

# **Title 14 INDEPENDENT AGENCIES**

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

### ***14.01.01 General Provisions***

*Authority: Health-General Article, § 21-2C-03(f), Annotated Code of Maryland*

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

The Prescription Drug Affordability Board proposes to adopt new Regulation .01 under a new chapter, **COMAR 14.01.01 General Provisions**.

#### **Statement of Purpose**

The purpose of this action is to define vocabulary used in COMAR 14.01.

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

There are limited federal standards comparable to this proposed action. The below definitions incorporate their federal counterparts by reference where possible and practicable.

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

The proposed action has minimal or no economic impact.

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

The proposed action has minimal or no economic impact on small businesses.

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

The proposed action has no impact on individuals with disabilities.

#### **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.

**.01 Definitions.**

*A. In this subtitle, the following terms have the meanings indicated.*

*B. Terms Defined.*

*(1) "Biologic" means a biological product, as defined in 42 U.S.C. § 262(i)(1).*

*(2) "Biosimilar" means a biological product, as defined in 42 U.S.C. § 262(i)(2), that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(K)(3).*

*(3) "Board" has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.*

*(4) "Brand name drug" has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.*

*(5) "Carrier" has the meaning stated in Health-General Article, § 19-132, Annotated Code of Maryland.*

*(6) "Chairperson" means the chair of the Board, as provided for in Health-General Article, §21-2C-03, Annotated Code of Maryland.*

*(7) "Fund" means the Prescription Drug Affordability Fund, as provided for in Health-General Article, §21-2C-11, Annotated Code of Maryland.*

*(8) "Generic drug" has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.*

*(9) "Manufacturer" has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.*

*(10) "Pharmacy benefit manager" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.*

*(11) "Prescription drug product" has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.*

*(12) "Stakeholder Council" means the Prescription Drug Affordability Stakeholder Council, as provided for in Health-General Article, §21-2C-04, Annotated Code of Maryland.*

*(13) "Wholesale distributor" has the meaning stated in Health-Occupations Article, 12-6C-01, Annotated Code of Maryland.*