

SENATE BILL 997

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By: **Senator Conway**

Introduced and read first time: February 3, 2017

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacists – Substitution and Dispensing of Biological Products**

3 FOR the purpose of authorizing a pharmacist to substitute an interchangeable biological
4 product for a certain prescribed product under certain circumstances; requiring a
5 pharmacist or the pharmacist's designee, except under certain circumstances, to
6 inform certain consumers of the availability of an interchangeable biological product
7 and the approximate cost difference as compared to a certain drug; requiring the
8 State Board of Pharmacy to maintain on its Web site a link to certain lists of
9 biological products; requiring a pharmacist who makes a certain substitution to
10 notify the patient in writing that a certain product is interchangeable and to record
11 and keep a record of certain information relating to the substitution; authorizing the
12 Department of Health and Mental Hygiene to disqualify an interchangeable
13 biological product from being used as a substitute in the State under certain
14 circumstances; requiring the Department to provide an opportunity for public
15 comment under certain circumstances; providing that a pharmacist who substitutes
16 an interchangeable biological product in compliance with certain provisions of law
17 incurs no greater liability than would be incurred in filling the prescription by
18 dispensing a certain drug or device; requiring, within a certain period of time after
19 dispensing a biological product to a patient, the dispensing pharmacist or the
20 pharmacist's designee to communicate the specific biological product dispensed,
21 including certain information, to the prescriber except under certain circumstances;
22 specifying the methods by which the communication must be provided except under
23 certain circumstances; defining certain terms; and generally relating to the
24 substitution and dispensing of biological products.

25 BY renumbering

26 Article – Health Occupations
27 Section 12–101(c) through (j) and (k) through (aa), respectively
28 to be Section 12–101(d) through (k) and (n) through (dd), respectively
29 Annotated Code of Maryland
30 (2014 Replacement Volume and 2016 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY repealing and reenacting, without amendments,
2 Article – Health Occupations
3 Section 12–101(a)
4 Annotated Code of Maryland
5 (2014 Replacement Volume and 2016 Supplement)

6 BY adding to
7 Article – Health Occupations
8 Section 12–101(c), (l), and (m) and 12–504.1
9 Annotated Code of Maryland
10 (2014 Replacement Volume and 2016 Supplement)

11 BY repealing and reenacting, with amendments,
12 Article – Health Occupations
13 Section 12–504
14 Annotated Code of Maryland
15 (2014 Replacement Volume and 2016 Supplement)

16 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
17 That Section(s) 12–101(c) through (j) and (k) through (aa), respectively, of Article – Health
18 Occupations of the Annotated Code of Maryland be renumbered to be Section(s) 12–101(d)
19 through (k) and (n) through (dd), respectively.

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

22 **Article – Health Occupations**

23 12–101.

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

25 (c) **“BIOLOGICAL PRODUCT” HAS THE MEANING STATED IN 42 U.S.C. § 262.**

26 (L) **“DRUG” HAS THE MEANING STATED IN § 21–101 OF THE**
27 **HEALTH – GENERAL ARTICLE.**

28 (M) **“INTERCHANGEABLE BIOLOGICAL PRODUCT” MEANS A BIOLOGICAL**
29 **PRODUCT THAT IS:**

30 (1) **LICENSED AND DETERMINED BY THE UNITED STATES FOOD AND**
31 **DRUG ADMINISTRATION TO MEET THE STANDARDS FOR INTERCHANGEABILITY**
32 **UNDER 42 U.S.C. § 262(k)(4); OR**

1 **(2) DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS STATED**
2 **IN THE LATEST EDITION OF OR SUPPLEMENT TO THE UNITED STATES FOOD AND**
3 **DRUG ADMINISTRATION'S APPROVED DRUG PRODUCTS WITH THERAPEUTIC**
4 **EQUIVALENCE EVALUATIONS (THE "ORANGE BOOK").**

5 12-504.

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

8 (b) (1) Subject to the provisions of this subtitle, a pharmacist, or the
9 pharmacist's designee, who is under the direct supervision of the pharmacist, shall inform
10 a retail consumer to the best of the pharmacist's or the pharmacist's designee's knowledge
11 of the availability of a generically equivalent drug **OR AN INTERCHANGEABLE**
12 **BIOLOGICAL PRODUCT** and shall inform a retail consumer of the approximate cost
13 difference as compared to the brand name drug.

