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By Electronic Submission

October 23, 2023

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
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Re: Maryland Prescription Drug Affordability Board: Proposed amendments to the General Provisions Rule (COMAR 14.01.01.01); and proposed Rules for Construction and Open Meetings (COMAR 14.01.01.02-.03); Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04); Public Comment Procedures (COMAR 14.01.01.05); and Cost Review Study Process (COMAR 14.01.04.01-05)

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the proposed amendments to the General Provisions rule (COMAR 14.01.01.01); and proposed rules for Rules of Construction and Open Meetings (COMAR 14.01.01.02-.03); Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04); Public Comment Procedures (COMAR 14.01.01.05); and Cost Review Study Process (COMAR 14.01.04.01-.05) (collectively, "Proposed Rules"), which were published for public comment by the Maryland Prescription Drug Affordability Board ("Board") on September 22, 2023.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA had previously provided comments on draft versions of these regulations that were published by the Board, and we renew and incorporate the concerns that were described in those letters which remain unaddressed.[2] PhRMA recognizes the Board's work to establish rules that implement the Maryland PDAB Statute ("PDAB Statute").[3] However, as described below and in our prior comments, PhRMA is concerned about the approach contemplated by the Proposed Rules. Among other issues, the Proposed Rules do not provide clear definitions and standards for significant areas of the Board's cost review process. PhRMA is also concerned about the adequacy of the Board's safeguards to ensure the confidentiality of protected information.[4] We provide our comments on the Proposed Rules below.

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[1] 50 Md. Reg. 845-72.

[2] *See* 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 General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023). Copies of these letters are included below. PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Proposed Rules.

[3] *See* Md. Code Annotated, Health-General Article §§ 21-2C-01–16.

[4] In filing this comment letter requesting changes to the Proposed Rules, PhRMA reserves all rights to legal arguments with respect to the Maryland PDAB statute.

I. COST REVIEW PROPOSED RULE

A. Lack of Clear Standards

PhRMA believes that the Proposed Rules do not provide clear and meaningful standards and procedures for how the Board will conduct its cost review study process, as are necessary to guard against the risk of arbitrary and inconsistent decision-making.[5]

Revisions to the Proposed Rules from prior drafts have not addressed PhRMA's ongoing concerns regarding lack of clear standards. For example, in the Proposed Rules the Board has revised its draft regulations governing the process for identifying drugs eligible for cost reviews to reinforce already broad and discretionary language (i.e., "the Board may consider. . .") with additional caveats that the Board may consider such information "to the extent practicable."[6] In addition, the Board's proposed rule governing selecting drugs for cost reviews includes an added consideration related to whether a particular prescription drug product is designated by the Food and Drug Administration ("FDA") as a "drug for a rare disease or condition" under 21 U.S.C. § 360bb ("Orphan Drug").[7] Yet the Board's proposal lacks any information about how Orphan Drug status will be specifically factored into the Board's consideration. To the extent such factor is considered, the Board should provide sufficiently meaningful standards to ensure clear, consistent, and non-arbitrary consideration of Orphan Drug status that does not penalize a prescription drug for treating patients with a rare medical condition.

More broadly, the absence of clear standards and the broad discretionary language in the Proposed Rules may lead to material differences in how the cost review process is conducted for similarly situated drugs, permitting the Board to operate in an ad hoc manner rather than providing clear, binding guidelines for how the cost review process will be conducted. A lack of concrete guidelines for the Board's processes would reduce the already limited transparency that stakeholders have regarding the standards and methodology that the Board intends to apply, and would inevitably increase the risk of arbitrary and capricious determinations in the selection of drugs for and conducting of cost reviews. As PhRMA has previously explained, 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.[8] Prior to finalizing the Proposed Rules, we strongly encourage the Board to revise its rules to articulate more specific, concrete, and meaningful procedures and standards that will provide binding guidelines for how the Board will make use of the information it obtains from various disparate sources. This is particularly important given the complexity of the information that the Board is responsible for compiling and considering.[9]

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[5] PhRMA also incorporates and reiterates its concerns regarding the Board's contemplated approach to the cost review study process from its prior comment letters. *See, e.g.*, Letter from PhRMA to Board 2–3 (June 30, 2023).

