPL not just the availability of the drug, but specific access challenges or restrictions that may arise across the drug class. A concern many patient groups have raised with both state PDABs and CMS IRA implementation is the possibility of increased utilization management or formulary restrictions as payers adjust to new policies regarding drug pricing.

The Arthritis Foundation has been building a list of questions for consideration as PDABs deliberate on how an Upper Payment Limit (UPL) would be designed and operationalized, as the implementation of a UPL could have wide-ranging implications. Questions that may be relevant for the purposes of this policy review document include:

1. How would the PDAB ensure any methodology is patient-centered and accurately incorporates patient experiences and preferences?
2. How would the PDAB specifically engage with the patient community in the design of the UPL?
3. Once implemented, how might the UPL affect other drugs in the class and the designation of preferred and non-preferred drugs?
4. How can the PDAB ensure that a UPL doesn't negatively impact access to the drug in which the UPL was established and the ability of that drug to remain on formularies?
5. Has the PDAB considered unintended consequences such as increased utilization management and the potential for patients to be inappropriately switched to a less effective drug?
6. What is the potential impact on other pricing structures, including 340B calculations?
7. What is the potential impact to providers and pharmacists in terms of reimbursement for stocking and/or administering the drug?

Finally, we would caution that establishing a UPL will not necessarily make a drug more affordable for a patient. Insurance design and employer benefit packages are such that many patients are on high deductible health plans (often with no other option) and

specialty drugs are often placed on specialty tiers with co-insurance. For Exchange plans, it is not uncommon for co-insurance to reach 40-50%. Even if you set a UPL that is half the current list price, a 40% co-insurance will still make that drug unaffordable to most patients without some form of cost-sharing assistance.

We encourage the PDAB to continue working directly with patient groups like ours throughout the process of affordability reviews and designing appropriate, patient-centered UPL methodologies. We believe being part of the process is critically important and are eager to coordinate a process with the PDAB and staff to ensure the patient community is included in this work moving forward. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation

AstraZeneca
1800 Concord Pike
Wilmington, DE 19850
astrazeneca.com

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: Draft Upper Payment Limit Regulations

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca is writing this letter to provide comments to the Prescription Drug Affordability Board (PDAB) related to the draft Upper Payment Limit (UPL) Regulations it has published. As was mentioned by PDAB staff at the November 4, 2024 Prescription Drug Affordability Stakeholder Council (PDASC) meeting, we look forward to the opportunity to provide further comments on these regulations as they move through the administrative process. The work done to date by the PDAB is not comprehensive enough to satisfy the needs of the patient, the state or to those business entities that will be impacted by a UPL. Any consideration of the draft Regulations is premature, and more work should be completed to provide appropriate specificity to everyone involved. The PDAB also needs to develop a deeper understanding of unintended consequences to the patient and pharmaceutical supply chain.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal and Metabolism, and Respiratory. Based in Cambridge, UK, AstraZeneca is committed to developing innovative, lifesaving medicines and making these medicines accessible to patients.

Throughout the PDAB's existence, the manufacturing industry has continually voiced concerns with the design and construction of the PDAB, and with the Board's focus on UPLs as the main tool to control costs for state-funded programs. While the statute allows for any number of policy recommendations to offset a finding of "unaffordability," the Board's laser-like focus on UPLs misconstrues the mechanics and economics of the drug supply chain, and the impact that other players in the supply chain have on the cost of drugs. Instead of considering flaws across the system, the Board has instead focused on a very narrow and inappropriate set of supposed cost drivers (namely, WAC price) that demonstrates a fundamental lack of understanding about how rebates and other cost calculations are used by actors within the supply chain to manipulate the cost to the patient. According to a report by

BRG[1], in reality, less than 50 percent of the total cost of a drug ends up with the manufacturer. This significant portion of spend on brand medications goes to other non-manufacturer entities like insurers, Pharmacy Benefit Managers (PBMs), hospitals, pharmacies, governments, and others. The disproportionate focus on list price fails to recognize that a patient's final out-of-pocket costs for a medicine are primarily a function of their health benefit plan design. The actual amount paid by the patient is typically set by the PBM or plan sponsor, entities that receive significant rebates from the manufacturer but do not fully pass those rebates on when it charges patients for out-of-pocket costs. This dynamic is also true for commercial plans that provide services to State employees and Maryland Medicaid Managed Care plans.

AstraZeneca has concerns over the lack of detail currently included in the draft Regulations. The lack of specificity creates uncertainty for patients and other stakeholders who will be directly and significantly impacted by a potential UPL. This approach could be burdensome for Maryland patients who could face higher prices or restricted access to a drug that has a UPL placed on it. **The PDAB should be more thorough in its approach and provide further details in the draft Regulations to address the concerns that have been raised.**

Specifically, the PDAB should include clear processes, methodologies, and contextual information that will be used in the UPL process. This clarity will allow manufacturers to engage in a meaningful way to ensure all aspects of the supply chain, as well as the effect on the patient, are considered in the setting of a UPL. This will allow everyone involved to provide the most applicable and helpful insights and information for the PDAB to consider. Specifically, the draft Regulations should include details on the following criteria that are currently not included:

- Clearly define the criteria for what it means for a drug to have, or lead to, "affordability challenges".
- Establish what criteria needs to be met to establish that a UPL is in the best interest of the state.
- Establish clear criteria to use in order to determine if it is appropriate to apply a UPL for a drug subject to a cost review.
- Set out a clearly defined process on how a UPL is set with appropriate timelines.
- Establish what other policy recommendations should be considered before a UPL is applied with an explanation of why those policies would not adequately address affordability concerns.

[1] https://www.thinkbrg.com/news/more-than-half-brand-medicine-spending-goes-to-supply-chain-middlemen-other-stakeholders/

- Determine how the Board will determine the effect of a UPL on Medicaid Best Price and other statutory and regulatory calculations, with a clear explanation of how the Board will avoid impact to those calculations.
- Define what "minimal utilization" by Eligible Governmental Entities means that would result in a UPL not being appropriate.
- Establish the Board's methodology on how they plan to limit or minimize adverse outcomes and the risk of unintended consequences in the UPL setting process on an individual drug.
- Clearly state how a UPL will be implemented within the supply chain considering current statutory and legal limitations.
- Provide specificity on the type of methodology the PDAB intends to implement. Currently, the draft Regulations list several options or a mix of multiple methodologies. The purpose of these draft Regulations should be to provide this level of thinking and detail.

