STATE OF NEW YORK

7954--A

2023-2024 Regular Sessions

IN ASSEMBLY

August 18, 2023

Introduced by M. of A. SIMON, COOK, DINOWITZ, GUNTHER, HUNTER, LAVINE, MAGNARELLI, RAMOS, RIVERA, L. ROSENTHAL, REYES, BENEDETTO, CRUZ, EPSTEIN, COLTON, PAULIN, SILLITTI, JEAN-PIERRE, GONZALEZ-ROJAS, SMITH, FORREST, JACKSON, SIMONE, HEVESI, LUNSFORD, LEVENBERG, SANTABARBARA, LUPARDO, DeSTEFANO, DAVILA, CLARK, BURDICK, ARDILA, STECK, SHRESTHA, SEAWRIGHT, DICKENS, CURRAN, K. BROWN, SHIMSKY -- Multi-Sponsored by -- M. of A. BUTTENSCHON, THIELE -- read once and referred to the Committee on Higher Education -- recommitted to the Committee on Higher Education 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 and the education law, in relation to creating a wholesale prescription drug importation program

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

Section 1. The public health law is amended by adding a new section 280-d to read as follows:

§ 280-d. Wholesale prescription drug importation program. 1. As used in this section, the following terms shall have the following meanings:

(a) "Wholesale prescription drug importation program" or "program" means the wholesale prescription drug importation program created under this section.

(b) "Prescription drug wholesaler" means an entity authorized to acquire prescription drugs and sell or distribute them wholesale in the state.

(c) "Approved wholesaler" means a prescription drug wholesaler authorized to participate in the importation program under this section pursuant to approval by the state education department under section sixty-eight hundred eight of the education law.

2. The commissioner, in consultation with the commissioner of education and other appropriate federal and state agencies, shall design a

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

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wholesale prescription drug importation program for the wholesale importation of prescription drugs from Canada. The program design shall comply with applicable federal requirements, including 21 U.S.C. § 384, and requirements regarding safety and cost savings. Under the program design:

(a) prescription drugs shall only be acquired from Canadian prescription drug suppliers regulated and authorized under the laws of Canada or one or more Canadian provinces, or both;

(b) only prescription drugs meeting the federal Food and Drug Administration's safety, effectiveness, misbranding, adulteration and other standards shall be imported under the program;

(c) only prescription drugs expected to generate substantial savings for consumers in the state shall be imported;

(d) the prescription drug is not:

(i) a controlled substance as defined in 21 U.S.C. § 802;

(ii) a biological product as defined in 42 U.S.C. § 262;

(iii) an infused drug, including a peritoneal dialysis solution;

(iv) an intravenously injected drug;

(v) a drug that is inhaled during surgery;

(vi) a drug which is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to public health;

(e) any approved wholesaler shall at all times comply with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent practicable prior to imported prescription drugs coming into the possession of the approved wholesaler, and fully comply with those requirements after imported prescription drugs are in the possession of the approved wholesaler;

(f) an approved wholesaler shall not sell, distribute or dispense prescription drugs imported under the program outside of the state;

(g) the commissioner may impose an annual fee on approved wholesalers, which may be based in whole or in part on the value of prescription drugs imported by the approved wholesaler under the program, to support the operation of the program;

(h) every approved wholesaler shall provide the commissioner and the commissioner of education with information on its participation in the program as required by such commissioners including but not limited to:

(i) the name and quantity of the active ingredient of the drug;

(ii) a description of the dosage form of the drug;

(iii) the date on which the drug is received;

(iv) the quantity of the drug that is received;

(v) the point of origin and destination of the drug; and

(vi) the price paid by the approved wholesaler for the drug

(i) the commissioner shall provide for auditing of the program, including making sure that prescription drugs are made available at substantial savings to consumers as a result of the program, ensuring that the prescription drugs are approved for marketing in the United States, meet all labeling requirements under state and federal laws and regulations, and is not adulterated or misbranded, and ensuring that prescription drugs are authentic and in compliance with the federal Food and Drug Administration's approved drug specifications and standards.

3. The department, in consultation with the state education department, shall promulgate rules and regulations to design the program in accordance with subdivision two of this section.

4. (a) The commissioner, in consultation with the commissioner of education, shall seek all necessary approvals and certification by the

secretary of the U.S. Department of Health and Human Services and/or other appropriate federal officials or agencies for the wholesale prescription drug importation program designed under this section.

(b) The commissioner shall seek the appropriate federal approvals, waivers, exemptions, or agreements, or a combination thereof, as needed to enable all covered entities enrolled in or eligible for the drug discount program authorized by section 340B of the federal public health service act (42 U.S.C. § 256b) to participate in the wholesale prescription drug importation program to the fullest extent possible without jeopardizing their eligibility for such drug discount program.

5. Upon receipt of federal approval and certification under paragraph (a) of subdivision four of this section, the commissioner shall implement the program pursuant to this section.

6. The commissioner shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by an approved wholesaler if the commissioner discovers that any drug or activity is in violation of this section or any federal or state law or regulation, and shall immediately notify the commissioner of education of such suspension. Furthermore, the commissioner shall inform the commissioner of education of all facts and circumstances leading to such suspension as soon as practicable, and shall cooperate with the commissioner of education in any disciplinary investigation or action pursuant to title eight of the education law related to such wholesaler.

7. Nothing in this section shall be construed as affecting or in any way interfering with the commissioner of education's oversight of wholesalers.

8. The commissioner shall annually report to the governor, the temporary president of the senate, and the speaker of the assembly regarding the implementation of a federally approved wholesale prescription drug importation program. The report shall include, at a minimum:

(a) a list of the prescription drugs imported under the program;

(b) a list of all participating Canadian prescription drug suppliers, approved wholesalers, and other participating entities;

(c) estimated cost savings during the previous fiscal year;

(d) information regarding audit findings; and

(e) any other relevant information.

§ 2. Section 6808 of the education law is amended by adding a new subdivision 10 to read as follows:

10. Prescription drug importation program wholesalers. a. A wholesaler shall not participate in the wholesale prescription drug importation program under section two hundred eighty-d of the public health law without prior application and approval by the department.

b. Such application shall be made on a form prescribed by the department.

c. Such application shall be accompanied by a fee determined by the department.

d. All approvals shall be renewed on dates set by the department.

e. All approvals shall meet applicable federal laws and regulations including under 21 U.S.C. § 384, as amended, and any regulations promulgated thereunder.

§ 3. This act shall take effect eighteen months after it shall have become a law. 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.