

Comments to PDAB Proposed Regulations — 14.01.01 & 14.01.02

PDAB Board Meeting

August 17, 2021

Andrew York, Executive Director



MARYLAND
Prescription Drug Affordability Board

Background

- On May 24, 2021, the Board authorized PDAB staff to begin the promulgation process for two new chapters of regulations
 - The General Provisions chapter, 14.01.01, provides definitions for terms that will be used throughout PDAB's assigned subtitle in COMAR
 - The Prescription Drug Affordability Fund chapter, 14.01.02, sets the structure and implementation of the Prescription Drug Affordability Fund, as required under Health-General Article § 21-2C-11
- These regulations were published on July 2, 2021, in the Maryland Register. This triggered a 30-day public comment period that ended on August 3, 2021
- We received three comments during the comment period



Summary of Comments

- The comments covered issues ranging from a late fee penalty in the first year, the inclusion of manufacturers of animal drugs in the fee assessment, and the exclusion of non-profit entities from the fee assessment
- We plan to address the commenters directly, but the responses did not require any changes in policy or regulatory language
- Recommendation: Publish the Final Regulations with no changes



Questions?

