

- 1 certification and approval to import safe prescription
2 drugs that will provide savings to consumers;
- 3 (2) The program uses Canadian suppliers who are regulated
4 under the appropriate Canadian laws;
- 5 (3) The program implements a process to sample the purity,
6 chemical composition, and potency of imported
7 prescription drugs;
- 8 (4) The program only imports prescription drugs that are
9 expected to generate substantial savings for
10 consumers;
- 11 (5) Imported prescription drugs shall not be distributed,
12 dispensed, or sold outside of the State;
- 13 (6) Pharmacies and health care providers shall not charge
14 individual consumers and health plans more than the
15 actual acquisition cost of the dispensed, imported
16 prescription drug;
- 17 (7) Health plan payments of the prescription drug
18 component of pharmacy and health care provider billing
19 are not more than the health plan's share of the
20 actual acquisition cost of the dispensed, imported
21 prescription drug;



- 1 (8) Participating health plans update their formularies
2 and claims payment systems with the prescription drugs
3 that are provided through the wholesale prescription
4 drug importation program;
- 5 (9) Participating health plans shall not base patient
6 cost-sharing upon more than the patient's share of the
7 actual acquisition cost of the dispensed, imported
8 prescription drug;
- 9 (10) Participating health plans demonstrate to the
10 satisfaction of the director of health that savings on
11 imported prescription drugs are reflected in premiums;
- 12 (11) The profit margin of any participating wholesaler or
13 distributor of imported prescription drugs is limited
14 to a specified amount, to be established by the
15 department of health;
- 16 (12) The program shall not import generic prescription
17 drugs that would violate federal patent laws for
18 federally-branded prescription drugs;
- 19 (13) The program complies with the requirements of title 21
20 United States Code sections 360eee and 360eee-1,
21 pertaining to the track and trace requirements as



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1 enacted in Title II of the Drug Quality and Security
2 Act (Public Law 113-54) to the extent practical and
3 feasible before imported prescription drugs come into
4 possession of the state wholesaler, and complies fully
5 after imported prescription drugs are in the
6 possession of the state wholesaler;

7 (14) The program is adequately financed through a fee on
8 each prescription or other appropriate approach, but
9 the size of the fee shall not jeopardize significant
10 consumer savings; and

11 (15) The program shall be audited regularly to ensure that:

12 (A) The department of health determines the most
13 cost-effective prescription drugs to include on
14 an ongoing basis in the prescription drug
15 importation program;

16 (B) The department of health selects Canadian
17 suppliers of high quality and performance that
18 are in full compliance with Canadian law and
19 regulation;

20 (C) Imported prescription drugs under the state
21 program are not shipped, sold, or dispensed



- 1 outside the State once in the possession of the
2 State;
- 3 (D) Imported prescription drugs are pure,
4 unadulterated, potent, and safe;
- 5 (E) Participating pharmacies and administering
6 providers do not charge more than the actual
7 acquisition cost to any consumer or any
8 participating health plan;
- 9 (F) Participating health plan formularies and claims
10 processing systems remain updated with all
11 relevant aspects of the prescription drug
12 importation program;
- 13 (G) Participating health plans base patient
14 coinsurance and other cost sharing upon the
15 patient's share of the actual acquisition cost of
16 covered, imported prescription drugs;
- 17 (H) Participating health plans reimburse
18 participating pharmacies and administering
19 providers the health plan's share of actual
20 acquisition cost for dispensed, imported
21 prescription drugs;



- 1 (I) The program is adequately financed to support all
- 2 administrative functions while generating
- 3 significant consumer savings;
- 4 (J) The program does not put consumers at higher risk
- 5 than if the program did not exist; and
- 6 (K) The program continues to provide consumers in the
- 7 State with substantial savings on prescription
- 8 drugs.

9 **§ -2 Monitoring for anti-competitive behavior.** The
10 department of health shall coordinate with the department of the
11 attorney general to identify the potential for anti-competitive
12 behavior in industries that would be affected by a program of
13 wholesale prescription drug importation.

14 **§ -3 Submission of request for federal certification and**
15 **approval.** The department of health shall submit a formal
16 request to the Secretary of the United States Department of
17 Health and Human Services for certification of the State's
18 wholesale prescription drug importation program.

19 **§ -4 Implementation and additional administrative**
20 **requirements.** Upon certification and approval by the Secretary
21 of the United States Department of Health and Human Services,



1 the department of health shall begin implementation of the
2 wholesale prescription drug importation program and shall begin
3 to operate the program within six months of the date of the
4 Secretary's certification. As part of the implementation
5 process, the department of health shall:

6 (1) Become licensed as a wholesaler or license an entity
7 to become a wholesaler;

8 (2) Contract with a state-licensed distributor or
9 distributors;

10 (3) Contract with a licensed or regulated Canadian
11 supplier or suppliers;

12 (4) Engage health plans, employers, pharmacies, providers,
13 and consumers;

14 (5) Develop a registration process for participating
15 health plans, pharmacies, and administering providers;

16 (6) Create a publicly available list of prices of imported
17 prescription drugs that will be available to all
18 participating entities and consumers;

19 (7) Create an outreach and marketing plan to generate
20 program awareness;



1 (8) Create and staff a hotline to respond to inquiries
2 from consumers, employers, plans, pharmacies, and
3 providers;

4 (9) Establish an audit process and a two-year audit work
5 plan cycle; and

6 (10) Conduct any other activities necessary to the
7 successful implementation, as determined by the
8 department of health.

9 **§ -5 Report to the governor and the legislature.** The
10 department of health shall provide an annual report to the
11 governor and the legislature that includes:

12 (1) The prescription drugs covered in the wholesale
13 prescription drug importation program;

14 (2) The number of participating pharmacies, providers, and
15 health plans;

16 (3) The number of prescriptions dispensed under the
17 program in the reporting period;

18 (4) The estimated savings to consumers, health plans, and
19 employers that resulted from the program in the
20 reporting period;



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Report Title:

DOH; Prescription Drugs; Importation

Description:

Directs the Department of Health to implement a program for wholesale importation of prescription drugs.

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