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By Electronic Submission

May 1, 2023

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
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Re: Maryland Prescription Drug Affordability Board: Draft Amendments to General Provisions (COMAR 14.01.01.01) and Fee Assessment, Exemption, Waiver, and Collection Amendments (COMAR 14.01.02.02); Draft Regulations on Cost Review 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 the draft amendments to the General Provisions (COMAR 14.01.01.01, "General Provisions Proposed Rule") and Fee Assessment, Exemption, Waiver, and Collection regulations (COMAR 14.01.02.02, "Fee Assessment Proposed Rule"); and proposed Cost Review Process regulations (COMAR 14.01.03, "Cost Review Proposed Rule") (collectively, "Proposed Rules"), which were issued by the Maryland Prescription Drug Affordability Board ("Board") on April 14, 2023. 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.

We provide below our comments and concerns with respect to the Proposed Rules. PhRMA appreciates the Board's work to establish rules that implement its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[1] PhRMA has concerns, however, about the approach contemplated by the Proposed Rules. Among other things, and as explained in detail below, PhRMA is concerned that the Proposed Rules lack clear definitions and standards for conducting the cost review process. PhRMA is also concerned about the lack of standards and processes for evaluating the reliability of the data sources that the Board intends to rely upon as described in the Proposed Rules. In addition, PhRMA has concerns about the adequacy of the Board's safeguards to ensure the confidentiality of all trade secret, confidential, and proprietary information used in association with the cost review process and other activities of the Board.[2]

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

[2] In filing this comment letter requesting changes to the Proposed Rules, PhRMA reserves all rights to legal arguments with respect to the constitutionality of the Maryland PDAB statute. PhRMA appreciates this early opportunity to comment, 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 in order 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 AND DEFINITION PROPOSALS

A. Lack of Clear and Meaningful Standards

PhRMA is concerned that, in significant respects, the Cost Review Proposed Rule lacks sufficiently clear and meaningful standards and procedures to guard against the risk of inconsistent and arbitrary decision-making. The PDAB Statute requires the Board to promulgate regulations that: (1) establish methods for the collection of additional data necessary to carry out the Board's duties; and (2) identify circumstances under which the cost of a prescription drug may create affordability challenges.[3] These requirements demonstrate the legislature's plain intent that the Board establish specific methods and standards governing the cost review process. The legislature did so with good reason. Clear and meaningful standards are necessary to prevent inconsistent decision-making.[4] Further, "[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."[5]

The Cost Review Proposed Rule incorporates extensive lists and categories of information and data sources that the Board must (or may) consider as part of identifying eligible drugs, selecting them for cost reviews, and ultimately conducting such reviews—such as various spending and pricing data metrics and other data elements.[6] However, the Cost Review Proposed Rule lacks 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.

Because the Proposed Rule lacks meaningful standards for consistent decision-making, it also fails to give stakeholders visibility into how and under what circumstances the Board will use various categories of information. This lack of clear and concrete standards prevents stakeholders from meaningfully participating in and commenting on the Board's processes. Moreover, without these standards, it would be difficult or impossible for manufacturers and other stakeholders to predict if specific drugs may become subject to the Board's determinations. The vagueness of the applicable standards raises inherent concerns about whether selection decisions will be appropriately grounded in statutorily relevant factors bearing on affordability for Maryland residents. PhRMA urges the Board to revise the Cost Review Proposed Rule to provide greater clarity, including more specific information about how the Board will evaluate affordability and how various data sources will be considered and weighed as the Board makes its decision.

The lack of specific procedures and standards in the Proposed Rules and the varying timing of the different proposed rules that the Board will be releasing to implement the PDAB Statute makes it difficult to provide comprehensive comments without a complete view of what the Board is proposing. Once the Board has

[3] Md. Code Ann., Health-Gen. § 21-2C-08(b).

[4] *See Harvey v. Marshall*, 389 Md. 243, 302, 884 A.2d 1171, 1207 (2005) ("[A]n agency action nonetheless may be 'arbitrary or capricious' if it is irrationally inconsistent with previous agency decisions.").

[5] *Id.*

[6] *See, e.g.*, Cost Review Proposed Rule §§ 14.01.03.02–.05. The Cost Review Proposed Rule is unclear about the pricing and spending metrics upon which the Board will rely. For example, the Proposed Rule appears to contemplate assessing pricing or sales (or estimated sales) information at the NDC-level, but it is not clear what data source the Board will rely on or how the Board will assess drugs based on NDC-level information, which may include differing doses, administrations, and other characteristics for the same drug product.

released all planned proposed rules implementing the PDAB Statute, the Board should provide a separate comment period where stakeholders have the opportunity to comment on the complete set of proposed rules to ensure that there has been full, fair, and meaningful opportunity to comment on the entirety of the proceedings.

PhRMA provides below a non-exhaustive list of examples of the lack of clear standards within the Proposed Rules:

- **Drug Identification and Selection Processes**. The Cost Review Proposed Rule requires the Board to consider, "to the extent practicable," a number of metrics and criteria "[i]n addition to" those listed in the PDAB Statute, including aggregated top 100 spending and pricing data and patient out-of-pocket metrics for prescription drug products.[7] The selection of drugs process similarly contemplates the Board considering a range of information and data sources, including Food and Drug Administration ("FDA") approval type and date information, therapeutic class information; certain product specific spending, pricing, and out-of-pocket cost data; and publicly available direct-to-consumer advertising data.[8] However, the Cost Review Proposed Rule provides no explanation as to how these varied types of information will be weighed or balanced. Without some specific and principled methodology for how the Board proposes to use such information, it is impossible to ensure that these data sources will be evaluated in a consistent and reasonable manner.

