S T A T E O F N E W Y O R K

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I N A S S E M B L Y

January 7, 2016

Introduced by M. of A. GOTTFRIED, TITONE, SKOUFIS, RAIA, LUPINACCI, BARRETT, McDONOUGH, QUART, STECK -- read once and referred to the Committee on Higher Education -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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 ASSEMBLY, DO ENACT AS FOLLOWS:

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

27. "BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT AS DEFINED IN SUBSECTION (I) OF SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT 42 U.S.C. SECTION 262(I).

28. "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT LICENSED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO 42 U.S.C. SECTION 262(K)(4) AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION LISTS OF LICENSED BIOLOGICAL PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS, SOMETIMES REFERRED TO AS THE "PURPLE BOOK," OR A BIOLOGICAL PRODUCT DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, SOMETIMES REFERRED TO AS THE "ORANGE BOOK."

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

(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 INTER-

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

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CHANGEABLE 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.

[(c)] (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.

S 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 BIOLOGICAL PRODUCT HAS BEEN DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH THE PRESCRIBED 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 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 BY USING FACSIMILE OR ELECTRONIC TRANSMISSION.

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

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

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

5. THE DEPARTMENT SHALL MAINTAIN A LINK ON ITS WEB SITE TO THE CURRENT LIST OF ALL BIOLOGICAL PRODUCTS DETERMINED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR A SPECIFIC BIOLOGICAL PRODUCT.

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

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

(I) pharmaceutically and therapeutically equivalent and has listed such drug product on the list of approved drugs products with the therapeutic equivalence evaluations, provided, however, that the list prepared by the commissioner shall not include any drug product which the commissioner of the Federal Food and Drug Administration has identified as having an actual or potential bioequivalence problem; OR

(II) AS AN INTERCHANGEABLE BIOLOGICAL PRODUCT AND HAS LISTED SUCH PRODUCT ON THE LIST OF APPROVED DRUG PRODUCTS WITH INTERCHANGEABILITY.

S 5. This act shall take effect immediately.