

Title 14

INDEPENDENT AGENCIES

Subtitle 01 – Prescription Drug Affordability Board

Chapter .04

Authority: Health-General Article, §§ 21-2C-03(f)(1), 21-2C-08(b), and 21-2C-09, Annotated Code of Maryland

.01. [Public Reporting of Drug Affordability Issues.

A. Individual members of the public may report their personal experience with a drug or drugs that have caused or are causing an affordability issue for the individual.

B. Individuals may report a drug:

- (1) By completing the form available on the Board’s website electronically; or
- (2) By downloading or obtaining the form from the Board, completing the form, and submitting it to the Board.

C. Blank forms may be requested by contacting the Board by email or phone.]

Circumstances Under Which Use of a Drug May Create an Affordability Challenge.

A. *The Board may determine that use of a drug has led or will lead to an affordability challenge for the State health care system.*

B. *The circumstances under which use of a drug has led or will lead to an affordability challenge for the State health care system include, but are not limited to:*

(1) *High spending by entities that pay for the prescription drug product, as may be indicated by:*

- (a) *Spending on the drug makes up a large proportion of the impacted budget;*
- (b) *Spending on the drug makes up a large proportion of the increase in drug or health care spending of the impacted budget; or*
- (c) *Large price increases, such as the wholesale acquisition cost (WAC) increasing substantially faster than inflation.*

(2) *At its current net or gross price, a drug does not provide sufficient value to the State health care system, as may be indicated by:*

- (a) *The drug is not cost-effective at the current average net price;*
- (b) *The average net price of the drug exceeds the average net price for therapeutic alternatives that provide similar clinical outcomes; or*
- (c) *Compared to therapeutic alternatives, the drug was approved with limited evidence of improvement in clinical outcomes and has substantial spending.*

(3) *Conduct that delays or prevents market competition, as may be indicated by:*

- (a) *Use of patent or regulatory extensions of a government-granted monopoly that have the effect of delaying or preventing market competition;*
- (b) *Use of regulatory tools that have the effect of delaying or preventing competition, such as the scheduling of drugs by the Drug Enforcement Agency (“DEA”) and risk evaluation and mitigation strategies approved by the FDA; or*
- (c) *Manufacturer conduct that has the effect of inhibiting, delaying or preventing other manufacturers from entering the market.*

(4) *Barriers to affordable access for insured patients, as may be indicated by:*

- (a) *Coverage of the prescription drug product is not coextensive with FDA approved indications;*
- (b) *High occurrence of required prior authorization or high claims rejection rate;*
- (c) *The drug is not covered by entities that pay for the prescription drug product due to the high cost of the drug; or*

(d) *At a certain percentile, patient out-of-pocket cost in certain markets is disproportionate to the average net cost paid by payors;*

(5) *Any other circumstance identified by the Board under which use of a drug has or will lead to an affordability challenge for the State health care system.*

C. *The Board may determine that use of a drug has led or will lead to high out-of-pocket costs for patients.*

D. *The circumstances under which use of a drug has or will lead to high out-of-pocket costs for patients may be indicated by but not limited to:*

- (1) *The average total out-of-pocket costs for a drug make up a large proportion of the average income;*
- (2) *At a certain percentile, patient out-of-pocket cost in certain markets is disproportionate to the average net cost paid by payors;*
- (3) *A large proportion of patients do not take the drug as prescribed;*
- (4) *There are disparities in costs or utilization of the drug in priority populations; or*
- (5) *Any other circumstance identified by the Board under which use of a drug has or will lead to high out-of-pocket costs for patients.*