

Department of Legislative Services
Maryland General Assembly
2000 Session

FISCAL NOTE

House Bill 813 (Delegate Elliott. *et al.*)

Environmental Matters

Prescription Drugs - Substitution of Narrow Therapeutic Index Drugs - Restrictions

This bill provides that a prescription for a narrow therapeutic index drug must be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription unless the pharmacist: (1) notifies the prescriber prior to dispensing another product; and (2) the patient gives documented informed consent to receiving a drug other than the originally prescribed drug. A narrow therapeutic index drug is a drug that: (1) has a narrowly-defined range between the risk and the benefit associated with taking the drug; (2) exhibits substantial pharmacokinetic variability; (3) displays limited or erratic absorption; (4) exhibits formulation-dependent bioavailability; and (5) requires blood level monitoring.

In addition, the bill requires the Department of Health and Mental Hygiene, upon the advice of the Board of Pharmacy and the Board of Physician Quality Assurance, to designate what drugs constitute narrow therapeutic index drugs and adopt regulations necessary to carry out the bill's requirements.

Fiscal Summary

State Effect: The designation of narrow therapeutic index drugs and the adoption of regulations could be handled with existing Board of Pharmacy and Board of Physician Quality Assurance resources. Revenues would not be affected.

Local Effect: None.

Small Business Effect: Minimal. Pharmacists that are small businesses may incur additional administrative costs in order to comply with the bill's requirements.

Analysis

Current Law: In general, a pharmacist may substitute a generic drug for a brand name drug unless the prescriber specifically states that no substitution is allowed. There is no statutory provision regarding the substitution of another drug for a narrow therapeutic index drug.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene (Board of Pharmacy, Laboratories Administration), Department of Legislative Services

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