STATE OF NEW YORK

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IN ASSEMBLY

(Prefiled)

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Introduced by M. of A. GOTTFRIED, BARRON, CAHILL, COOK, DINOWITZ, ENGLEBRIGHT, GALEF, GUNTHER, HUNTER, LAVINE, MAGNARELLI, MONTESANO, RAMOS, J. RIVERA, L. ROSENTHAL, SEAWRIGHT, SIMON, ZEBROWSKI, JACOBSON, STIRPE, HEVESI, CARROLL, MIKULIN, REYES, BENEDETTO, CRUZ, EPSTEIN, COLTON, NIOU -- Multi-Sponsored by -- M. of A. BUTTENSCHON, LUPARDO, THIELE -- read once and referred to the Committee on Higher Education

AN ACT to amend the public health 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. Title 2 of article 2-A of 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. (a) There is hereby created in the department a wholesale prescription drug importation program.

(b) As used in this section, unless the context clearly requires otherwise, the following terms shall have the following meanings:

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

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

(iii) "Approved wholesaler" means a prescription drug wholesaler approved under this section to participate in the program.

(c) The commissioner shall develop and implement the program in consultation with interested stakeholders and appropriate federal officials. The program shall comply with applicable federal requirements, including 21 U.S.C. § 384, and requirements regarding safety and cost savings. Under the program:

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

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(i) the commissioner shall approve one or more prescription drug wholesalers to seek federal certification and approval to import prescription drugs from one or more other countries, to be sold or distributed wholesale in the state;

(ii) prescription drugs shall only be acquired from suppliers regulated and authorized under the laws of the other country or a jurisdiction thereof;

(iii) only prescription drugs meeting the U.S. Food and Drug Administration's safety, effectiveness, and other standards shall be imported under the program;

(iv) only prescription drugs expected to generate substantial savings for consumers shall be imported;

(v) the 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 feasible and practical, including prior to imported prescription drugs coming into its possession;

(vi) an approved wholesaler shall not sell or distribute prescription drugs imported under the program outside the state;

(vii) 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;

(viii) every approved wholesaler shall provide the commissioner with information on its participation in the program as reasonably required by the commissioner; the commissioner may provide for keeping certain information confidential within the department where reasonably necessary for successful operation of the program; and

(ix) 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.

(d) The commissioner shall make regulations and take other actions reasonably necessary to implement the program.

2. The commissioner shall consult with the attorney general to identify the potential for, and to monitor, anticompetitive behavior under or in relation to the program.

3. (a) The commissioner shall seek all necessary approvals and certification by the secretary of the U.S. Department of Health and Human Services or other appropriate federal officials or agencies for the wholesale prescription drug importation program.

(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 federal 340B drug pricing program to participate in the wholesale prescription drug importation program to the fullest extent possible without jeopardizing their eligibility for the 340B program.

4. The commissioner shall establish procedures for prescription drug wholesalers to apply and be approved to be an approved wholesaler, including requirements for periodic renewal of that approval. The commissioner shall provide reasonable grounds for suspending or revoking approval of an approved wholesaler under this section, including reasonable provision for notice, opportunity to be heard, and appeal.

5. The commissioner shall annually report to the assembly committees on health and on ways and means and the senate committees on health and on finance regarding the operation of the wholesale prescription drug importation program.

§ 2. This act shall take effect immediately.