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

145

2015-2016 Regular Sessions

I N A S S E M B L Y

(PREFILED)

January 7, 2015

Introduced by M. of A. PAULIN, GOTTFRIED, DINOWITZ, GALEF, HOOPER, JAFFEE, MARKEY, MILLER, RIVERA -- read once and referred to the Committee on Health

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:

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 Paragraph (o) of subdivision 1 of section 206 of the public health law is REPEALED.

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

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

(A) THE DRUG PRODUCT HAS BEEN CERTIFIED OR APPROVED BY THE COMMISSIONER OF THE FEDERAL FOOD AND DRUG ADMINISTRATION AS BEING SAFE AND EFFECTIVE FOR ITS LABELED INDICATIONS FOR USE, AND A NEW-DRUG APPLICATION OR AN ABBREVIATED NEW-DRUG APPLICATION APPROVED PURSUANT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IS HELD FOR SUCH DRUG PRODUCT; AND

(B) THE COMMISSIONER OF THE FEDERAL FOOD AND DRUG ADMINISTRATION HAS EVALUATED SUCH DRUG PRODUCT AS PHARMACEUTICALLY AND THERAPEUTICALLY EQUIVALENT AND HAS LISTED SUCH DRUG PRODUCT ON THE LIST OF APPROVED DRUG 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.

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

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2. THE MANUFACTURER OF A GENERIC DRUG PRODUCT SHALL MAKE AVAILABLE TO THE DEPARTMENT THE BIOPHARMACEUTIC STUDIES AND SUMMARIES, INCLUDING BIOEQUIVALENCE DATA AND INCIDENCE OF ADVERSE EVENTS, AND ASSOCIATED ANALYTICAL METHODS, INCLUDING DISSOLUTION DATA AND TEST METHODS PROVIDED TO THE FEDERAL FOOD AND DRUG ADMINISTRATION AS PART OF THE APPLICATION FOR SUCH GENERIC DRUG PRODUCT. THE DEPARTMENT SHALL MAKE SUCH INFORMATION FREELY AND PUBLICLY AVAILABLE ON ITS WEBSITE.

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

(a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Every electronic prescription shall provide for the prescriber's electronic signature, which shall validate the electronic prescription. Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a GENERIC drug product pursuant to [paragraph (o) of subdivision one of] section [two hundred six] TWO HUNDRED EIGHT-Y-A of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height, or in comparable form for an electronic prescription as may be specified by regulation of the commissioner. Immediately below such box shall be imprinted in six point type the words "Dispense As Written". Notwithstanding any other provision of law, no state official, agency, board or other entity shall promulgate any regulation or guideline modifying those elements of the prescription form's contents specified in this subdivision. To the extent otherwise permitted by law, a prescriber may modify only those elements of the prescription form's contents not specified in this subdivision. Notwithstanding any other provision of this section or any other law, when a generic drug is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required. If the generic drug 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 brand name 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.

(d) No prescriber shall be subjected to civil liability arising solely from authorizing, in accordance with this subdivision, the substitution by a pharmacist of a GENERIC drug product pursuant to [paragraph (o) of

subdivision one of] section [two hundred six] TWO HUNDRED EIGHTY-A of the public health law.

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

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

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