

HOUSE BILL 684

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J2

2003 Regular Session
(31r1845)

ENROLLED BILL

-- Health and Government Operations/Education, Health, and
Environmental Affairs --

Introduced by **Delegates Haynes, Anderson, Barkley, Benson, Branch,
Bromwell, Burns, Cane, Cardin, Carter, Conroy, D. Davis, Donoghue,
Doory, Dumais, Fulton, Gaines, Goldwater, Gordon, Griffith, Hammen,
Harrison, Holmes, Howard, Hubbard, Jones, Kaiser, Kelley, Kelly, Kirk,
Lee, Love, Madaleno, Mandel, Marriott, McDonough, McHale, Menes,
Moe, Murray, Nathan-Pulliam, Niemann, Oaks, Paige, Parker,
Patterson, Pendergrass, Proctor, Ramirez, Rawlings, Ross, Rudolph,
Smigiel, Taylor, Trueschler, F. Turner, V. Turner, Vaughn, Weldon, and
~~Zirkin~~ Zirkin, Boutin, Costa, Elliott, Kach, Morhaim, Redmer, and
Rosenberg**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this
____ day of _____ at _____ o'clock, ____ M.

Speaker.

CHAPTER _____

1 AN ACT concerning

2 **Pharmacists and Pharmacies - Practice - Advice of Information on Generic**
3 **Drug Option**

4 FOR the purpose of requiring ~~an employee of a pharmacy or a pharmacist, or the~~
5 pharmacist's designee, who is under the direct supervision of the pharmacist, to
6 ~~advise~~ inform retail consumers of generically equivalent drugs; requiring ~~an~~
7 ~~employee of a pharmacy or a pharmacist to advise~~ inform retail consumers of the

1 approximate cost difference of generically equivalent drugs as compared to
 2 brand name drugs; requiring the Board to adopt procedures to assure
 3 compliance with this Act; providing for certain exceptions to the requirements of
 4 this Act; and generally relating to providing information on generic drug
 5 options.

6 BY repealing and reenacting, with amendments,
 7 Article - Health Occupations
 8 Section 12-504
 9 Annotated Code of Maryland
 10 (2000 Replacement Volume and 2002 Supplement)

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

13 **Article - Health Occupations**

14 12-504.

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

17 (B) (1) ~~SUBJECT TO THE PROVISIONS OF THIS SUBTITLE, AN EMPLOYEE OF~~
 18 ~~THE PHARMACY OR A PHARMACIST, OR THE PHARMACIST'S DESIGNEE, WHO IS~~
 19 UNDER THE DIRECT SUPERVISION OF THE PHARMACIST, SHALL ADVISE THE INFORM
 20 A RETAIL CONSUMER TO THE BEST OF THE PHARMACIST'S OR THE PHARMACIST'S
 21 DESIGNEE'S KNOWLEDGE OF THE AVAILABILITY OF A GENERICALLY EQUIVALENT
 22 DRUG AND SHALL ADVISE THE INFORM A RETAIL CONSUMER OF THE APPROXIMATE
 23 COST DIFFERENCE AS COMPARED TO THE BRAND NAME DRUG.

24 (2) THE BOARD SHALL ADOPT PROCEDURES FOR:

25 (I) A CONSUMER TO NOTIFY THE BOARD WHEN A PHARMACIST
 26 FAILS TO PROVIDE THE INFORMATION REQUIRED UNDER PARAGRAPH (1) OF THIS
 27 SUBSECTION; AND

28 (II) ADVISING A PHARMACIST TO BRING THE PHARMACIST INTO
 29 COMPLIANCE WITH THE REQUIREMENTS OF PARAGRAPH (1) OF THIS SUBSECTION.

30 (3) PARAGRAPH (1) OF THIS SUBSECTION DOES NOT APPLY:

31 (I) TO A PRESCRIPTION THAT IS WRITTEN FOR A GENERIC DRUG;

32 (II) WHEN THE AUTHORIZED PRESCRIBER STATES EXPRESSLY
 33 THAT THE PRESCRIPTION IS TO BE DISPENSED ONLY AS DIRECTED;

34 (III) TO A PHARMACIST WHO WORKS IN A PHARMACY, WHETHER
 35 CENTRALIZED OR DECENTRALIZED, WHICH PRIMARILY SERVES PUBLIC OR PRIVATE
 36 INSTITUTIONAL RECIPIENTS; OR

1 (IV) WHEN THE COST OF THE PRESCRIPTION IS REIMBURSED BY A
2 THIRD PARTY PAYER, INCLUDING MEDICAL ASSISTANCE.

3 [(b)] (C) A pharmacist may substitute a generically equivalent drug or device
4 product, of the same dosage form and strength, for any brand name drug or device
5 product prescribed, if:

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

8 (2) The substitution is recognized in the United States Food and Drug
9 Administration's current list of approved drug or device products with therapeutic
10 equivalence evaluations; and

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

13 [(c)] (D) If a drug or device product is substituted under this section, the
14 pharmacist shall:

15 (1) Notify the patient in writing that the drug or device product
16 dispensed is a generic equivalent of the prescribed drug or device product; and

17 (2) Record on the prescription and keep a record of the name and
18 manufacturer of the substituted drug or device product.

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

23 [(e)] (F) The Department may disqualify a drug or device product on the
24 United States Food and Drug Administration's current list from being used in
25 Maryland as a generic substitute if the Department determines that the drug or
26 device is therapeutically nonequivalent or has a negative physical or biological effect
27 on the consumer of that drug or device product:

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

30 (2) Prior to providing an opportunity for public comment, if the
31 Department believes that a particular generic drug or device product constitutes an
32 imminent danger to the public health, safety or welfare, and the Department:

33 (i) Provides an opportunity for public comment as provided in Title
34 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the
35 drug or device product; and

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

1 [(f)] (G) For a drug or device product that the Department has disqualified
2 from being used in Maryland as a generic substitute under subsection [(e)] (F) of this
3 section, the Department shall provide an opportunity for public comment as provided
4 in Title 10, Subtitle 1 of the State Government Article before reinstating the drug or
5 device product for use in Maryland as a generic substitute.

6 [(g)] (H) A pharmacist who substitutes a drug or device product in compliance
7 with this section incurs no greater liability in filling the prescription by dispensing
8 the equivalent drug or device product than would be incurred in filling the
9 prescription by dispensing the prescribed brand name drug or device.

10 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
11 October 1, 2003.