

STATE OF NEW YORK

133

2021-2022 Regular Sessions

IN ASSEMBLY

(Prefiled)

January 6, 2021

Introduced by M. of A. GOTTFRIED, BARRON, CAHILL, COOK, DINOWITZ, ENGLE-BRIGHT, 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 whole-sale 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.

LBD00370-01-1

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

5 (ii) prescription drugs shall only be acquired from suppliers regu-
6 lated and authorized under the laws of the other country or a jurisdic-
7 tion thereof;

8 (iii) only prescription drugs meeting the U.S. Food and Drug Adminis-
9 tration's safety, effectiveness, and other standards shall be imported
10 under the program;

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

13 (v) the approved wholesaler shall at all times comply with the track-
14 ing and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the
15 extent feasible and practical, including prior to imported prescription
16 drugs coming into its possession;

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

19 (vii) the commissioner may impose an annual fee on approved whole-
20 salers, which may be based in whole or in part on the value of
21 prescription drugs imported by the approved wholesaler under the
22 program, to support the operation of the program;

23 (viii) every approved wholesaler shall provide the commissioner with
24 information on its participation in the program as reasonably required
25 by the commissioner; the commissioner may provide for keeping certain
26 information confidential within the department where reasonably neces-
27 sary for successful operation of the program; and

28 (ix) the commissioner shall provide for auditing of the program,
29 including making sure that prescription drugs are made available at
30 substantial savings to consumers as a result of the program.

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

33 2. The commissioner shall consult with the attorney general to identi-
34 fy the potential for, and to monitor, anticompetitive behavior under or
35 in relation to the program.

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

40 (b) The commissioner shall seek the appropriate federal approvals,
41 waivers, exemptions, or agreements, or a combination thereof, as needed
42 to enable all covered entities enrolled in or eligible for the federal
43 340B drug pricing program to participate in the wholesale prescription
44 drug importation program to the fullest extent possible without jeopard-
45 izing their eligibility for the 340B program.

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

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

56 § 2. This act shall take effect immediately.