

# HOUSE BILL 631

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CF SB 415

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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–Melnyk, 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

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## 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”

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Annotated Code of Maryland  
2 (2015 Replacement Volume and 2016 Supplement)

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

5 **Article – Health – General**

6 **SUBTITLE 8. PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL GENERIC**  
7 **DRUGS.**

8 **2–801.**

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

11 (B) “AVERAGE MANUFACTURER PRICE” HAS THE MEANING STATED IN 42  
12 U.S.C. § 1396R–8.

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

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

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

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

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

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

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

28 (E) “STATE HEALTH PLAN” HAS THE MEANING STATED IN § 2–601 OF THIS  
29 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

1 (II) WOULD RESULT IN AN INCREASE OF 50% OR MORE IN THE  
2 PRICE PAID BY THE MARYLAND MEDICAL ASSISTANCE PROGRAM FOR THE DRUG  
3 WITHIN THE PRECEDING 2-YEAR PERIOD.

4 (B) WITHIN 20 DAYS AFTER THE DATE OF RECEIPT OF A NOTICE UNDER  
5 SUBSECTION (A) OF THIS SECTION, THE MANUFACTURER OF AN ESSENTIAL GENERIC  
6 DRUG SHALL SUBMIT A STATEMENT TO THE ATTORNEY GENERAL:

7 (1) (I) ITEMIZING THE COMPONENTS OF THE COST OF PRODUCING  
8 THE ESSENTIAL GENERIC DRUG; AND

9 (II) IDENTIFYING THE CIRCUMSTANCES AND TIMING OF ANY  
10 INCREASE IN MATERIALS OR MANUFACTURING COSTS THAT CAUSED ANY INCREASE  
11 IN THE PRICE OF THE ESSENTIAL GENERIC DRUG WITHIN THE 2-YEAR PERIOD  
12 PRECEDING THE DATE OF THE PRICE INCREASE;

13 (2) (I) IDENTIFYING THE CIRCUMSTANCES AND TIMING OF ANY  
14 EXPENDITURES MADE BY THE MANUFACTURER TO EXPAND ACCESS TO THE  
15 ESSENTIAL GENERIC DRUG; AND

16 (II) EXPLAINING ANY IMPROVEMENT IN PUBLIC HEALTH  
17 ASSOCIATED WITH THOSE EXPENDITURES; AND

18 (3) PROVIDING ANY OTHER INFORMATION THAT THE  
19 MANUFACTURER BELIEVES TO BE RELEVANT TO A DETERMINATION OF WHETHER A  
20 VIOLATION OF THIS SUBTITLE HAS OCCURRED.

21 (C) THE ATTORNEY GENERAL MAY REQUIRE A MANUFACTURER TO  
22 PRODUCE ANY RECORDS OR OTHER DOCUMENTS THAT MAY BE RELEVANT TO A  
23 DETERMINATION OF WHETHER A VIOLATION OF THIS SUBTITLE HAS OCCURRED.

24 (D) ON PETITION OF THE ATTORNEY GENERAL, A CIRCUIT COURT MAY  
25 ISSUE AN ORDER:

26 (1) COMPELLING THE MANUFACTURER OF AN ESSENTIAL GENERIC  
27 DRUG:

28 (I) TO PROVIDE THE STATEMENT REQUIRED UNDER  
29 SUBSECTION (B) OF THIS SECTION; OR

30 (II) TO PRODUCE SPECIFIC RECORDS OR OTHER DOCUMENTS  
31 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.