SENATE BILL 537

J2 1lr1835
CF HB 429

By: **Senator Hershey**
Introduced and read first time: January 26, 2021
Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: February 26, 2021

CHAPTER _____

AN ACT concerning

Pharmacists – Required Notification and Authorized Substitution – Lower–Cost Drug or Device Product

FOR the purpose of requiring a pharmacist, or the pharmacist's designee who is under certain supervision, to inform a certain consumer of the availability of certain therapeutically equivalent drugs and the cost difference between the therapeutically equivalent drug and a certain prescribed drug; altering the cost difference of which a pharmacist, or the pharmacist's designee, is required to inform a retail consumer under certain circumstances; applying a certain provision of law governing the provision of certain information to a retail consumer regarding the availability of certain drugs and products and certain cost differences to a prescription that is written for a generic drug or an interchangeable biological product; authorizing a pharmacist to substitute certain drugs and device products for any originally prescribed drug or device product, rather than only for originally prescribed brand name drug or device products; authorizing a pharmacist to substitute a therapeutically equivalent brand name drug or device product for a certain prescribed drug or device product under certain circumstances; requiring a pharmacist to provide certain notice or maintain a certain record of certain notice to a patient and make and keep a certain record if a certain therapeutically equivalent brand name drug or device is substituted for a certain drug or device product; altering a certain provision of law to allow a pharmacist to maintain a record that a patient has been notified in a certain manner of a certain substitution; requiring that a certain determination be based on a consumer's prescription benefit and formulary under certain circumstances; making stylistic and conforming changes; and generally relating to pharmacists and drugs and device products.

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.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–504
Annotated Code of Maryland
(2014 Replacement Volume and 2020 Supplement)

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

Article – Health Occupations

12–504.

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

(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 availability of a generically equivalent drug**, A THERAPEUTICALLY EQUIVALENT BRAND NAME DRUG THAT IS THE LOWEST–COST ALTERNATIVE TO THE ORIGINALLY PRESCRIBED GENERICALLY EQUIVALENT DRUG,** or an interchangeable biological product and shall inform a retail consumer of the approximate cost difference **OF THE LOWEST–COST ALTERNATIVE** as compared to the **[**brand name**]** **ORIGINALLY PRESCRIBED** drug.

(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)**]** 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) **(1)** A pharmacist may substitute a generically equivalent drug or device product**, A THERAPEUTICALLY EQUIVALENT BRAND NAME DRUG OR DEVICE PRODUCT TO THE ORIGINALLY PRESCRIBED GENERICALLY EQUIVALENT DRUG OR DEVICE PRODUCT,** or an interchangeable biological product, of the same dosage form and strength, for **[**any brand name**] THE** drug or device product **ORIGINALLY** prescribed, if:

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

[(2)**] (II)** The substitution is:

[(i)**] 1.** Recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; or

[(ii)**] 2.** An interchangeable biological product for the **[**brand name**]** drug or device product **ORIGINALLY** prescribed; and

[(3)**] (III)** The consumer is charged less for the substituted drug or device or interchangeable biological product than the price of the **[**brand name**] ORIGINALLY PRESCRIBED** drug or device.

(2) IF A RETAIL CONSUMER IS USING PRESCRIPTION DRUG COVERAGE FOR THE PRESCRIPTION, THE DETERMINATION OF WHETHER THE CONSUMER WOULD BE CHARGED LESS FOR THE SUBSTITUTED DRUG OR DEVICE OR INTERCHANGEABLE BIOLOGICAL PRODUCT SHALL BE BASED ON THE CONSUMER'S PRESCRIPTION DRUG BENEFIT AND FORMULARY, IF THAT INFORMATION IS READILY AVAILABLE.

(e) If a drug or device product or an interchangeable biological product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing**, OR MAINTAIN A RECORD THAT INDICATES THE PATIENT HAS BEEN NOTIFIED IN WRITING OR ORALLY,** that the drug or device product or interchangeable biological product dispensed is a generic equivalent of**, A BRAND NAME DRUG OR DEVICE PRODUCT THAT IS THERAPEUTICALLY**

EQUIVALENT TO, or is interchangeable with the **ORIGINALLY** prescribed drug or device product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug or device product or interchangeable biological product.

(f) The Department may list any additional drug or device products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic 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 drug or 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 drug or device or interchangeable biological product is therapeutically nonequivalent or not interchangeable, respectively, or has a negative physical or biological effect on the consumer of that drug or 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 generic drug or device product or 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 drug or device product or interchangeable biological product; and

(ii) After providing an opportunity for public comment, determines whether the drug or device product or interchangeable biological product should remain disqualified.

(h) For a drug or 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 drug or device product or interchangeable biological product for use in Maryland as a substitute.

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

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

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.