Unofficial Copy 2000 Regular Session
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By: **Delegates Elliott, Sophocleus, and Bozman**
Introduced and read first time: February 11, 2000
Assigned to: Environmental Matters

A BILL ENTITLED

AN ACT concerning

Prescription Drugs - Substitution of Narrow Therapeutic Index Drugs - Restrictions

FOR the purpose of requiring that a prescription for a certain class of drugs be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription except under certain circumstances; requiring the Secretary of Health and Mental Hygiene to designate a certain class of drugs; authorizing the Secretary to adopt certain regulations; defining certain terms; and generally relating to the substitution of prescription drugs.

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section 12-101 and 12-504
Annotated Code of Maryland
(1994 Replacement Volume and 1999 Supplement)

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

Article - Health Occupations

12-101.

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

(b) "Authorized prescriber" means any licensed dentist, licensed physician, licensed podiatrist, licensed veterinarian, certified nurse midwife to the extent permitted in § 8-601 of this article, certified nurse practitioner to the extent permitted in § 8-508 of this article, or other individual authorized by law to prescribe prescription or nonprescription drugs or devices.

(c) "Board" means the State Board of Pharmacy.

(d) (1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

(2) "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(e) (1) "Device" means a device used in the diagnosis, treatment, or prevention of disease.

(2) "Device" does not include any:

(i) Surgical or dental instrument;

(ii) Physical therapy equipment;

(iii) X-ray apparatus; or

(iv) Component part or accessory of any of these items.

(f) "Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(1) Interpretation of an authorized prescriber's prescription for a drug or device;

(2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

(g) (1) "Distribute" means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under the Health Occupations Article, prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

(2) "Distribute" does not include the operations of a person who holds a permit issued under §§ 12-601 and 12-602 of this title.

(h) "License" means, unless the context requires otherwise, a license issued by the Board to practice pharmacy.

(i) "Licensed pharmacist" means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

(J) "NARROW THERAPEUTIC INDEX" MEANS A NARROWLY DEFINED RANGE BETWEEN RISK AND BENEFIT FOR CERTAIN PHARMACEUTICALS.

(K) "NARROW THERAPEUTIC INDEX DRUG" MEANS A DRUG THAT IS CHARACTERIZED BY A NARROW THERAPEUTIC INDEX, EXHIBITS SUBSTANTIAL PHARMACOKINETIC VARIABILITY, DISPLAYS LIMITED OR ERRATIC ABSORPTION, EXHIBITS FORMULATION-DEPENDENT BIOAVAILABILITY, AND REQUIRES BLOOD LEVEL MONITORING.

[(j)] (L) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and regulations of this State and the federal government.

[(k)] (M) "Nonresident pharmacy" means a pharmacy located outside this State that, in the normal course of business, as determined by the Board, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.

[(l)] (N) "Pharmaceutical care" means the provision of a patient's drug regimen for the purpose of achieving definite outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and which may include patient counseling and providing information to licensed and certified health care providers.

[(m)] (O) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

[(n)] (P) "Pharmacy" means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

[(o)] (Q) "Pharmacy permit" means a permit issued by the Board to establish and operate a pharmacy.

[(p)] (R) (1) "Practice pharmacy" means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices; or

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices.

(2) "Practice pharmacy" does not include the operations of a person who holds a permit issued under §§ 12-601 and 12-602 of this title.

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) [A] EXCEPT AS PROVIDED IN PARAGRAPH (G) OF THIS SECTION, 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.

(c) 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.

(d) 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.

(e) 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.

(f) For a drug or device product that the Department has disqualified from being used in Maryland as a generic substitute under subsection (e) 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.

(G) (1) A PRESCRIPTION FOR A NARROW THERAPEUTIC INDEX DRUG SHALL BE REFILLED USING ONLY THE SAME DRUG PRODUCT BY THE SAME MANUFACTURER THAT THE PHARMACIST LAST DISPENSED UNDER THE PRESCRIPTION UNLESS:

(I) THE PRESCRIBER IS NOTIFIED BY THE PHARMACIST PRIOR TO THE DISPENSING OF ANOTHER MANUFACTURER'S PRODUCT; AND

(II) THE PATIENT GIVES DOCUMENTED INFORMED CONSENT TO THE DISPENSING OF THE OTHER MANUFACTURER'S PRODUCT.

(2) THE SECRETARY, UPON THE ADVICE OF THE PRESIDENT OF THE BOARD OF PHARMACY AND CHAIRMAN OF THE BOARD OF PHYSICIAN QUALITY ASSURANCE, SHALL DESIGNATE NARROW THERAPEUTIC INDEX DRUGS AND MAY ADOPT REGULATIONS NECESSARY TO CARRY OUT THE PURPOSE OF THIS SECTION.

[(g)] (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.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2000.