STATE OF NEW YORK

612--A

2019-2020 Regular Sessions

IN ASSEMBLY

(Prefiled)

January 9, 2019

Introduced by M. of A. PAULIN, GOTTFRIED, DINOWITZ, GALEF, JAFFEE, M. G. MILLER, RIVERA, WEPRIN, ABINANTI -- read once and referred 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:

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 Paragraph (o) of subdivision 1 of section 206 of the public health law is REPEALED.

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

§ 280-d. 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: (i) 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 or (ii) as an interchangeable biological product and has listed

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

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such product on the list of approved drug products with interchangeability.

2. The manufacturer of a generic drug product shall make available to the department the studies and summaries, including bioequivalence data, therapeutic equivalence 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.

§ 3. Paragraphs (a) and (e) of subdivision 6 of section 6810 of the education law, paragraph (a) as amended by chapter 590 of the laws of 2011 and paragraph (e) as amended by chapter 357 of the laws of 2017, 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 (e) of subdivision one of~~] section [~~two hundred six~~] two hundred eighty-d 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.

(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 **generic** drug product pursuant to [~~**paragraph (o) of subdivision one of**~~] section two hundred [~~**six**~~] **eighty-d** of the public health law.

§ 4. Paragraph (d) of subdivision 6 of section 6810 of the education law, as added by chapter 913 of the laws of 1986, is amended to read as follows:

(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**~~] **eighty-d** of the public health law.

§ 5. 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-d** of the public health law; and

§ 6. This act shall take effect on the ninetieth day after it shall have become a law; provided that the amendments to paragraph (e) of subdivision 6 of section 6810 of the education law, made by section three of this act, shall not affect the expiration of such paragraph, when upon such date the provisions of section four of this act shall take effect. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.