

# HOUSE BILL 631

J1

(7lr1025)

## ENROLLED BILL

— *Health and Government Operations and Economic Matters/Finance* —

Introduced 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, R. Lewis, Lierman, Lisanti, Luedtke, McCray, McIntosh, A. Miller, Moon, Morales, Oaks, Patterson, Pena–Melynk, 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~~ P. Young, Pendergrass, Angel, Kipke, McDonough, Metzgar, Miele, Saab, West, Aumann, Carey, Mautz, and S. Howard**

Read and Examined by Proofreaders:

\_\_\_\_\_  
Proofreader.  
\_\_\_\_\_  
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this \_\_\_\_\_ day of \_\_\_\_\_ at \_\_\_\_\_ o'clock, \_\_\_\_\_ M.  
\_\_\_\_\_  
Speaker.

CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Public Health – Essential Off–Patent or Generic Drugs – Price Gouging –**  
3 **Prohibition**

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### EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

*Italics indicate opposite chamber/conference committee amendments.*



1 FOR the purpose of prohibiting a manufacturer or wholesale distributor from engaging in  
 2 price gouging in the sale of an essential ~~off-patent or generic drug~~; *establishing that*  
 3 *it is not a violation of a certain provision of this Act for a wholesale distributor to*  
 4 *increase a price of an essential off-patent or generic drug under certain*  
 5 *circumstances; requiring authorizing* the Maryland Medical Assistance Program to  
 6 notify ~~the manufacturer of an essential generic drug and~~ the Attorney General of a  
 7 certain increase in the price of ~~the an~~ essential off-patent or generic drug under  
 8 certain circumstances; requiring a manufacturer of an essential off-patent or generic  
 9 drug to submit a certain statement to the Attorney General within a certain time  
 10 frame; authorizing the Attorney General to require a manufacturer of an essential  
 11 off-patent or generic drug to produce certain records or other documents that may  
 12 be relevant in determining whether a certain violation has occurred; authorizing a  
 13 circuit court, under certain circumstances, to issue certain orders compelling certain  
 14 actions, restraining or enjoining certain violations, and imposing a certain civil  
 15 penalty; ~~making certain information subject to public inspection only to the extent~~  
 16 ~~permitted under certain provisions of law; providing that information included in a~~  
 17 ~~certain statement~~ *requiring that certain information provided to the Attorney*  
 18 *General under this Act be considered confidential commercial information for certain*  
 19 *purposes except under certain circumstances; prohibiting the Attorney General from*  
 20 *bringing a certain action under certain circumstances; prohibiting a person who is*  
 21 *alleged to have violated a requirement of this Act from asserting a certain defense;*  
 22 *defining certain terms; and generally relating to prohibiting price gouging in the sale*  
 23 *of essential off-patent or generic drugs.*

24 BY adding to  
 25 Article – Health – General  
 26 Section 2–801 through 2–803 to be under the new subtitle “Subtitle 8. Prohibition  
 27 Against Price Gouging for Essential Off-Patent or Generic Drugs”  
 28 Annotated Code of Maryland  
 29 (2015 Replacement Volume and 2016 Supplement)

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

32 **Article – Health – General**

33 **SUBTITLE 8. PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL**  
 34 **OFF-PATENT OR GENERIC DRUGS.**

35 **2–801.**

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

38 ~~(B) “AVERAGE MANUFACTURER PRICE” HAS THE MEANING STATED IN 42~~  
 39 ~~U.S.C. § 1396r-8.~~

1       ~~(C)~~ **(B)**       **(1)**    “ESSENTIAL OFF-PATENT OR GENERIC DRUG” MEANS ANY  
2 PRESCRIPTION DRUG:

3                               **(I)**    FOR WHICH ~~ANY~~ ALL EXCLUSIVE MARKETING RIGHTS, IF  
4 ANY, GRANTED UNDER ~~FEDERAL LAW~~ THE FEDERAL FOOD, DRUG, AND COSMETIC  
5 ACT, § 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT  
6 LAW HAVE EXPIRED;

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

9                                               2.     **THAT HAS BEEN DESIGNATED BY THE SECRETARY AS**  
10 **AN ESSENTIAL MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE-THREATENING**  
11 **HEALTH CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY**  
12 **IMPAIRS AN INDIVIDUAL’S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY LIVING; ~~AND~~**

13                                               **(III)**    **THAT IS ACTIVELY MANUFACTURED AND MARKETED FOR**  
14 **SALE IN THE UNITED STATES BY THREE OR FEWER MANUFACTURERS; AND**

15                               ~~(H)~~ **(IV)**    **THAT IS MADE AVAILABLE FOR SALE IN THE STATE.**

16                               **(2)**    “ESSENTIAL OFF-PATENT OR GENERIC DRUG” INCLUDES ANY  
17 DRUG-DEVICE COMBINATION PRODUCT USED FOR THE DELIVERY OF ~~AN ESSENTIAL~~  
18 ~~GENERIC~~ A DRUG FOR WHICH ALL EXCLUSIVE MARKETING RIGHTS, IF ANY,  
19 GRANTED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, § 351 OF THE  
20 FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT LAW HAVE  
21 EXPIRED.