Each of these issues is particularly important to understand because of the potential harm to each patient who is on or will be prescribed a drug subjected to a UPL. The unintended impacts of a UPL on the supply chain, the patient, and to the state should be understood prior to the approval of the draft UPL Regulations by the Board.

Please let us know if you have any questions or require further information.

Sincerely,

Geoffrey A Gallo
Head of Corporate & State Government Affairs

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA Electronic Delivery

November 8, 2024

Mr. Van Mitchell, Chair

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

Re: Maryland Prescription Drug Affordability Board Draft Proposed Regulations: Definitions, Hearing Procedures, and Policy Review, Final Action, Upper Payment Limits

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s Draft Proposed Regulations: COMAR 14.01.01.01- Definitions, COMAR 14.01.01.06- Hearing Procedures, 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.

General Comments

As BIO has stated in previous comments, BIO remains concerned that the proposed UPL process allows for the subjective and arbitrary gathering and utilizing of information that may not be relevant or appropriate to consider. It is critical that the Board follow a documented repeatable process that will be applied consistently across each drug to ensure equity and fairness. This should include establishing a clear and consistent definition of affordability that clearly includes the planned weighting or prioritization of factors and methodologies, the exact criteria that will be met or considered, and an ordered list of steps to be taken to ensure the process is transparent, repeatable and applied equitably. It is critical that the Board provide details around information on the planned sources for information, the exact definition of metrics (i.e., net price), the documented process/best practices to be followed, and the weighting or hierarchy of information that will be considered during UPL setting. All the methods and factors should be presented in a way that is transparent and repeatable to aid in the efficient collection/provision of information.

In addition, we continue to urge the Board to provide stakeholders and interested parties with sufficient time to provide adequate feedback. As it stands, a two-week comment period

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is insufficient for stakeholders to provide thoughtful and constructive feedback. Periods for public comment on drafts must allow for sufficient time for stakeholders to review and provide a response, recognizing the limited resources for many groups, and to ensure that all stakeholders have their voices heard.

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

Definitions (COMAR 14.01.01.01)

BIO is concerned that the draft regulations frequently reference "net cost," "total patient out-of-pocket cost," and "utilization," as outlined in COMAR 14.01.01.01, to inform the Board's work on affordability challenges and to determine whether to set UPL. While the Board uses these terms as a basis for the UPL methodology and factors, the Board fails to consider that manufacturers do not have control over net cost, manufacturers do not have insight into patient OOP cost and utilization, and the ability for a manufacturer to validate this information is very limited. Instead, the true drivers that impact patient OOP cost are determined by the patient's health plan design. Pharmaceutical benefit managers (PBMs) and plan sponsors have continued to shift more cost-sharing responsibility to patients, causing patients to struggle to afford and adhere to their medications. The proliferation of accumulator and maximizer programs prevent manufacturer cost-sharing assistance from accruing toward patient deductibles and annual OOP maximums. In addition, savings provided by manufacturers in the form of rebates and discounts paid to pharmaceutical benefit managers (PBMs) and plan sponsors, are not used to lower patient out-of-pocket costs.

We continue to encourage the Board to consider other affordability solutions (e.g., accumulator adjustment program bans) as a more effective and meaningful way to help ensure patients are able to afford their medicines rather than additional regulation on biopharmaceutical manufacturers that would have little to no impact on OOP.

Definition of "net cost"

Net cost is defined as "the per-unit cost paid by payors and purchasers of a drug after accounting for all price concessions, discounts, and rebates." Within the regulations, the Board should clearly specify how net cost will be calculated and how that information will be collected. As the Board collects data to inform its analysis of net cost, it is critical that the Board provide transparency into its calculations and how it chooses to derive net cost. This information should be made available both upon request and before any hearings.

Definition of "purchaser"

Purchaser is defined as "*an entity that purchases prescription drug products that is not a payor or a patient."* From this definition, is unclear whether the Board is referring to distributors, (such as a full line wholesaler, specialty distributor, etc.), and/or pharmacy benefit providers (e.g. retail pharmacy), and/or medical benefit providers (e.g. a hospital, physician's office, etc.), or another entity/entities. BIO requests that the Board clarify this definition to avoid potential confusion.

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Policy Review, Final Action, Upper Payment Limits (COMAR 14.01.05)

Criteria for Setting an Upper Payment Limit (14.01.04.02)

.02B(3): The regulation states that when determining whether to set a UPL, the UPL will be set "in a way to minimize adverse outcomes and minimize the risk of unintended consequences." Given that the UPL will evidently create many adverse outcomes, both intended and unintended, we encourage the Board to specify the types of adverse outcomes and unintended consequences that the Board will consider in their criteria.

.02B(4): The regulation states that the Board "shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug." We urge the Board to clearly define what qualifies as a "high proportion."

.02(C): The regulation states that "the Board shall not set an UPL if utilization… by Eligible Governmental Entities is minimal; or (if) the prescription drug product is a generic and there are nine (9) or more marketed therapeutic equivalents for the product." BIO urges the board to define the threshold for what is considered "minimal" utilization. It is critical that this threshold is explicit, transparent, and applied consistently across drug reviews. Instead, BIO advises that the Board shall not set an UPL for *any* drug if a generic or biosimilar is available.

.02(D): The regulation states that "the Board shall not set an UPL at an amount that impacts statutory or regulatory amounts, such as Medicaid Best Price." BIO requests that the Board clarify how "impact" is defined, and whether this also includes average sales price (ASP).

Policy Review-Information Gathering (14.01.04.04)

04(D)(4)(a): The regulation states that "Board staff may provide the Board with policy research and analyses related to the drivers of the potential affordability and potential options." BIO requests that the Board provide more detail and transparency into the standard that will be used for policy research and analyses, including what sources will be used, how such sources and analyses be validated, and how the Board will consider the potential for bias.

Policy Review—Preliminary Policy Recommendations (14.01.04.05)

When recommending UPL or non-UPL policy options, we urge the Board to specifically consider patient out-of-pocket costs and how, if at all, the proposed policy will impact patients.