- **Out-of-Pocket Cost and Price Concession, Discount, or Rebate Information**. PhRMA recommends that the Board consider the full context of factors impacting the affordability of prescription drugs, including on patient out-of-pocket cost. The Cost Review Proposed Rule includes consideration of various out-of-pocket cost related metrics as part of identification and selection of drugs for cost reviews and in the course of such reviews.[9] It is also unclear how the Board intends to use this information and whether the Board's approach will appropriately account for the full range of factors driving such out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment[10] and copay maximizer programs)[11] and fees, rebates, and other price concessions paid by drug manufacturers to pharmacy benefit managers ("PBMs") and health insurance plans that the PBMs and plans are not sharing directly with patients at the point of sale.

[7] Cost Review Proposed Rule § 14.01.03.02(D). PhRMA requests an appeals process or some other mechanism whereby manufacturers can submit data to correct any erroneous data in the lists.

[8] Cost Review Proposed Rule § 14.01.03.03. See Section I.C., below, for a discussion of PhRMA's concerns that some of the proposed metrics are not relevant to whether or not a drug "has led or will lead to affordability challenges for the State health care system or high out–of–pocket costs for patients." Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).

[9] Cost Review Proposed Rule §§ 14.01.03.02(D)(2), 14.01.03.03(B)(5), 14.01.03.05(C)(1). *See also* Section I.B., below, for a more comprehensive discussion of reliability of data sources.

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

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

These factors, which are determined by health plans and PBMs, are contributing to the inability of Marylanders to afford their health care. Yet it is not clear what weight the Board will give to the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of health plans and PBMs. The context for how out-of-pocket costs are determined should be considered alongside those costs so that proper weight can be given to the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of health plans and PBMs.

In addition, PhRMA notes that the Board's Proposed Rule appears only to contemplate consideration of benefit design and price concession, discount, and rebate information at the time of the cost review itself, and not at the time of identification of eligibility or selection of drugs for cost reviews.[12] The context of the benefit design and price concessions, discounts, and rebates is relevant to the cost and affordability of drugs and the selection of drugs for affordability review, and should be considered at *all* stages of the Board's process. For any drug that the Board does select for cost review, the Board should provide an explanation as to why affordability challenges posed by the drug are not the result of benefit design.

- **Public Input Regarding Personal Experiences with a Drug**. The Cost Review Proposed Rule would permit individual members of the public to report to the Board "their personal experiences with a drug or drugs that have caused or are causing an affordability issue for the individual."[13] While consideration of patient experience is important, PhRMA asks for clarification as to how this information will be considered, used, and weighed in context with other information considered by the Board, as well as how the Board will evaluate the individual report (e.g., to determine whether commenters are Marylanders who are commenting based on their own experience; whether the information is generalizable; whether the experience is due to insurance benefit design).[14]

  PhRMA also recommends that patients be able to share more than just personal experiences with drugs that have caused affordability issues, as this limits the Board's consideration to a one-sided perspective. Equally important is the ability of patients to share their experiences with a drug where they have *not* experienced affordability issues, including the clinical and quality of life benefits of a particular medicine.

[12] *See* Cost Review Proposed Rule § 14.01.03.05(C)(1)(d) (cost review provision allowing consideration of benefit design as part of evaluating patient access—but no parallel provision in the identification and selection sub-provisions), § 14.01.03.05(C)(1)(b) (cost review provision allowing consideration of rebate-related information—but no parallel provision in the identification and selection sub-provisions).

[13] Cost Review Proposed Rule § 14.01.03.01(A)(1).

[14] *See* Md. Code Ann., Health-Gen. § 21-2C-02(b) ("The purpose of the Board is to protect State residents" and others.). In particular, if this requirement is finalized as written, PhRMA asks that the Board design the form described in the Cost Review Proposed Rule to gather specific information regarding the specific drug product the individual is reporting on and the particular health plan or program under which the individual sought coverage of the drug. Cost Review Proposed Rule § 14.01.03.01(B). Without these key pieces of information, it will not be possible for the Board to consider these reports in a consistent or contextualized manner.

- **Drug-Specific "Patient Access Programs**." As part of the cost review process, the Board proposes that it may consider "the current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer."[15] Over the last several years, commercial health plans have increasingly shifted the burden of prescription drug costs to patients by exposing them to higher deductibles and to coinsurance as opposed to copays.[16] Coinsurance is based on the undiscounted list price of the medicine, which results in higher out-of-pocket costs for patients versus when fixed copays are used. Exacerbating the problem is that the health insurance company is paying the negotiated rate, reflecting manufacturer discounts, without directly passing those discounts on to patients. Due to this erosion of insurance coverage, manufacturers have stepped in to fill the void by offering cost-sharing assistance to help patients access and afford the medicines they need. In 2021, cost-sharing assistance offset $12 billion in patient out-of-pocket costs, up 50% from $6 billion in 2014.[17]

  In considering this information, the Board should not overlook the substantial patient benefits associated with patient assistance programs. A comprehensive literature review has found that cost-sharing assistance was associated with improved patient adherence to medicines, with the share of patients staying on treatment for one year increasing by up to 47%.[18] Given the important role of these programs for patients, PhRMA believes it would be beneficial if the Board further clarifies its standards surrounding consideration of information related to such programs as part of the cost review process.

  PhRMA notes that manufacturer support for charitable foundations typically is not directed to supporting a specific drug, given that federal guidance from the U.S. Department of Health and Human Services Office of Inspector General limits such direct support. Rather, donations are made by a manufacturer to a charitable foundation, and the foundation retains the authority and discretion to apply such support as they see fit (which may include providing cost-sharing assistance for multiple drugs from different manufacturers or providing financial support to patients for other, non-pharmaceutical products or services). Manufacturers retain no influence or control over how the charity administers its assistance program.

- **Data Management**. PhRMA asks for clarification about the Board's proposal to "account for data errors and extreme outliers" for any data-based metrics it relies on.[19] In particular, PhRMA would like to better understand how the Board intends to accomplish this, including how the Board will evaluate whether a data point is an "extreme outlier" and under what situations those data points may be excluded from the Board's consideration.

