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By Electronic Submission

June 30, 2023

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

Re: Maryland Prescription Drug Affordability Board: Draft Regulations on Definitions (COMAR 14.01.01.01); Rules of Construction and Open Meetings (COMAR 14.01.01.02); Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04); and Cost Review Study Process (COMAR 14.01.03.01-05)

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on revised drafts (v.2.0) of the Definitions (COMAR 14.01.01.01); Rules of Construction and Open Meetings (COMAR 14.01.01.02); Confidential Information (COMAR 14.01.01.04); and the Cost Review Study Process (COMAR 14.01.03.01-05) proposed rules (collectively, "Proposed Rules"), which were published June 16, 2023 by the Maryland Prescription Drug Affordability Board ("Board"). 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 recognizes the Board's work to establish rules that implement the Maryland PDAB Statute ("PDAB Statute").[1] However, consistent with our prior comment letters, PhRMA remains concerned about the approach contemplated by the revised drafts of the Proposed Rules.[2] Among other issues, the revised drafts of 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.[3] We provide our comments on the Proposed Rules below, primarily focusing on changes within the revised drafts.

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

[2] *See* Letter from Pharmaceutical Research and Manufacturers of America ("PhRMA") to Md. Prescription Drug Affordability Board ("Board") (May 1, 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). PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Proposed Rules.

[3] 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. PhRMA appreciates this opportunity to comment on the Board's draft Proposed Rules, and welcomes additional opportunities to comment on future drafts, but emphasizes that a separate 30+ day comment period will be necessary pursuant to the Maryland Administrative Procedure Act, and to give stakeholders a full and fair opportunity to comment. *See generally* Md. Code Ann., State Gov't § 10-111(a)(3) (comment period generally required to be at least 30 days).

I. COST REVIEW STUDY PROCESS PROPOSED RULE

A. Continuing Lack of Clear Standards

As explained in detail in its prior comment letters, PhRMA believes that the Cost Review Study Process Proposed Rule does not provide clear and meaningful standards and procedures to guard against the risk of arbitrary and inconsistent decision-making.[4] Further, as discussed below, certain changes in the revised drafts of the Proposed Rules heighten PhRMA's concerns regarding the Proposed Rules' lack of clear standards.

As an example, we note that the revised draft of the Cost Review Study Process Proposed Rule includes 43 instances where discretionary language (e.g., "The Board may determine…") is used to describe the Board's considerations and decision-making processes, 10 of which were introduced in the revised draft.[5] Broad discretion 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. 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 for selecting any given drug for a cost review and would inevitably increase the risk of arbitrary and capricious determinations in the selection of drugs for cost review. 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.[6]

We strongly encourage the Board to articulate more specific, concrete, and meaningful procedures and standards that explain how the Board intends to 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 proposing to consider.[7] We note that in the October 24, 2022 PDAB staff presentation, the Board indicated its intent to release additional information regarding how it intends to prioritize and weigh various data elements. The Proposed Rules do not provide such additional detail, and we encourage the Board to continue developing this additional information for subsequent drafts of the Proposed Rules.

B. Need for Additional Transparency and Opportunities for Comment

PhRMA also urges the Board to provide increased transparency and opportunities for stakeholder feedback throughout the cost review process. The Proposed Rules contemplate a multi-faceted process, where the Board will analyze a broad array of information drawn from diverse data sources for each drug. Without adequate stakeholder engagement, the complexity of this process heightens the risk of inadvertent errors. As such, it is important for the Board to establish processes that allow manufacturers and other stakeholders to have the opportunity to review and verify the data, analyses, and modeling that

[4] Letter from PhRMA to Board (May 1, 2023), at 2-5.

[5] Cost Review Proposed Rule §§ 14.01.04.02(B), (D), 14.01.04.03(A)–(D), (F), and (H), 14.01.04.05(A)–(B) and (F). *See, e.g.*, Cost Review Proposed Rule §§ 14.01.04.02(D), 14.01.04.05(A).

[6] *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).