Policy Review—Process for Establishing a UPL (14.01.04.06)

A(3)(a): We encourage the Board to specify that they will post staff's recommendations on the Board's website *at least two weeks* in advance of the Board meeting to allow stakeholders the opportunity to meaningfully provide comment.

Methodologies (14.01.04.06B)

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As BIO has stated in previous comments, BIO is strongly concerned by the menu of UPL methodologies from which the Board can choose, which seems to authorize use of different methodologies for different drugs. Applying inconsistent criteria and considerations across the UPLs of different drugs is extremely problematic and increases the potential for arbitrary and capricious determinations. The complex methodologies also fail to address considerations and complexities of being able to validate prices and to actually operationalize UPLs, creating the potential for WAC comparison errors and other complications. It is essential that the Board applies its methodology or methodologies in a consistent, non-arbitrary manner across different drugs and therapeutic areas. Rather than focusing on arbitrary cost containment factors, the methodology or methodologies chosen must account for the true value of the drugs, including improved patient outcomes, reduced hospitalizations, increased productivity, and overall healthcare system savings.

Cost Effectiveness Analysis- BIO opposes the PDAB's proposed use of cost effectiveness analysis (CEA) due to its widely inappropriate and discriminatory nature. As BIO has stated in previous comments, cost-effectiveness analysis anchors to composite health metrics - such as the quality-adjusted life year (QALY) - that have been proven to have discriminatory properties. The Board has not clarified what methods will be used for CEA, and what sources or information will be used to gather net prices for drugs in other states or from other countries.

Therapeutic Class Reference Upper Payment Limit – BIO opposes the use of this methodology, which demonstrates a lack of perceived value between therapeutic options, a lack of consideration for the complexity of dosing, and a lack of understanding for pricing complexities in the attempt of making prices equal across competitor sets. As BIO has previously stated, the lowest net price is influenced by many factors and using it may actually result in Best Price implications for products under review if competitive net price is below the product under review. Given these complications, it is unlikely that states will be able to effectively operationalize this methodology.

Launch Price-Based UPL- BIO opposes the launch price-based methodology which penalizes manufacturers for market dynamics that are outside of their control. Launch price-based UPLs ignore the clinical and economic value of drugs and their market factors and instead only address a partial context of price changes, which is significantly misleading and provides an inaccurate interpretation of pricing data.

Same Molecule Reference Upper Payment Limit- BIO opposes any methodology that sets the UPL for a particular company/product based on the price of a separate product manufactured by another company. By comparing drugs by active ingredients, the Board leaves no incentive for therapeutic advancement and harms investments into new therapies, including for orphan and hard to treat diseases.

Domestic Reference Upper Payment Limit – Similar to the above, BIO opposes any methodology that sets the UPL for a particular company/product based on the price of a separate product manufactured by another company. It is evident that manufacturers do not have visibility to net costs for purchasers or payors. Further, the language used in the regulation," net price received by the manufacturer," is ambiguous and requires clarification.

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International Reference Upper Payment Limit – BIO opposes any methodology that relies on international reference pricing, which divorces a product's reimbursement from the value it provides in favor of prices set by foreign governments based on factors that are not applicable to the U.S. market. The regulation also remains unclear whether the International Reference UPL would be at WAC or a net price comparison. It is evident that any use of international reference prices as a basis for decision-making would be complex to evaluate and to validate, and would not account for possible variations in drug pricing due to differences in healthcare systems, market sizes and conditions, such as competition or negotiation practices, and pricing structures between countries

Budget Impact-Based Upper Payment Limits- BIO opposes the use of budget impact-based UPLs, which could unfairly penalize highly effective drugs that have high upfront costs but long-term positive patient outcomes. It is inappropriate to establish a UPL based on non-health related external factors, which would completely disregard the holistic value of the drug itself and the value of the drug to the overall healthcare system.

Blend of Multiple Methodologies– BIO opposes blending methodologies, which impermissibly allows for UPLs to be based on inconsistent considerations, disregards the express limitations of certain methodologies, and ultimately leads to arbitrary and capricious decisions. Rather than blending methodologies, it is important that the Board focus on a well-defined and systematically applied methodology that is based on economically and scientifically sound principles that can be applied across products equally.

UPL Values (14.01.04.06D)

.06D(3)(b) &(c): The regulations state that the Board will post a public version of "Staff'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." BIO requests that the Board clearly specify that the inputs/ calculations/ methods of the aforementioned analyses will also be made transparent in advance to address any deficiencies or biases. The regulations also state that the Board will post "A request for public written comment on the Board's website." BIO requests that the Board should allow at least 30 days for public comment on the UPL values. The Board should also clearly specify that additional public comment opportunities will be provided each time staff modifies or amends the UPL values.

Establishing and Monitoring a UPL (*14.01.04.08)*

08(A)(2): The regulation states that "The Board and staff shall 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." BIO remains concerned that this could lead to alternative ways for implementing the UPL, which would create challenges for enforcement and validation, unpredictable and unreliable outcomes, and a lack of accountability.

.08(A)(3): The regulation states that "The final net ingredient cost paid by the eligible governmental entities shall not exceed the UPL amount established by the Board." This language does not clearly define "net ingredient cost," which may lead to confusion as to

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whether the net ingredient cost is different from the drug product itself. BIO requests that the Board clearly define "net ingredient cost" and specify how this would be calculated.

08B(1): BIO requests that the regulation should specify the mechanisms that the Board will use to monitor the availability of any prescription drug product for which it sets a UPL.

08(B)(2): BIO requests that this language be broadened to align with *14.01.04.09* that states that the Board may reconsider a UPL for any reason. *08(B)(2)* should reflect the broad authority of the Board to suspend or modify the UPL, not only during a shortage of the prescription drug product, but also in the event of other challenges that may impede patient access.

Reconsideration (14.01.04.09)

09A(1)&(2): As stated above, BIO recommends that the language should be broadened so that the Board shall reconsider the UPL not only during a shortage of the prescription drug product, but also in the event of other challenges that may impede patient access.

BIO also recommends that the Board be required to repeal a UPL for a brand or biologic if a generic or biosimilar comes to market.

