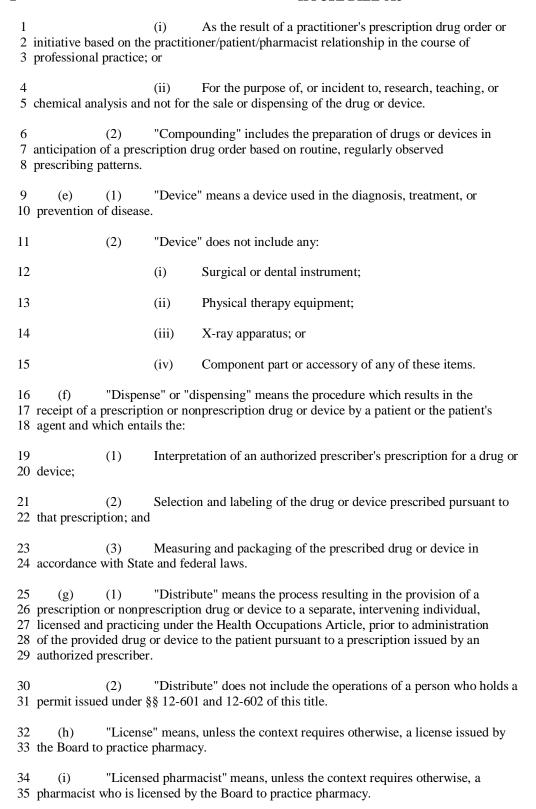
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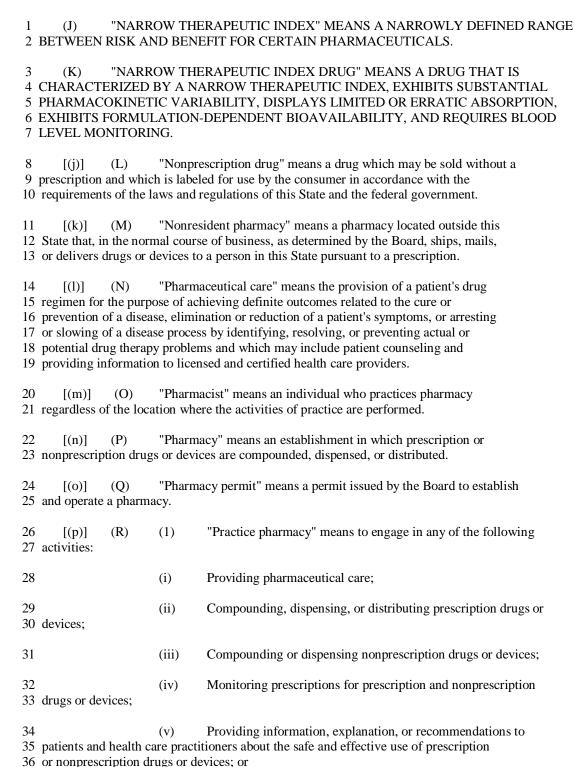
2000 Regular Session 0lr1034

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

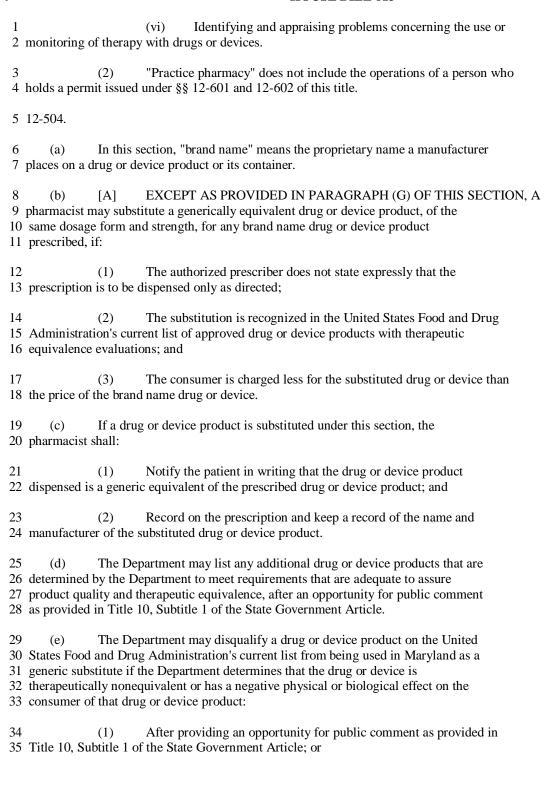
	A BILL ENTITLED
1	AN ACT concerning
2 3	Prescription Drugs - Substitution of Narrow Therapeutic Index Drugs - Restrictions
4 5 6 7 8 9 10	FOR the purpose of requiring that a prescription for a certain class of drugs be refilled using only the same drug product by the same manufacturer that the pharmacist 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.
11 12 13 14 15	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)
16 17	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
18	Article - Health Occupations
19	12-101.
20	(a) In this title the following words have the meanings indicated.
23 24	(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.
26	(c) "Board" means the State Board of Pharmacy.
27 28	(d) (1) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

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	(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
7 8	(ii) After providing an opportunity for public comment, determines whether the drug or device product should remain disqualified.
11 12	(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.
16	(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:
18 19	(I) THE PRESCRIBER IS NOTIFIED BY THE PHARMACIST PRIOR TO THE DISPENSING OF ANOTHER MANUFACTURER'S PRODUCT; AND
20 21	(II) THE PATIENT GIVES DOCUMENTED INFORMED CONSENT TO THE DISPENSING OF THE OTHER MANUFACTURER'S PRODUCT.
24	(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.
28	[(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.
30 31	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2000.