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By Electronic Submission

May 4, 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 Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04)

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 regulations regarding Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04) ("Proposed Rule"), which were issued by the Maryland Prescription Drug Affordability Board ("Board") on April 24, 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 our comments and concerns below with respect to the Proposed Rule. 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 adequacy of the Board's safeguards for ensuring the confidentiality of all trade secret, confidential, or proprietary information used in association with the cost review process and other activities of the Board, and for preventing the unlawful and unconstitutional disclosure of such information.[2]

As the Board is aware, the PDAB Statute provides robust protections with respect to confidential information of manufacturers and other stakeholders. The PDAB Statute states: "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."[3]

These requirements in the PDAB Statute are consistent with the protections for trade secret, confidential, and proprietary information provided under state and federal law; such information cannot be publicly

[1] *See* Md. Code Ann., Health-Gen. §§ 21-2C-01–16.
[2] In filing this comment letter requesting changes to the Proposed Rule, 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, 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).
[3] Md. Code Ann., Health-Gen. § 21-2C-10(a)–(b).

disclosed without violating state and federal prohibitions against the misappropriation of trade secrets.[4] In addition, the Fifth Amendment of the US Constitution prohibits taking private property without just compensation and thus similarly prohibits the uncompensated disclosure of trade secrets.[5] 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."[6]

PhRMA is concerned that the Proposed Rule does not adequately effectuate the strong confidentiality safeguards guaranteed under federal and state law. PhRMA refers the Board to our letter submitted on May 1, 2023 with respect to general confidentiality concerns, including those pertaining to the Board's current proposed definitions and cost review processes.

PhRMA specifically emphasizes the following considerations related to the Board's Confidentiality Proposed Rule:[7]

- First, PhRMA is concerned that the Proposed Rule does 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 Rule requires a person submitting information to the Board to "clearly designate" the specific information that the person considers to be confidential, trade-secret, or proprietary.[8] Yet for information *not* specifically designated by the submitter, the Proposed Rule merely states that the Board "may" determine such information is confidential, trade secret, or proprietary.

  PhRMA emphasizes that the PDAB Statute imposes an independent obligation on the Board to ensure that all such confidential, trade-secret, and proprietary information is protected against disclosure, as it is the Board and its staff (not submitters) that bear the statutory obligation to ensure confidentiality of all such information.[9] As such, PhRMA recommends that the Proposed Rule be revised to clarify that the Board has a mandatory obligation to ascertain if information is legally protected as confidential, trade-secret, or proprietary.

  This is especially important because the Board is soliciting information from multiple stakeholders that may possess relevant information obtained from other entities.[10] 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 and commercially sensitive 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 entity may receive no notice of the submission, and thus will

[4] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); Md. Code Ann., Com. Law §§ 11-1201–1209 (Maryland Uniform Trade Secrets Act).
[5] *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.
[6] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).
[7] *See* Proposed Rule § 14.01.01.04.
[8] Proposed Rule § 14.01.01.04(A)(1)(a).
[9] *See* Md. Code Ann., Health-Gen. § 21-2C-10(a).
[10] *See, e.g.*, Cost Review Proposed Rule § 14.01.03.03(B)(1)–(4).

have no opportunity to "clearly designate" the specific information as confidential, trade secret, or proprietary (because they will not be the direct submitter of the information).[11]

- Second, the Board should adopt a rule that requires it to consult with the submitter and any other party whose trade secret, confidential, or proprietary information is at issue, and to provide such parties the opportunity to demonstrate that the information is in fact trade secret, confidential, or proprietary. While the Proposed Rule states that "[t]he Board may seek additional information regarding whether the information is confidential, trade-secret, proprietary, or not otherwise publicly available,"[12] this consultation is not mandatory and therefore does not provide adequate protection to avoid inadvertent disclosure of information that is protected by federal and state law. The statute's prohibition on the disclosure of trade secret, confidential, and proprietary information would be illusory—and it would raise serious due process, takings, and other constitutional concerns—if the Board retained unilateral discretion to release the information without a pre-release opportunity for administrative and judicial review.

- Third, the Board should revise Proposed Rule § 14.01.01.04(B)(1)(a) to state that "[t]rade secret, confidential, or proprietary information obtained by the Board . . . may be accessed ***or used*** only by" Board members, Board staff, and qualified independent third parties that have contracted with the Board and are subject to a nondisclosure agreement. The Board should also clarify that the Board, its staff, and any independent third party that contracts with the Board have an affirmative legal obligation to safeguard such information from disclosure.

- Fourth, PhRMA recommends that the Board provide more specific details about the precise processes and safeguards that the Board intends to put into place to protect against inadvertent disclosures. The Proposed Rule includes certain provisions about management of information received by the Board.[13] However, these provisions are generally very high level and do not supply particularized details about the processes the Board intends to put into place to discharge its obligations to protect sensitive information against disclosure. For example, the Proposed Rule states that confidential, trade-secret, and proprietary information will be considered in closed session—and that the Board will not disclose such information in an open meeting, the Board's public meeting materials, or the Board's summary reports, but the Board does not specify the particularized processes that could help avoid inadvertent disclosures.[14]

- Finally, PhRMA recommends that the Board carefully consider whether there are specific security controls that need to be included in its electronic systems, including user access right limitations that can help prevent improper access by individuals who do not have a specific programmatic need to obtain confidential records. Robust security controls should also be in place to help protect against malicious cyber-attacks and other intrusions that could imperil sensitive information belonging to manufacturers and other stakeholders.

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[11] Proposed Rule § 14.01.01.04(A)(1)(a).
[12] *Id.* § 14.01.01.04(A)(1)(c)
[13] Proposed Rule § 14.01.01.04(B).
[14] *See* Proposed Rule § 14.01.01.04(B)(2).

We thank you again for this opportunity to provide comments and feedback on the Proposed Rule and for your consideration of our concerns and requests for revisions. Although PhRMA has concerns with the Proposed Rule, 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 at 202-572-7785.

Sincerely,

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