SENATE BILL 537

J2 5lr0654
CF HB 733

By: **Senator Conway**
Introduced and read first time: February 6, 2015
Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 17, 2015

CHAPTER _____

AN ACT concerning

Pharmacists – Substitution and Dispensing – Interchangeable Biological Products

FOR the purpose of authorizing certain pharmacists to substitute certain interchangeable biological products for certain prescribed products only under certain circumstances; requiring certain pharmacists or certain designees to inform certain consumers of the availability of an interchangeable biological product and the approximate cost difference as compared to a certain drug; providing that the requirement to provide certain information to certain consumers does not apply to a prescription that is written for an interchangeable biological product; requiring the State Board of Pharmacy to maintain on its Web site a link to a certain list of biological products; requiring certain pharmacists who make certain substitutions to notify certain patients that a certain product is interchangeable and to record and keep a record of certain information relating to the substitution; authorizing the Department of Health and Mental Hygiene to disqualify an interchangeable biological product from being used as a substitute in Maryland under certain circumstances; requiring the Department to provide an opportunity for public comment under certain circumstances; providing that certain pharmacists who substitute an interchangeable biological product in compliance with certain provisions of law incur no greater liability than would be incurred in filling the prescription by dispensing a certain drug or device; requiring certain pharmacists or their designees to notify certain prescribers of the provision of a certain product to a patient within a certain period of time after dispensing the product; specifying the methods by which certain notice must be provided, subject to ~~a certain exception~~ certain exceptions; providing

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.

a certain exception to the notice requirement; defining certain terms; and generally relating to the substitution and dispensing of interchangeable biological products.

BY renumbering
Article – Health Occupations
Section 12–101(c) through (i) and (j) through (w), respectively
to be Section 12–101(d) through (j) and (m) through (aa), respectively
Annotated Code of Maryland
(2014 Replacement Volume)

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

BY adding to
Article – Health Occupations
Section 12–101(c), (k), and (l) and 12–504.1
Annotated Code of Maryland
(2014 Replacement Volume)

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

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 12–101(c) through (i) and (j) through (w), respectively, of Article – Health Occupations of the Annotated Code of Maryland be renumbered to be Section(s) 12–101(d) through (j) and (m) through (aa), respectively.

SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article – Health Occupations

12–101.

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

(C) "BIOLOGICAL PRODUCT" HAS THE MEANING STATED IN 42 U.S.C. § 262(I).

(K) "DRUG" HAS THE MEANING STATED IN § 21–101 OF THE HEALTH – GENERAL ARTICLE.

(L) "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT THAT IS:

(1) LICENSED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND DETERMINED TO BE INTERCHANGEABLE UNDER 42 U.S.C. § 262(K)(4); OR

(2) DETERMINED TO BE THERAPEUTICALLY EQUIVALENT UNDER THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S CURRENT LIST OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (THE "ORANGE 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.

(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 **OR INTERCHANGEABLE BIOLOGICAL PRODUCT** and shall inform a retail consumer of the approximate cost difference as compared to the brand name 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 INTERCHANGEABLE BIOLOGICAL PRODUCT**;

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

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

(iv) 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 TO THE CURRENT LIST OF BIOLOGICAL PRODUCTS DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH A SPECIFIC BIOLOGICAL PRODUCT.

[(c)**] (D)** A pharmacist may substitute a generically equivalent drug or device product **OR AN INTERCHANGEABLE BIOLOGICAL PRODUCT**, of the same dosage form and strength, for any brand name drug or device product prescribed, if:

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

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

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

(II) AN INTERCHANGEABLE BIOLOGICAL PRODUCT; AND

(3) The consumer is charged less for the substituted drug or device **OR INTERCHANGEABLE BIOLOGICAL PRODUCT** than the price of the brand name drug or device.

[(d)**] (E)** If a drug or device product **OR 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; 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**.

[(e)**] (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.

[(f)**] (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 **[**generic**]** 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.

[(g)**] (H)** For a drug or device product **OR INTERCHANGEABLE BIOLOGICAL PRODUCT** that the Department has disqualified from being used in Maryland as a **[**generic**]** substitute under subsection **[**(f)**] (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 **[**generic**]** substitute.

[(h)**] (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 prescribed brand name drug or device.

12–504.1.

(A) WITHIN A REASONABLE TIME, NOT EXCEEDING ~~10~~ 5 DAYS, AFTER ~~DISPENSING A BIOLOGICAL PRODUCT FOR WHICH THERE IS A UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE BIOLOGICAL PRODUCT PRESCRIBED~~ SUBSTITUTING AN INTERCHANGEABLE BIOLOGICAL PRODUCT UNDER § 12–504 OF THIS SUBTITLE, THE PHARMACIST OR THE PHARMACIST'S DESIGNEE SHALL NOTIFY THE AUTHORIZED PRESCRIBER OF THE BIOLOGICAL PRODUCT PROVIDED TO THE PATIENT, INCLUDING THE NAME OF THE BIOLOGICAL PRODUCT AND ITS MANUFACTURER.

(B) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, THE NOTICE REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL BE PROVIDED BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE AUTHORIZED PRESCRIBER THROUGH:

(I) AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM;

(II) AN ELECTRONIC PRESCRIBING TECHNOLOGY; OR

(III) A PHARMACY RECORD.

(2) SUBJECT TO SUBSECTION (C) OF THIS SECTION, IF ONE OF THE METHODS LISTED UNDER PARAGRAPH (1) OF THIS SUBSECTION IS NOT AVAILABLE, THEN NOTICE MAY OTHERWISE BE PROVIDED BY FACSIMILE, TELEPHONE, ELECTRONIC TRANSMISSION, OR OTHER MEANS.

(C) THE REQUIREMENT TO PROVIDE NOTICE UNDER SUBSECTION (B)(2) OF THIS SECTION DOES NOT APPLY IF A REFILL PRESCRIPTION IS NOT CHANGED FROM THE BIOLOGICAL PRODUCT DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2015.

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.