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[15] Cost Review Proposed Rule § 14.01.03.05(C)(1)(d)(iii).

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

[17] Fein, A. Drug Channels Institute. "2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers" (2022).

[18] Hung, A. B., D.V.; Miller, J.; McDermott, J.; Wessler, H.; Oakes, M.M.; Reed, S.D.; Bosworth, H.B.; Zullig, L.L.. Impact of Financial Medication Assistance on Medication Adherence: A Systematic Review. In Journal of Managed Care & Specialty Pharmacy (Vol. 27, pp. 924-935) (2021).

[19] Cost Review Proposed Rule § 14.01.03.03(C)(2).

B. Reliability of Information Sources Used by the Board

As a global matter, the Cost Review Proposed Rule contemplates the Board considering and using data from a range of disparate sources. For example, the Cost Review Proposed Rule states that various data elements used in identifying eligible drugs will be obtained from the Maryland All-Payer Claims Database's Medical Care Data Base ("MCDB")[20] or "data obtained from [alternative] governmental and commercial databases, other databases, and other data sets as available."[21] Likewise, for purposes of cost reviews, the Proposed Rule contemplates the potential for data from various entities.[22] The Board also proposes that it may use data and analyses derived from other sources, including Board staff analyses, external analyses and modeling studies, and from the MCDB or other databases.[23]

It is unclear how the Board will appropriately consider and weigh the reliability and validity of these varied data sources and how the Board will limit its consideration of data from these varied sources to the factors listed in the PDAB Statute and Cost Review Proposed Rule. Board decision-making can be only as accurate as the data sources that the Board relies upon, so PhRMA requests that the Board adopt processes to help reduce the risk that the Board's analyses may rely on erroneous, incomplete, or otherwise misleading datasets or analyses. We recommend that the Board provide a clear notice and comment period of at least 60 days between the identification of eligible drugs and the selection of drugs to allow for public comment, including on the data sources specifically relied upon by the Board in identifying an eligible drug. The PDAB statute requires collaboration and input from the public and the Stakeholder Council, and opportunities to provide such input will help the Board identify any areas where the data or analyses it relies upon may be misleading or incomplete.[24]

PhRMA notes the following as illustrative examples of its overarching concerns with respect to data reliability:

- **All-Payer Claims Database**. Despite the name, All-Payer Claims Databases such as the MCDB do not include all payers, and thus do not capture claims data for all insured individuals in Maryland. Rather, the MCDB categorically excludes data for various groups, such as for self-insured ERISA plans.[25] It likewise does not include any data for Federal Employee Program covered lives or Medicare and Medicaid data.[26]

  When using claims data from the MCDB, the Board should consider and account for the context in which those data are generated and collected, including any gaps or potential inaccuracies in the data, as well as the broader societal and economic trends or processes that may have

[20] Cost Review Proposed Rule § 14.01.03.02(A)(1).
[21] Cost Review Proposed Rule § 14.01.03.02(A)(2).
[22] Cost Review Proposed Rule § 14.01.03.03.
[23] Cost Review Proposed Rule § 14.01.03.05(B)(2).
[24] Cost Review Proposed Rule § 14.01.03.03(C)(2), (F), (G).
[25] *See* Maryland Health Comm'n, MCDB Data Release, https://mhcc.maryland.gov/mhcc/pages/apcd/apcd_data_release/apcd_data_release_mcdb.aspx (last updated Dec. 9, 2022).
[26] *Id*.; RAND, The History, Promise and Challenges of State All Payer Claims Databases 44 (2021) (stating the MCDB does not receive Medicare or Medicaid data).

impacted the data. In light of the recognized limitations of all-payer claims databases, we ask that the Board adopt mechanisms to verify that any consideration or use of MCDB-based data by the Board be evaluated for whether it may be biased or misleading. Stakeholders should also be given an opportunity to review and critique any MCDB data that the Board intends to rely upon and provide additional or alternative data or context for the Board's consideration.

- **Net Cost and Net Sales Amounts**. When estimating manufacturer "net-cost and net-sale amounts" for prescription drugs subject to cost review,[27] it is not clear which data sources the Board intends to rely upon to obtain this information or how such estimates will be derived and evaluated. It is also unclear how the Board will weigh this information when taken together with other information, potentially from other sources, that the Board is considering. PhRMA emphasizes that certain sources of information may 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.

More broadly, PhRMA asks that the Board provide an opportunity for stakeholder review and comment on the datasets and analyses or modeling that the Board relies upon for its activities.[28] These procedures will facilitate more robust and accurate analyses and decision-making and will help to mitigate the risk that the Board's decision-making could otherwise be inadvertently predicated on erroneous or incomplete data.[29]

C. Nomination and Selection of Drugs for Eligibility

PhRMA has significant concerns about the Board's proposed processes for identifying eligible drugs and selecting the drugs for review.

First, with respect to the eligibility process, PhRMA is concerned about the breadth of factors proposed to be considered. PhRMA notes that the PDAB Statute focuses the identification of eligible drugs on certain concrete factors, such as brand name drugs with a wholesale acquisition cost at launch of $30,000 or more or a wholesale acquisition cost increase of $3,000 or more in any 12-month period (or course of treatment if less than 12 months).[30] While the PDAB Statute also includes a provision that permits the Board to consider, in consultation with the Stakeholder Council, "other . . . drugs that may create affordability challenges" beyond those meeting the specific statutory factors,[31] PhRMA is concerned that

[27] Cost Review Proposed Rule § 14.01.03.05(C)(1)(a)(ii).

[28] Where providing that opportunity to stakeholders would require the disclosure of confidential, trade secret, or proprietary information, such disclosure should be strictly limited only to those entities for whom access would not violate state and federal protections for the information. Any confidential, trade secret, or proprietary information contained in stakeholder comments should be appropriately protected by the Board from disclosure. *See* discussion of appropriate protections for confidential, trade secret, and proprietary information in Section III, below.

