Department of Legislative Services

Maryland General Assembly
2020 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 664 (Chair, Health and Government Operations Committee)(By Request - Departmental - Health)

Health and Government Operations

Pharmacists - Required Notification and Authorized Substitution - Lower-Costing Drugs, Medical Devices, and Biological Products

This departmental bill permits a pharmacist to substitute a "therapeutically equivalent drug" or a "substantially equivalent medical device" for any prescribed drug, medical device, or biological product if (1) the prescriber does not expressly state that the prescription must be dispensed only as directed and (2) the consumer is charged less for the substitution. If a substitution is made, the pharmacist must (1) notify the patient in writing that the substitution is a therapeutically equivalent drug or substantially equivalent medical device and (2) record on the prescription and keep a record of specified information. A pharmacist must inform a retail consumer of the availability of a therapeutically equivalent drug or a substantially equivalent medical device that costs less than the prescribed drug, device, or biological product and the cost difference between the two. A substitution may be made even if the prescription is written for a generic drug or an interchangeable biological product. **The bill takes effect January 1, 2021.**

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: The Maryland Department of Health (MDH) has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services concurs with this assessment.

Analysis

Bill Summary: "Substantially equivalent medical device" means a medical device that the U.S. Food and Drug Administration (FDA) determines to be substantially equivalent to another medical device. "Therapeutically equivalent drug" means a brand-name drug or a generic drug that is of the same dosage form and strength and determined to be therapeutically equivalent to another drug as stated in the latest addition of or supplement to FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*.

In addition to therapeutically equivalent drugs and substantially equivalent medical devices, MDH may list any additional drugs or medical devices that are determined by the department to meet specified requirements and therapeutic equivalence or substantial equivalence, after an opportunity for public comment.

MDH may disqualify a therapeutically equivalent drug, a substantially equivalent medical device, or an interchangeable biological product from being used in Maryland as a substitute if the department makes specified determinations. For a therapeutically equivalent drug, a substantially equivalent medical device, or an interchangeable biological product that the department has disqualified, MDH must provide an opportunity for public comment before reinstating the drug, device, or the biological product for use in Maryland as a substitute.

A pharmacist who substitutes a therapeutically equivalent drug, a substantially equivalent medical device, or an interchangeable biological product in compliance with these requirements incurs no greater liability in filling the prescription by dispensing the therapeutically equivalent drug, substantially equivalent device, or interchangeable biological product than would be incurred in filling the prescribed drug, device, or biological product.

The bill also changes a reference to FDA's "Orange Book" with a reference to FDA's "Purple Book" in the definition of interchangeable biological product. The "Orange Book" (*Approved Drug Products with Therapeutic Equivalence Evaluations*) identifies drug products approved on the basis of safety and effectiveness by FDA and related patent and exclusivity information. The "Purple Book" (*Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations)* lists biological products, including any biosimilar and interchangeable biological products licensed by FDA.

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 FDA's current list of approved drug or device products with therapeutic equivalence evaluations 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.

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.

Background: Current law allows a brand-name drug or device to be substituted with a less expensive generic alternative. According to MDH, although generic drugs typically cost less than brand-name drugs, in recent years, the cost of some generic drugs and devices has begun to exceed that of brand-name drugs and devices. The bill is intended to provide a parallel provision in law permitting a pharmacist to substitute a less expensive brand-name drug or device when a more expensive generic drug or device is prescribed in order to allow consumers to have access to the prescription drug at the lowest possible cost.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

Information Source(s): U.S. Food and Drug Administration; Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - February 23, 2020
mm/ljm

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ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

TITLE OF BILL: Pharmacists - Required Notification and Authorized Substitution – Lower-Costing Drugs, Medical Devices, and Biological Products

BILL NUMBER: HB 664

PREPARED BY: Webster Ye, Bradley Clark

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

_X_ WILL HAVE MINIMAL OR NO ECONOMIC IMPACT ON MARYLAND SMALL BUSINESS

OR

___ WILL HAVE MEANINGFUL ECONOMIC IMPACT ON MARYLAND SMALL BUSINESSES

PART B. ECONOMIC IMPACT ANALYSIS

None