

# **Title 14 INDEPENDENT AGENCIES**

## **Subtitle 01 PRESCRIPTION DRUG AFFORDABILITY BOARD**

### ***14.01.02 Prescription Drug Affordability Fund***

*Authority: Health-General Article, § 21-2C-11, Annotated Code of Maryland*

#### **Notice of Proposed Action**

The Prescription Drug Affordability Board proposes to adopt new Regulations **.01—.05** under a new chapter, **COMAR 14.01.02 Prescription Drug Affordability Fund**.

#### **Statement of Purpose**

The purpose of this action is to set forth the structure and implementation of the Prescription Drug Affordability Fund, as required under Health-General Article, § 21-2C-11, Annotated Code of Maryland.

#### **Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

#### **Estimate of Economic Impact**

The proposed action levies an annual assessment on certain entities identified in Health-General Article, § 21-2C-11, Annotated Code of Maryland. The Board will collect an assessment amounts of \$1,000 per entity unless an assessed entity demonstrates that \$1,000 exceeds 1% of its revenue in Maryland for their preceding fiscal year. Applying for the waiver may impose minimal administrative burdens on businesses notwithstanding the avoidance of the fee. The Board estimates that the assessments would produce between \$750,000 to \$1,500,000 in special fund revenue for the Board's Prescription Drug Affordability Fund. This revenue is the only source of funding for the Board's operation. The proposed action does not impose a mandate on a local government unit.

#### **Economic Impact on Small Businesses**

The proposed action has minimal to no impact on small businesses.

#### **Impact on Individuals with Disabilities**

The proposed action has no direct impact on individuals with disabilities.

Date: May 17, 2021

### **Opportunity for Public Comment**

Comments may be sent to Kris Vallecillo, Policy & Special Projects Manager, Prescription Drug Affordability Board, 16900 Science Drive, Suite 112-114, Bowie, MD 20715, or email [support.pdab@maryland.gov](mailto:support.pdab@maryland.gov). Comments will be accepted through **DATE**. A public hearing has not been scheduled in the interest of public health and safety.

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**.01 Prescription Drug Affordability Fund**

A. The Prescription Drug Affordability Fund is a special, non-lapsing fund that is not subject to State Procurement Article, § 7–302, Annotated Code of Maryland.

B. The Prescription Drug Affordability Fund consists of:

- (1) the assessment provided for by §.02 of this Regulation;
- (2) money appropriated by the State budget;
- (3) interest earnings; and
- (4) any other money from any other source accepted for the benefit of the Fund.

**.02 Assessment of Entities, Notification of Assessment, and Collection of Fees**

A. The Board shall collect an annual assessment from the entities identified in Health-General Article, § 21–2C–11, Annotated Code of Maryland and specified in §.02 of this Regulation.

B. No later than July 15, 2021, and July 15 of every year thereafter, the Board shall issue a notification to these entities of their obligation to pay the annual assessment.

C. The Board shall issue invoices no later than October 1, 2021, and October 1 of every year thereafter.

D. Any bill not paid within 30 days of the payment due date may be subject to an interest penalty to be determined and collected by the Board.

E. In addition to any penalties the Board may impose on an entity that fails to pay the fee assessed by the Board in a timely manner, the Board may also refer an entity's delinquent account to the Department of Budget and Management's Central Collection Unit, pursuant to the procedures in State Finance and Procurement Article, Title 3, Subtitle 3, Annotated Code of Maryland, and COMAR 17.01.01.

F. The Board shall waive the fee assessment upon request by an assessed entity, provided that entity demonstrates, through attestation and supporting documentation, that the fee assessment exceeds 1% of that entity's revenue earned in the State during their preceding fiscal year.

**.03 Amount of Assessment**

A. Entities identified in Health-General Article, § 21–2C–11, Annotated Code of Maryland, shall be subject to the following fee schedule:

(1) Manufacturers engaged in wholesale distribution, as defined in § 12–6C–01 of the Health Occupations Article, shall pay an assessment of \$1,000;

(2) Wholesale distributors, as defined in § 12–6C–01 of the Health Occupations Article, that distribute prescription drugs shall pay an assessment of \$1,000;

(3) Pharmacy benefits managers, as defined in § 15–1601 of the Insurance Article, shall pay an assessment of \$1,000; and

(4) Carriers, as defined § 19–132 of the Health-General Article; shall pay an assessment of \$1,000.

B. As provided for in §.02 of this Regulation, upon demonstration that the fee assessment exceeds 1% of that entity's revenue in the State during their preceding fiscal year, the Board shall waive the fee assessment for that year.

**.04 Use of Funds**

*A. The Fund may only be used to finance the operation of the Board, as permitted in Health-General Article, § 21-2C-11(C)(6).*

*B. Interest earned from the monies collected through the assessment in §.02 of this Regulation shall be retained to the credit of the Fund.*

***.05 Surplus Funds***

*A. If the amount of assessed funds collected in a calendar year exceeds the cap identified in Health-General Article, § 21-2C-11(B)(4), the Board shall:*

- (1) Issue a notice of such surplus; and*
- (2) Remit the surplus funds in a fair and equitable manner across all qualifying entities that have paid the assessment.*

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