

# STATE OF NEW YORK

7509--A

2017-2018 Regular Sessions

## IN ASSEMBLY

April 28, 2017

Introduced by M. of A. GOTTFRIED, QUART, RAIA -- Multi-Sponsored by --  
M. of A. ENGLEBRIGHT, JEAN-PIERRE -- read once and referred to the  
Committee on Higher Education -- reported and referred to the Commit-  
tee on Rules -- Rules Committee discharged, bill amended, ordered  
reprinted as amended and recommitted to the Committee on Rules

AN ACT to amend the education law and the public health law, in relation  
to the substitution of interchangeable biological products for  
prescribed products; and providing for the expiration of such  
provisions

The People of the State of New York, represented in Senate and Assem-  
bly, do enact as follows:

1 Section 1. Section 6802 of the education law is amended by adding two  
2 new subdivisions 27 and 28 to read as follows:

3 27. "Biological product" means a biological product as defined in  
4 subsection (i) of section 351 of the Public Health Service Act, 42  
5 U.S.C. Section 262(i).

6 28. "Interchangeable biological product" means a biological product  
7 licensed by the United States Food and Drug Administration pursuant to  
8 42 U.S.C. Section 262(k)(4) as set forth in the latest edition or  
9 supplement of the United States Food and Drug Administration Lists of  
10 Licensed Biological Products with Reference Product Exclusivity and  
11 Biosimilarity or Interchangeability Evaluations, sometimes referred to  
12 as the "Purple Book," or a biological product determined by the United  
13 States Food and Drug Administration to be therapeutically equivalent as  
14 set forth in the latest edition or supplement of the United States Food  
15 and Drug Administration Approved Drug Products with Therapeutic Equiv-  
16 alence Evaluations, sometimes referred to as the "Orange Book."

17 § 2. Paragraphs (b), (c) and (d) of subdivision 6 of section 6810 of  
18 the education law, paragraph (b) as amended and paragraph (d) as added  
19 by chapter 913 of the laws of 1986, paragraph (c) as added by chapter  
20 776 of the laws of 1977, are amended to read as follows:

EXPLANATION--Matter in italics (underscored) is new; matter in brackets  
[-] is old law to be omitted.

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(b) Notwithstanding any other provision of this section or any other law, when an interchangeable biological product is not available and the biological product originally prescribed is available and the pharmacist agrees to dispense the prescribed biological product for a price that will not exceed the price that would have been charged for the interchangeable biological substitute had it been available, substitution of an interchangeable biological product will not be required. If the interchangeable biological product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the prescribed biological product at his regular price. In such instances the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions.

(c) The prescriber shall inform the patient whether he or she has prescribed a brand name or its generic equivalent drug product or interchangeable biological product.

~~[(e)]~~ (d) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

~~[(d)]~~ (e) No prescriber shall be subjected to civil liability arising solely from authorizing, in accordance with this subdivision, the substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law.

§ 3. Section 6816-a of the education law is amended by adding three new subdivisions 3, 4 and 5 to read as follows:

3. A pharmacist shall substitute a less expensive biological product for a prescribed biological product provided that all of the following conditions are met:

(a) the substituted biological product is either an interchangeable biological product for the prescribed product or the substituted biological product is one for which the prescribed product is an interchangeable biological product;

(b) the prescriber does not designate that a substitution is prohibited as described in subdivision six of section sixty-eight hundred ten of this article; and

(c) the pharmacist indicates on the label affixed to the immediate container in which the biological product is sold or distributed the name and strength of the product and its manufacturer unless the prescriber specifically states otherwise.

4. (a) Within five business days following the dispensing of a substituted biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed to the prescriber (i) by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology or a pharmacy record; or (ii) by using facsimile, electronic transmission or other electronic means. If an electronic means described in this paragraph is not available to the pharmacist at the time of communication, the dispensing pharmacist or the pharmacist's designee may communicate the information by telephone.

(b) Communication under paragraph (a) of this subdivision shall not be required where:

(i) there is no FDA-approved interchangeable biological product for the product prescribed; or

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

3 5. The department shall maintain a link on its web site to the current  
4 list of all biological products determined by the Federal Food and Drug  
5 Administration to be an interchangeable biological product for a specif-  
6 ic biological product.

7 § 4. Subparagraph 2 of paragraph (o) of subdivision 1 of section 206  
8 of the public health law, as amended by chapter 913 of the laws of 1986,  
9 is amended to read as follows:

10 (2) The commissioner of the Federal Food and Drug Administration has  
11 evaluated such drug product as:

12 (i) pharmaceutically and therapeutically equivalent and has listed  
13 such drug product on the list of approved drugs products with the thera-  
14 peutic equivalence evaluations, provided, however, that the list  
15 prepared by the commissioner shall not include any drug product which  
16 the commissioner of the Federal Food and Drug Administration has identi-  
17 fied as having an actual or potential bioequivalence problem; or

18 (ii) as an interchangeable biological product and has listed such  
19 product on the list of approved drug products with interchangeability.

20 § 5. This act shall take effect immediately and shall expire five  
21 years after having become a law.