[6] Proposed Rules § 14.01.04.02(D).

[7] Proposed Rules § 14.01.04.03(B)(1)(d). This factor was not included in the prior draft rules that PhRMA commented on.

[8] *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).

[9] *See, e.g.*, Proposed Rules §§ 14.01.04.02–.05.

B. Other Comments

PhRMA also urges the Board to revise its Proposed Rules to further enhance consistency with the PDAB Statute; incorporate additional process to protect stakeholders; and better address the concerns mentioned above regarding the Proposed Rules' lack of clear standards. PhRMA provides below a non-exhaustive list of examples of these issues within the Proposed Rules as currently drafted:

- **Open Meeting Process**. PhRMA recognizes the value of the open meeting process to allow for meaningful participation by members of the public. To make this process as meaningful as possible and allow for more full and fair stakeholder engagement, PhRMA reiterates its request that the Board revise the Proposed Rules to explicitly require the public posting of non-confidential materials that will be presented and considered at the open meeting at least 60 days in advance to allow the public the opportunity to review and comment.

- **Explanatory Statements**. The Proposed Rules state that if a Board member proposes to an additional drug product for inclusion on the list of drugs eligible for cost review, that Board member will identify "how" the prescription drug product "may create affordability challenges for the State health care system or patients."[10] As described below and in PhRMA's prior comment letters, the Board cannot, consistent with its legal obligations to protect confidential, trade secret, and proprietary information, disclose any confidential or otherwise protected information as part of providing such explanatory statements.[11] We therefore ask that the Board revise the Proposed Rules to clarify that any confidential, trade secret, and proprietary information considered for or included in the Board's explanatory statements for "how" a drug may create affordability challenges should be disclosed only in an executive session. We also remind the Board of its obligation to conduct the drug selection and cost review processes by reviewing and carefully considering the full scope of enumerated factors available for a particular drug.[12]

- **Stakeholder Council Process**. PhRMA reiterates concerns described in our prior comment letters regarding the Stakeholder Council.[13] We reiterate that greater clarity is needed surrounding the process of how products will be referred to the Stakeholder Council. Among other things, PhRMA urges the Board to clarify the timing of when drugs referred to the Stakeholder Council will be posted on the Board's website and specifically, how far in advance of final selection that posting will occur. Consistent with our prior comments, PhRMA also reiterates that the Board should revise the Proposed Rules to provide at least 60 days for stakeholders to review and comment.[14]

- **Therapeutic Alternatives**. PhRMA notes that the Proposed Rules also state that the Board "shall" (as opposed to "may" as in prior draft rules) approve the therapeutic alternatives to be used in conducting a cost review study.[15] As described in our prior comments, PhRMA remains concerned

[10] Proposed Rules § 14.01.04.02(E)(2).
[11] See Section IV for a more detailed discussion of confidentiality.
[12] Md. Code Annotated, Health-General Article § 21-2C-09(a), (b)(2); *see also* Proposed Rules §§ 14.01.04.03(A)–(B), 14.01.04.05(C) (enumerated factors for the Board's consideration not including Board member explanatory statements).
[13] Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process 3 (June 30, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 7–9 (May 1, 2023).
[14] *See* Proposed Rules § 14.01.04.03(F)(2) (currently providing only 30 days to comment). Consistent with the Board's obligation to prevent disclosure of confidential, trade secret, and proprietary information, presentation and consideration of confidential, trade secret, and proprietary information should only occur in an executive session. *See* Section IV, below.
[15] Proposed Rules § 14.01.04.03(I)(8).

with the Board's proposed consideration of therapeutic alternatives, including the potential risk of misleading comparisons. PhRMA recommends that the Board revise the Proposed Rules to clarify that the Board has no obligation to approve some or all of the list of therapeutic alternatives provided by the Board staff for use in cost review study. Rather, the Board should review the recommendations of the staff as well as any written comments provided by members of the public and independently determine which, if any, of the recommended therapeutic alternatives are appropriate for inclusion in the cost study review.

