

6739--A

I N S E N A T E

March 5, 2014

Introduced by Sen. LANZA -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law and the education law, in relation to generic drug products; and to repeal paragraph (o) of subdivision 1 of section 206 of the public health law relating thereto

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1 Section 1. Paragraph (o) of subdivision 1 of section 206 of the public  
2 health law is REPEALED.

3 S 2. The public health law is amended by adding a new section 280-a to  
4 read as follows:

5 S 280-A. GENERIC DRUG PRODUCTS. 1. THE COMMISSIONER SHALL ESTABLISH  
6 AND PUBLISH A LIST OF DRUG PRODUCTS, REFERRED TO IN THIS SECTION AS  
7 "GENERIC DRUG" PRODUCTS, EACH OF WHICH SHALL MEET THE FOLLOWING CONDI-  
8 TIONS:

9 (A) THE DRUG PRODUCT HAS BEEN CERTIFIED OR APPROVED BY THE COMMISSION-  
10 ER OF THE FEDERAL FOOD AND DRUG ADMINISTRATION AS BEING SAFE AND EFFEC-  
11 TIVE FOR ITS LABELED INDICATIONS FOR USE, AND A NEW-DRUG APPLICATION OR  
12 AN ABBREVIATED NEW-DRUG APPLICATION APPROVED PURSUANT TO THE FEDERAL  
13 FOOD, DRUG, AND COSMETIC ACT IS HELD FOR SUCH DRUG PRODUCT; AND

14 (B) THE COMMISSIONER OF THE FEDERAL FOOD AND DRUG ADMINISTRATION HAS  
15 EVALUATED SUCH DRUG PRODUCT AS PHARMACEUTICALLY AND THERAPEUTICALLY  
16 EQUIVALENT AND HAS LISTED SUCH DRUG PRODUCT ON THE LIST OF APPROVED DRUG  
17 PRODUCTS WITH THE THERAPEUTIC EQUIVALENCE EVALUATIONS, PROVIDED, HOWEV-  
18 ER, THAT THE LIST PREPARED BY THE COMMISSIONER SHALL NOT INCLUDE ANY  
19 DRUG PRODUCT WHICH THE COMMISSIONER OF THE FEDERAL FOOD AND DRUG ADMIN-  
20 ISTRATION HAS IDENTIFIED AS HAVING AN ACTUAL OR POTENTIAL BIOEQUIVALENCE  
21 PROBLEM.

22 2. THE MANUFACTURER OF A GENERIC DRUG PRODUCT SHALL MAKE AVAILABLE TO  
23 THE DEPARTMENT THE BIOPHARMACEUTIC STUDIES AND SUMMARIES, INCLUDING  
24 BIOEQUIVALENCE DATA AND INCIDENCE OF ADVERSE EVENTS, AND ASSOCIATED  
25 ANALYTICAL METHODS, INCLUDING DISSOLUTION DATA AND TEST METHODS PROVIDED

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

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1 TO THE FEDERAL FOOD AND DRUG ADMINISTRATION AS PART OF THE APPLICATION  
2 FOR SUCH GENERIC DRUG PRODUCT. THE DEPARTMENT SHALL MAKE SUCH INFORMA-  
3 TION FREELY AND PUBLICLY AVAILABLE ON ITS WEBSITE.

4 S 3. Paragraphs (a) and (d) of subdivision 6 of section 6810 of the  
5 education law, paragraph (a) as amended by chapter 590 of the laws of  
6 2011 and paragraph (d) as added by chapter 913 of the laws of 1986, are  
7 amended to read as follows:

8 (a) Every prescription written in this state by a person authorized to  
9 issue such prescription shall be on prescription forms containing one  
10 line for the prescriber's signature. The prescriber's signature shall  
11 validate the prescription. Every electronic prescription shall provide  
12 for the prescriber's electronic signature, which shall validate the  
13 electronic prescription. Imprinted conspicuously on every prescription  
14 written in this state in eight point upper case type immediately below  
15 the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED  
16 GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless  
17 the prescriber writes d a w in such box in the prescriber's own hand-  
18 writing or, in the case of electronic prescriptions, inserts an elec-  
19 tronic direction to dispense the drug as written, the prescriber's  
20 signature or electronic signature shall designate approval of substi-  
21 tution by a pharmacist of a GENERIC drug product pursuant to [paragraph  
22 (o) of subdivision one of] section [two hundred six] TWO HUNDRED EIGHT-  
23 Y-A of the public health law. No other letters or marks in such box  
24 shall prohibit substitution. No prescription forms used or intended to  
25 be used by a person authorized to issue a prescription shall have 'd a  
26 w' preprinted in such box. Such box shall be placed directly under the  
27 signature line and shall be three-quarters inch in length and one-half  
28 inch in height, or in comparable form for an electronic prescription as  
29 may be specified by regulation of the commissioner. Immediately below  
30 such box shall be imprinted in six point type the words "Dispense As  
31 Written". Notwithstanding any other provision of law, no state offi-  
32 cial, agency, board or other entity shall promulgate any regulation or  
33 guideline modifying those elements of the prescription form's contents  
34 specified in this subdivision. To the extent otherwise permitted by law,  
35 a prescriber may modify only those elements of the prescription form's  
36 contents not specified in this subdivision. Notwithstanding any other  
37 provision of this section or any other law, when a generic drug is not  
38 available and the brand name drug originally prescribed is available and  
39 the pharmacist agrees to dispense the brand name product for a price  
40 that will not exceed the price that would have been charged for the  
41 generic substitute had it been available, substitution of a generic drug  
42 product will not be required. If the generic drug product is not avail-  
43 able and a medical emergency situation, which for purposes of this  
44 section is defined as any condition requiring alleviation of severe pain  
45 or which threatens to cause disability or take life if not promptly  
46 treated, exists, then the pharmacist may dispense the brand name product  
47 at his regular price. In such instances the pharmacist must record the  
48 date, hour and nature of the medical emergency on the back of the  
49 prescription and keep a copy of all such prescriptions.

50 (d) No prescriber shall be subjected to civil liability arising solely  
51 from authorizing, in accordance with this subdivision, the substitution  
52 by a pharmacist of a GENERIC drug product pursuant to [paragraph (o) of  
53 subdivision one of] section [two hundred six] TWO HUNDRED EIGHTY-A of  
54 the public health law.

1 S 4. Paragraph (b) of subdivision 1 of section 6816-a of the education  
2 law, as added by chapter 776 of the laws of 1977, is amended to read as  
3 follows:

4 (b) The substituted drug product is contained in the list of GENERIC  
5 drug products established pursuant to [paragraph (o) of subdivision one  
6 of] section [two hundred six] TWO HUNDRED EIGHTY-A of the public health  
7 law; and

8 S 5. This act shall take effect on the ninetieth day after it shall  
9 have become a law. Effective immediately, the addition, amendment and/or  
10 repeal of any rule or regulation necessary for the implementation of  
11 this act on its effective date is authorized to be made and completed on  
12 or before such effective date.