Department of Legislative Services

Maryland General Assembly
2013 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 781 (Senator Conway)
Education, Health, and Environmental Affairs Health and Government Operations

Pharmacists - Biosimilar Biological Products - Substitutions

This bill authorizes a pharmacist to substitute a biosimilar biological product for a prescribed biological reference product if (1) the biosimilar biological product is approved by the U.S. Food and Drug Administration (FDA) to be interchangeable with the prescribed biological reference product and (2) the authorized prescriber does not state expressly that the prescription is to be dispensed only as directed.

Fiscal Summary

State Effect: Any additional workload on the State Board of Pharmacy can be handled within existing budgeted resources. The State Employee and Retiree Health and Welfare Benefits Program (the State plan) currently does not purchase these products as they are not yet available in the United States. The Department of Budget and Management indicates that, to the extent that biosimilar biological products are less expensive than other prescription drug options, the limitations around which drugs are permitted for substitutions under the bill may result in diminished savings for the State plan. According to the Department of Health and Mental Hygiene (DHMH), the bill does not impact the Medicaid Program.

Local Effect: To the extent that biosimilar biological products are less expensive than other prescription drug options, the limitations around which drugs are permitted for substitutions under the bill may result in diminished savings.

Small Business Effect: Minimal.

Analysis

Bill Summary: If a pharmacist substitutes an interchangeable biosimilar product for a prescribed biological reference product, the pharmacist or the pharmacist's designee must (1) notify the patient in writing that the biological product dispensed has been approved by FDA as an interchangeable biosimilar biological product for the prescribed biological reference product; (2) provide electronic, written, or telephonic notification of the substitution to the authorized prescriber or the authorized prescriber's staff within five business days after the dispensing; and (3) record specified information on the prescription label and record of dispensing.

Records of substitutions must be maintained for at least five years. A pharmacist who substitutes an interchangeable biosimilar product in compliance with the bill incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed biological reference product.

Current Law: Under federal law (42 U.S.C. § 262(i)) "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings. "Biosimilar" means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; further, there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. "Interchangeable" means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. "Reference product" means the single licensed biological product against which a biological product is evaluated.

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 FDA'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.

If a drug or device product is substituted, a pharmacist must (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.

DHMH may list any additional drug or device products that are determined by DHMH to meet requirements that are adequate to assure product quality and therapeutic equivalence, after an opportunity for public comment. DHMH may disqualify a drug or device product on FDA's current list from being used in Maryland as a generic substitute if DHMH 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 – if the department provides specified opportunity for public comment.

A pharmacist who substitutes a drug or device product in compliance with the law 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.

Background: The federal Biologics Price Competition and Innovation Act (BPCIA), passed as part of the Patient Protection and Affordable Care Act (ACA) in 2010, established an abbreviated approval pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product. According to FDA, biological products are generally produced using a living system or organism. Biological products may be manufactured through biotechnology, derived from natural sources, or produced synthetically. An application for a biosimilar biological product must demonstrate that it is biosimilar to the reference product; it uses the same mechanism of action for the proposed condition as the reference product; conditions of use proposed in labeling have been previously approved for the reference product; and the biosimilar product has the same route of administration, dosage, and strength as the reference product.

The European Union has approved 14 biosimilar products. There are no biosimilar products on the market in the United States, and FDA has yet to receive an application for a biosimilar version of an FDA-licensed biological product.

Legislation has been introduced in at least eight states regarding biosimilar products, typically to expand state drug substitution laws to include biosimilar products. Virginia passed legislation in February 2013 that permits pharmacists to dispense a biosimilar product licensed by FDA as interchangeable with similar limitations proposed in this bill.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): U.S. Food and Drug Administration, Department of Budget and Management, Department of Health and Mental Hygiene, Department of Legislative Services

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