§2046. Design of program

1. Design requirements. The Department of Health and Human Services, in consultation with appropriate federal and other state agencies, other states and interested parties, shall design the program to comply with the applicable requirements of 21 United States Code, Section 384, including requirements regarding safety and cost savings. The program design must:

A. Designate a state agency to become a licensed drug wholesaler or to contract with a licensed drug wholesaler in order to seek federal certification and approval, pursuant to subsection 3, to import safe prescription drugs and provide cost savings to consumers in the State; [PL 2021, c. 293, Pt. A, §6 (NEW).]

B. Use prescription drug suppliers in Canada regulated under the laws of Canada or of one or more Canadian provinces, or both; [PL 2021, c. 293, Pt. A, §6 (NEW).]

C. Ensure that only prescription drugs meeting the federal Food and Drug Administration's safety, effectiveness and other standards are imported by or on behalf of the State; [PL 2021, c. 293, Pt. A, §6 (NEW).]

D. Import only those prescription drugs expected to generate substantial cost savings for consumers in the State; [PL 2021, c. 293, Pt. A, §6 (NEW).]

E. Ensure that the program complies with the transaction and tracing requirements of 21 United States Code, Sections 360eee and 360eee-1 to the extent feasible and practical prior to imported prescription drugs coming into the possession of the licensed drug wholesaler and that the program complies fully with those federal requirements after imported prescription drugs are in the possession of the licensed drug wholesaler; [PL 2021, c. 293, Pt. A, §6 (NEW).]

F. Consider whether the program may be developed on a multistate basis through collaboration with other states; [PL 2021, c. 293, Pt. A, §6 (NEW).]

G. Prohibit the distribution, dispensing or sale of imported prescription drugs outside of the State; [PL 2021, c. 293, Pt. A, §6 (NEW).]

H. Recommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program; [PL 2021, c. 293, Pt. A, §6 (NEW).]

I. Apply for and receive funds, grants or contracts from public and private sources; and [PL 2021, c. 293, Pt. A, §6 (NEW).]

J. Include an audit function. [PL 2021, c. 293, Pt. A, §6 (NEW).]
[PL 2021, c. 293, Pt. A, §6 (NEW).]

2. Rules. The Department of Health and Human Services shall adopt rules to design the program in accordance with the requirements of subsection 1 no later than January 1, 2020. Rules adopted pursuant to this subsection are major substantive rules as defined in chapter 375, subchapter 2-A.
[PL 2021, c. 293, Pt. A, §6 (NEW).]

3. Request for federal approval and certification. The Department of Health and Human Services shall submit a request for approval and certification of the program to the United States Department of Health and Human Services no later than May 1, 2020.
[PL 2021, c. 293, Pt. A, §6 (NEW).]

SECTION HISTORY

PL 2021, c. 293, Pt. A, §6 (NEW).