

Prescription Drug Affordability Board Emergency Regulations — 14.01.02

PDAB Board Meeting

October 27, 2021

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MARYLAND
Prescription Drug Affordability Board

Background

- The Prescription Drug Affordability Board (PDAB) published two new chapters of regulations in the August 27, 2021 Issue of the Maryland Register
 - The General Provisions chapter, 14.01.01, provides definitions for terms that will be used throughout the 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 (PDAF), as required under Health-General Article
- The Board issued invoices for the Fiscal Year (FY) 2022 Fee Assessment for the Maryland PDAF at the end of September, as authorized by Health-General § 21-2C-11 and COMAR 14.01.02



Emergency Regulations - Implementation

- In implementing the assessments as required by Health-General § 21-2C-11, it became evident that some entities that received invoices may not meet the statutory definition of qualifying entity
- As a result, a process was needed to evaluate and determine whether an entity was covered by the assessment
- These issues were not clear until the implementation of the invoicing process



Emergency Regulations - Summary

- Creates an Exemption process for entities that received an invoice for the PDAF Fee Assessment, but do not qualify for the fee assessment under the PDAF statute or regulations
- Clarifies the Waiver application process for entities that qualify for the fee assessment, but may apply for a waiver because the PDAF fee assessment exceeds 1% of their Maryland revenue



Emergency Regulations - Next Steps

Recommendations:

- Publish the proposed Emergency Regulations, without changes
- Authorize staff to request that the emergency regulation be effective as soon as possible.



Questions?

