HB 117 - AS AMENDED BY THE SENATE

06/05/2025 2325s

2025 SESSION

25-0075
09/02

HOUSE BILL ***117***

AN ACT relative to the substitution of biological products.

SPONSORS: Rep. Layon, Rock. 13; Rep. Burroughs, Carr. 2; Rep. Spier, Hills. 6; Rep. Kofalt, Hills. 32; Rep. Potucek, Rock. 13; Rep. Wheeler, Hills. 33; Sen. Prentiss, Dist 5

COMMITTEE: Health, Human Services and Elderly Affairs

ANALYSIS

This bill modifies the definition of "interchangeable biological product" and allows for interchangeable biological products to be provided by pharmacists subject to certain restrictions.

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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Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.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 Five

AN ACT relative to the substitution of biological products.

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) "Biosimilar" or "biosimilarity" means:

(1) The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(2) 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.

[~~(b)~~] ***(c)*** "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)~~] ***(d)*** "Interchangeable biological product" means a biological product that ***meets the definition under 42 U.S.C. section 262(i)(3)*** [~~the federal Food and Drug Administration:~~

~~(1) Has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. section 262(k)(4); or~~

~~(2) 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~~].

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 it has been licensed by the federal Food and Drug Administration as an interchangeable biological product~~] for the prescribed biological product ***when it meets the definition of interchangeable biological product***.

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.

V. A pharmacist shall not substitute an interchangeable biological product pursuant to this section if***:***

(a) 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***; or***

(b) The patient informs the pharmacist that he or she does not wish to receive an interchangeable biological product.

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.

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