

STATE OF NEW YORK

8345

2023-2024 Regular Sessions

IN ASSEMBLY

December 13, 2023

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

AN ACT to amend the public health law, in relation to enacting the "New York affordable drug manufacturing act"

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

1 Section 1. Short title. This act shall be known and may be cited as
2 the "New York affordable drug manufacturing act".

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

TITLE IV

NEW YORK AFFORDABLE DRUG MANUFACTURING ACT

Section 282. Definitions.

8 283. Partnerships; production and distribution of prescription
9 drugs.

10 284. Reporting.

11 285. Proprietary information.

12 § 282. Definitions. As used in this title, the following terms shall
13 have the following meanings:

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

18 2. "Partnerships" shall include, but are not 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 § 283. Partnerships; production and distribution of prescription
23 drugs. 1. (a) The commissioner shall enter into partnerships, consistent
24 with paragraph (b) of subdivision two of this section, in consultation
25 with all appropriate state agencies and the department of health or

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

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1 equivalent institution of any other state as determined by the commis-
2 sioner, to increase competition, lower prices, and address shortages in
3 the market for generic prescription drugs, to reduce the cost of
4 prescription drugs for public and private purchasers, taxpayers, and
5 consumers, and to increase patient access to affordable drugs.

6 (b) The department shall have the ability to hire staff to oversee and
7 project-manage the partnerships for manufacturing or distribution of
8 generic prescription drugs.

9 2. (a) The commissioner shall enter into partnerships resulting in the
10 production or distribution of generic prescription drugs, with the
11 intent that these drugs be made widely available to public and private
12 purchasers, facilities licensed pursuant to article twenty-eight of this
13 chapter, and pharmacies as defined in section six thousand eight hundred
14 two of the education law, as appropriate. The generic prescription drugs
15 shall be produced or distributed by a drug company or generic drug
16 manufacturer that is registered with the United States Food and Drug
17 Administration.

18 (b) (i) The commissioner shall only enter into partnerships pursuant
19 to paragraph (a) of this subdivision to produce a generic prescription
20 drug at a price that results in savings, targets failures in the market
21 for generic drugs, and improves patient access to affordable medica-
22 tions.

23 (ii) For top drugs identified pursuant to the criteria listed in
24 subparagraph (v) of this paragraph, the department shall determine if
25 viable pathways exist for partnerships to manufacture or distribute
26 generic prescription drugs by examining the relevant legal, market,
27 policy, and regulatory factors.

28 (iii) The department shall consider the following, if applicable, when
29 setting the price of the generic prescription drug:

30 (1) United States Food and Drug Administration user fees.

31 (2) Abbreviated new drug application acquisition costs amortized over
32 a five-year period.

33 (3) Mandatory rebates.

34 (4) Total contracting and production costs for the drug, including a
35 reasonable amount for administrative, operating, and rate-of-return
36 expenses of the drug company or generic drug manufacturer.

37 (5) Research and development costs attributed to the drug over a five-
38 year period.

39 (6) Other initial start-up costs amortized over a five-year period.

40 (iv) Each drug shall be made available to providers, patients, and
41 purchasers at a transparent price and without rebates, other than feder-
42 ally required rebates.

43 (v) The department shall prioritize the selection of generic
44 prescription drugs that have the greatest impact on lowering drug costs
45 to patients, increasing competition and addressing shortages in the
46 prescription drug market, improving public health, or reducing the cost
47 of prescription drugs to public and private purchasers.

48 (c) (i) In identifying generic prescription drugs to be produced, the
49 department shall consider prescription drug retail price lists made
50 pursuant to section two hundred seventy-eight of this article.

51 (ii) The partnerships entered into pursuant to paragraph (a) of this
52 subdivision shall include the production of at least one form of insu-
53 lin, provided that a viable pathway for manufacturing a more affordable
54 form of insulin exists.

55 (iii) The department shall prioritize drugs for chronic and high-cost
56 conditions.

1 (d) The department shall consult with all of the following public and
2 private purchasers to assist in developing a list of generic
3 prescription drugs to be manufactured or distributed through partner-
4 ships and to determine the volume of each generic prescription drug that
5 can be procured over a multiyear period to support a market for a lower
6 cost generic prescription drug:

7 (i) The department of mental hygiene, the office for people with
8 developmental disabilities, the office of general services, and the
9 department of corrections and community supervision, or the entities
10 acting on behalf of each of those state purchasers.

11 (ii) Health insurers licensed pursuant to the insurance law.

12 (iii) Hospitals.

13 (iv) Any other entity as determined by the commissioner.

14 (e) Before effectuating a partnership pursuant to this section, the
15 commissioner shall determine minimum thresholds for procurement of an
16 entity's expected volume of a targeted drug from the company or manufac-
17 turer over a multiyear period.

18 (f) All state agencies shall be required to purchase prescription
19 drugs from the department or entities that contract or partner with the
20 department pursuant to this chapter.

21 (g) The department shall not be required to consult with every entity
22 listed in subparagraphs (ii), (iii) and (iv) of paragraph (d) of this
23 subdivision, so long as purchaser engagement includes a reasonable
24 representation from these groups.

25 § 284. Reporting. 1. On or before January first, two thousand twenty-
26 six, the department shall submit a report to the legislature that
27 assesses the feasibility of directly manufacturing generic prescription
28 drugs and selling generic prescription drugs at a fair price. The report
29 shall include, but not be limited to, an analysis of governance struc-
30 ture options for manufacturing functions, including chartering a private
31 organization, a public-private partnership, or a public board of direc-
32 tors.

33 2. On or before March first, two thousand twenty-five, the department
34 shall report to the legislature on both of the following:

35 (a) A description of the status of all drugs targeted under this chap-
36 ter.

37 (b) An analysis of how the activities of the department may impact
38 competition, access to targeted drugs, the costs of those drugs, and the
39 costs of generic prescription drugs to public and private purchasers.

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

44 § 3. Severability. If any clause, sentence, paragraph, section or part
45 of this act shall be adjudged by any court of competent jurisdiction to
46 be invalid and after exhaustion of all further judicial review, the
47 judgment shall not affect, impair or invalidate the remainder thereof,
48 but shall be confined in its operation to the clause, sentence, para-
49 graph, section or part of this act directly involved in the controversy
50 in which the judgment shall have been rendered.

51 § 4. This act shall take effect immediately.