STATE OF NEW YORK

8345--A

2023-2024 Regular Sessions

IN ASSEMBLY

December 13, 2023

Introduced by M. of A. RAJKUMAR -- read once and referred to the Committee on Health -- recommitted to the Committee on Health in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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:

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

§ 2. 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 282. Definitions.
283. Partnerships; production and distribution of generic prescription drugs.
284. Reporting.
285. Proprietary information.

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

1. "Generic prescription drug" means a drug that is approved pursuant to an application submitted under 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) that is not under patent.

2. "Partnerships" means 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.

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

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§ 283. Partnerships; production and distribution of generic prescription drugs. 1. (a) The commissioner shall enter into partnerships, consistent with paragraph (b) of subdivision two of this section, in consultation with all appropriate state agencies and the department of health or equivalent institution of any other state as determined by the commissioner, to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs.

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

2. (a) The commissioner shall enter into partnerships resulting in the production or distribution of 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. The generic prescription drugs shall be produced or distributed by a drug company or generic drug manufacturer that is registered with the United States Food and Drug Administration.

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

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

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

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

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

(3) Mandatory rebates.

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

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

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

(iv) Each drug shall be made available to providers, patients, and purchasers at a transparent price and without rebates, other than federally required rebates.

(v) The department shall prioritize the selection 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.

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

(ii) The partnerships entered into pursuant to paragraph (a) of this subdivision shall include the production of at least one form of insu-

lin, provided that a viable pathway for manufacturing a more affordable form of insulin exists.

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

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

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

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

(iii) Hospitals.

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

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

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

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

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

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

(a) A description of the status of all drugs targeted under this chapter.

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

§ 285. 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.

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

§ 4. This act shall take effect on the first of January next succeeding one year after it shall have become a law.