HOUSE BILL 664

J2 0lr0104

By: **Chair, Health and Government Operations Committee (By Request – Departmental – Health)**
Introduced and read first time: January 29, 2020
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Pharmacists – Required Notification and Authorized Substitution – Lower–Costing Drugs, Medical Devices, and Biological Products

FOR the purpose of requiring a pharmacist or a pharmacist's designee who is under certain supervision to inform a certain consumer of the availability of certain therapeutically equivalent drugs, substantially equivalent medical devices, or interchangeable biological products and the cost difference between those drugs, devices, or products and certain prescribed drugs, medical devices, or biological products; repealing the exclusion of prescriptions written for generic and interchangeable biological products from certain provisions of law requiring pharmacists and pharmacists' designees to inform retail consumers of certain information; authorizing a pharmacist to substitute certain therapeutically equivalent drugs, substantially equivalent medical devices, or interchangeable biological products for certain prescribed drugs, medical devices, or biological products under certain circumstances; requiring a pharmacist to provide certain notice to a patient if a certain therapeutically equivalent drug, substantially equivalent medical device, or interchangeable biological product is substituted for a prescribed drug, medical device, or biological product; authorizing the Maryland Department of Health, under certain circumstances, to disqualify certain drugs or medical devices from being used in the State as a substitute; defining certain terms; altering a certain definition; repealing a certain definition; providing for a delayed effective date; making stylistic and conforming changes; and generally relating to pharmacists and drugs, medical devices, and biological products.

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–101(a)
Annotated Code of Maryland
(2014 Replacement Volume and 2019 Supplement)

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–101(m) and 12–504
Annotated Code of Maryland
(2014 Replacement Volume and 2019 Supplement)

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

Article – Health Occupations

12–101.

(a) In this title the following words have the meanings indicated.

(m) "Interchangeable biological product" means a biological product that is:

(1) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

(2) Determined to be therapeutically equivalent as stated in the latest edition of or supplement to the United States Food and Drug Administration's approved drug products with therapeutic equivalence evaluations (the "**[**Orange**]** **PURPLE** Book").

12–504.

[(a) In this section, "brand name" means the proprietary name a manufacturer places on a drug or device product or its container.**]**

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "PRESCRIBED DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT" MEANS A BRAND NAME DRUG, GENERIC DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT PRESCRIBED BY A HEALTH CARE PROVIDER WHO IS LICENSED UNDER THIS ARTICLE AND AUTHORIZED TO PRESCRIBE THE BRAND NAME DRUG, GENERIC DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT.

(3) "SUBSTANTIALLY EQUIVALENT MEDICAL DEVICE" MEANS A MEDICAL DEVICE THAT THE UNITED STATES FOOD AND DRUG ADMINISTRATION DETERMINES TO BE SUBSTANTIALLY EQUIVALENT TO ANOTHER MEDICAL DEVICE UNDER § 510(K) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(4) "THERAPEUTICALLY EQUIVALENT DRUG" MEANS A BRAND NAME DRUG OR A GENERIC DRUG THAT IS OF THE SAME DOSAGE FORM AND STRENGTH AND DETERMINED TO BE THERAPEUTICALLY EQUIVALENT TO ANOTHER BRAND NAME DRUG OR GENERIC DRUG AS STATED IN THE LATEST EDITION OF OR SUPPLEMENT TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (THE "ORANGE BOOK").

(b) (1) Subject to the provisions of this subtitle, a pharmacist, or the pharmacist's designee, who is under the direct supervision of the pharmacist, shall inform a retail consumer to the best of the pharmacist's or the pharmacist's designee's knowledge of **[**the**]:**

(I) THE availability of a **[**generically**]** **THERAPEUTICALLY** equivalent drug**, A SUBSTANTIALLY EQUIVALENT MEDICAL DEVICE,** or an interchangeable biological product **[**and shall inform a retail consumer of the approximate cost difference as compared to the brand name drug**]** **THAT COSTS LESS THAN THE PRESCRIBED DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT; AND**

(II) THE COST DIFFERENCE BETWEEN THE PRESCRIBED DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT AND THE LOWER–COSTING THERAPEUTICALLY EQUIVALENT DRUG, SUBSTANTIALLY EQUIVALENT MEDICAL DEVICE, OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

(2) The Board shall adopt procedures for:

(i) A consumer to notify the Board when a pharmacist fails to provide the information required under paragraph (1) of this subsection; and

(ii) Advising a pharmacist to bring the pharmacist into compliance with the requirements of paragraph (1) of this subsection.

(3) Paragraph (1) of this subsection does not apply:

[(i) To a prescription that is written for a generic drug or an interchangeable biological product;**]**

[(ii)**] (I)** When the authorized prescriber states expressly that the prescription is to be dispensed only as directed;

[(iii)**] (II)** To a pharmacist who works in a pharmacy, whether centralized or decentralized, which primarily serves public or private institutional recipients; or

[(iv)**] (III)** When the cost of the prescription is reimbursed by a third

party payer, including medical assistance.