- **Cost Review Request for Information**. The proposed rule regarding Requests for Information states that "an entity that has not received a request for information from the Board may submit relevant information in accordance with this regulation."[16] PhRMA requests that the Board clarify which elements of the regulation apply to submission of information by entities that have not received a request from the Board, and specifically whether the same timeframes, extension provisions, and procedures for designating confidential, trade secret, and proprietary information under section 14.01.01.04 of the Proposed Rules would still apply. We also note that the Proposed Rules now state that responses to information requests must be provided within 30 days of the request, with the opportunity to request one 30-day extension.[17] PhRMA recommends that there be the opportunity for additional extensions where good cause and the interests of fairness and equity support such additional extensions.

- **Public Comment on Cost Review Study**. The Proposed Rules give members of the public 60 days to provide written comments from the date of the Board posting on its website a drug's selection for cost review study.[18] PhRMA asks that the Board revise this regulation to permit extensions for good cause to allow greater flexibility to account for circumstances where additional time may be appropriate.

II. DEFINITIONS PROPOSED RULE

PhRMA reiterates its concerns with a number of the definitions included in the Proposed Rules. Our prior comments to the Board, including in the letter dated June 30, 2023, discuss these concerns at length and we refer the Board to those comments where the issues they describe are not addressed in the Proposed Rules. We provide the following as a non-exhaustive list of comments and suggestions regarding the definitions in the Proposed Rules:

§	Proposed Term	PhRMA Comment
14.01.01(B)(22); 14.01.01(B)(32); 14.01.01(B)(64); 14.01.01(B)(65)	"Deductible"; "Gross Spending"; "Total Gross Spending"; "Total Patient Out-of-Pocket Cost"	PhRMA notes that these definitions reference *calendar* years, whereas health plan expenditure is typically based, calculated, and reported on a plan year basis. Accordingly, the Board should consider revising these definitions to use plan year as opposed to calendar year.

[16] Proposed Rules § 14.01.04.04(A)(5).
[17] Proposed Rules § 14.01.04.04(A)6)–(8). Prior draft rules provided entities 60 days to respond from the date of the request.
[18] Proposed Rules § 14.01.04.05(C)(2).

§	Proposed Term	PhRMA Comment
14.01.01(B)(23); 14.01.01(B)(56)	"Discount"; "Rebate"	The Board proposes to remove the term "negotiated" from the definitions of "discount" and "rebate" (i.e., "a ~~negotiated~~ monetary adjustment…"). Removing this term may make these definitions unclear and overly broad. A "discount" and a "rebate" should be directly or indirectly *negotiated* in some fashion in order to distinguish them from other forms of price adjustment – for example, an error that results in an inadvertent price reduction. PhRMA asks that the Board revise the Proposed Rules to include the term "negotiated" in these definitions.
14.01.01(B)(61)	"Therapeutic Alternative"	Consistent with its prior comments, PhRMA notes that not every drug product that has the same or similar indication as a particular drug can be considered a therapeutic alternative. Further, treatments that are the best option for some individuals are not as effective for others.[19] A narrower, more selective definition of "therapeutic alternative" will help limit the Board's considerations to therapeutic alternatives based on demonstrated clinical evidence, and will help avoid comparisons between drugs that may not be appropriate. Accordingly, PhRMA recommends that the Board adopt a revised definition of "therapeutic alternative" that requires a drug "*to have been shown through peer-reviewed clinical studies to have similar therapeutic effect, a similar safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose*" to be considered a therapeutic alternative.

III. PUBLIC COMMENT PROCEDURES PROPOSED RULE

In addition to the comments raised in its prior letters with respect to the proposed rule regarding Public Comment Procedures, PhRMA notes the Board's revised proposal states that members of the public may submit written comments "[i]f a regulation *expressly provides* for public written comment."[20] PhRMA believes this provision should be revised to make clear that there will be opportunity for public comment on *all* new or modified regulations and policy guidance. Public comment plays an important role in enhancing transparency, allowing for the genuine interchange of ideas, and refining or improving Board proposals. Especially given the substantial ramifications of the Board's work, we believe that there should be opportunities for comment on *all* policies, processes, and decisions being considered by the Board. To provide meaningful opportunities for comment, we also ask that the Proposed Rules be revised to require

[19] Letter from PhRMA to Board 11–12 (May 1, 2023); *see also* McRae, J., Onukwugha, E. *Why the Gap in Evaluating the Social Constructs and the Value of Medicines?,* PharmacoEconomics (2021), *available at* https://doi.org/10.1007/s40273-021-01075-w.