[7] *See, e.g.*, Cost Review Proposed Rule §§ 14.01.04.02–.05.

the Board relies upon, although we note that such processes should be consistent with the protections for trade secret, confidential, and proprietary information under the PDAB Statute and other legal protections.[8]

PhRMA specifically highlights the following key areas to illustrate where the Board should establish procedures that allow stakeholders to review, verify, and comment on the Board's materials:

- The Cost Review Proposed Rule provides that Board staff may compile a dashboard containing the prescription drug products identified for cost review under the relevant statutory metrics and regulatory criteria, after which such data will be used by the Board in considering which drugs may be referred to the Stakeholder Council or selected for cost review.[9] Subject to appropriate protections for confidential, trade secret, and proprietary information, the Board should give manufacturers and other stakeholders the opportunity to review and verify the data and provide comment before it is considered by the Board as part of its decision-making processes.

- The Cost Review Proposed Rule provides that Board staff may develop a list of therapeutic alternatives for each prescription drug product referred to the Stakeholder Council and provides that the Board staff "may" post the list of therapeutic alternatives on the Board's website for comment.[10] Subject to appropriate confidentiality protections, the Board should revise this provision to state that the Board shall post the list of therapeutic alternatives on the Board's website and provide an opportunity for public comment on the list before it is finalized.

- The Cost Review Proposed Rule provides that the Board may discuss the outcome of a Cost Review Study at an open meeting.[11] To allow for full and meaningful participation by stakeholders and the public, the Board should revise the rule 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. Presentation and consideration of confidential, trade secret, and proprietary information should only occur in a executive session.

- The Cost Review Proposed Rule provides that the Board may create and adopt a report of the cost review study.[12] The Board should provide an opportunity for public comment on a draft version of the report before it is finalized.

Aside from allowing for more meaningful public participation, these additional opportunities for stakeholder engagement and comment will facilitate more robust and accurate analyses and decision-making by the Board, and will help to mitigate the risk that the Board's decision-making could otherwise be inadvertently predicated on erroneous or incomplete data.

C. Need for Other Cost Review Process Reforms

[8] *See* Section IV, below.
[9] Cost Review Study Process Proposed Rule §§ 14.01.04.03(A), (B), (C), (H).
[10] *Id*. § 14.01.04.03(G).
[11] *Id*. § 14.01.04.05(D). PhRMA requests that the Proposed Rule be revised to explicitly require advance posting of this information.
[12] *Id*. § 14.01.04.05(F).

There are a number of other concerning aspects about the Board's Cost Review Proposed Rule. PhRMA highlights the following as examples:[13]

- ***Consideration of Medicare Drug Price Negotiation List***.[14] PhRMA opposes the Board's proposal to consider whether a drug has been selected for price negotiation under the federal Inflation Reduction Act ("IRA") as part of the Board's cost review process. It is premature for the Board to incorporate elements of the Medicare price setting process into its cost review selection process. The Medicare drug price setting process is not yet fully implemented, and its price setting will not take effect for several years. Incorporating elements of the IRA into Maryland's cost review process will create additional complexity and uncertainty given the many operational and legal issues of both processes that remain to be sorted out. The federal methodology is also designed to target drugs commonly used in an older and/or more disabled Medicare population, not the broader, younger, and more diverse population of Maryland patients. In addition, until the federal methodology has been implemented and taken effect, the Board will be unable to determine the impact that the IRA will have on a drug's accessibility and patient affordability. We therefore urge the Board to refrain from adding any reference to the Medicare process into these rules until that process is fully implemented and its impact on patients is understood.

- ***Assessment of the True Cost of Drugs (Gross vs. Net)***. PhRMA is concerned that the revised draft of the Proposed Rules would limit the Board's consideration to gross prices and revenue in certain circumstances.[15] Gross price and revenue information provide an incomplete picture of the affordability of prescription drugs; net price and cost information, which takes into account rebates, discounts, and other price concessions, more accurately reflect the true cost of drugs to payers and patients. On average, discounts, rebates, and price concessions lower the price that plans ultimately pay for medication by 49 percent.[16] PhRMA recommends that the Board consider, to the extent practicable, net price and cost information rather than, or in conjunction with, gross price and revenue information in order to more accurately determine the affordability of a prescription drug product.