(c) The Board shall maintain a link on its **[**Web site**]** **WEBSITE** to the current lists of biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

(d) A pharmacist may substitute a **[**generically**]** **THERAPEUTICALLY** equivalent drug **[**or**],** **A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or an interchangeable biological product**[**, of the same dosage form and strength,**]** for any **[**brand name drug or device product prescribed**]** **PRESCRIBED DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT**, if:

(1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed; **AND**

[(2) The substitution is:

(i) Recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; or

(ii) An interchangeable biological product for the brand name drug or device product prescribed; and**]**

[(3)**]** **(2)** The consumer is charged less for the substituted **THERAPEUTICALLY EQUIVALENT** drug **[**or**], SUBSTANTIALLY EQUIVALENT MEDICAL** device**,** or interchangeable biological product than the price of the **[**brand name drug or device**]** **PRESCRIBED DRUG, MEDICAL DEVICE, OR BIOLOGICAL PRODUCT**.

(e) If a **THERAPEUTICALLY EQUIVALENT** drug **[**or**], A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or an interchangeable biological product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that **[**the drug or device product or interchangeable biological product dispensed is a generic equivalent of or is interchangeable with the prescribed drug or device product**]:**

(I) THE DISPENSED DRUG IS A THERAPEUTICALLY EQUIVALENT DRUG TO THE PRESCRIBED DRUG;

(II) THE DISPENSED MEDICAL DEVICE IS A SUBSTANTIALLY EQUIVALENT MEDICAL DEVICE TO THE PRESCRIBED MEDICAL DEVICE; OR

(III) THE DISPENSED BIOLOGICAL PRODUCT IS AN INTERCHANGEABLE BIOLOGICAL PRODUCT TO THE PRESCRIBED BIOLOGICAL

PRODUCT; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted **THERAPEUTICALLY EQUIVALENT** drug **[**or**],** **SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or interchangeable biological product.

(f) **[**The**]** **IN ADDITION TO THERAPEUTICALLY EQUIVALENT DRUGS AND SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES IDENTIFIED AS SUBSTITUTIONS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION, THE** Department may list any additional **[**drug or device products**]** **DRUGS OR MEDICAL DEVICES** that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence **OR SUBSTANTIAL EQUIVALENCE**, after an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article.

(g) The Department may disqualify a **THERAPEUTICALLY EQUIVALENT** drug **[**or**], A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or an interchangeable biological product **[**on the United States Food and Drug Administration's current list**]** from being used in Maryland as a substitute if the Department determines that the **THERAPEUTICALLY EQUIVALENT** drug **[**or**], SUBSTANTIALLY EQUIVALENT MEDICAL** device**,** or interchangeable biological product is therapeutically nonequivalent**, SUBSTANTIALLY NONEQUIVALENT,** or not interchangeable, respectively, or has a negative physical or biological effect on the consumer of that **THERAPEUTICALLY EQUIVALENT** drug **[**or**], SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or interchangeable biological product:

(1) After providing an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article; or

(2) Prior to providing an opportunity for public comment, if the Department believes that a particular **THERAPEUTICALLY EQUIVALENT DRUG THAT IS A** generic drug **[**or**], A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or **AN** interchangeable biological product constitutes an imminent danger to the public health, safety or welfare, and the Department:

(i) Provides an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the **THERAPEUTICALLY EQUIVALENT** drug **[**or**], THE SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or **THE** interchangeable biological product; and

(ii) After providing an opportunity for public comment, determines whether the **THERAPEUTICALLY EQUIVALENT** drug **[**or**], THE SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or **THE** interchangeable biological product should remain disqualified.

(h) For a **THERAPEUTICALLY EQUIVALENT** drug **[**or**], A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or an interchangeable biological product that the Department has disqualified from being used in Maryland as a substitute under subsection (g) of this section, the Department shall provide an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article before reinstating the **THERAPEUTICALLY EQUIVALENT** drug **[**or**], THE SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or **THE** interchangeable biological product for use in Maryland as a substitute.

(i) A pharmacist who substitutes a **THERAPEUTICALLY EQUIVALENT** drug **[**or**], A SUBSTANTIALLY EQUIVALENT MEDICAL** device **[**product**],** or an interchangeable biological product in compliance with this section incurs no greater liability in filling the prescription by dispensing the **THERAPEUTICALLY** equivalent drug **[**or**], SUBSTANTIALLY EQUIVALENT** device **[**product**],** or interchangeable biological product than would be incurred in filling the **[**prescription by dispensing the prescribed brand name**] PRESCRIBED** drug **[**or**], MEDICAL** device**, OR BIOLOGICAL PRODUCT**.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2021.