PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

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 Public Information Act (COMAR 14.01.04)

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 the Public Information Act (COMAR 14.01.04) ("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.[1] PhRMA appreciates the Board's work to establish rules that implement its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] ***However, because the PDAB Statute restricts the Board and its staff from disclosure of trade secret, confidential, and proprietary information, we urge the Board to expressly state in the Proposed Rule that such information is not subject to the Board's procedures under the Public Information Act.[3] 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, and to our letter submitted along with this letter on the draft regulations regarding Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04).***

[1] 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 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).

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

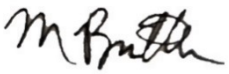
[3] Md. Code Ann., Health-Gen. § 21-2C-10(a)–(b) ("Only Board members and staff may access trade secrets and confidential and proprietary data and information"; "all information and data" shall be "considered to be a trade secret and confidential and proprietary information" and "is not subject to disclosure under the Public Information Act" if it is obtained by the Board "and is not otherwise publicly available.").

In addition, while the Proposed Rule appears largely based on the model regulations of the Office of the Attorney General's Public Information Act Manual ("PIA Manual"),[4] PhRMA believes there are areas where the Proposed Rule could be further tailored to the specific nature of the Board's work and the information it involves. PhRMA therefore recommends that the Board consider revisions to the Proposed Rule to better align with the requirements under the PDAB Statute and to reduce the risk of inadvertent disclosure of trade secret, confidential, or proprietary information.

For example, the Proposed Rule contemplates that, except as otherwise required, the Board "shall make public records of the Board available for inspection by an applicant without demanding a written request."[5] However, the Maryland Public Information Act further requires that each agency "designate types of public records . . . that are to be made available to any applicant immediately on request . . ."[6] PhRMA recommends that the Board revise the Proposed Rule to specify the categories of information, if any, which the Board may possess that do not contain any trade secret, confidential, or proprietary information and which may be disclosed without violating the protections for such information under PDAB Statute. Such categories of information, to the extent a written request is not otherwise determined to be necessary, can be made available to applicants without demanding a written request. The Proposed Rule should also state that any category of information that may contain trade secret, confidential, or proprietary information will require a written request for the Board's review.[7]

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,



Charise Johnson
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

---

[4] *Compare* Office of the Attorney General, Maryland Public Information Act Manual (2022), ch. 12 § F (model regulations), https://www.marylandattorneygeneral.gov/OpenGov%20Documents/PIA_manual_printable.pdf *with* COMAR 14.01.04 (Proposed Rule).

[5] Proposed Rule § 14.01.04.06(A)(1). The Board "shall require a written request if [it] reasonably believes that: (a) The Act or any other law may prevent the disclosure of the public record to the applicant; or (b) A written request will materially assist the Board in responding." Proposed Rule § 14.01.04.06(A)(2). As above, any information obtained by the Board that "is not otherwise publicly available" is not subject to disclosure under the Public Information Act. Md. Code Ann., Health-Gen. § 21-2C-10(a).

[6] Md. Code Ann., Gen. Provisions § 4-201(c)(1); *see also* PIA Manual, ch. 4 § A.

[7] As an additional, non-exhaustive example, PhRMA requests that the Board provide the owner of information an opportunity to review the brief description of the undisclosed record(s) contemplated under proposed § 14.01.04.06(C)(3) to ensure it does not contain information that could compromise the protection of trade secret, confidential, or proprietary information. *See* PIA Manual, ch. 3 § C(4) ("[E]ven in ordinary cases, custodians should generally consult with the owner of the information to obtain its views before the record(s) in question are disclosed to a requester and give the owner a chance to object to the release of any such information.")