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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:

1 Section 1. The public health law is amended by adding a new section
2 279-a to read as follows:

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

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

8 (B) "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT
9 LICENSED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO
10 42 U.S.C. SECTION 262(K)(4) OR A BIOLOGICAL PRODUCT DETERMINED BY THE
11 UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE THERAPEUTICALLY EQUIV-
12 ALENT AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE UNITED
13 STATES FOOD AND DRUG ADMINISTRATION APPROVED DRUG PRODUCTS WITH THERA-
14 PEUTIC EQUIVALENCE EVALUATIONS, SOMETIMES REFERRED TO AS THE "ORANGE
15 BOOK."

16 2. A PHARMACIST SHALL SUBSTITUTE A BIOLOGICAL PRODUCT FOR A PRESCRIBED
17 BIOLOGICAL PRODUCT ONLY IF ALL OF THE FOLLOWING CONDITIONS ARE MET:

18 (A) THE BIOLOGICAL PRODUCT HAS BEEN DETERMINED BY THE UNITED STATES
19 FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH THE PRESCRIBED
20 PRODUCT;

21 (B) THE PRESCRIBER DOES NOT DESIGNATE THAT A SUBSTITUTION IS PROHIBIT-
22 ED AS DESCRIBED IN SUBDIVISION SIX OF SECTION SIXTY-EIGHT HUNDRED TEN OF
23 THE EDUCATION LAW; AND

24 (C) THE PHARMACIST INDICATES ON THE LABEL AFFIXED TO THE IMMEDIATE
25 CONTAINER IN WHICH THE BIOLOGICAL PRODUCT IS SOLD OR DISTRIBUTED THE
26 NAME AND STRENGTH OF THE PRODUCT AND ITS MANUFACTURER UNLESS THE PRES-
27 CRIBER 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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1 PRESCRIPTION FORM THE BRAND NAME OR THE NAME OF THE MANUFACTURER OF THE
2 DRUG PRODUCT DISPENSED.

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

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

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

23 6. NO PRESCRIBER SHALL BE SUBJECTED TO CIVIL LIABILITY ARISING SOLELY
24 FROM AUTHORIZING, IN ACCORDANCE WITH THIS SUBDIVISION, THE SUBSTITUTION
25 BY A PHARMACIST OF A DRUG PRODUCT PURSUANT TO PARAGRAPH (O) OF SUBDIVI-
26 SION ONE OF SECTION TWO HUNDRED SIX OF THIS CHAPTER.

27 7. (A) WITHIN FIVE BUSINESS DAYS FOLLOWING THE DISPENSING OF A BIOLOG-
28 ICAL PRODUCT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE
29 SHALL COMMUNICATE TO THE PRESCRIBER THE SPECIFIC PRODUCT PROVIDED TO THE
30 PATIENT, INCLUDING THE NAME OF THE PRODUCT AND THE MANUFACTURER. THE
31 COMMUNICATION SHALL BE CONVEYED (I) BY MAKING AN ENTRY THAT IS ELECTRON-
32 ICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH AN INTEROPERABLE ELECTRONIC
33 MEDICAL RECORDS SYSTEM, AN ELECTRONIC PRESCRIBING TECHNOLOGY OR A PHAR-
34 MACY RECORD; OR (II) BY USING FACSIMILE, TELEPHONE, ELECTRONIC TRANS-
35 MISSION, OR OTHER PREVAILING MEANS.

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

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

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

42 8. THE DEPARTMENT SHALL MAINTAIN A LINK ON ITS WEB SITE TO THE CURRENT
43 LIST OF ALL BIOLOGICAL PRODUCTS DETERMINED BY THE FEDERAL FOOD AND DRUG
44 ADMINISTRATION TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR A SPECIF-
45 IC BIOLOGICAL PRODUCT.

46 S 2. This act shall take effect immediately.