[29] *See* discussion about establishment of a process for stakeholder submission of information throughout the Board's process in Section I.H. below.

[30] Md. Code Ann., Health-Gen. § 21-2C-08(c)(1).

[31] *Id.* § 21-2C-08(c)(4). As part of its statutorily mandated "consultation with the Stakeholder Council," PhRMA requests that the Board routinely involve the Stakeholder Council in substantive discussions of its selection of drugs for potential cost review, particularly for drugs selected not based on the statutory thresholds listed under

the list of additional data elements identified in the Board's proposed rule risks hijacking the Board's focus away from the core factors specifically identified by the legislature. The plain text of the PDAB Statute enables the Board to consider additional prescription drug products "in consultation with the Stakeholder Council" on a case-by-case basis, and not to add myriad new criteria that fundamentally change the scope of drugs that can be considered for cost review, while only consulting with the Stakeholder Council "if practicable."[32]

Second, PhRMA is concerned that some of the data elements that the Board proposes to consider are not relevant to the affordability of a prescription drug. For example, information about direct-to-consumer ("DTC") advertising is not relevant to whether a given medicine may create affordability challenges,[33] so it would be misleading to consider such information. DTC advertising has proven to benefit patients by raising awareness, removing stigma from certain conditions, promoting adherence to medicine, and encouraging productive patient-provider discussions.[34] Surveys conducted concur with these findings, including a survey by the U.S. Food and Drug Administration ("FDA") that concluded, "[b]y and large, DTC advertising seems to increase [patients'] awareness of conditions and treatments, motivate questions for the health care provider, and help patients ask better questions."[35] Additionally, marketing and promotion activities are highly regulated by FDA, and companies devote significant resources to ensure responsible and truthful promotion. The Office of Prescription Drug Promotion ("OPDP") within FDA is dedicated to overseeing all biopharmaceutical marketing and promotion activities.[36]

PhRMA also has serious concerns with respect to the Board's proposal to consider federal support for research and development ("R&D") and pricing data from other countries in situations where the Board is unable to determine if a drug has produced affordability challenges.[37] Neither of these factors has any bearing on whether a particular drug is affordable for Maryland residents. Empirical research has shown that public-sector research tends to increase private R&D rather than to decrease it, and according to a

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Md. Code Ann., Health-Gen. § 21-2C-08(c). Such consultation should provide Stakeholder Council members an opportunity to meaningfully comment on the Board's determinations.

[32] Cost Review Proposed Rule § 14.01.03.03(F). *See also, e.g.*, *Wynn v. State*, 351 Md. 307, 333, 718 A.2d 588, 601 (1998) ("Under this argument, the exception would swallow the rule . . . We do not believe that . . . the exception goes so far."). For example, the Board proposes to categorically identify "all insulins marked in the State" as eligible for cost review. Cost Review Proposed Rule § 14.01.03.02(D)(4). It is contrary to the requirements of the PDAB Statute for the Board to assume an entire class of therapies could create affordability challenges, particularly to do so without undertaking the drug-specific identification and Stakeholder Council consultation processes required by the PDAB Statute.

[33] *See* Cost Review Proposed Rule § 14.01.03.03(B)(5).

[34] Food and Drug Administration, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drug – Summary of FDA Survey Research Results," November 19, 2004.

[35] *Id.*

[36] In addition to government oversight, PhRMA has adopted a voluntary Code on Interactions with Health Care Professionals and Direct to Consumer Advertising Principles that provide guidelines for companies' promotional communications. *See PhRMA,* "Code on Interactions With Health Care Professionals," https://phrma.org/resource-center/Topics/STEM/Code-on-Interactions-with-Health-Care-Professionals; PhRMA, "Direct to Consumer Advertising Principles," https://phrma.org/resourcecenter/Topics/Cost-and-Value/Direct-to-Consumer-Advertising-Principles.

[37] *See* Cost Review Proposed Rule § 14.01.03.05(E).

Congressional Budget Office report they are complements, not substitutes.[38] Several recent studies have associated increases in National Institutes of Health ("NIH")-funded basic research with increased private R&D efforts.[39] This complementary relationship is largely due to the fact that NIH funding focuses primarily on basic research, while private spending focuses on applying that basic research to the development of new medicines. With regard to pricing data from other countries, these prices reflect health systems that prioritize cost control over patient access to new medicines. Years of research have consistently shown that significantly fewer new medicines are available to patients in those countries, which also experience significant delays in the availability of medicines that patients do eventually access.[40] As a result, reliance on these data elements could be highly misleading and is ultimately inconsistent with the Board's statutory mandate to assess affordability challenges for Marylanders.

Third, PhRMA has serious concerns about the process for Board members nominating and the Board selecting eligible drugs. The Cost Review Proposed Rule contemplates permitting Board members to propose one or more additional prescription drug products for inclusion on the list of eligible drugs.[41] After discussion at the open meeting, the Board may vote to add nominated drugs to the list of drugs eligible for selection for cost review.[42] PhRMA is concerned that the Board's proposed approach creates the risk of arbitrary decision-making.[43] We urge the Board to modify its proposal to require that Board members provide explanations for both the nomination and selection for eligibility list decisions, and that such explanations be included on the record and explain how and why the selection of the drug is relevant to the Board's objectives.[44] Agency action must be consistent with the enabling statute and the statute's policy goals, and the agency must provide a contemporaneous record of its decision-making: agency action cannot be upheld "unless it is sustainable on the agency's findings and for the reasons stated by the agency."[45] These steps are a necessary pre-requisite to a fair and transparent process.

