

STATE OF NEW YORK

500

2025-2026 Regular Sessions

IN ASSEMBLY

(Prefiled)

January 8, 2025

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:

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

TITLE IV

NEW YORK AFFORDABLE DRUG MANUFACTURING ACT

Section 285. Definitions.

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

9 287. Partnerships; production and distribution of prescription
10 drugs.

11 288. Proprietary information.

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

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

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

22 § 286. Generic drug research and development laboratory and production
23 facility; empire state biosimilar insulin initiative. 1. (a) The depart-

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

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1 ment shall establish a generic drug research and development laboratory
2 and production facility within the university of the state of New York
3 system.

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

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

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

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

28 3. Until such time as the generic drug research and development labo-
29 ratory and production facility is completed and the empire state biosi-
30 milar insulin initiative begins, the commissioner shall enter into part-
31 nerships resulting in the production or distribution of at least one
32 generic form of insulin pursuant to section two hundred eighty-seven of
33 this title.

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

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

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

51 § 2. This act shall take effect immediately.