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–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**

Read and Examined by Proofreaders:

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Proofreader.

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Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____M.

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Speaker.

CHAPTER _____

AN ACT concerning

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

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.

FOR the purpose of prohibiting a manufacturer or wholesale distributor from engaging in price gouging in the sale of an essential off–patent or generic drug; *establishing that it is not a violation of a certain provision of this Act for a wholesale distributor to increase a price of an essential off–patent or generic drug under certain circumstances;* ~~requiring~~ *authorizing* 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~~ an essential off–patent or generic drug under certain circumstances; requiring a manufacturer of an essential off–patent or 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 off–patent or 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; ~~making certain information subject to public inspection only to the extent permitted under certain provisions of law; providing that information included in a certain statement~~ *requiring that certain information provided to the Attorney General under this Act* be considered confidential commercial information for certain purposes *except under certain circumstances; prohibiting the Attorney General from bringing a certain action under certain circumstances*; 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 off–patent or 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 Off–Patent or 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 OFF–PATENT OR 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)~~ (B) (1) "ESSENTIAL OFF–PATENT OR GENERIC DRUG" MEANS ANY PRESCRIPTION DRUG:

(I) FOR WHICH ~~ANY~~ ALL EXCLUSIVE MARKETING RIGHTS, IF ANY, GRANTED UNDER ~~FEDERAL LAW~~ THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, § 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT 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 ACTIVELY MANUFACTURED AND MARKETED FOR SALE IN THE UNITED STATES BY THREE OR FEWER MANUFACTURERS; AND

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

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

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

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

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

~~(G)~~ (F) "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)~~ (G) "WHOLESALE ACQUISITION COST" HAS THE MEANING STATED IN 42 U.S.C. § 1395W–3A.

2–802.

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

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

2–803.

(A) THE MARYLAND MEDICAL ASSISTANCE PROGRAM ~~SHALL~~ *MAY* NOTIFY THE ~~MANUFACTURER OF AN ESSENTIAL GENERIC DRUG AND THE~~ ATTORNEY GENERAL OF ANY INCREASE IN THE PRICE OF AN ESSENTIAL OFF–PATENT OR 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)~~ *(1)* 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~~ 1–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~~ 1–YEAR PERIOD; AND

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

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

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

(B) ~~WITHIN 20 DAYS AFTER THE DATE OF RECEIPT OF A NOTICE UNDER SUBSECTION (A) OF THIS SECTION~~ ON REQUEST OF THE ATTORNEY GENERAL, THE MANUFACTURER OF AN ESSENTIAL OFF–PATENT OR GENERIC DRUG ~~SHALL~~ IDENTIFIED IN A NOTICE UNDER SUBSECTION (A) OF THIS SECTION, WITHIN ~~20~~ *45* DAYS AFTER THE REQUEST, 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~~ 1–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 OR A WHOLESALE DISTRIBUTOR 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 *AND SUBJECT TO SUBSECTION (E) OF THIS SECTION*, A CIRCUIT COURT MAY ISSUE AN ORDER:

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

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

(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 OFF–PATENT OR 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) THE ATTORNEY GENERAL MAY NOT BRING AN ACTION FOR A REMEDY UNDER SUBSECTION (D)(2) THROUGH (5) OF THIS SECTION UNLESS THE ATTORNEY GENERAL HAS PROVIDED THE MANUFACTURER OR WHOLESALE DISTRIBUTOR AN OPPORTUNITY TO MEET WITH THE ATTORNEY GENERAL TO OFFER A JUSTIFICATION

FOR THE INCREASE IN THE PRICE OF THE ESSENTIAL OFF–PATENT OR GENERIC DRUG.

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

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

~~(E)~~ ~~(F)~~ ***(G)*** **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.

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.