D. Use of Active Moiety or Active Ingredient Information in Selecting Drugs

PhRMA has concerns about the Board's proposal to include "all NDCs with the same moiety or active ingredient" in the cost review for a selected drug.[46] The plain language of the PDAB Statute requires identification of drug products based on individualized consideration of each selected drug. The PDAB Statute provides an express definition of "prescription drug product" that defines the term to mean a

[38] Congressional Budget Office (CBO). Research and Development in the Pharmaceutical Industry (2021), https://www.cbo.gov/publication/57126#footnote-042.
[39] See Wendy H. Schacht, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Report RL32324 (Congressional Research Service), November 30, 2012.
[40] Global Access to New Medicines Report, April 2023, https://phrma.org/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report.
[41] PhRMA also refers the Board to its separate discussion below in Section I.D. about concerns with the Board's proposal to add drugs to the review process that share an active moiety or active ingredient with a selected drug.
[42] *See generally* Cost Review Proposed Rule § 14.01.03.02(E)–(F).
[43] *See* Md. Code Ann., Health-Gen. § 21-2C-01.
[44] The Board "shall determine whether . . . 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." Md. Code Ann., Health-Gen. § 21-2C-09(b)(1)
[45] *Maryland Racing Comm'n v. Belotti*, 130 Md. App. 23, 52 (1999) ("The courts may not accept appellate counsel's post hoc rationalizations for agency action.").
[46] Cost Review Proposed Rule § 14.01.03.03(G)(5).

brand name drug, a generic drug, a biologic, or a biosimilar.[47] The terms "brand name drug," "generic drug," "biologic," and "biosimilar" are also statutorily defined terms, and are defined by reference to their distinct FDA approvals or licensures (e.g., based on the distinct New Drug Application ("NDA") or Biologics License Application ("BLA") approval).[48] Drugs with distinct FDA approvals or licensures may nonetheless be based on a common active moiety or active ingredient.

The legislature unambiguously defined these terms with respect to each drug's individual approval and mandated that each prescription drug product be separately and independently evaluated before being subject to a cost review. The Board cannot propose to short circuit this statutory requirement by automatically including drugs with the same active ingredient or active moiety into the cost review that applies to a different prescription drug product. The Board's proposal is expressly contrary to the language of the PDAB Statute because it impermissibly treats distinct prescription drug products as being the same for purposes of initiating a cost review.

It is especially concerning that the Board would propose to do so because grouping drugs by active ingredient or active moiety could result in exceedingly broad and misleading comparisons. It would result in disparate products being unfairly grouped together for cost review purposes. This could have troubling implications and would ultimately risk misrepresenting the affordability of distinct prescription drug products considered as part of the cost review process.

E. Accelerated Approval Pathways and Other Information

The Board's Cost Review Proposed Rule contemplates consideration of whether a "prescription drug product was approved through an FDA accelerated approval pathway" as part of the cost review selection process[49] and for the cost review itself.[50] However, the Cost Review Proposed Rule does not explain how the Board intends to use or weigh this information in its decision-making, and we ask that the Board clarify how it plans to do so.

Prescription drugs approved through FDA's accelerated approval pathway are critical for the treatment of many diseases.[51] For example, FDA has noted that the "accelerated approval pathway is commonly used for approval of oncology drugs in part due to the serious and life-threatening nature of cancer."[52] Medicines granted accelerated approval must adhere to the same standards for safety and effectiveness as medicines receiving a traditional FDA approval, including substantial evidence of effectiveness based on adequate and well-controlled clinical investigations.[53] The availability of FDA's accelerated approval pathway is important because the development of innovative medicines is a lengthy and complex process, taking an average of 10 to 15 years. The accelerated approval pathway has expedited the availability of

[47] Md. Code Ann., Health-Gen. § 21-2C-08(c).
[48] *See* Md. Code Ann., Health-Gen. § 21-2C-01(b), (c), (e), (f).
[49] Cost Review Proposed Rule § 14.01.03.03(B)(1)(c).
[50] Cost Review Proposed Rule § 14.01.03.05(B)(3).
[51] Nat'l Org. for Rare Diseases, FDA's Accelerated Approval Pathway: A Rare Disease Perspective (2021), *available at* NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf (rarediseases.org).
[52] FDA, FDA Issues Draft Guidance Aimed at Improving Oncology Clinical Trials for Accelerated Approval (Mar. 24, 2023).
[53] See FDA, Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), *available at* https://www.fda.gov/media/86377/download.

drugs that offer substantial health gains, making therapies available to patients many years (a median of 3.2 years) earlier than under traditional pathways.[54] In fact, research has shown that drugs approved through the accelerated pathway "offered larger health gains, compared to drugs approved through conventional review processes."[55]

PhRMA also requests greater clarification as to the Board's intent in considering certain other information, such as the date of first approval and, if applicable, when the last patent expired or will expire.[56] It is not clear from the Proposed Rules how the Board will use and weigh this information. PhRMA requests that the Board revise the Cost Review Proposed Rule to supply greater details about how the Board will determine and consider this information within its affordability review of prescription drugs.

F. Therapeutic Alternatives

PhRMA strongly recommends that the Board use caution when considering information regarding "therapeutic alternatives" for particular medications. Unlike FDA-recognized therapeutic equivalents, a therapeutic alternative does not use the same active ingredient and may have broader variability in its chemical make-up, thereby increasing the risk of negative outcomes. Drugs within a particular therapeutic class will often have significant differences, including in their chemical formulas, mechanism of action, and safety and effectiveness profiles, even though the drugs treat a similar clinical indication. A patient who can safely and effectively use one drug in a therapeutic class may experience increased risk of negative outcomes (e.g., drug interactions, side effects, treatment failures) with another drug in the class. Patients respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-morbidities. This means that treatments that are the best option for some individuals are not as effective for others.[57]

The Board should carefully consider when and under what circumstances it will consider information regarding therapeutic alternatives, especially those that are not therapeutically equivalent. Currently, the Board proposes to define "therapeutic alternative" to mean a drug product that "(1) contains a different therapeutic agent than the subject drug, (2) is in the same or a different pharmacological or therapeutic class, and (3) has similar therapeutic effects, safety profile, and expected outcomes when administered to patients in a therapeutically equivalent dose."[58] However, the proposed definition does not describe how the Board will determine whether a drug is "similar" in effect, safety profile, and outcomes to its comparator.

