

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, R. 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~~ P. Young, Pendergrass, Angel, Kipke, McDonough, Metzgar, Miele, Saab, West, Aumann, Carey, Mautz, and S. Howard**

Introduced and read first time: January 30, 2017

Assigned to: Health and Government Operations and Economic Matters

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 16, 2017

CHAPTER _____

1 AN ACT concerning

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

4 FOR the purpose of prohibiting a manufacturer or wholesale distributor from engaging in
5 price gouging in the sale of an essential off–patent or generic drug; requiring the
6 Maryland Medical Assistance Program to notify ~~the manufacturer of an essential~~
7 ~~generic drug and~~ the Attorney General of a certain increase in the price of ~~the an~~
8 essential off–patent or generic drug under certain circumstances; requiring a
9 manufacturer of an essential off–patent or generic drug to submit a certain
10 statement to the Attorney General within a certain time frame; authorizing the
11 Attorney General to require a manufacturer of an essential off–patent or generic
12 drug to produce certain records or other documents that may be relevant in
13 determining whether a certain violation has occurred; authorizing a circuit court,

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.



1 under certain circumstances, to issue certain orders compelling certain actions,
 2 restraining or enjoining certain violations, and imposing a certain civil penalty;
 3 making certain information subject to public inspection only to the extent permitted
 4 under certain provisions of law; providing that information included in a certain
 5 statement be considered confidential commercial information for certain purposes;
 6 prohibiting a person who is alleged to have violated a requirement of this Act from
 7 asserting a certain defense; defining certain terms; and generally relating to
 8 prohibiting price gouging in the sale of essential off-patent or generic drugs.

9 BY adding to

10 Article – Health – General

11 Section 2–801 through 2–803 to be under the new subtitle “Subtitle 8. Prohibition
 12 Against Price Gouging for Essential Off–Patent or Generic Drugs”

13 Annotated Code of Maryland

14 (2015 Replacement Volume and 2016 Supplement)

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

17 **Article – Health – General**

18 **SUBTITLE 8. PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL**
 19 **OFF–PATENT OR GENERIC DRUGS.**

20 **2–801.**

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

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

25 ~~(C)~~ (B) (1) “ESSENTIAL OFF–PATENT OR GENERIC DRUG” MEANS ANY
 26 PRESCRIPTION DRUG:

27 (I) FOR WHICH ~~ANY~~ ALL EXCLUSIVE MARKETING RIGHTS, IF
 28 ANY, GRANTED UNDER FEDERAL LAW THE FEDERAL FOOD, DRUG, AND COSMETIC
 29 ACT, § 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT
 30 LAW HAVE EXPIRED;

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

33 2. THAT HAS BEEN DESIGNATED BY THE SECRETARY AS
 34 AN ESSENTIAL MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE–THREATENING

1 HEALTH CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY
2 IMPAIRS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY LIVING; AND

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

4 (2) "ESSENTIAL OFF-PATENT OR GENERIC DRUG" INCLUDES ANY
5 DRUG-DEVICE COMBINATION PRODUCT USED FOR THE DELIVERY OF ~~AN ESSENTIAL~~
6 ~~GENERIC~~ A DRUG FOR WHICH ALL EXCLUSIVE MARKETING RIGHTS, IF ANY,
7 GRANTED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, § 351 OF THE
8 FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT LAW HAVE
9 EXPIRED.

10 ~~(D)~~ (C) "PRICE GOUGING" MEANS AN UNCONSCIONABLE INCREASE IN
11 THE PRICE OF A PRESCRIPTION DRUG.

12 ~~(E)~~ (D) "STATE HEALTH PLAN" HAS THE MEANING STATED IN § 2-601 OF
13 THIS TITLE.

14 ~~(F)~~ (E) "STATE HEALTH PROGRAM" HAS THE MEANING STATED IN § 2-601
15 OF THIS TITLE.

