

HOUSE BILL 429

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HB 1119/20 – HGO

11r1834
CF 11r1835

By: **Delegate Shetty**

Introduced and read first time: January 15, 2021

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacists – Required Notification and Authorized Substitution – Lower-Cost**
3 **Drug or Device Product**

4 FOR the purpose of requiring a pharmacist, or the pharmacist’s designee who is under
5 certain supervision, to inform a certain consumer of the availability of certain
6 therapeutically equivalent drugs and the cost difference between the therapeutically
7 equivalent drug and a certain prescribed drug; altering the cost difference of which
8 a pharmacist, or the pharmacist’s designee, is required to inform a retail consumer
9 under certain circumstances; applying a certain provision of law governing the
10 provision of certain information to a retail consumer regarding the availability of
11 certain drugs and products and certain cost differences to a prescription that is
12 written for a generic drug or an interchangeable biological product; authorizing a
13 pharmacist to substitute certain drugs and device products for any originally
14 prescribed drug or device product, rather than only for originally prescribed brand
15 name drug or device products; authorizing a pharmacist to substitute a
16 therapeutically equivalent brand name drug or device product for a certain
17 prescribed drug or device product under certain circumstances; requiring a
18 pharmacist to provide certain notice to a patient and make and keep a certain record
19 if a certain therapeutically equivalent brand name drug or device is substituted for
20 a certain drug or device product; requiring that a certain determination be based on
21 a consumer’s prescription benefit and formulary under certain circumstances;
22 making stylistic and conforming changes; and generally relating to pharmacists and
23 drugs and device products.

24 BY repealing and reenacting, with amendments,
25 Article – Health Occupations
26 Section 12–504
27 Annotated Code of Maryland
28 (2014 Replacement Volume and 2020 Supplement)

29 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 That the Laws of Maryland read as follows:

2 **Article – Health Occupations**

3 12–504.

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

6 (b) (1) Subject to the provisions of this subtitle, a pharmacist, or the
7 pharmacist’s designee, who is under the direct supervision of the pharmacist, shall inform
8 a retail consumer to the best of the pharmacist’s or the pharmacist’s designee’s knowledge
9 of the availability of a generically equivalent drug, **A THERAPEUTICALLY EQUIVALENT**
10 **BRAND NAME DRUG THAT IS THE LOWEST-COST ALTERNATIVE TO THE ORIGINALLY**
11 **PRESCRIBED GENERICALLY EQUIVALENT DRUG**, or an interchangeable biological
12 product and shall inform a retail consumer of the approximate cost difference **OF THE**
13 **LOWEST-COST ALTERNATIVE** as compared to the [brand name] **ORIGINALLY**
14 **PRESCRIBED** drug.

15 (2) The Board shall adopt procedures for:

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

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

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

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

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

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

28 [(iv)] **(III)** When the cost of the prescription is reimbursed by a third
29 party payer, including medical assistance.

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

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

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

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

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

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

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

17 (2) **IF A RETAIL CONSUMER IS USING PRESCRIPTION DRUG**
18 **COVERAGE FOR THE PRESCRIPTION, THE DETERMINATION OF WHETHER THE**
19 **CONSUMER WOULD BE CHARGED LESS FOR THE SUBSTITUTED DRUG OR DEVICE OR**
20 **INTERCHANGEABLE BIOLOGICAL PRODUCT SHALL BE BASED ON THE CONSUMER'S**
21 **PRESCRIPTION DRUG BENEFIT AND FORMULARY.**

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

24 (1) Notify the patient in writing that the drug or device product or
25 interchangeable biological product dispensed is a generic equivalent of, **A BRAND NAME**
26 **DRUG OR DEVICE PRODUCT THAT IS THERAPEUTICALLY EQUIVALENT TO**, or is
27 interchangeable with the **ORIGINALLY** prescribed drug or device product; and

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

31 (f) The Department may list any additional drug or device products that are
32 determined by the Department to meet requirements that are adequate to assure product
33 quality and therapeutic equivalence, after an opportunity for public comment as provided
34 in Title 10, Subtitle 1 of the State Government Article.

1 (g) The Department may disqualify a drug or device product or an
2 interchangeable biological product on the United States Food and Drug Administration's
3 current list from being used in Maryland as a substitute if the Department determines that
4 the drug or device or interchangeable biological product is therapeutically nonequivalent
5 or not interchangeable, respectively, or has a negative physical or biological effect on the
6 consumer of that drug or device product or interchangeable biological product:

7 (1) After providing an opportunity for public comment as provided in Title
8 10, Subtitle 1 of the State Government Article; or

9 (2) Prior to providing an opportunity for public comment, if the
10 Department believes that a particular generic drug or device product or interchangeable
11 biological product constitutes an imminent danger to the public health, safety or welfare,
12 and the Department:

13 (i) Provides an opportunity for public comment as provided in Title
14 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the drug or
15 device product or interchangeable biological product; and

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

19 (h) For a drug or device product or an interchangeable biological product that the
20 Department has disqualified from being used in Maryland as a substitute under subsection
21 (g) of this section, the Department shall provide an opportunity for public comment as
22 provided in Title 10, Subtitle 1 of the State Government Article before reinstating the drug
23 or device product or interchangeable biological product for use in Maryland as a substitute.

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

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