PhRMA is concerned that this proposed definition will result in invalid and inconsistent comparisons. Accordingly, we recommend 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 a similar therapeutic

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[54] Beakes-Read, G., Neisser, M., Frey, P. et al. Analysis of FDA's Accelerated Approval Program Performance December 1992–December 2021, Ther Innov Regul Sci (2022), *available at* https://doi.org/10.1007/s43441-022-00430-z.

[55] James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process, 36 Health Affairs 1408, 1408 (2017).

[56] Cost Review Proposed Rule § 14.01.03(B)(1).

[57] 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.

[58] General Provisions Proposed Rule § 14.01.01.01(57).

effect, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose in order to be considered a therapeutic alternative. Additionally, in any situation where the Board considers therapeutic alternatives, patients with unique requirements, such as immunocompromised patients, pediatric patients, women—particularly those who are pregnant—and the elderly, who require multiple medications for acute and chronic illnesses, should be given special consideration.

G. Consideration of Cost-Effectiveness Analyses

The Cost Review Proposed Rule permits the Board to consider cost and comparative effectiveness analyses as part of its cost review, including information about incremental costs associated with prescription drugs (compared to baseline effects of existing therapeutic alternatives) and information derived from health and economics and outcomes research.[59] PhRMA strongly urges the Board to exclude cost-effectiveness analyses that rely on quality-adjusted life years ("QALYs") or similar metrics from consideration.[60]

PhRMA is concerned that QALYs and similar value assessment metrics fail to account for important elements of value that matter to patients and society. QALYs obscure important differences that are disproportionately faced by underserved populations. In fact, QALYs are acknowledged by experts to discriminate against people with disabilities by placing a lower value on their lives.[61] The Board should not give weight to these types of measures, which inappropriately assign diminished value to the elderly and disabled and do not put a premium value on preservation of life.[62]

PhRMA also cautions against the use of metrics, such as the "equal value life year granted" ("evLYG") metric, which purport to resolve issues associated with the QALY, but that still fail to capture the full benefits, both direct and indirect, that treatments may have on improving a patient's quality of life. While the evLYG addresses some issues with QALYs, there remains stakeholder-wide consensus that the evLYG has significant limitations and is far from an adequate alternative to the QALY.

Such measurements accounting for "clinical efficacy" also often obscure the distinct needs of disadvantaged populations, including communities of color, by rendering judgments about value based on "average" study results, which often reflect primarily white populations and ignore diversity in preferences and other factors that impact health, such access to care, education, and literacy.[63] For example, the value of a lifesaving treatment for Black patients can be automatically valued up to 10% less than for white patients due to biased value metrics such as the QALY.[64]

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[59] *See* Cost Review Proposed Rule § 14.01.03.05(C)(1)(e).

[60] Under the PDAB Statute, the Board has clear discretion *not* to consider such QALY-related metrics. *See*, e.g.*,* Md. Code Ann., Health-Gen. § 21-2C-09(a)(2)(ii) (no mandate to consider cost-effectiveness research, much less any particular type of cost-effectiveness research).

[61] National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. (Nov. 2019) https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

[62] *See id.*

[63] Broder, M, Ortendahl, J. Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research (2021), *available at* https://blogsite.healtheconomics.com/2021/08/is-cost-effectiveness-analysis-racist/.

[64] *Id.*

PhRMA strongly believes that in the interests of health equity and sound policy judgment, the Board should commit to excluding consideration of QALY-based measures and similar metrics, such as the evLYG, from the Board's decision-making. If, despite their discriminatory impact, the Board decides to permit consideration of these metrics, PhRMA requests that the Board establish clear standards surrounding the use of such information, including prohibitions against giving material weight to evidence based on QALYs or other metrics where doing so would discriminate against persons with disabilities, communities of color, and other under-served populations.

H. Information Request Provisions

PhRMA believes there should be greater opportunity for manufacturers and other stakeholders to provide appropriately protected confidential information for the Board's consideration in closed session and through written comments, including information that may provide important context for the Board's evaluation of statutory or proposed regulatory factors for consideration.[65]

Currently, the Board's proposal permits the Board in instances "where there is no publicly available information to conduct an aspect of the statutory cost review" to solicit information from manufacturers and certain other entities.[66] However, other than this information request, the only opportunity to provide information to the Board appears to be through either public statements or written comments related to the open meeting process.[67]

In order to facilitate an exchange between the Board and manufacturers of information relevant to the cost review process, PhRMA encourages the Board to revise its Proposed Rules to give stakeholders a process for submitting information to the Board, with appropriate safeguards for protecting stakeholders' confidential, trade secret, and proprietary information.[68] Among other things, PhRMA believes there should be multiple opportunities for submission of information, including at the selection, eligibility, and cost review phases of the Board's assessment.

I. Proposed Definitions

PhRMA is concerned with a number of definitions proposed in the General Provisions Proposed Rule and provides the following non-exhaustive list to illustrate the need for greater clarity with respect to various proposed definitions:

§	Term	PhRMA Comment
General Provisions Proposed Rule, § 14.01.01.01(B)(10)	"Average wholesale price (AWP)"	PhRMA recommends that the Board revise its definition to reflect that it will obtain Average Wholesale Price

[65] The same protections can also apply to information provided in responses to a Board request, e.g., under Cost Review Proposed Rule § 14.01.03.04.
[66] *See* Cost Review Proposed Rule § 14.01.03.04(A)(2), (C); *see also* Md. Code Ann., Health-Gen. § 21-2C-09(a)(2).
[67] *See* Cost Review Proposed Rule § 14.01.03.03(D).
[68] *See generally* Cost Review Proposed Rule § 14.01.03.04. *See also* the discussion of the Board's protection of confidential, trade secret and proprietary information in Section III, below.