16 ~~(G)~~ (F) "UNCONSCIONABLE INCREASE" MEANS AN INCREASE IN THE
17 PRICE OF A PRESCRIPTION DRUG THAT:

18 (1) IS EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING
19 THE DRUG OR THE COST OF APPROPRIATE EXPANSION OF ACCESS TO THE DRUG TO
20 PROMOTE PUBLIC HEALTH; AND

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

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

25 (II) INSUFFICIENT COMPETITION IN THE MARKET FOR THE
26 DRUG.

27 ~~(H)~~ (G) "WHOLESALE ACQUISITION COST" HAS THE MEANING STATED IN
28 42 U.S.C. § 1395W-3A.

29 2-802.

30 A MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY NOT ENGAGE IN PRICE
31 GOUGING IN THE SALE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG.

1 2-803.

2 (A) THE MARYLAND MEDICAL ASSISTANCE PROGRAM SHALL NOTIFY THE
3 ~~MANUFACTURER OF AN ESSENTIAL GENERIC DRUG AND THE~~ ATTORNEY GENERAL
4 OF ANY INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG
5 WHEN:

6 (1) THREE OR FEWER MANUFACTURERS ARE ACTIVELY
7 MANUFACTURING AND MARKETING THE ~~ESSENTIAL GENERIC~~ DRUG FOR SALE IN
8 THE UNITED STATES; ~~AND~~

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

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

14 (II) WOULD RESULT IN AN INCREASE OF 50% OR MORE IN THE
15 PRICE PAID BY THE MARYLAND MEDICAL ASSISTANCE PROGRAM FOR THE DRUG
16 WITHIN THE PRECEDING ~~2-YEAR~~ 1-YEAR PERIOD; ~~AND~~

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

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

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

30 (B) ~~WITHIN 20 DAYS AFTER THE DATE OF RECEIPT OF A NOTICE UNDER~~
31 ~~SUBSECTION (A) OF THIS SECTION~~ ON REQUEST OF THE ATTORNEY GENERAL, THE
32 MANUFACTURER OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG SHALL
33 IDENTIFIED IN A NOTICE UNDER SUBSECTION (A) OF THIS SECTION, WITHIN 20 DAYS
34 AFTER THE REQUEST, SHALL SUBMIT A STATEMENT TO THE ATTORNEY GENERAL:

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

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

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

10 (II) EXPLAINING ANY IMPROVEMENT IN PUBLIC HEALTH
11 ASSOCIATED WITH THOSE EXPENDITURES; AND

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

15 (C) THE ATTORNEY GENERAL MAY REQUIRE A MANUFACTURER OR A
16 WHOLESALE DISTRIBUTOR TO PRODUCE ANY RECORDS OR OTHER DOCUMENTS
17 THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS
18 SUBTITLE HAS OCCURRED.

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

21 (1) COMPELLING ~~THE~~ A MANUFACTURER OR A WHOLESALE
22 DISTRIBUTOR ~~OF AN ESSENTIAL-GENERIC DRUG~~;

23 (I) TO PROVIDE THE STATEMENT REQUIRED UNDER
24 SUBSECTION (B) OF THIS SECTION; ~~OR~~ AND

25 (II) TO PRODUCE SPECIFIC RECORDS OR OTHER DOCUMENTS
26 REQUESTED BY THE ATTORNEY GENERAL UNDER SUBSECTION (C) OF THIS SECTION
27 THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS
28 SUBTITLE HAS OCCURRED;

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

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

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

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

10 **(E) (1) ANY INFORMATION PROVIDED TO THE ATTORNEY GENERAL**
 11 **UNDER THIS SUBTITLE SHALL BE SUBJECT TO PUBLIC INSPECTION ONLY TO THE**
 12 **EXTENT PERMITTED UNDER TITLE 4 OF THE GENERAL PROVISIONS ARTICLE.**

13 **(2) THE INFORMATION INCLUDED IN THE STATEMENT PROVIDED**
 14 **UNDER SUBSECTION (B) OF THIS SECTION SHALL BE CONSIDERED CONFIDENTIAL**
 15 **COMMERCIAL INFORMATION FOR PURPOSES OF § 4-335 OF THE GENERAL**
 16 **PROVISIONS ARTICLE.**

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.