22                               ~~(D)~~ **(C)**       “**PRICE GOUGING**” MEANS AN UNCONSCIONABLE INCREASE IN  
23 THE PRICE OF A PRESCRIPTION DRUG.

24                               ~~(E)~~ **(D)**       “**STATE HEALTH PLAN**” HAS THE MEANING STATED IN § 2-601 OF  
25 THIS TITLE.

26                               ~~(F)~~ **(E)**       “**STATE HEALTH PROGRAM**” HAS THE MEANING STATED IN § 2-601  
27 OF THIS TITLE.

28                               ~~(G)~~ **(F)**       “**UNCONSCIONABLE INCREASE**” MEANS AN INCREASE IN THE  
29 PRICE OF A PRESCRIPTION DRUG THAT:

30                                               **(1)**    **IS EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING**  
31 **THE DRUG OR THE COST OF APPROPRIATE EXPANSION OF ACCESS TO THE DRUG TO**  
32 **PROMOTE PUBLIC HEALTH; AND**

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

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

5 (II) INSUFFICIENT COMPETITION IN THE MARKET FOR THE  
 6 DRUG.

7 ~~(H)~~ (G) "WHOLESALE ACQUISITION COST" HAS THE MEANING STATED IN  
 8 42 U.S.C. § 1395W-3A.

9 2-802.

10 (A) A MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY NOT ENGAGE IN  
 11 PRICE GOUGING IN THE SALE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG.

12 (B) IT IS NOT A VIOLATION OF SUBSECTION (A) OF THIS SECTION FOR A  
 13 WHOLESALE DISTRIBUTOR TO INCREASE THE PRICE OF AN ESSENTIAL OFF-PATENT  
 14 OR GENERIC DRUG IF THE PRICE INCREASE IS DIRECTLY ATTRIBUTABLE TO  
 15 ADDITIONAL COSTS FOR THE DRUG IMPOSED ON THE WHOLESALE DISTRIBUTOR BY  
 16 THE MANUFACTURER OF THE DRUG.

17 2-803.

18 (A) THE MARYLAND MEDICAL ASSISTANCE PROGRAM ~~SHALL~~ MAY NOTIFY  
 19 THE ~~MANUFACTURER OF AN ESSENTIAL GENERIC DRUG AND THE~~ ATTORNEY  
 20 GENERAL OF ANY INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR  
 21 GENERIC DRUG WHEN:

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

25 ~~(2)~~ (1) THE PRICE INCREASE, BY ITSELF OR IN COMBINATION WITH  
 26 OTHER PRICE INCREASES:

27 (I) WOULD RESULT IN AN INCREASE OF 50% OR MORE IN THE  
 28 ~~AVERAGE MANUFACTURER PRICE OR~~ WHOLESALE ACQUISITION COST OF THE DRUG  
 29 WITHIN THE PRECEDING ~~2-YEAR~~ 1-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~~ 1-YEAR PERIOD; AND

4 ~~(3)~~ (2) (I) A 30-DAY SUPPLY OF THE MAXIMUM RECOMMENDED  
5 DOSAGE OF THE DRUG FOR ANY INDICATION, ACCORDING TO THE LABEL FOR THE  
6 DRUG APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, WOULD  
7 COST MORE THAN \$80 AT THE DRUG'S WHOLESALE ACQUISITION COST;

8 (II) A FULL COURSE OF TREATMENT WITH THE DRUG,  
9 ACCORDING TO THE LABEL FOR THE DRUG APPROVED UNDER THE FEDERAL FOOD,  
10 DRUG, AND COSMETIC ACT, WOULD COST MORE THAN \$80 AT THE DRUG'S  
11 WHOLESALE ACQUISITION COST; OR

12 (III) IF THE DRUG IS MADE AVAILABLE TO CONSUMERS ONLY IN  
13 QUANTITIES THAT DO NOT CORRESPOND TO A 30-DAY SUPPLY, A FULL COURSE OF  
14 TREATMENT, OR A SINGLE DOSE, IT WOULD COST MORE THAN \$80 AT THE DRUG'S  
15 WHOLESALE ACQUISITION COST TO OBTAIN A 30-DAY SUPPLY OR A FULL COURSE OF  
16 TREATMENT.

