

# HOUSE BILL 429

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HB 1119/20 – HGO

1lr1834  
CF SB 537

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By: **Delegate Shetty**

Introduced and read first time: January 15, 2021

Assigned to: Health and Government Operations

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: February 25, 2021

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## CHAPTER \_\_\_\_\_

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 or maintain a certain record of certain notice to  
19 a patient and make and keep a certain record if a certain therapeutically equivalent  
20 brand name drug or device is substituted for a certain drug or device product;  
21 altering a certain provision of law to allow a pharmacist to maintain a record that a  
22 patient has been notified in a certain manner of a certain substitution; requiring that  
23 a certain determination be based on a consumer’s prescription benefit and formulary  
24 under certain circumstances; making stylistic and conforming changes; and  
25 generally relating to pharmacists and drugs and device products.

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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.



1 BY repealing and reenacting, with amendments,  
2 Article – Health Occupations  
3 Section 12–504  
4 Annotated Code of Maryland  
5 (2014 Replacement Volume and 2020 Supplement)

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

8 **Article – Health Occupations**

9 12–504.

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

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

21 (2) The Board shall adopt procedures for:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (1) After providing an opportunity for public comment as provided in Title  
17 10, Subtitle 1 of the State Government Article; or

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

22 (i) Provides an opportunity for public comment as provided in Title  
23 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the drug or  
24 device product or interchangeable biological product; and

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

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

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

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

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.