- ***Consideration of International Prices.*** The Board proposes to request information from manufacturers on unit prices charged to purchasers in the United Kingdom, Germany, France, and Canada, which it may then consider as part of its cost review study process.[17] These prices are the result of price setting in those countries, and such policies have been shown to significantly limit patients' access to innovative medicines. For example, 85 percent of all new medicines launched between 2012 and 2021 are reimbursed in Medicare/Medicaid programs, compared to other countries' public health care programs where only 61 percent of new medicines are reimbursed in Germany, 48 percent in the United Kingdom, 43 percent in France, and 21 percent in Canada.[18] If the Board retains this element of the Proposed Rules despite the impact these price

[13] This list is not an exhaustive set of PhRMA's concerns regarding the Proposed Rules. As noted, PhRMA incorporates by reference its prior comments addressing various other areas of concern (e.g., accelerated approval, direct-to-consumer advertising, etc.).
[14] *Id*. § 14.01.04.03(B)(6).
[15] *Id.* §§ 14.01.04.02(D), 14.01.04.03(B)(3), 14.01.04.04(B)(1)(l).
[16] IQVIA, Use of Medicines in the US: Spending and Usage Trends and Outlook to 2026 (April 2022).
[17] Cost Review Proposed Rule §§ 14.01.04.04(B)(1)(i); 14.01.04.05(B)(1), (3).
[18] PhRMA analysis of IQVIA MIDAS and country regulatory data, October 2022. Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. A medicine is

setting policies have on patient access to medicines, we urge the Board to include consideration of patient access to medicines in those countries as well.[19]

II. DEFINITIONS PROPOSED RULE

PhRMA continues to have concerns with a number of the definitions used by the Board's Proposed Rules. PhRMA refers the Board to its prior comment letters (including its letter dated May 1, 2023) for a more comprehensive discussion of PhRMA's existing concerns related to various Board definitions. PhRMA also provides the following non-exhaustive list of comments and suggestions regarding the Board's June update to the Definitions Proposed Rule.

§	Proposed Term	PhRMA Comment
(B)(20)	Cost share	The Board proposes to define "Cost share" as "a patient's total out-of-pocket costs divided by the *patient's* total spending for a prescription drug product" (emphasis added). It is unclear from this definition which "costs" and "spending" are referred to. We recommend the definition be revised instead to define "Cost share" as "... *a patient's total out-of-pocket costs divided by the payor's cost for a prescription drug product*."
(B)(24)	Discount	The Board proposes to define "discount" as "a negotiated monetary adjustment that reduces the price paid or dollar amount received by an entity engaging in a prescription drug transaction that occurs during the prescription drug transaction as reflected on the invoice." PhRMA is concerned that this definition introduces unnecessary ambiguity and will be confusing to implement. Among other things, the wording of the definition makes it unclear if it would capture all price concessions that would traditionally be understood to constitute a discount (potentially including certain discounts that may or may not be reflected on an invoice). PhRMA recommends that the Board instead define "discount" to be "a reduction in the price, whether direct or indirect, that would otherwise be paid by a payor for a prescription drug, including any negotiated price reductions that may accrue directly or indirectly to a payor in connection with the dispensing or administration of a prescription drug that serve to reduce the payor's or payor's agent's liabilities for a prescription drug. PhRMA also notes that the Board's proposed definition of "discount" (and the Board's proposed definition of "rebate") uses the term "prescription drug transaction," but the term is not defined.[20] This makes the scope of the definition unclear.
(B)(59)	Standard medical practice	The Board proposes to define "Standard medical practice" as "the customary treatment by medical professionals: (a) Based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community; (b) Consistent with physician specialty society

considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is reimbursed by the public plan. A medicine is considered publicly reimbursed in the United Kingdom if recommended by England's National Institute for Health and Care Excellence (NICE) for funding by England's National Health Services (NHS).

[19] Additionally, reliance on prices set by foreign governments would indirectly import metrics like the quality adjusted life year ("QALY"). As discussed in our previous comment letters, patients and persons with disabilities in the U.S. have long held concerns about using the QALY. Yet drug reimbursement in the U.K. and Canada, two of the countries that would be referenced, are in part informed by an application of the QALY, which devalues innovative medicines. For further discussion on PhRMA's concerns regarding the use of QALYs or similar measures, *see* Letter from PhRMA to Board (May 1, 2023), at 12-13.

[20] Definitions Proposed Rule § (B)(55).