17 (B) ~~WITHIN 20 DAYS AFTER THE DATE OF RECEIPT OF A NOTICE UNDER~~  
18 ~~SUBSECTION (A) OF THIS SECTION ON REQUEST OF THE ATTORNEY GENERAL, THE~~  
19 ~~MANUFACTURER OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG SHALL~~  
20 ~~IDENTIFIED IN A NOTICE UNDER SUBSECTION (A) OF THIS SECTION, WITHIN 20 45~~  
21 ~~DAYS AFTER THE REQUEST, SHALL~~ SUBMIT A STATEMENT TO THE ATTORNEY  
22 GENERAL:

23 (1) (I) ITEMIZING THE COMPONENTS OF THE COST OF PRODUCING  
24 THE ~~ESSENTIAL-GENERIC~~ DRUG; AND

25 (II) IDENTIFYING THE CIRCUMSTANCES AND TIMING OF ANY  
26 INCREASE IN MATERIALS OR MANUFACTURING COSTS THAT CAUSED ANY INCREASE  
27 IN THE PRICE OF THE ~~ESSENTIAL-GENERIC~~ DRUG WITHIN THE ~~2-YEAR~~ 1-YEAR  
28 PERIOD PRECEDING THE DATE OF THE PRICE INCREASE;

29 (2) (I) IDENTIFYING THE CIRCUMSTANCES AND TIMING OF ANY  
30 EXPENDITURES MADE BY THE MANUFACTURER TO EXPAND ACCESS TO THE  
31 ~~ESSENTIAL-GENERIC~~ DRUG; AND

32 (II) EXPLAINING ANY IMPROVEMENT IN PUBLIC HEALTH  
33 ASSOCIATED WITH THOSE EXPENDITURES; AND

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

4           **(C) THE ATTORNEY GENERAL MAY REQUIRE A MANUFACTURER OR A**  
5 **WHOLESALE DISTRIBUTOR TO PRODUCE ANY RECORDS OR OTHER DOCUMENTS**  
6 **THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS**  
7 **SUBTITLE HAS OCCURRED.**

8           **(D) ON PETITION OF THE ATTORNEY GENERAL AND SUBJECT TO**  
9 **SUBSECTION (E) OF THIS SECTION, A CIRCUIT COURT MAY ISSUE AN ORDER:**

10           **(1) COMPELLING ~~THE~~ A MANUFACTURER OR A WHOLESALE**  
11 **DISTRIBUTOR ~~OF AN ESSENTIAL GENERIC DRUG~~:**

12                   **(I) TO PROVIDE THE STATEMENT REQUIRED UNDER**  
13 **SUBSECTION (B) OF THIS SECTION; ~~OR~~ AND**

14                   **(II) TO PRODUCE SPECIFIC RECORDS OR OTHER DOCUMENTS**  
15 **REQUESTED BY THE ATTORNEY GENERAL UNDER SUBSECTION (C) OF THIS SECTION**  
16 **THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS**  
17 **SUBTITLE HAS OCCURRED;**

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

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

22           **(4) REQUIRING A MANUFACTURER THAT HAS ENGAGED IN PRICE**  
23 **GOUGING IN THE SALE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG TO MAKE**  
24 **THE ~~ESSENTIAL GENERIC~~ DRUG AVAILABLE TO PARTICIPANTS IN ANY STATE**  
25 **HEALTH PLAN OR STATE HEALTH PROGRAM FOR A PERIOD OF UP TO 1 YEAR AT THE**  
26 **PRICE AT WHICH THE DRUG WAS MADE AVAILABLE TO PARTICIPANTS IN THE STATE**  
27 **HEALTH PLAN OR STATE HEALTH PROGRAM IMMEDIATELY PRIOR TO THE**  
28 **MANUFACTURER'S VIOLATION OF THIS SUBTITLE; AND**

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

31           **(E) THE ATTORNEY GENERAL MAY NOT BRING AN ACTION FOR A REMEDY**  
32 **UNDER SUBSECTION (D)(2) THROUGH (5) OF THIS SECTION UNLESS THE ATTORNEY**  
33 **GENERAL HAS PROVIDED THE MANUFACTURER OR WHOLESALE DISTRIBUTOR AN**  
34 **OPPORTUNITY TO MEET WITH THE ATTORNEY GENERAL TO OFFER A JUSTIFICATION**

1 FOR THE INCREASE IN THE PRICE OF THE ESSENTIAL OFF-PATENT OR GENERIC  
2 DRUG.

3 ~~(E) (F) (1)~~ ANY INFORMATION PROVIDED BY A MANUFACTURER OR A  
4 WHOLESALE DISTRIBUTOR TO THE ATTORNEY GENERAL UNDER THIS SUBTITLE  
5 SUBSECTIONS (B) AND (C) OF THIS SECTION SHALL BE SUBJECT TO PUBLIC  
6 INSPECTION ONLY TO THE EXTENT PERMITTED UNDER TITLE 4 OF THE GENERAL  
7 PROVISIONS ARTICLE.

8 ~~(2)~~ THE INFORMATION INCLUDED IN THE STATEMENT PROVIDED  
9 UNDER SUBSECTION (B) OF THIS SECTION SHALL BE CONSIDERED CONFIDENTIAL  
10 COMMERCIAL INFORMATION FOR PURPOSES OF § 4-335 OF THE GENERAL  
11 PROVISIONS ARTICLE UNLESS THE CONFIDENTIALITY OF THE INFORMATION IS  
12 WAIVED BY THE MANUFACTURER OR WHOLESALE DISTRIBUTOR.

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

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

Approved:

\_\_\_\_\_  
Governor.

\_\_\_\_\_  
Speaker of the House of Delegates.

\_\_\_\_\_  
President of the Senate.