Hearing Procedures (COMAR 14.01.06)

As stated above, BIO is concerned that the Board does not provide stakeholders with sufficient time to meaningfully review and comment. The Board must ensure that processes for collecting stakeholder feedback allow for multiple feedback channels (including both written and verbal feedback), provide sufficient time for groups to offer meaningful responses, and ensure that timelines and steps to incorporate and address feedback are clear and transparent. As such, it is imperative that the regulation includes a specific timeframe for the posting of a general hearing notice and relevant materials on the PDAB's website; BIO recommends that the notice and materials be publicly posted no less than two weeks prior to a scheduled hearing. Accordingly, B(1)(a) and C(1)(c) should be amended so that the notice of the hearing and any "questions, topics or matters about which the Board would like to receive information," should be published no less than two weeks before the hearing. For those who are unable to attend the hearing, BIO requests that the Board publicly post records of hearings on its website and include language in the regulation to that effect.

In addition, the regulation states that the Board may convene an informational hearing (*.06 C)* to seek feedback from the general public before making recommendations or taking action with respect to policy. BIO recommends that this language be strengthened so that the Board *must* convene an informational hearing to seek feedback from the general public before rendering a final determination with respect to policy.

Lastly, BIO suggests that the Board consider adding language in the draft regulations to address conflict of interest disclosures within the technical hearing process.

***

Biotechnology Innovation Organization
1201 New York Avenue NW
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Washington, DC, 20005
202-962-9200

BIO appreciates 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.

/s/

Melody Calkins
Director
Health Policy and Reimbursement

Kimberly Y. Robinson
Vice President
State Government Affairs

CareFirst BlueCross BlueShield
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November 8, 2024

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

Submitted via email to comments.pdab@maryland.gov

RE: Draft Proposed Regulations for Comment

To Whom It May Concern:

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

In our 86th 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. In reviewing the proposed regulations, CareFirst has identified 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 encourage the Board to amend the definition of "net cost" to explicitly include patient cost sharing. Including the out-of-pocket (OOP) costs paid by patients would more accurately reflect the total spend on drugs selected for UPLs. The term "net cost" will impact several aspects of the UPL process. The PDAB proposes to prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug. If "net cost" includes OOP costs in the denominator, the proportion could shift significantly, changing the likelihood that a UPL is deemed necessary. Similarly, "net cost" is used in several proposed methodologies for calculating a UPL, for example by looking at the lowest 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. 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 patient cost-sharing amounts should be included in the definition of net cost.

The Board proposes to not set a UPL if utilization of the prescription drug by an eligible governmental entity is "minimal." We recommend the Board not establish a "minimal" utilization threshold for determining whether to set a UPL at this time but reserve the right to reconsider this policy in the future after careful monitoring of which drugs are selected for UPLs. Focusing on the volume of prescriptions for a given drug to determine whether to set a payment limit could exclude certain high-costs drugs, such as cell and gene therapies and other specialty products, that are used by a relatively small proportion of the population but pose significant affordability challenges. Rather than proceed with a policy that could have unintended consequences in achieving improved affordability, we recommend the Board take additional time to consider how best to account for the full range of drugs that may not have significant utilization.

We 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 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 recommend the Board clarify what enforcement and monitoring procedures 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.

CSRO
Coalition of State Rheumatology Organizations

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November 7, 2024

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

Re: New Chapter - COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits)

Members of the Maryland Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) would like to share concerns regarding COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits), which implements a process for establishing an Upper Payment Limit (UPL) on medications selected by the Board. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

06. Policy Review – Process for Establishing a UPL
The Board has identified a robust set of methodologies and factors to establish the UPL. We respectfully share concerns with the following criteria:

Therapeutic Class. In setting the UPL to the lowest net price among all competitor products within the same therapeutic class, the Board will significantly disrupt the market by arbitrarily cutting the most expensive products while still allowing products in the median to remain at market value. We fear this may cause manufacturers to limit the availability of the medications impacted by the UPL. This has ripple effects throughout the system, such as driving medication shortages, which the Board has recognized in its proposal.

Therapeutic class refers to all drugs that are indicated to treat a certain disease state. Within this class there can be many different mechanisms of action (MOA) for how the drug works. Assuming that patients can just "switch" to another medication that is indicated for their condition clearly ignores the fact that "how" a medication works (MOA) is just as important as to "what" condition the medication treats. Rheumatologic patients often require a highly personalized approach as we manage their chronic illnesses. This could be extremely harmful to patients who only respond to a certain mechanism of action which is now no longer available, even though there are other drugs in the same therapeutic class still available, but not helpful for their condition.

Domestic Reference. In setting the UPL to the Medicare Maximum Fair Price (MFP), the Board risks patient access as MFP is likely to under reimburse for physician administered medications. (It's important to note that the first set of MFP drugs was just selected, and implications of the program are not yet realized.) We have serious concerns that MFP will not properly account for acquisition costs of providers who "buy and bill" physician administered medications. If MFP based reimbursement drops below acquisition costs for selected drugs, independent medical practices, as well as free standing infusion centers and some hospitals, may stop offering the selected drugs until acquisition costs can meet reimbursement levels, further driving state-based drug shortage concerns and total lack of access for patients requiring that particular medication with its particular mechanism of action.

International Reference. In setting the UPL to the lowest price paid by the United Kingdom, Germany, France or Canada, the Board neglects to recognize that the pharmaceutical supply chain operates very differently in these countries than it does in the United States. The most notable difference is that pharmacy benefit managers (PBM) do not play a role in formulary construction and drug pricing in the included countries. In the United States, PBMs incentivize higher prices by choosing drugs with higher list price for preferred placement as their revenue is based on a percentage of list price. Conversely, formulary construction in the other suggested countries is completely different, with placement often based on "lowest price". We believe it is ill advised to reference these international prices when those prices are set in a way that is so vastly different than the U.S. market.

Furthermore, we encourage the Board to adopt criteria that require any UPL to also account for healthcare provider acquisition costs – including, but not limited to, intake and storage, equipment and preparation, staff, facilities, and spoilage insurance – so that healthcare providers are not responsible for personally funding the difference in healthcare costs and expenditures.

Physician Administered Medications: Rebate Proposal

The UPL currently caps provider reimbursement for a prescription drug consistent with the rate determined by the Board. It does not, however, require that providers acquire the medication at a rate sufficiently below the UPL to account for acquisition costs to the provider. To maintain the viability of administering drugs in cost-effective outpatient settings, reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance. Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices at risk. Furthermore, if patients are unable to receive their medications in outpatient settings, they will be forced to receive provider administered care in hospital settings, which are more expensive to the payer and to the state.