14 (2) The Board shall adopt procedures for:

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

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

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

20 (i) To a prescription that is written for a generic drug **OR AN**
21 **INTERCHANGEABLE BIOLOGICAL PRODUCT;**

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

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

26 (iv) When the cost of the prescription is reimbursed by a third party
27 payer, including medical assistance.

28 **(C) THE BOARD SHALL MAINTAIN A LINK ON ITS WEB SITE TO THE CURRENT**
29 **LISTS OF BIOLOGICAL PRODUCTS DETERMINED BY THE UNITED STATES FOOD AND**
30 **DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH A SPECIFIC BIOLOGICAL**
31 **PRODUCT.**

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

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

6 (2) The substitution is [recognized]:

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

10 (II) **AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE**
11 **BRAND NAME DRUG OR DEVICE PRODUCT PRESCRIBED; AND**

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

15 [(d)] (E) If a drug or device product **OR AN INTERCHANGEABLE BIOLOGICAL**
16 **PRODUCT** is substituted under this section, the pharmacist shall:

17 (1) Notify the patient in writing that the drug or device product **OR**
18 **INTERCHANGEABLE BIOLOGICAL PRODUCT** dispensed is a generic equivalent of **OR IS**
19 **INTERCHANGEABLE WITH** the prescribed drug or device product; and

20 (2) Record on the prescription and keep a record of the name and
21 manufacturer of the substituted drug or device product **OR INTERCHANGEABLE**
22 **BIOLOGICAL PRODUCT**.

23 [(e)] (F) The Department may list any additional drug or device products that
24 are determined by the Department to meet requirements that are adequate to assure
25 product quality and therapeutic equivalence, after an opportunity for public comment as
26 provided in Title 10, Subtitle 1 of the State Government Article.

27 [(f)] (G) The Department may disqualify a drug or device product **OR AN**
28 **INTERCHANGEABLE BIOLOGICAL PRODUCT** on the United States Food and Drug
29 Administration's current list from being used in Maryland as a [generic] substitute if the
30 Department determines that the drug or device **OR INTERCHANGEABLE BIOLOGICAL**
31 **PRODUCT** is therapeutically nonequivalent **OR NOT INTERCHANGEABLE,**
32 **RESPECTIVELY**, or has a negative physical or biological effect on the consumer of that drug
33 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 AN 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) EXCEPT AS PROVIDED IN SUBSECTION (D) OF THIS SECTION, WITHIN 5 BUSINESS DAYS AFTER DISPENSING A BIOLOGICAL PRODUCT TO A PATIENT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE SHALL COMMUNICATE THE SPECIFIC BIOLOGICAL PRODUCT DISPENSED, INCLUDING THE NAME AND MANUFACTURER OF THE BIOLOGICAL PRODUCT, TO THE PRESCRIBER.

(B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION:

(1) THE COMMUNICATION REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL BE PROVIDED BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH:

(I) AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM;

1 (II) AN ELECTRONIC PRESCRIBING TECHNOLOGY;

2 (III) A PHARMACY BENEFITS MANAGEMENT SYSTEM; OR

3 (IV) A PHARMACY RECORD; AND

4 (2) MAKING AN ENTRY THROUGH A MECHANISM LISTED IN
5 PARAGRAPH (1) OF THIS SUBSECTION IS PRESUMED TO PROVIDE THE
6 COMMUNICATION TO THE PRESCRIBER REQUIRED UNDER SUBSECTION (A) OF THIS
7 SECTION.

8 (C) IF THE MECHANISMS LISTED IN SUBSECTION (B)(1) OF THIS SECTION
9 ARE NOT AVAILABLE, THE COMMUNICATION REQUIRED UNDER SUBSECTION (A) OF
10 THIS SECTION MAY BE PROVIDED BY FACSIMILE, TELEPHONE, ELECTRONIC
11 TRANSMISSION, OR OTHER MEANS.

12 (D) THE COMMUNICATION REQUIREMENT UNDER SUBSECTION (A) OF THIS
13 SECTION DOES NOT APPLY IF:

14 (1) THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS
15 NOT APPROVED AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE
16 BIOLOGICAL PRODUCT PRESCRIBED TO THE PATIENT; OR

17 (2) A REFILL PRESCRIPTION IS NOT CHANGED FROM THE
18 BIOLOGICAL PRODUCT DISPENSED ON THE MOST RECENT FILLING OF THE
19 PRESCRIPTION.

20 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
21 October 1, 2017.