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

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I N S E N A T E

(PREFILED)

January 6, 2016

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend 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. The public health law is amended by adding a new section 279-a to read as follows:

S 279-A. INTERCHANGEABLE BIOLOGICAL PRODUCTS. 1. AS USED IN THIS SECTION:

(A) "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).

(B) "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) 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."

2. A PHARMACIST SHALL SUBSTITUTE A BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT ONLY IF 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 THE EDUCATION LAW; 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, AND THE PHARMACIST RECORDS ON THE

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

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PRESCRIPTION FORM THE BRAND NAME OR THE NAME OF THE MANUFACTURER OF THE DRUG PRODUCT DISPENSED.

3. 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 THE 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.

4. THE PRESCRIBER SHALL INFORM THE PATIENT WHETHER HE OR SHE HAS PRESCRIBED A SPECIFIC BIOLOGICAL PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT.

5. THE PROVISIONS OF THIS SUBDIVISION SHALL NOT APPLY TO A HOSPITAL AS DEFINED IN ARTICLE TWENTY-EIGHT OF THIS CHAPTER.

6. 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 THIS CHAPTER.

7. (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 (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, TELEPHONE, ELECTRONIC TRANSMISSION, OR OTHER PREVAILING MEANS.

(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.

8. 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 2. This act shall take effect immediately.