

# 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.

LBD11241-02-7

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

16 (c) The prescriber shall inform the patient whether he or she has  
17 prescribed a brand name or its generic equivalent drug product or inter-  
18 changeable biological product.

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

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

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

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

30 (a) the substituted biological product is either an interchangeable  
31 biological product for the prescribed product or the substituted biolog-  
32 ical product is one for which the prescribed product is an interchangea-  
33 ble biological product;

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

37 (c) the pharmacist indicates on the label affixed to the immediate  
38 container in which the biological product is sold or distributed the  
39 name and strength of the product and its manufacturer unless the pres-  
40 criber specifically states otherwise.

41 4. (a) Within five business days following the dispensing of a substi-  
42 tuted biological product, the dispensing pharmacist or the pharmacist's  
43 designee shall communicate to the prescriber the specific product  
44 provided to the patient, including the name of the product and the  
45 manufacturer. The communication shall be conveyed to the prescriber (i)  
46 by making an entry that is electronically accessible to the prescriber  
47 through an interoperable electronic medical records system, an electron-  
48 ic prescribing technology or a pharmacy record; or (ii) by using facsim-  
49 ile, electronic transmission or other electronic means. If an electronic  
50 means described in this paragraph is not available to the pharmacist at  
51 the time of communication, the dispensing pharmacist or the pharmacist's  
52 designee may communicate the information by telephone.

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

55 (i) there is no FDA-approved interchangeable biological product for  
56 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.