

HB0631/376789/1

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 631

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and P. Young” and substitute “P. Young, Pendergrass, Angel, Kipke, McDonough, Metzgar, Miele, Saab, West, Aumann, Carey, Mautz, and S. Howard”; in lines 2 and 20, in each instance, after “Essential” insert “Off-Patent or”; in lines 4, 6, 7, 9, and 16, in each instance, after “essential” insert “off-patent or”; in lines 5 and 6, strike “the manufacturer of an essential generic drug and”; in line 6, strike the third “the” and substitute “an”; and in line 13, after “penalty;” insert “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 be considered confidential commercial information for certain purposes;”.

AMENDMENT NO. 2

On page 2, in line 6, after “**ESSENTIAL**” insert “**OFF-PATENT OR**”; strike in their entirety lines 11 and 12; in lines 13, 26, and 28, strike “**(C)**”, “**(D)**”, and “**(E)**”, respectively, and substitute “**(B)**”, “**(C)**”, and “**(D)**”, respectively; in lines 13 and 23, in each instance, after “**ESSENTIAL**” insert “**OFF-PATENT OR**”; in line 14, strike “**ANY**” and substitute “**ALL**”; in the same line, after “**RIGHTS**” insert “**, IF ANY,**”; in line 15, strike “**FEDERAL LAW**” and substitute “**THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, § 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT LAW**”; in line 24, strike “**AN ESSENTIAL GENERIC**” and substitute “**A**”; and in line 25, after “**DRUG**” insert “**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**”.

AMENDMENT NO. 3

(Over)

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On page 3, in lines 1, 3, and 14, strike “(F)”, “(G)”, and “(H)”, respectively, and substitute “(E)”, “(F)”, and “(G)”, respectively; in lines 18 and 22, in each instance, after “ESSENTIAL” insert “OFF-PATENT OR”; in line 21, strike “MANUFACTURER OF AN ESSENTIAL GENERIC DRUG AND THE”; in line 24, strike “ESSENTIAL GENERIC”; in line 25, strike “AND”; in line 29, strike “AVERAGE MANUFACTURER PRICE OR”; and in line 30, strike “2-YEAR” and substitute “1-YEAR”.

On page 4, in lines 3 and 11, in each instance, strike “2-YEAR” and substitute “1-YEAR”; in line 3, after “PERIOD” insert “; AND”

(3) (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;

strike beginning with “WITHIN” in line 4 down through “SECTION” in line 5 and substitute “ON REQUEST OF THE ATTORNEY GENERAL”; in line 5, after “ESSENTIAL” insert “OFF-PATENT OR”; in line 6, strike “SHALL” and substitute “IDENTIFIED IN A NOTICE UNDER SUBSECTION (A) OF THIS SECTION, WITHIN 20”

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DAYS AFTER THE REQUEST, SHALL"; in lines 8, 11, and 15, in each instance, strike "ESSENTIAL GENERIC"; in lines 21 and 26, in each instance, after "MANUFACTURER", insert "**OR A WHOLESALE DISTRIBUTOR**"; in line 26, strike "THE" and substitute "**A**"; in lines 26 and 27, strike "OF AN ESSENTIAL GENERIC DRUG"; and in line 29, strike "OR" and substitute "**AND**".

On page 5, in line 8, after "ESSENTIAL" insert "**OFF-PATENT OR**"; and in lines 8 and 9, strike "ESSENTIAL GENERIC".

AMENDMENT NO. 4

On page 5, after line 15, insert:

"(E) (1) ANY INFORMATION PROVIDED TO THE ATTORNEY GENERAL UNDER THIS SUBTITLE 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.";

and in line 16, strike "**(E)**" and substitute "**(F)**".