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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 Rules of Construction and Open Meetings (COMAR 14.01.01.02-.03)

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 Rules of Construction and Open Meetings (COMAR 14.01.01.02-.03) ("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.

PhRMA appreciates the Board's work to establish rules that implement its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[1] The Proposed Rule would adopt various procedures, including with respect to the process for open meetings, public oral comments, and public written comments. PhRMA thanks the Board for setting forth these proposed processes, but believes additional details and safeguards would help provide stakeholders with greater opportunity to provide relevant information and feedback that could inform the Board's activities. Greater clarity in these processes will ultimately result in more open and productive discussion between the Board and members of the public.[2]

PhRMA provides below a non-exhaustive list of examples where additional procedural details would improve the ability of members of the public to participate in the Board's activities:

- First, PhRMA recommends that the Board revise its Proposed Rule to provide clear timelines for publication of its agenda and materials for consideration ahead of the Board's meetings, with specific standards for how far in advance of the meeting such publication will occur. Advance publication of the Board's agenda and materials gives stakeholders a full and fair opportunity to review them and to prepare written comments or to submit notice that they will provide oral

[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 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).

comments prior to the Board's proposed deadlines.[3] Failure to provide such advance publication impedes the ability of stakeholders to provide relevant information for the Board's consideration, restricting the ability of members of the public to participate in the Board's deliberations and limiting the value of the public comment process.

- Second, the Board's Proposed Rule characterizes the written comment process as relating to the submission of "*Public* Written Comments for a Board Meeting."[4] PhRMA recommends that the Board also provide procedures for the submission of confidential information that may be relevant to a given agenda item under consideration by the Board. As noted in our letter submitted along with this letter on the draft regulations regarding Confidential, Trade-Secret, and Proprietary Information (COMAR 14.01.01.04), PhRMA also requests greater clarity surrounding how meetings will be "closed" for the oral presentation or discussion of confidential information.[5]

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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

[3] Proposed Rule § 14.01.01.03(B)(1) ("A member of the public may register to provide oral comments at a Board meeting by: . . . (b) Submitting the written notice to the Board at least three work days before the scheduled meeting.") (emphasis added). Proposed Rule § 14.01.01.03(C)(3) ("Written comments received two work days before the scheduled Board meeting will be: . . . (ii) made part of the record on the issue or matter before the Board where applicable . . ."') (emphasis added); Proposed Rule § 14.01.01.03(C)(6) ("Written comments received less than two work days before the scheduled Board meeting may be considered at the next Board meeting if the issue, matter or decision is still pending.").

[4] Proposed Rule § 14.01.01.03(C) (emphasis added).

[5] PhRMA incorporates by reference this separate letter addressing COMAR 14.01.01.04, as well as our prior 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.