§	Term	PhRMA Comment
		information from a recognized national drug pricing reference file.
(B)(22)	"Coupon"	PhRMA is concerned that use of the term "voucher" in the definition of "coupon" is unnecessarily limiting and creates ambiguity. In practice, patient financial assistance takes many forms and is not limited to vouchers. The Board should consider revising as follows: "Coupon" means a voucher, debit card, or other form of financial assistance intended to help consumers pay their cost-sharing obligation for a prescription drug product.
(B)(24)	"Discount"	The Board's proposed definition of "discount" is limited to consideration provided by a supply chain entity "to a pharmacy," when in practice discounts may be provided to other entities, including wholesalers, distributors, PBMs, insurers, and health plans. We also note that, as proposed, the term "rebate" is limited to amounts paid by a manufacturer while a "discount" can be paid by any supply chain entity. The reason for this distinction is unclear, as rebates may be paid by entities other than manufacturers.
(B)(25)	"Drug Class"	See the discussion of therapeutic class and use of active moiety or active ingredient information in selecting drugs in Section I.D., above. Such criteria could result in broad and misleading comparisons.
(B)(26)	"Drug specific patient access program"	See the discussion of patient assistance programs at Section I.A., above.
(B)(44)	"Net Cost"[69]	See the discussion of net cost and net sale amounts at Section I.B., above.

[69] *See also* the discussion of reliability of data sources at Section I.B., above.

§	Term	PhRMA Comment
(B)(46)	"Payor"	The Board's proposed definition of "payor" could be interpreted to include entities other than health insurers, health benefits plans, or government benefits programs that pay for health care costs. For example, the proposed definition could be read to include family members who are responsible for paying a patient's deductibles or cost-sharing on the patient's behalf.
(B)(52)	"Rebate"	PhRMA is concerned that the Board's proposed definition of "rebate" does not capture the full range of potential price concessions. We recommend that the Board define "rebate" broadly to capture the full spectrum of these payments, as follows: "Rebate" means: (a) Negotiated price concessions including but not limited to base price concessions (whether described as a "rebate" or otherwise) and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue directly or indirectly to the payor during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug product, and (b) Reasonable estimates of any negotiated price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through, to a payor and serve to reduce the payor's liabilities for a prescription drug product.
(B)(57)	"Therapeutic alternative"	See the discussion in Section I.F., above, regarding PhRMA's concerns with the

§	Term	PhRMA Comment
		Board's proposed definition of "therapeutic alternative."

PhRMA notes that the General Provisions Proposed Rule also incorporates some definitions that do not appear to be used in the Proposed Rules currently set forth by the Board.[70] To the extent that these proposed definitions are provided in anticipation of future proposed rules, PhRMA requests that stakeholders be given an additional opportunity to comment on these terms once the additional substance of those future proposed rules has been provided by the Board.

II. FEE ASSESSMENT, EXEMPTION, WAIVER, AND COLLECTION AMENDMENTS PROPOSALS

A. Fee Assessment Methodology

While PhRMA recognizes that the Board's total fee assessments are capped under the PDAB statute, we also note that the PDAB Statute requires the Board to assess fees in a "fair and equitable manner."[71] PhRMA requests that the Board adopt a specific fee methodology addressing how the Board will meet this requirement.

B. Exemption Process

PhRMA appreciates the Board's efforts to specify an exemption process, which PhRMA understands to be intended to reduce burdens on regulated entities. However, PhRMA requests that the Board adopt a broader approach for seeking exemptions than what it has proposed. Under the Fee Assessment Proposed Rule, exemption requests would be limited to being made within 30 days of receiving notice of an assessment.[72] The exemptions process appears to be aimed at identifying entities for which the Board lacks statutory authority to assess a fee.[73] As such, PhRMA requests that the Board accept exemption requests that are received more than 30 days of the notice of assessment because such entities are statutorily exempt from fee assessments even after 30 days have elapsed. At a minimum, additional time beyond 30 days should be provided to submit an exemption where the applicant shows there is good cause for the submission of the request.

C. Reconsideration Process

PhRMA also recommends additional procedural protections related to reconsideration.[74] The Fee Assessment Proposed Rule would give regulated entities 15 days to request reconsideration of a denial of an exemption request, which must include any additional information and documentation needed to support the request. If additional information or documentation is not provided, the request will be

[70] For example, the definition of "aggrieved person" in General Provisions Proposed Rule § 14.01.01.01(B)(4).
[71] Md. Code Ann., Health-Gen. § 21-2C-11(b)(4), (b)(2)(ii).
[72] Fee Assessment Proposed Rule § 14.01.02.02(B).
[73] *Compare* Md. Code Ann., Health-Gen. § 21-2C-11(b)(1) with Fee Assessment Proposed Rule § 14.01.02.02(B)(2)(a)-(c).
[74] *See* Fee Assessment Proposed Rule § 14.01.02.02(C).

automatically denied.[75] PhRMA believes there are several ways the reconsideration process could be improved:

- First, as drafted, the process appears only intended to address situations where additional documentation or information may overturn the Board's previous denial.[76] However, there may be other reasons for which an assessed party seeks the Board's reconsideration, for instance due to a mistake of fact or law in the underlying decision. PhRMA asks that the Board create a reconsideration appeal that permits reevaluation of information or documents previously submitted, as well as new information or documents. As the enforcement entity that decides whether to impose a penalty in the first instance, the Board is not a neutral party to the initial denial of the exemption or waiver request.[77] As such, in order to protect the fairness of that process, the reevaluation should be conducted by a neutral third-party adjudicator rather than Board staff who may have been involved in the underlying decision making and appeals process.[78]

- Second, PhRMA requests that the Board provide a reconsideration process for both exemption and waiver requests.

