HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

May 2, 2023

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Healthcare Distribution Alliance Comments
Re: §14.01.03.01-05, the Maryland Prescription Drug Affordability Board Cost Review Process

On behalf of our member companies, the Healthcare Distribution Alliance (HDA) thanks you for this opportunity to provide comments on proposed **§14.01.03.01-05, the Maryland Prescription Drug Affordability Board Cost Review Process**. HDA respectfully believes our suggested changes will help the Board better advance its directive by collecting more precise and pertinent information.

HDA is the national trade association representing the nation's wholesale pharmaceutical distributors, the vital link between the nation's pharmaceutical manufacturers and more than 180,000 pharmacies and other healthcare settings nationwide. An estimated 93% of US prescription drugs are handled by our members, who work around the clock to save the US Healthcare System billions annually through efficient management of drug supply chain logistics. Additionally, distributors are unlike any other supply chain participants – their core business does not involve manufacturing, marketing, prescribing or dispensing medicines, nor do they set the Wholesale Acquisition Cost (WAC) list price of prescription drugs, influence prescribing patterns or determine patient-benefit design. Rather, they are the logistical experts within the supply chain who ensure products are physically on shelves where and when patients need them.

HDA respectfully requests that the Board consider the following changes:

- **Proposed Change #1**
  - Page 3 Section (5-6)

The prescription drug product shall be identified by:

(a) NDC; and

(b) active moiety or active ingredient.

(6) If the Board selects a prescription drug product for cost review, the Board will identify ~~and approve~~ all NDCs with the same moiety or active ingredient. The Board will then identify whether each subsequentially identified NDC meets the criteria and standards laid out in both Health General Article, § 21-2C-08(c) and §14.01.03 in order to determine whether each additional NDC should ~~to~~ be included in the cost review.

- Explanation: HDA proposes the above change because subjecting an entire product family to the drug review process based simply on a shared NDC could result in products which are not an affordability challenge being artificially and arbitrarily captured in the Board's drug review process. For example, a product with the same NDC might be available as a tablet or a liquid; however only the liquid product presents an affordability challenge, and arbitrarily including the tablet product in the review process would create unnecessary red tape for both the Board and the entities operating in the state. HDA recommends that the Board identify whether each individual product meets the standards and requirements laid out in statute before adding any products to the final cost review list.

- **Proposed Change #2**
  - Page 8 Section E:

    At an open meeting, a Board member may propose one or more additional prescription drug products for inclusion on the list of drugs eligible for cost review by:
    (1) Moving that the prescription drug product(s) be added to the eligible list; and
    (2) ~~Identifying the reasons why~~ Demonstrating that the prescription drug product(s) meets the statutory metrics and criteria laid out in both the Health General Article, § 21-2C-08(c) and §14.01.03.~~should be added.~~

  - Explanation: HDA proposes the above change because we are concerned that the language as it stands is too broad and negates the otherwise carefully laid out standards and criteria in these proposed rules. We believe that any decisions that the Board makes should be restricted to set parameters, ensuring the Board follows the most direct pathway to achieving its directive without creating additional unnecessary reporting requirements for entities operating in Maryland.

- **Proposed Change #3**
  - Page 11 Section B. (4) *Wholesale Distributors*:

    (a) Prices charged by distributors to typical purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers (but not to include contract prices established by manufacturers with such downstream customers).

  - Explanation: HDA proposes the above change because it provides explicit clarification that wholesale distributors would be responsible for reporting data directly generated and controlled by distributors themselves, without the unintentional inclusion of pricing data generated by manufactures via their contracts with downstream customers. This proposed clarifying language will ensure the Board does not collect duplicative data.

HDA thanks you for your consideration of our proposed language changes as the Board moves forward with rulemaking. Please contact me at any time with questions or for further conversation at kmemphis@hda.org or at 443.375.6541.

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance