HOUSE BILL 435

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CF 8lr0784

By: **Delegates Pena–Melnyk, Benson, Glenn, Barnes, Beitzel, Costa, Davis, Donoghue, Dumais, Elliott, Hubbard, Kach, Kipke, Kullen, McDonough, Mizeur, Montgomery, Morhaim, Nathan–Pulliam, Oaks, Reznik, Riley, Tarrant, and V. Turner**

Introduced and read first time: January 29, 2008
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Pharmacists – Generic Drugs – Treatment of Epileptic Seizures

FOR the purpose of prohibiting a pharmacist from substituting a generically equivalent drug or another brand name drug for a certain drug prescribed for the treatment of epileptic seizures without certain notification and consent; and generally relating to drug substitution for the treatment of epileptic seizures.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–504
Annotated Code of Maryland
(2005 Replacement Volume and 2007 Supplement)

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

Article – Health Occupations

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.

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW**.
[Brackets**]** indicate matter deleted from existing law.

(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.

(I) NOTWITHSTANDING SUBSECTION (C) OF THIS SECTION, A PHARMACIST MAY NOT SUBSTITUTE A GENERICALLY EQUIVALENT DRUG OR ANOTHER BRAND NAME DRUG FOR AN ANTIEPILEPTIC DRUG PRESCRIBED FOR THE TREATMENT OF EPILEPTIC SEIZURES WITHOUT THE PRIOR NOTIFICATION AND WRITTEN CONSENT OF:

(1) THE PRESCRIBING HEALTH CARE PRACTITIONER; AND

(2) (I) THE PATIENT; OR

(II) THE PARENT, LEGAL GUARDIAN, OR SPOUSE OF THE PATIENT.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2008.