During several PDAB meetings, Executive Director York has stated that "the framework that we're putting forward… won't change reimbursement amounts to the supply chain. It's all done kind of on the back end through rebates on reconciliation."[1] While we are encouraged that the state intends to make healthcare practices that directly administer medications on an outpatient basis whole, we are concerned that none of the proposals to date have outlined this practice or even mentioned a rebate model. We urge you to immediately release Draft Proposed Regulations for Comment on this rebate model.

We appreciate your consideration, and we are happy to further detail our comments to the Board upon request.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

[1] Legislative Policy Committee. "Review of the Upper Payment Limit Action Plan approved by the Prescription Drug Affordability Board." October 22, 2024. Time: 44:20

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November 8, 2024

Maryland Prescription Drug Affordability Board
169000 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comment on Proposed Regulations

Honorable Members of the Maryland Prescription Drug Affordability Board,

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

Today, we write with exceptional concern regarding proposed rulemaking and the Board's and staff's failure to meet statutory obligations, recognize existing data, and the current failure to meaningfully involve patients.

Process and Proposed Rules Inhibit Patient Engagement; No "Emergency" Exists

Prior to discussing the content of the proposed rulemaking, CANN must first point out that the process of the proposed rules has left patient communities and other stakeholders less than 10 calendar days (fewer than 6 business days) in which to engage with proposed "emergency" rulemaking without clearly establishing what "emergency" the Board and staff are seeking to address. Such actions necessarily degrade public trust in the institution of the Board and staff.

We urge the Board to reconsider proposed rulemaking wholesale and work to meaningfully engage the public. We are also gravely concerned that any good work to come from the Board may be washed away in an administrative procedure challenge due to failure to meaningfully engage the public.

Statutory Obligations Remain Unmet

Maryland's enacting statute *requires* the Board and staff to sufficiently establish monitoring metrics for any imposed "upper payment limit" (UPL). To date, the Board has failed to clearly and specifically establish such monitoring metrics. The Board's UPL "action plan" makes only a passing reference to such monitoring metrics, without even establishing "concepts of a plan".

Directly, the failure to establish such monitoring *prior* to establishing or imposing a UPL similarly means no "baseline" data will exist and any outcomes of a monitoring program will be fatally flawed.

In specificity, the following related sections of proposed regulation raise great concern:

> *Section .02(B-3)*: **The Board shall: (3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences;**
> Minimizing adverse outcomes and unintended consequences is an important goal. However, previous Board deliberations highlighted a concern that it is difficult to predict the future, and the only means to evaluate outcomes is waiting to observe the consequences of instituting a UPL. In light of this, what mechanisms are being set forth to preemptively minimize adverse effects?
>
> *Section .02(C1)*: **The Board shall not set an upper payment limit if: (1) Utilization of the prescription drug product by Eligible Governmental Entities is minimal**
> This verbiage would imply that drugs, such as those for rare diseases would be exempt from a UPL given the low numbers of people utilizing them in comparison to many other drugs. Will the Board set definitive criteria establishing "minimal utilization"?
>
> *Section .08(A-4)*: **The Board shall provide for the automatic suspension of the UPL for the time that the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list by regulation**.
> We suggest that the criteria for automatic suspension be expanded to include other lists. In the last meeting, the Board discussion highlighted the issue that state pharmacists maintain a larger drug shortage list than that of the FDA and that hospitals also have shortage lists specific to the state hospitals.

"Preliminary Affordability Determinations" Usurp Patient Engagement and Display Board Bias
In addition to the Board's failure to establish access monitoring metrics, the Board's consideration of "preliminary affordability determinations" similarly displays the Board's predetermined bias. The nature of "preliminary determinations" as described in the proposed rules excludes patient engagement of any kind. Such an action, if adopted and taken, undermines the Board and staff's stated interest in involving patients and the public writ large, again, opening the door to bias and administrative challenges.

Regarding patient engagement, the draft contains multiple references to information gathering and stakeholder feedback. Additionally, during meeting deliberations members of the Board have continuously expressed a desire for more feedback from stakeholders and patient input. Presently, we feel the current structure and timelines set for comment do not display a meaningful desire for a robust inclusion of patient input. We suggest looking at ways other states have sought to solicit meaningful input. This would include meaningfully constructed surveys disseminated to patients to solicit information that is not captured by APCD data, such as drug costs by those who are uninsured transportation and familial costs related to prescription drug access.

Additionally, with proper outreach, patients can give feedback about affordability concerns for medications the Board has not identified with their current criteria, resulting in an analysis of the costs of drugs ***patients*** define as their real-world drug affordability challenges. Staff could conduct patient forums that permit dialogue about patient concerns in an environment more conducive to candid discussion than a legislative hearing.

In specificity, the following related sections of proposed regulation raise great concern:

> *Section .02(B -1)*: **The Board shall: (1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;**
> We encourage the Board to thoroughly consider costs that have not previously come up during public meeting deliberations. There are important costs to consider that are not as conveniently documented in the manner that costs such as pharmacy dispensing fees are. One example is physician and staff time. A UPL could drive a PBM to institute utilization management requirements such as prior authorization for a drug. Prior authorization would add to physician and staff time due to the required clinical documentation necessary. Additionally, prior authorization can cost patients time in the form of delays associated with prior authorization denial.

> *Section .03(B-1)*: **The purpose of the policy review process is to: (1) Based on the best available information…**
> Previous Board deliberations have highlighted concerns with the quality of available information. There have been questions concerning the age of data, desired data points that haven't been previously included, and concerns about necessary data that may be very difficult, if not impossible, to obtain. We inquire as to what standards will be set to define "best." Additionally, if the parameters of the defined "best" are not met, what will be the course of action?

> *Section .06(B-2)*: **Therapeutic Class Reference Upper Payment Limit**
> Drugs may be in the same therapeutic class, but they all do not have the same efficacy or demand. Thus, their prices should be and are different. Therefore, setting a price based on the lowest net cost among all competitor products in the same therapeutic class is problematic.

> *Section .06(B-2a)*: **Under this methodology, a UPL value may be set as the initial price at which the drug was first marketed (launch price) adjusted for inflation.**
> This methodology does not consider factors other than inflation that affect a drug's pricing over time.

