

HOUSE BILL 631

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CF SB 415

By: **The Speaker (By Request – Office of the Attorney General) and Delegates Bromwell, Anderson, Atterbeary, Barkley, B. Barnes, D. Barnes, Barron, Barve, Beidle, Brooks, Carr, Chang, Clippinger, Conaway, Cullison, Davis, Dumais, Ebersole, Fennell, Fraser–Hidalgo, Frick, Frush, Gaines, Gilchrist, Glenn, Gutierrez, Hayes, Haynes, Healey, Hettleman, Hill, Hixson, Holmes, C. Howard, Jackson, Jalisi, Jameson, Jones, Kelly, Knotts, Krimm, Lafferty, Lam, Lewis, Lierman, Lisanti, Luedtke, McCray, McIntosh, A. Miller, Moon, Morales, Oaks, Patterson, Pena–Melnik, Platt, Proctor, Queen, Reznik, Robinson, Rosenberg, Sample–Hughes, Sanchez, Sophocleus, Stein, Sydnor, Tarlau, Turner, Valderrama, Vallario, Waldstreicher, Walker, A. Washington, M. Washington, C. Wilson, K. Young, and P. Young**

Introduced and read first time: January 30, 2017

Assigned to: Health and Government Operations and Economic Matters

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Essential Generic Drugs – Price Gouging – Prohibition**

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

17 BY adding to

18 Article – Health – General

19 Section 2–801 through 2–803 to be under the new subtitle “Subtitle 8. Prohibition

20 Against Price Gouging for Essential Generic Drugs”

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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
U.S.C. § 1396R–8.

(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
IMPAIRS 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.

1 (F) “STATE HEALTH PROGRAM” HAS THE MEANING STATED IN § 2-601 OF
2 THIS TITLE.

3 (G) “UNCONSCIONABLE INCREASE” MEANS AN INCREASE IN THE PRICE OF
4 A PRESCRIPTION DRUG THAT:

5 (1) IS EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING
6 THE DRUG OR THE COST OF APPROPRIATE EXPANSION OF ACCESS TO THE DRUG TO
7 PROMOTE PUBLIC HEALTH; AND

8 (2) RESULTS IN CONSUMERS FOR WHOM THE DRUG HAS BEEN
9 PRESCRIBED HAVING NO MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE
10 DRUG AT AN EXCESSIVE PRICE BECAUSE OF:

11 (I) THE IMPORTANCE OF THE DRUG TO THEIR HEALTH; AND

12 (II) INSUFFICIENT COMPETITION IN THE MARKET FOR THE
13 DRUG.

14 (H) “WHOLESALE ACQUISITION COST” HAS THE MEANING STATED IN 42
15 U.S.C. § 1395W-3A.

16 2-802.

17 A MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY NOT ENGAGE IN PRICE
18 GOUGING IN THE SALE OF AN ESSENTIAL GENERIC DRUG.

19 2-803.

20 (A) THE MARYLAND MEDICAL ASSISTANCE PROGRAM SHALL NOTIFY THE
21 MANUFACTURER OF AN ESSENTIAL GENERIC DRUG AND THE ATTORNEY GENERAL
22 OF ANY INCREASE IN THE PRICE OF AN ESSENTIAL GENERIC DRUG WHEN:

23 (1) THREE OR FEWER MANUFACTURERS ARE ACTIVELY
24 MANUFACTURING AND MARKETING THE ESSENTIAL GENERIC DRUG FOR SALE IN
25 THE UNITED STATES; AND

26 (2) THE PRICE INCREASE, BY ITSELF OR IN COMBINATION WITH
27 OTHER PRICE INCREASES:

28 (I) WOULD RESULT IN AN INCREASE OF 50% OR MORE IN THE
29 AVERAGE MANUFACTURER PRICE OR WHOLESALE ACQUISITION COST OF THE DRUG
30 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:

(I) 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

1 THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS
2 SUBTITLE HAS OCCURRED;

3 (2) RESTRAINING OR ENJOINING A VIOLATION OF THIS SUBTITLE;

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

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

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

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

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