

# 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.