[20] Proposed Rules § 14.01.01.05(B)(1)(b) (emphasis added); *see also id.* § 14.01.01.05(B)(4).

comment periods that allow sufficient time for stakeholders to fully and meaningfully review and respond to the Board's proposals.[21]

IV. CONFIDENTIALITY

PhRMA remains concerned that the Proposed Rules offer insufficient protections for confidential, trade-secret, and proprietary information. PhRMA previously provided comments to the Board on this issue on May 4, 2023, noting ways that the Board's Proposed Rule was insufficient to safeguard constitutional and statutory rights.[22] None of those concerns are addressed in the Proposed Rules.

As discussed in our prior comments, the Board has a statutory obligation to protect confidential, trade-secret, and proprietary information because "[o]nly Board members and staff may access trade secrets and confidential and proprietary data and information obtained under [the statute] that is not otherwise publicly available."[23] This obligation requires the Board to review *all* submissions to determine whether they contain confidential, trade-secret, or proprietary information. The Board cannot rely on the submitting party to accurately identify all such information,[24] particularly because the submitting party may be providing information derived from third parties. Further, the designation of information as confidential provides insufficient protection for constitutional and statutory rights if the Board remains free in its unfettered discretion to override a confidentiality designation.[25] We thus reiterate our request that the Board revise the Proposed Rules so that, *before* the Board is allowed to override a confidentiality designation, the Board must notify the designator and the designator be permitted to challenge that decision through an administrative process that is subject to judicial review.[26]

The Proposed Rules also fail to provide adequate assurances that confidential, trade-secret, and proprietary information will be safeguarded once in the Board's possession. As currently drafted, the Proposed Rules regulate only who may "access" confidential, trade-secret, or proprietary information.[27] PhRMA reiterates that the Proposed Rules should be revised to clarify not only that Board members, Board staff, and qualified independent third parties are the only ones who may access confidential information, but also that they are the only ones who may use such information, regardless of who initially accessed the information. Moreover, the Proposed Rules lack meaningful guidance to those permitted access regarding how such information should be safeguarded. Specific, particularized processes are necessary

[21] PhRMA also urges the Board to take adequate steps to protect all confidential, trade secret, proprietary, or otherwise protected information obtained as part of the comment process as against improper disclosure. *See generally* Proposed Rules § 14.01.01.05(B)(5). *See also* Section IV, below.

[22] *See* Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023).

[23] *See* Md. Code Ann., Health-Gen. § 21-2C-10(b) ().

[24] Proposed Rules § 14.01.01.04(A)(1)(a).

[25] *Id.* § 14.01.01.04(A)(1)(b)-(c).

[26] *See* Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule 3 (May 4, 2023). The Proposed Rules would also require individuals submitting public comments to the Board with redacted confidential, trade-secret, or proprietary information to submit a certification that such redacted information is not otherwise publicly available and has been handled and maintained to preserve its confidential, trade-secret, or proprietary nature. Proposed Rules § 14.01.01.05(B)(5)(a)(ii); *see also* Proposed Rules § 14.01.01.04(A)(1)(a)(ii). The Proposed Rules do not indicate what the purpose of this certification is, or what role it may play in the Board's review of confidential, trade secret, or proprietary information that is submitted to it. To the extent the Board intends to review such certifications in connection with its determination whether information it receives is confidential, trade secret, or proprietary, such review should also be subject to administrative challenge and judicial review as described above.

[27] *Id.* § 14.01.01.04(B).

to prevent inadvertent disclosures of confidential information. The Proposed Rules' current instructions, which provide guidance only at a very high level, are insufficient.

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

Sincerely,

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