Proposed Rules Include Existing State Government Data, Which the Board has Already Refused to Consider

We do wish to acknowledge the proposed rules include several beneficial aspects while still being problematic in process. Namely, proposed rules include consideration of other state data regarding UPLs and affects on patient accessibility. However, the Board has *already* been presented with data from Oregon's PDAB regarding potential impacts to their state's Medicaid program and safety net provider network.

In summary, Oregon's PDAB requested an assessment from the state's Medicaid program, in which consultants Stauffer & Meyer presented findings. Those findings include an unknown but largely anticipated impact of reduced rebate values for both the Medicaid program and 340B, safety net providers. The most measurable anticipated outcome noticed by Stauffer & Meyer includes a less than half a million dollar "savings" in the

state's $36 billion Medicaid program due singularly to rebate value reductions. Stauffer & Meyer encouraged Oregon's PDAB to request information from safety net provider entities as to 340B value reduction impacts on services and scope of program reach as such financial changes would be significant.

While Board Member Anderson and Director York have dismissed these concerns, they remain unanswered in any meaningful way. The risk that comes from this lack of direct answer is cutting off Maryland's most vulnerable populations from provider services and harming the stability of the state's Medicaid program with no appreciable benefit for patients or the state's budget. Indeed, such dramatic changes in the financial stability of the drug supply chain will very likely require the state of Maryland to appropriate additional dollars in order to stabilize both the Medicaid program and safety net providers.

Plainly put, while Board Member Anderson has stated that he views reduced values in 340B rebates as a provider consideration, it is not limited to provider entities as an impact. If patients from highly marginalized and disproportionately affected communities cannot get the services we need and see our providers due to lack of sufficient funding, we cannot get either the diagnoses or prescriptions we need to live and thrive. And to be as precise as possible in our concerns, CANN wishes to highlight that such negative impacts will absolutely prove most harmful to patients already struggling to have our healthcare needs met.

> *Section .06(B-5)*: **Domestic Reference Upper Payment Limit**
> It is problematic to set limits based on prices paid by other purchasers. Due to the opacity of the drug supply chain and pricing process, it isn't possible to gain robust details on how a particular purchaser arrived at their net price. Using another payer's situation could have unforeseen negative consequences on the best interests of the Maryland system.

The Board's Consideration of QALYs or International Pricing Data Dependent upon QALYs Violates Federal Non-discrimination Rules

Earlier this year, the federal Department of Health and Human Services and Centers for Medicare and Medicaid Services finalized federal rules recognizing "quality adjusted life years" and similarly situated metrics as necessarily discriminatory toward persons with chronic health conditions and older patients. Those same rules, integrating protections under the Americans with Disability Act and Section 504 are directly addressed in terms of "cost containment" efforts as detailed below from 89 FR 4006, *Nondiscrimination on the Basis of Disability In Programs or Activities Receiving Federal Assistance* (Section: *Value Assessments [84.57]*);

> *Comment:*
>
> *The Department requested comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities. Numerous commenters indicated that value assessment methods could limit people with disabilities' access to health care goods and services, including pharmaceutical interventions, and expressed concern that the use of the QALY unfairly limited access to emerging pharmaceutical interventions that could extend the lives of people with disabilities.*
>
> *Response:*
>
> *While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities.*

Comment:

One commenter argued that the use of the QALYs and other methods of value assessment that frequently entail discounting the value of life extension on the basis of disability are not discriminatory because they are "only one step" in a process of decision-making, noting that policymakers also take into account other factors in their ultimate decision-making.

Response:

Although recipients may make use of multiple factors to influence their decision-making, the use of a measure of value that assigns lower value to extending the lives of people with disabilities to determine eligibility, referral, or provision or withdrawal of an aid, benefit, or service can be nonetheless discriminatory.

These federal rules apply specifically to state Medicaid programs as recipients of federal assistance dollars. The Board *must* acknowledge these rules or risk running affront of federal authority on the issue.

Section .06(B-6): **International Reference Upper Payment Limit**

We would like to reiterate previous concerns about this methodology. Drug prices paid in other countries should not be considered. Other countries' markets are very different from those in the U.S., including those with a single-payer system and vastly different means of price control. Additionally, utilizing this data presents a potential backdoor insertion of QALY methodology which is prohibited.

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

CANN recognizes the above issues are uncomfortable to consider and meaningfully integrating our feedback would require dramatic adjustments both to the Board's process and its current operation. However, the good-faith effort of the Board to improve access to and affordability of care for Marylanders is in dramatic risk because of the Board's and staff's failure to address these issues as previously raised by the public and, specifically, patient communities. We do not wish to see the public's trust or the legislative intent of the Board undermined because the Board is rushing headlong with pre-determined biases rather than an objective, systematic, and unbiased approach to the issues patients and the state of Maryland are facing. Codifying the current proposed rules as drafted, however, will not only result in a completely foreseeable cause of action for litigation, but it will destroy the last shreds of objectivity, cooperation with the public, and priority for patients the Board was tasked with meeting.

We urge the Board to reject both the process of these proposed rules and the problematic sections of the proposed rules as outlined above for the sake of Maryland's budget and patients.

Respectfully submitted,

Ranier Simons
Director of State Policy
Community Access National Network

On behalf of

Jen Laws
President & CEO
Community Access National Network

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

November 8, 2024

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

RE: Draft Proposed Regulations for Comment

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

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

On behalf of our national network of patient organizations, 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. 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.

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.

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

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

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

November 8, 2024

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

Healthcare Distribution Alliance Comment Letter
COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits

On behalf of our member companies, the Healthcare Distribution Alliance (HDA) would like to share feedback with the Maryland Prescription Drug Affordability Board regarding proposed regulations, COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits), which we hope the Board will take under advisement.

HDA is the national trade association representing pharmaceutical wholesale distributors, the vital link between roughly 1,400 pharmaceutical manufacturers and more than 180,000 pharmacies and other healthcare settings nationwide, including over 4,600 sites of care in Maryland. As you know, **distributors operate a unique role in the supply chain. They do not set list prices or determine the amount patients pay for medicines, but rather are the logistical experts in the supply chain**. Distributors do not play a role in determining the amount patients pay for medicines, which medicines are included on formularies, benefit design decisions, or reimbursement rates for dispensing pharmacies. Their core business does not involve manufacturing, marketing, prescribing or dispensing medicines, nor do they set the Wholesale Acquisition Cost (WAC) or list price of prescription drugs, influence prescribing patterns, determine patient-benefit design, or impact what patients pay at the counter. Rather, our members serve as the logistical experts within the physical supply chain who ensure products are physically on pharmacy shelves where and when patients need them by executing manufacturer contracts and physically fulfilling pharmacy orders.

