A BILL ENTITLED

AN ACT concerning

Public Health – Essential Generic Drugs – Price Gouging – Prohibition

FOR the purpose of prohibiting a manufacturer or wholesale distributor from engaging in price gouging in the sale of an essential generic drug; requiring the Maryland Medical Assistance Program to notify the manufacturer of an essential generic drug and the Attorney General of a certain increase in the price of the essential generic drug under certain circumstances; requiring a manufacturer of an essential generic drug to submit a certain statement to the Attorney General within a certain time frame; authorizing the Attorney General to require a manufacturer of an essential generic drug to produce certain records or other documents that may be relevant in determining whether a certain violation has occurred; authorizing a circuit court, under certain circumstances, to issue certain orders compelling certain actions, restraining or enjoining certain violations, and imposing a certain civil penalty; prohibiting a person who is alleged to have violated a requirement of this Act from asserting a certain defense; defining certain terms; and generally relating to prohibiting price gouging in the sale of essential generic drugs.

BY adding to

Article – Health – General

Section 2–801 through 2–803 to be under the new subtitle “Subtitle 8. Prohibition Against Price Gouging for Essential Generic Drugs”
Annotated Code of Maryland
(2015 Replacement Volume and 2016 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 8. PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL GENERIC
DRUGS.

2–801.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
INDICATED.

(B) “AVERAGE MANUFACTURER PRICE” HAS THE MEANING STATED IN 42

(C) (1) “ESSENTIAL GENERIC DRUG” MEANS ANY PRESCRIPTION DRUG:

(I) FOR WHICH ANY EXCLUSIVE MARKETING RIGHTS GRANTED
UNDER FEDERAL LAW HAVE EXPIRED;

(II) 1. THAT APPEARS ON THE MODEL LIST OF ESSENTIAL
MEDICINES MOST RECENTLY ADOPTED BY THE WORLD HEALTH ORGANIZATION; OR

2. THAT HAS BEEN DESIGNATED BY THE SECRETARY AS
AN ESSENTIAL MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE–THREATENING
HEALTH CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY
IMPAINS AN INDIVIDUAL’S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY LIVING; AND

(III) THAT IS MADE AVAILABLE FOR SALE IN THE STATE.

(2) “ESSENTIAL GENERIC DRUG” INCLUDES ANY DRUG–DEVICE
COMBINATION PRODUCT USED FOR THE DELIVERY OF AN ESSENTIAL GENERIC
DRUG.

(D) “PRICE GOUGING” MEANS AN UNCONSCIONABLE INCREASE IN THE
PRICE OF A PRESCRIPTION DRUG.

(E) “STATE HEALTH PLAN” HAS THE MEANING STATED IN § 2–601 OF THIS
TITLE.
(F) “State health program” has the meaning stated in § 2–601 of this title.

(G) “Unconscionable increase” means an increase in the price of a prescription drug that:

(1) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and

(2) results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:

(i) the importance of the drug to their health; and

(ii) insufficient competition in the market for the drug.

(H) “Wholesale acquisition cost” has the meaning stated in 42 U.S.C. § 1395w–3a.

2–802.

A manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential generic drug.

2–803.

(A) The Maryland Medical Assistance Program shall notify the manufacturer of an essential generic drug and the Attorney General of any increase in the price of an essential generic drug when:

(1) three or fewer manufacturers are actively manufacturing and marketing the essential generic drug for sale in the United States; and

(2) the price increase, by itself or in combination with other price increases:

(i) would result in an increase of 50% or more in the average manufacturer price or wholesale acquisition cost of the drug within the preceding 2–year period; or
(II) Would result in an increase of 50% or more in the price paid by the Maryland Medical Assistance Program for the drug within the preceding 2-year period.

(B) Within 20 days after the date of receipt of a notice under subsection (a) of this section, the manufacturer of an essential generic drug shall submit a statement to the Attorney General:

(1) (I) Itemizing the components of the cost of producing the essential generic drug; and

(II) Identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the essential generic drug within the 2-year period preceding the date of the price increase;

(2) (I) Identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the essential generic drug; and

(II) Explaining any improvement in public health associated with those expenditures; and

(3) Providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this subtitle has occurred.

(C) The Attorney General may require a manufacturer to produce any records or other documents that may be relevant to a determination of whether a violation of this subtitle has occurred.

(D) On petition of the Attorney General, a circuit court may issue an order:

(1) Compelling the manufacturer of an essential generic drug:

(1) To provide the statement required under subsection (b) of this section; or

(II) To produce specific records or other documents requested by the Attorney General under subsection (c) of this section
THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS
SUBTITLE HAS OCCURRED;

(2) RESTRaining OR ENJOINING A VIOLATION OF THIS SUBTITLE;

(3) RESTORING TO ANY CONSUMER, INCLUDING A THIRD PARTY
PAYOR, ANY MONEY ACQUIRED AS A RESULT OF A PRICE INCREASE THAT VIOLATES
THIS SUBTITLE;

(4) REQUIRING A MANUFACTURER THAT HAS ENGAGED IN PRICE
GOUGING IN THE SALE OF AN ESSENTIAL GENERIC DRUG TO MAKE THE ESSENTIAL
GENERIC DRUG AVAILABLE TO PARTICIPANTS IN ANY STATE HEALTH PLAN OR
STATE HEALTH PROGRAM FOR A PERIOD OF UP TO 1 YEAR AT THE PRICE AT WHICH
THE DRUG WAS MADE AVAILABLE TO PARTICIPANTS IN THE STATE HEALTH PLAN OR
STATE HEALTH PROGRAM IMMEDIATELY PRIOR TO THE MANUFACTURER’S
VIOLATION OF THIS SUBTITLE; AND

(5) IMPOSING A CIVIL PENALTY OF UP TO $10,000 FOR EACH
VIOLATION OF THIS SUBTITLE.

(E) IN ANY ACTION BROUGHT BY THE ATTORNEY GENERAL UNDER
SUBSECTION (D) OF THIS SECTION, A PERSON WHO IS ALLEGED TO HAVE VIOLATED
A REQUIREMENT OF THIS SUBTITLE MAY NOT ASSERT AS A DEFENSE THAT THE
PERSON DID NOT DEAL DIRECTLY WITH A CONSUMER RESIDING IN THE STATE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
October 1, 2017.