SENATE BILL 781

J2 3lr2292

By: **Senator Conway**
Introduced and read first time: February 1, 2013
Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 11, 2013

CHAPTER _____

AN ACT concerning

Pharmacists – Biosimilar Biological Products – Substitutions

FOR the purpose of authorizing certain pharmacists to substitute certain biosimilar biological products for prescribed biological reference products only under certain circumstances; requiring certain pharmacists or their designees to give certain notices and record certain information on a certain label and record of dispensing under certain circumstances; requiring records of certain substitutions to be maintained for a certain number of years; providing certain pharmacists certain liability protections under certain circumstances; defining certain terms; and generally relating to the substitution of biosimilar biological products for biological reference products.

BY renumbering
Article – Health Occupations
Section 12–101(c) through (i), (j) through (t), and (u) through (w), respectively to be Section 12–101(e) through (k), (n) through (x), and (z) through (bb), respectively
Annotated Code of Maryland
(2009 Replacement Volume and 2012 Supplement)

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–101(a) and 12–504
Annotated Code of Maryland
(2009 Replacement Volume and 2012 Supplement)

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 adding to
Article – Health Occupations
Section 12–101(c), (d), (l), (m), and (y) and 12–504.1
Annotated Code of Maryland
(2009 Replacement Volume and 2012 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 12–101(c) through (i), (j) through (t), and (u) through (w), respectively, of Article – Health Occupations of the Annotated Code of Maryland be renumbered to be Section(s) 12–101(e) through (k), (n) through (x), and (z) through (bb), respectively.

SECTION 2. AND BE 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).

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

(L) (1) "DRUG" HAS THE MEANING STATED IN § 21–101 OF THE HEALTH – GENERAL ARTICLE.

(2) "DRUG" INCLUDES A BIOLOGICAL PRODUCT.

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

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

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 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;

(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) A pharmacist may substitute a generically equivalent drug or device 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 in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; and

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

(d) If a drug or device product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug or device product dispensed is a generic equivalent of 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.

(e) 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) The Department may disqualify a drug or device 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 is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that drug or device 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 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; and

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

(g) For a drug or device product that the Department has disqualified from being used in Maryland as a generic substitute under subsection (f) 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 for use in Maryland as a generic substitute.

(h) A pharmacist who substitutes a drug or device product in compliance with this section incurs no greater liability in filling the prescription by dispensing the equivalent drug or device product than would be incurred in filling the prescription by dispensing the prescribed brand name drug or device.

12–504.1.

(A) A PHARMACIST MAY SUBSTITUTE A BIOSIMILAR BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL REFERENCE PRODUCT ONLY IF:

(1) THE BIOSIMILAR BIOLOGICAL PRODUCT HAS BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH THE PRESCRIBED BIOLOGICAL REFERENCE PRODUCT ~~FOR THE USE~~; AND

(2) THE AUTHORIZED PRESCRIBER DOES NOT STATE EXPRESSLY THAT THE PRESCRIPTION IS TO BE DISPENSED ONLY AS DIRECTED.

(B) IF A PHARMACIST SUBSTITUTES AN INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL REFERENCE PRODUCT, THE PHARMACIST, OR THE PHARMACIST'S DESIGNEE, SHALL:

(1) NOTIFY THE PATIENT IN WRITING THAT THE BIOLOGICAL PRODUCT DISPENSED HAS BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION AS AN INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT FOR THE PRESCRIBED BIOLOGICAL REFERENCE PRODUCT;

(2) PROVIDE ELECTRONIC, WRITTEN, OR TELEPHONIC NOTIFICATION OF THE SUBSTITUTION TO THE AUTHORIZED PRESCRIBER OR THE AUTHORIZED PRESCRIBER'S STAFF WITHIN 5 BUSINESS DAYS AFTER THE DISPENSING OF THE INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT; AND

(3) RECORD ON THE PRESCRIPTION LABEL AND RECORD OF DISPENSING:

(I) THE PRODUCT NAME OF THE INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT FOLLOWED BY THE WORDS "SUBSTITUTED FOR" AND THE NAME OF THE BIOLOGICAL REFERENCE PRODUCT FOR WHICH THE PRESCRIPTION WAS WRITTEN; AND

(II) THE MANUFACTURER OF THE INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.

(C) RECORDS OF SUBSTITUTIONS OF INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCTS SHALL BE MAINTAINED FOR AT LEAST 5 YEARS AFTER THE DISPENSING DATE.

(D) A PHARMACIST WHO SUBSTITUTES AN INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT IN COMPLIANCE WITH THIS SECTION INCURS NO GREATER LIABILITY IN FILLING THE PRESCRIPTION BY DISPENSING THE INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT THAN WOULD BE INCURRED IN FILLING THE PRESCRIPTION BY DISPENSING THE PRESCRIBED BIOLOGICAL REFERENCE PRODUCT.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2013.