

STATE OF NEW YORK

5682

2019-2020 Regular Sessions

IN SENATE

May 10, 2019

Introduced by Sen. SKOUFIS -- read twice and ordered printed, and when printed to be committed to the Committee on Health

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:

1 Section 1. Title 2 of article 2-A of the public health law is amended
2 by adding a new section 280-d to read as follows:

3 § 280-d. Wholesale prescription drug importation program. 1. (a)
4 There is hereby created in the department a wholesale prescription drug
5 importation program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 (b) The commissioner shall seek the appropriate federal approvals,
37 waivers, exemptions, or agreements, or a combination thereof, as needed
38 to enable all covered entities enrolled in or eligible for the federal
39 340B drug pricing program to participate in the wholesale prescription
40 drug importation program to the fullest extent possible without jeopard-
41 izing their eligibility for the 340B program.

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

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

52 § 2. This act shall take effect immediately.