As a representative of the logistical experts within the supply chain, HDA would like to share our concerns with the Board regarding the proposed regulations as well as the discussions which have occurred during the Board meetings, and the impact such policies could have on the physical pharmaceutical supply chain in Maryland.

Concern # 1- The negative impact of UPLs on the Entire Supply Chain

HDA has shared our concerns regarding the adverse outcomes and unintended consequences of UPLs in several previous letters, and we would like to share them again below. Additionally, we would like to further

expand on the difficulties such policies would have on Maryland pharmacies, and by extension the patients they serve. Specifically:

- **Domestic or International Reference Upper Payment Limits Would Have Adverse Outcomes and Unintended Consequences.** HDA appreciates language in the plan stating that the Board should consider the cost of administering the drug and delivering drugs to consumers; **however, we would like to share our view that state-level UPLs on the purchases and reimbursement of drugs do not adequately reflect the fact that prescription drugs are bought and paid for in the United States. The committee should be aware that establishing a state-level UPL would place a cap on in-state purchases but not out-of-state purchases. Even when allowing for a nominal fee, a healthcare provider or pharmacy may be unable to recoup costs for administering a product, and there would be little incentive or ability for them to continue to stock these medications.**

  Further, under the federal Inflation Reduction Act of 2021 created the Medicare Drug Price Negotiation Program, CMS will set a Maximum Fair Price (MFP) for certain prescription drugs. However, it is important to note that while the MFP represents the most that Medicare will pay for a drug, it does not change the "list price" of drugs, as set by manufacturers. Reductions in price to CMS will likely be achieved through a number of actions, such as rebates paid to Medicare. With very limited exceptions, a provider such as a pharmacy, hospital, or clinic that dispenses or administers drugs to patients must first purchase the physical product and then receive reimbursement to cover the cost of that product. The complex system in which prescription drugs are purchased and distributed from a manufacturer to a wholesaler, then to a healthcare provider, and finally to a patient involves numerous transactions between each entity and with insurance companies, pharmacy benefit managers, and government payers. At each step along the way, these transactions are subject to private negotiations and often involve complicated discount and rebate arrangements which often take place nationally and cannot be adequately achieved at the state level. An international reference price also does not adequately take into account the way the nation's supply chain operates.

  It is also important to note that many independent pharmacies are already struggling to maintain their businesses, the UPL proposal would further reduce their ability to maintain overhead when dealing with specific medications, undoubtedly leading to further consolidation or closures within the pharmacy and provider community. This would also come at a time when pharmacies are already trying to determine how to manage and operationalize the federal MFP program. For example, a recent National Community Pharmacists Association (NCPA) survey indicated that over 90% of independent pharmacies may not sell drugs with prices negotiated under Medicare Part D.

  In summary, utilizing UPLs such as MFP or international reference prices at a state-level UPL will likely result in some products being unavailable or difficult to access in Maryland. HDA therefore opposes the use of UPLs modeled on Medicare MFP or on international reference rates.

Concern #2- The process for setting UPLs, reconsidering UPLs, and monitoring for shortages needs to be further refined according to the following recommendations:

- Recommendation #1- Given the harmful disruptions UPLs would have on the supply chain as shared above, and echoed by numerous other entities in the supply chain such as manufacturers, healthcare providers, and pharmacies, **HDA recommends the final regulations state that any UPLs selected by the Board must done so through an unanimous vote.**

- Recommendation #2- Distributors work hard every day to help support a resilient supply chain; however, drug shortages are a serious issue facing the nation, and ultimately distributors cannot deliver products that are not available from manufacturers. HDA once again recommends that to ensure supply chain stability, **final regulations should state that UPLs cannot be applied to drugs that have been in shortage anytime within the past two years. The final regulations should further state that in cases where a UPL is modified, suspended, or repealed due to an identified shortage whether through a monitoring process established by the MD PDAB or through the FDA's drug shortage list, a UPL cannot be reconsidered or unsuspended for that drug until it has been out of shortage for at least two years.** HDA would further like to emphasize the importance of the MD PDAB creating a robust and detailed shortage monitoring plan as soon as possible for stakeholder input, and that such a plan would include monitoring and considering the impact shortages caused by consider supply disruptions from events such as hurricanes. HDA believes these recommendations above will help ensure that the manufacturing and supply of a drug recently in shortage can continue to stabilize, without undue hindrances.

In summary, HDA remains concerned with the overall disruption that establishing a UPL on drug products could have on the supply chain as a whole. Ultimately, any scenario establishing a UPL could lead to a disruption in patient care for Marylanders, the need to identify new drugs to offset the product being removed from market, and potential shortages of products given the instability in the marketplace.

With more states considering PDAB legislation and UPL policies, the resulting patchwork of state policies and pricing metrics for a variety of pharmaceutical products will ultimately exacerbate the overall cost in the supply chain and create unpredictability in the marketplace as a whole- often without even impacting the out-of-pocket price that patients pay. These concerns have been echoed in other states considering establishing a UPL, most recently outlined in the Oregon PDAB Constituent Group Engagement Draft Report developed by Myers and Stauffer LC which noted that "an analysis of qualitative survey data found that more than half of respondents did not believe a UPL would result in cost savings, with many expressing concerns regarding loss of revenue, decreased patient access, and increased patient costs. A number of respondents also expressed concern that implementation of a UPL would result in increased administrative burden, infrastructure costs, and operational challenges."

HDA also remains concerned that these UPLs would be based on data collections that are currently underway by the PDAB without there being clear processes in place to protect the "consideration and discussion of proprietary, confidential, and trade secret information and that the board will have a closed session."

Thank you for the opportunity to share our concerns with the establishment of a UPL on drug products in Maryland and to further highlight the unique and critical role that wholesale distributors play in the supply chain. HDA is available to serve as further resource and looks forward to having our feedback taken into consideration. Please contact kmemphis@hda.org for further discussion.