§	Proposed Term	PhRMA Comment
		recommendations; or (c) Consistent with the views of physicians practicing in the relevant clinical areas." PhRMA believes that adopting a more specific set of references in this definition will help guide the Board's considerations and enable the Board to avoid considering medical treatments that may be lacking in demonstrated medical evidence. In place of the (a), (b), and (c) elements in its current definition, PhRMA recommends that the Board adopt the following definition for "Standard medical practice": "*(a) citations in one or more of the statutory compendia used for Medicare or Medicaid payment purposes; (b) clinical practice guidelines issues by national medical societies; (c) Medicare coverage manuals, such as the Medicare Benefit Policy Manual; or (d) clinical research that appears in peer-reviewed medical literature appearing in the regular edition of at least one of the publications listed in Chapter 15, Section 50.4.5(C) of the Medicare Benefit Policy Manual and satisfies the criteria set forth in such section.*"
(B)(61)	Therapeutic alternative	The Board proposes to revise its definition of "Therapeutic alternative" to be "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug," and proposes to adopt a public comment process by which it will gather additional information on therapeutic alternatives for a particular prescription drug product.[21] As described in PhRMA's prior comments, not every drug product that has the same or similar indication as a particular drug can be considered a therapeutic alternative, and treatments that are the best option for some individuals are not as effective for others.[22] A narrower, more selective definition 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. RULES OF CONSTRUCTION PROPOSED RULE

As described in PhRMA's prior comments, the Board's Rules of Construction Proposed Rule lacks procedural details that would improve the ability of members of the public to participate in the Board's activities.[23] Among other things, we continue to recommend that the Board revise the Proposed Rule to provide clearer timelines as to the amount of advance notice that will be given regarding opportunities to provide oral and written comments and to establish clearer processes, including with respect to the submission of confidential information.

IV. CONFIDENTIAL, TRADE-SECRET, AND PROPRIETARY INFORMATION PROPOSED RULE

Consistent with our prior comment letters, PhRMA emphasizes the importance of safeguards against the disclosure of confidential information. While PhRMA appreciates the elements of the Board's proposed rules that aim to protect confidential, trade secret, and proprietary information, we continue to be

[21] Cost Review Proposed Rule §§ 14.01.01.01(B)(61) (definition of "Therapeutic alternative"); 14.01.04.03(G) (public comment process).
[22] Letter from PhRMA to Board (May 1, 2023), at 11-12. *See also* McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. PharmacoEconomics (2021), https://doi.org/10.1007/s40273-021-01075-w.
[23] Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023).

concerned that the Board's proposals are not sufficiently protective and do not adequately safeguard manufacturers' confidential, trade secret, and proprietary information, threatening the unlawful and unconstitutional disclosure of such information.[24]

The PDAB Statute imposes robust confidentiality protections on the information of manufacturers and other stakeholders. "Only Board members and staff may access trade secrets and confidential and proprietary data and information ... that is not otherwise publicly available"; "all information and data" shall be "considered to be a trade secret and confidential and proprietary information" and "is not subject to disclosure under the Public Information Act" if it is obtained by the Board "and is not otherwise publicly available."[25] These robust protections further bolster protections of confidential, trade secret, and proprietary information provided under federal and state law. Among other protections, the Fifth Amendment's prohibition against taking private property without just compensation prohibits the uncompensated disclosure of trade secrets, and courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[26]

PhRMA encourages the Board to incorporate clear standards in the Proposed Rules regarding how it will maintain the confidentiality of relevant information consistent with state and federal law, including by adopting the specific measures recommended in PhRMA's prior comment letters. This is especially critical because much of the information that the Board intends to collect from manufacturers and others is highly sensitive confidential, trade secret, proprietary, and otherwise non-public information.[27]

* * *

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 Charise Johnson at CJohnson@phrma.org.

Sincerely,

Joanne Chan
Senior Assistant General Counsel, Law
Head of State Legal Affairs

Charise Johnson
Director, State Policy

[24] *See, e.g.*, Confidential Information Proposed Rule; Definitions Proposed Rule § (B)(14) (definition of "Board staff"); Cost Review Proposed Rule § 14.01.04.05(D)(4).
[25] Md. Code Ann., Health-Gen. § 21-2C-10(a)–(b).
[26] *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). It has also long been recognized that manufacturers' confidential, trade secret, and proprietary information from disclosure cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act).
[27] *See generally* Cost Review Proposed Rule § 14.01.04.04.