HB 1273

Department of Legislative Services

Maryland General Assembly
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FISCAL AND POLICY NOTE
Third Reader

House Bill 1273 (Delegate Cullison, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

Pharmacists - Substitution and Dispensing of Biological Products

This bill authorizes a pharmacist to substitute an interchangeable biological product, of the same dosage form and strength, for any brand name drug if (1) the authorized prescriber does not expressly state that the prescription must be dispersed only as directed; (2) the substitution is recognized as specified; and (3) the consumer is charged less for the interchangeable biological product than the brand name drug.

Within five business days after dispensing a biological product to a patient, the dispensing pharmacist (or a designee) must communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product. This notice generally must be provided through an electronically accessible entry. Notification is not required if the U.S. Food and Drug Administration (FDA) has not approved an interchangeable biological product for the biological product prescribed to the patient or for refill prescriptions if the dispensed product is not changed.

Fiscal Summary

State Effect: Potential minimal increase in special fund expenditures for the State Board of Pharmacy. Revenues are not affected.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Interchangeable biological product" means a biological product that is (1) licensed and determined by FDA to meet specified federal standards for interchangeability or (2) determined to be therapeutically equivalent as stated in the latest edition of or supplement to FDA's list of approved drug products with therapeutic equivalence evaluations (the "orange book").

If a pharmacist substitutes an interchangeable biological product, the pharmacist must (1) notify the patient in writing that the interchangeable biological product dispensed is interchangeable with the prescribed drug and (2) record specified information on the prescription label and keep a record of the name and manufacturer of the interchangeable biological product. A pharmacist who substitutes an interchangeable biological product incurs no greater liability in filling the prescription than would be incurred otherwise.

Subject to requirements for public comment, the Department of Health and Mental Hygiene (DHMH) may disqualify an interchangeable biological product from being used in Maryland if it determines it is not interchangeable or has a negative physical or biological effect on the consumer.

The State Board of Pharmacy must maintain a link on its website to the current list of biological products determined by FDA to be interchangeable with a specific biological 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.

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 it determines 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, passed as part of the federal Patient Protection and Affordable Care Act 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.

FDA can designate a biological product as interchangeable when (1) the biological product is biosimilar to the reference biological product; (2) it can be expected to produce the same clinical results as the reference product in any given patient; and (3) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. As of November 2016, three products had gained full FDA approval as biosimilar, but not yet interchangeable.

According to the National Conference of State Legislatures, as of November 2016, 25 states and Puerto Rico had enacted biosimilar substitution legislation. Although state legislation varies, several features that are frequently included are (1) a product must be FDA-approved as interchangeable; (2) a prescriber can prevent substitution by stating "dispense as written" or "brand medically necessary"; (3) the pharmacist must notify or communicate with the prescriber, typically via an electronically accessible record; (4) the patient must be notified; (5) records of the substitution must be maintained; and (6) the state must maintain a public or web-based list of permissible substitutions. Some states also provide immunity to a pharmacist for making substitutions in compliance with state law and require the pharmacist to explain the cost or price of the biologic and the interchangeable biosimilar. Legislation enacted in Colorado, Georgia, Illinois, North Carolina, and Texas requires any allowable substitution to have the lowest cost.

State Expenditures: Special fund expenditures for the State Board of Pharmacy may increase by a minimal amount due to increased inspection times necessary to determine whether proper notice has been provided to prescribers as required under the bill. The board may impose additional disciplinary action to the extent pharmacists do not comply with the bill. Any additional expenditures are anticipated to be minimal and do not occur until such time as FDA approves biological products as interchangeable.

Additional Information

Prior Introductions: Similar legislation, SB 537 of 2015, passed the Senate and received a hearing in the House Health and Government Operations Committee, but no further action was taken. Its cross file, HB 733 of 2015, received a hearing from the House Health and Government Operations Committee, but no further action was taken.

Cross File: SB 997 (Senator Conway) - Education, Health, and Environmental Affairs.

Information Source(s): U.S. Food and Drug Administration; National Conference of State Legislatures; Department of Health and Mental Hygiene; Department of Legislative Services

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