Sincerely,

Kelly Memphis
Director, State Government Affairs Healthcare
Distribution Alliance

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).

CC: Diane Hilligoss, Assistant General Counsel, Eli Lilly and Company

MDCSCO
MARYLAND/DISTRICT OF COLUMBIA SOCIETY OF CLINICAL ONCOLOGY

ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY

November 7, 2024

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

Sent via email to comments.pdab@maryland.gov.

Re: Draft Proposed Regulation COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits).

Dear Mr. York and Members of the Maryland Prescription Drug Affordability Board,

The Maryland/District of Columbia Society of Clinical Oncology (MDCSCO) and the Association for Clinical Oncology (ASCO) are grateful for your consideration of our comments regarding the Board's proposed regulations on upper payment limits.

MDCSCO is committed to improving the quality and delivery of care in medical oncology in the State of Maryland and the District of Columbia. ASCO is the world's leading professional society representing physicians who care for people with cancer. With more than 50,000 members, our core mission is to ensure that patients with cancer have meaningful access to high quality, equitable cancer care.

Ahead of the Board's consideration of this rule, MDCSCO and ASCO would like to express our concern that the criteria for setting an upper payment limit could disproportionately impact Maryland patients with cancer. Oncologists do not set or control drug prices; they offer each patient the most appropriate, evidence-based treatment that will ensure the best outcome for an individual patient with cancer and his or her specific disease.

We are concerned that reimbursement for a physician-administered drug with an upper payment limit will fail to include an add-on payment to cover actual costs incurred for procuring, storing, preparing, and handling highly toxic agents. Medicare and private market reimbursement for physician-administered drugs includes an add-on payment to cover costs associated with drug treatments in physicians' offices. Without an add-on payment for drugs subject to an upper payment limit within state regulated plans, oncology practices could face a large financial burden that puts them at risk of closure. Patients could face delays in care or have to travel long distances for treatment. These concerns are in addition to the administrative burden to practices of having to track which drugs are subject to a UPL for patients enrolled in a state regulated plan.

While the proposed regulation requires the Board to consider the cost of administering a drug and delivering it to patients, as well as other relevant administrative costs, MDCSO and ASCO are concerned that this language is not clear enough to prevent an upper payment limit from negatively impacting reimbursement for a physician-administered drug. At a recent Legislative Policy Commission, reassurances were given that an upper payment limit would not impact pharmacy and hospital

reimbursement, which would be addressed through back-end rebate reconciliation. However, that process is not detailed in the draft regulation. MDCSCO and ASCO would appreciate the Board providing more information about this process and including clearer reimbursement language in the final regulation to ensure that physicians and their patients are not negatively impacted.

As the board deliberates criteria for setting an upper payment limit, we urge you to consider the unintended consequences of imposing an upper payment limit on physician-administered drugs used to treat cancer. We appreciate the opportunity to provide comments and offer ourselves as a resource to you as the process moves forward. Please contact Sarah Lanford at sarah.lanford@asco.org if you have any questions or if we can be of assistance.

Sincerely,

Paul Celano, MD, FACP
President
Maryland/DC Society of Clinical Oncology

Eric P. Winer, MD, FASCO
Chair of the Board
Association for Clinical Oncology

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

November 08, 2024

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

Re: COMAR 14.01.05

Dear Chair Mitchell,

On behalf of our members operating in Maryland, the National Association of Chain Drug Stores (NACDS) is writing to provide comments on the Maryland Prescription Drug Affordability Board's (Board) Policy Review Final Action (COMAR 14.01.05). NACDS is committed to providing and promoting high-quality patient care, improving patient access, and lowering healthcare costs across the care continuum for patients while supporting pharmacy providers in the process. To date, Prescription Drug Advisory Board (PDAB) legislation has been enacted in 11 states with the expectation that additional states will soon follow suit.[1] Of the eleven currently enacted PDABs, four contain UPL price limit threshold provisions.[2]

NACDS understands and supports ways to lower drug costs. However, as stated in our previous comments on the Board's Plan of Action for Implementing the Process for setting Upper Payment Limits (UPLs), we fear there may be a significant impact on the availability and accessibility of certain prescription drugs at a patient's neighborhood pharmacy in states where the UPL provision is being considered and effectuated in a manner that fails to ensure fair and adequate reimbursement levels for pharmacies.

COMAR14.01.05(.01)

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 and sustainable pharmacy services for beneficiaries. 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 more to provide quality patient care.[3] *Maryland Medicaid* performed a cost of dispensing (COD) study in 2020 that found on average, Maryland pharmacies, including

[1] Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon, and Washington.

[2] Colorado, Maryland, Minnesota, and Washington.

[3] 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

specialty, spent $13.72 to dispense most medications.[4] In the Maryland PDAB plan of action, Board 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 availability and access to certain prescription drugs for Marylanders, it is imperative that these cost considerations include *both* the product costs of the drug and a professional dispensing fee.

NACDS thanks the Board for recognizing and limiting 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 as to the provision of a professional dispensing fee. The Board noted during their September 10, 2024, PDAB meeting that the UPL methodology should not impact stakeholders within the supply chain, including pharmacies.[5] In an effort to ensure pharmacies are not subject to negative reimbursement, NACDS respectfully requests additional guidance and specificity regarding the provision of a professional dispensing fee when the prescription drug dispensed is subject to a UPL and urges the Board to consider the complete lack of transparency surrounding Pharmacy Benefit Manager rebates and fees that impact pharmacies across Maryland.

NACDS strongly encourages the incorporation of adequate reimbursement safeguards for all pharmacies, as mentioned above, in all the methodologies and factors used to set and implement a UPL. Without necessary guardrails to ensure reasonable and sufficient reimbursement for community pharmacies, UPLs 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. NACDS will continue to urge Maryland lawmakers and the Maryland PDAB to ensure increased patient access and fair and adequate reimbursement for pharmacists, pharmacies of all sizes, and the Marylanders they serve. For questions or further discussion, please contact NACDS at jmccormack@nacds.org (Jill McCormack, Director, State Government Affairs, Pharmacy, Transformation, and Advocacy).

Sincerely,

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

[4] 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

[5] https://www.youtube.com/watch?v=Q18vKKSd3_s at 57 minutes 01 second.

PhRMA
RESEARCH • PROGRESS • HOPE

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

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.

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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).