

7509

2017-2018 Regular Sessions

I N A S S E M B L Y

April 28, 2017

Introduced by M. of A. GOTTFRIED -- read once and referred to the
Committee on Higher Education

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

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 U.S.C.
5 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 S 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:

21 (b) NOTWITHSTANDING ANY OTHER PROVISION OF THIS SECTION OR ANY OTHER
22 LAW, WHEN AN INTERCHANGEABLE BIOLOGICAL PRODUCT IS NOT AVAILABLE AND THE
23 BIOLOGICAL PRODUCT ORIGINALLY PRESCRIBED IS AVAILABLE AND THE PHARMACIST
24 AGREES TO DISPENSE THE PRESCRIBED BIOLOGICAL PRODUCT FOR A PRICE THAT

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

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1 WILL NOT EXCEED THE PRICE THAT WOULD HAVE BEEN CHARGED FOR THE INTER-
2 CHANGEABLE BIOLOGICAL SUBSTITUTE HAD IT BEEN AVAILABLE, SUBSTITUTION OF
3 AN INTERCHANGEABLE BIOLOGICAL PRODUCT WILL NOT BE REQUIRED. IF THE
4 INTERCHANGEABLE BIOLOGICAL PRODUCT IS NOT AVAILABLE AND A MEDICAL EMER-
5 GENCY SITUATION, WHICH FOR PURPOSES OF THIS SECTION IS DEFINED AS ANY
6 CONDITION REQUIRING ALLEVIATION OF SEVERE PAIN OR WHICH THREATENS TO
7 CAUSE DISABILITY OR TAKE LIFE IF NOT PROMPTLY TREATED, EXISTS, THEN THE
8 PHARMACIST MAY DISPENSE THE PRESCRIBED BIOLOGICAL PRODUCT AT HIS REGULAR
9 PRICE. IN SUCH INSTANCES THE PHARMACIST MUST RECORD THE DATE, HOUR AND
10 NATURE OF THE MEDICAL EMERGENCY ON THE BACK OF THE PRESCRIPTION AND KEEP
11 A COPY OF ALL SUCH PRESCRIPTIONS.

12 (C) The prescriber shall inform the patient whether he or she has
13 prescribed a brand name or its generic equivalent drug product OR INTER-
14 CHANGEABLE BIOLOGICAL PRODUCT.

15 [(c)] (D) The provisions of this subdivision shall not apply to a
16 hospital as defined in article twenty-eight of the public health law.

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

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

23 3. A PHARMACIST SHALL SUBSTITUTE A LESS EXPENSIVE BIOLOGICAL PRODUCT
24 FOR A PRESCRIBED BIOLOGICAL PRODUCT PROVIDED THAT ALL OF THE FOLLOWING
25 CONDITIONS ARE MET:

26 (A) THE BIOLOGICAL PRODUCT HAS BEEN DETERMINED BY THE UNITED STATES
27 FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH THE PRESCRIBED
28 PRODUCT;

29 (B) THE PRESCRIBER DOES NOT DESIGNATE THAT A SUBSTITUTION IS PROHIBIT-
30 ED AS DESCRIBED IN SUBDIVISION SIX OF SECTION SIXTY-EIGHT HUNDRED TEN OF
31 THIS ARTICLE; AND

32 (C) THE PHARMACIST INDICATES ON THE LABEL AFFIXED TO THE IMMEDIATE
33 CONTAINER IN WHICH THE BIOLOGICAL PRODUCT IS SOLD OR DISTRIBUTED THE
34 NAME AND STRENGTH OF THE PRODUCT AND ITS MANUFACTURER UNLESS THE PRES-
35 CRIBER SPECIFICALLY STATES OTHERWISE.

36 4. (A) WITHIN FIVE BUSINESS DAYS FOLLOWING THE DISPENSING OF A BIOLOG-
37 ICAL PRODUCT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE
38 SHALL COMMUNICATE TO THE PRESCRIBER THE SPECIFIC PRODUCT PROVIDED TO THE
39 PATIENT, INCLUDING THE NAME OF THE PRODUCT AND THE MANUFACTURER. THE
40 COMMUNICATION SHALL BE CONVEYED TO THE PRESCRIBER (I) BY USING AN INTER-
41 OPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, AN ELECTRONIC PRESCRIBING
42 TECHNOLOGY OR A PHARMACY RECORD; OR (II) BY USING FACSIMILE, TELEPHONE,
43 ELECTRONIC TRANSMISSION, OR OTHER PREVAILING MEANS.

44 (B) COMMUNICATION UNDER PARAGRAPH (A) OF THIS SUBDIVISION SHALL NOT BE
45 REQUIRED WHERE:

46 (I) THERE IS NO FDA-APPROVED INTERCHANGEABLE BIOLOGIC FOR THE PRODUCT
47 PRESCRIBED; OR

48 (II) A REFILL PRESCRIPTION IS NOT CHANGED FROM THE PRODUCT DISPENSED
49 ON THE PRIOR FILLING OF THE PRESCRIPTION.

50 5. THE DEPARTMENT SHALL MAINTAIN A LINK ON ITS WEB SITE TO THE CURRENT
51 LIST OF ALL BIOLOGICAL PRODUCTS DETERMINED BY THE FEDERAL FOOD AND DRUG
52 ADMINISTRATION TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR A SPECIF-
53 IC BIOLOGICAL PRODUCT.

54 S 4. Subparagraph 2 of paragraph (o) of subdivision 1 of section 206
55 of the public health law, as amended by chapter 913 of the laws of 1986,
56 is amended to read as follows:

1 (2) The commissioner of the Federal Food and Drug Administration has
2 evaluated such drug product as:
3 (I) pharmaceutically and therapeutically equivalent and has listed
4 such drug product on the list of approved drugs products with the thera-
5 peutic equivalence evaluations, provided, however, that the list
6 prepared by the commissioner shall not include any drug product which
7 the commissioner of the Federal Food and Drug Administration has identi-
8 fied as having an actual or potential bioequivalence problem; OR
9 (II) AS AN INTERCHANGEABLE BIOLOGICAL PRODUCT AND HAS LISTED SUCH
10 PRODUCT ON THE LIST OF APPROVED DRUG PRODUCTS WITH INTERCHANGEABILITY.
11 S 5. This act shall take effect immediately.