STATE OF NEW YORK

9535

IN ASSEMBLY

March 20, 2024

Introduced by M. of A. STECK -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing a generic drug research and development laboratory and production facility and the empire state biosimilar insulin initiative

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Article 2-A of the public health law is amended by adding a new title IV to read as follows:

TITLE IV

NEW YORK AFFORDABLE DRUG MANUFACTURING ACT

Section 285. Definitions.

286. Generic drug research and development laboratory and production facility; empire state biosimilar insulin initiative.

287. Partnerships; production and distribution of prescription drugs.

288. Proprietary information.

§ 285. Definitions. 1. For the purposes of this title, the following terms shall have the following meanings:

(a) "Generic drug" shall mean a drug that is approved pursuant to subdivision (j) of section 355 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or a biosimilar, as defined under the federal Public Health Service Act (42 U.S.C. Sec. 262).

(b) "Partnerships" shall include, but not be limited to, agreements for the procurement of generic prescription drugs by way of contracts or purchasing by a payer, state governmental agency, group purchasing organization, nonprofit organization, or other entity.

§ 286. Generic drug research and development laboratory and production facility; empire state biosimilar insulin initiative. 1. (a) The department shall establish a generic drug research and development laboratory and production facility within the university of the state of New York system.

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

LBD13501-01-3

(b) The generic drug research and development laboratory and production facility established pursuant to paragraph (a) of this subdivision shall produce and distribute generic prescription drugs, with the intent that these drugs be made widely available to public and private purchasers, facilities licensed pursuant to article twenty-eight of this chapter, and pharmacies as defined in section six thousand eight hundred two of the education law, as appropriate.

(c) Each drug produced pursuant to paragraph (b) of this subdivision shall be made available to providers, patients, and purchasers at a price not to exceed the cost of such production for residents of the state.

(d) The department shall prioritize the development and production of generic prescription drugs that have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers.

2. The first initiative of the generic drug research and development laboratory and production facility established pursuant to subdivision one of this section shall be the empire state biosimilar insulin initiative. Such initiative shall include the research, development, and production of generic forms of the three most widely used forms of insulin. Such insulin shall be produced or distributed by a non-profit generic drug manufacturer that is registered with the United States Food and Drug Administration.

3. Until such time as the generic drug research and development laboratory and production facility is completed and the empire state biosimilar insulin initiative begins, the commissioner shall enter into partnerships resulting in the production or distribution of at least one generic form of insulin pursuant to section two hundred eighty-seven of this title.

§ 287. Partnerships; production and distribution of prescription drugs. 1. The commissioner shall enter into partnerships resulting in the production or distribution of at least one generic form of insulin, with the intent that such insulin be made widely available to public and private purchasers, facilities licensed pursuant to article twenty-eight of this chapter, and pharmacies as defined in section six thousand eight hundred two of the education law, as appropriate. Such insulin shall be produced or distributed by a non-profit generic drug manufacturer that is registered with the United States Food and Drug Administration.

2. Each form of insulin produced pursuant to subdivision one of this section shall be made available to providers, patients, and purchasers at a price not to exceed thirty dollars per monthly dose for residents of the state.

§ 288. Proprietary information. Notwithstanding any provision of law to the contrary, all nonpublic information and documents obtained by the department pursuant to this title shall not be required to be disclosed pursuant to article six of the public officers law.

§ 2. This act shall take effect immediately.