- Third, PhRMA is concerned that the Board's 15-day time window may not provide adequate time for stakeholders to file a complete reconsideration request, particularly in cases involving complex issues. PhRMA recommends that the 15-day period be extended to be 60 days by default, with opportunity for extensions where good cause and the interests of fairness and equity support additional extensions.

D. Waiver Process

PhRMA also appreciates the Board's proposal to establish a waiver process. However, as drafted, the Fee Assessment Proposed Rule appears to authorize waivers only where an entity attests, with supporting documentation, that the amount of the assessment would exceed 1 percent of the entity's Maryland revenue in a specified year.[79] PhRMA encourages the Board to consider a more flexible approach to waivers. Consistent with the language of the PDAB Statute, PhRMA recommends that the Board specify it has discretion to grant waivers where, based on the totality of circumstances, imposition of an assessment would violate principles of "fair[ness] and equit[y]" required in the calculation of annual fee amounts.[80] The Board could further specify that this includes, but is not limited to, any situations where the assessment would exceed the 1% of Maryland revenue benchmark currently set forth in the waiver section of the Fee Assessment Proposed Rule.

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[75] *Id.*

[76] *See* Fee Assessment Proposed Rule § 14.01.02.02(C)(1).

[77] *In re Murchison*, 349 U.S. 133, 136 (1955) ("[N]o man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.").

[78] *See In re Murchison*, 349 U.S. at 136 (1955) ("A fair trial in a fair tribunal is a basic requirement of due process"); *see also Concrete Pipe & Prod. of California, Inc. v. Constr. Laborers Pension Tr. for S. California*, 508 U.S. 602, 617 (1993) ("due process requires a 'neutral and detached judge.").

[79] *See* Fee Assessment Proposed Rule § 14.01.02.02([C])(2) (waiver proposal, which is the second subdivision (C) in the Proposed Rule provision).

[80] Md. Code Ann., Health-Gen. § 21-2C-11(b)(2).

E. Collection and Penalties

With respect to the collection and penalty provisions in the Fee Assessment Proposed Rule, PhRMA requests that the Board establish a mechanism that allows the accrual of interest to be fully or partially waived where good cause and the interests of equity and fairness supports such waiver under the totality of the circumstances.[81] PhRMA believes that a discretionary good cause waiver process is appropriate, as there may be circumstances where interest penalties would be disproportionate or where it would otherwise be unreasonable or unjust to impose interest penalties based on the facts and circumstances. We also ask that interest be suspended while reconsideration (or any appeal) is pending.

III. CONFIDENTIALITY

PhRMA appreciates the Board's proposed protections for confidential, trade secret, and proprietary information, but is concerned that the provisions do not sufficiently protect against the unlawful and unconstitutional disclosure of such information.

The PDAB Statute imposes robust confidentiality protections on the information of manufacturers and other stakeholders. Per the statute, "[o]nly Board members and staff may access trade secrets and confidential and proprietary data and information . . . that is not otherwise publicly available." Further, "all information and data" shall be "considered to be a trade secret and confidential and proprietary information" and shall not be "subject to disclosure under the Public Information Act" if it is obtained by the Board "and is not otherwise publicly available."[82]

These robust state law protections bolster guarantees of confidentiality provided under federal law. It has long been recognized that manufacturers' confidential, trade secret, and proprietary information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets.[83] In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets.[84] 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."[85] PhRMA is concerned that the Proposed Rules do not adequately provide the strong confidentiality safeguards guaranteed under federal and state law.

To illustrate these serious concerns and the need for stronger safeguards, PhRMA makes the following observations and recommendations:[86]

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[81] *See* Fee Assessment Proposed Rule § 14.01.02.02(D)(1).

[82] Md. Code Ann., Health-Gen. § 21-2C-10(a)–(b).

[83] See 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act).

[84] See, e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). The Fifth Amendment's Taking Clause applies against the states under the Fourteenth Amendment.

[85] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).

[86] PhRMA will be submitting additional comments regarding protection of confidential, trade secret, and proprietary information in response to the Board's Draft Regulations on Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04).

- First, PhRMA is concerned that the Proposed Rules do not incorporate adequate detail to demonstrate how the Board will maintain the confidentiality of sensitive information provided to the Board. For example, PhRMA notes that the Board's proposed Request For Information provisions contemplate persons submitting information to the Board "clearly designat[ing]" the specific information the person considers to be confidential, trade secret, or proprietary.[87] However, the PDAB Statute imposes an independent obligation on the Board and its staff, rather than on submitters, to ensure that all such confidential, trade secret, and proprietary information is protected against disclosure.[88] This distinction is especially important because the Cost Review Proposed Rule would permit the Board to request information from multiple stakeholders that may possess relevant information for the cost review process—information that such stakeholders may have obtained from other entities.[89] If a submitter possesses confidential information of another entity, there is a significant risk that the submitter may not appropriately label such information as confidential, trade secret, or proprietary because the submitter may not recognize that the information is treated as such by the other entity. This is particularly problematic because, in situations where one entity submits information obtained from a second entity, the second, non-submitting entity may receive no notice of the submission, and thus will have no opportunity to "clearly designate" the specific information as confidential, trade secret, or proprietary.[90]

- Second, where the Cost Review Proposed Rule states that the Board "may consider confidential, trade-secret and proprietary information in a closed session," PhRMA recommends that the Cost Review Proposed Rule be revised to specify that the Board may ***only*** consider such information in closed sessions.[91]

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 or 202-572-7785.

Sincerely,

Charise Johnson
Director, State Policy

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

[87] Cost Review Proposed Rule § 14.01.03.03(C)(2).
[88] *See* Md. Code Ann., Health-Gen. § 21-2C-10(a).
[89] *See, e.g.*, Cost Review Proposed Rule § 14.01.03.03(B)(1)-(4).
[90] Cost Review Proposed Rule § 14.01.03.03(C)(2).
[91] Cost Review Proposed Rule § 14.01.03.03(C)(5).