**HB 1119**

# Department of Legislative Services

Maryland General Assembly
2020 Session

## FISCAL AND POLICY NOTE
**Third Reader - Revised**

House Bill 1119 (Delegate Shetty, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

**Pharmacists – Required Notification and Authorized Substitution – Lower–Cost Drug or Device Product**

This bill permits a pharmacist to substitute a therapeutically equivalent brand-name drug or device product to the originally prescribed generically equivalent drug or device product if (1) the prescriber does not expressly state that the prescription must be dispensed only as directed; (2) the substitution is recognized, as specified; and (3) the consumer is charged less for the substitution than the originally prescribed drug or device. If a substitution is made, the pharmacist must take specified actions. A pharmacist must inform a retail consumer of the availability of a therapeutically equivalent brand-name drug that is the lowest cost alternative to the originally prescribed generically equivalent drug and the approximate cost difference as compared to the originally prescribed drug.

## Fiscal Summary

**State Effect:** The bill's changes can be handled with existing budgeted resources. Revenues are not affected.

**Local Effect:** None.

**Small Business Effect:** Minimal.

## Analysis

**Bill Summary**: Determination of whether the consumer would be charged less for the substitution must be based on the consumer's prescription drug benefit and formulary, if applicable.

If a substitution is made, the pharmacist must (1) notify the patient in writing that the substitution is a generic equivalent of a brand-name drug or device product that is therapeutically equivalent to or interchangeable with the originally prescribed drug or device product and (2) record on the prescription and keep a record of specified information.

A pharmacist who substitutes a drug or device product or an interchangeable biological product in compliance with law incurs no greater liability in filling the prescription by dispensing the equivalent drug or device product or interchangeable biological product than would be incurred in filling the prescription by dispensing the originally prescribed drug or device.

**Current Law:** A pharmacist (or the pharmacist's designee) must inform a retail consumer to the best of the pharmacist's or designee's knowledge of the availability of a generically equivalent drug or an interchangeable biological product and must inform a retail consumer of the approximate cost difference as compared to the brand-name drug. The State Board of Pharmacy must adopt procedures for a consumer to notify the board when a pharmacist fails to provide this required information and advising a pharmacist to bring the pharmacist into compliance with that requirement. However, the requirement does not apply (1) to a prescription written for a generic drug or an interchangeable biological product; (2) when the authorized prescriber states expressly that the prescription is to be dispensed only as directed; (3) to a pharmacist who works in a pharmacy that primarily serves institutional recipients; or (4) when the cost of the prescription is reimbursed by a third-party payer, including Medicaid.

A pharmacist may substitute a generically equivalent drug or device product or an interchangeable biological product, of the same dosage form and strength, for any brand-name drug or device product prescribed if (1) the prescriber does not state expressly that the prescription is to be dispensed only as directed; (2) the substitution is recognized in the U.S. Food and Drug Administration's (FDA) current list of approved drug or device products with therapeutic equivalence evaluation or is an interchangeable biological product for the brand-name drug; and (3) the consumer is charged less for the substituted drug or device or interchangeable biological product than the price of the brand-name drug or device.

If a drug or device product or an interchangeable biological product is substituted, a pharmacist must (1) notify the patient in writing that the drug or device product or interchangeable biological product dispensed is a generic equivalent of or is interchangeable with 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 or interchangeable biological product.

The Maryland Department of Health (MDH) 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. MDH may disqualify a drug or device product or an interchangeable biological product on FDA's current list from being used in Maryland as a substitute if MDH determines that the drug, device, or interchangeable biological product is therapeutically nonequivalent or not interchangeable or has a negative physical or biological effect on the consumer of that drug or device product or interchangeable biological product. However, when it does so, the department has to provide specified opportunity for public comment.

A pharmacist who substitutes a drug or device product or an interchangeable biological product in compliance with law incurs no greater liability in filling the prescription by dispensing the equivalent drug or device product or interchangeable biological product than would be incurred in filling the prescription by dispensing the prescribed brand-name drug or device.

## Additional Information

**Prior Introductions:** None.

**Designated Cross File:** None.

**Information Source(s):** Maryland Department of Health; Department of Legislative Services

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