HB 1365 - AS AMENDED BY THE HOUSE

28Mar2024... 1243h

2024 SESSION

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HOUSE BILL ***1365***

AN ACT relative to substitution of biological products by pharmacies.

SPONSORS: Rep. Merchant, Sull. 6

COMMITTEE: Commerce and Consumer Affairs

AMENDED ANALYSIS

This bill allows for the substitution by a pharmacist of an interchangeable biological product for another interchangeable biological product, and prohibits the substitution of an interchangeable biological product if the substitution would result in an increase in cost to the patient.

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Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty Four

AN ACT relative to substitution of biological products by pharmacies.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Pharmacists and Pharmacies; Pharmacies; Substituting Biological Products. Amend RSA 318:47-dd to read as follows:

318:47-dd Pharmacies; Substituting Biological Products.

I. In this section:

(a) "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.

(b) "Proper name" means the nonproprietary name for a biological product designated by the federal Food and Drug Administration license for use upon each package of the product.

(c) "Interchangeable biological product" means [~~a biological product that the federal Food and Drug Administration~~]:

(1) ***A biological product that the federal Food and Drug Administration*** has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. section 262(k)(4); [~~or~~]

(2) ***A biological product that the federal Food and Drug Administration*** has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations[~~.~~]***; or***

(3) A biological product licensed under section 42 U.S.C. section 262(k) that has been determined by the federal Food and Drug Administration to be interchangeable with the referenced biological product licensed by the federal Food and Drug Administration under 42 U.S.C. section 262(k).

II. The board shall maintain a link on its website to the federal Food and Drug Administration's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

III. A pharmacist may substitute a biological product pursuant to this section [~~only if~~] ***when*** it has been licensed by the federal Food and Drug Administration as an interchangeable biological product for the [~~prescribed~~] ***referenced*** biological product. ***This provision shall mean that all***

biological products listed by the Food and Drug Administration as interchangeable to the referenced biological product are themselves interchangeable with each other.

IV. When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist or his or her designee shall inform the patient ***and the prescriber***.

V. A pharmacist shall not substitute an interchangeable biological product pursuant to this section if the prescriber indicates that substitution is not authorized by specifying on the prescription "medically necessary" on a paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the biological product prescribed is medically necessary.

VI.(a) Within 3 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology; or

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

(b) Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where:

(1) There is no federal Food and Drug Administration-approved interchangeable biological product for the biological product prescribed; or

(2) A refill prescription is not changed from product dispensed on the prior filling of the prescription.

VII. The label of all biological products dispensed by a pharmacist shall include the proper name and the name of the manufacturer of the product.

VIII. A pharmacist shall not substitute an interchangeable biological product that results in an increased cost to the patient.

2 Effective Date. This act shall take effect 60 days after its passage.