
A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The Hawaii Revised Statutes is amended by
2 adding a new chapter to be appropriately designated and to read
3 as follows:
4 "CHAPTER
5 WHOLESALE IMPORTATION OF PRESCRIPTION DRUGS
6 § -1 Wholesale prescription drug importation program;
7 established. The department of health shall administer in
8 consultation with relevant state stakeholders and federal
9 offices and agencies, a wholesale prescription drug importation
10 program that will meet the requirements of title 21 United
11 States Code section 384, including requirements regarding safety
12 and cost savings. In developing a wholesale prescription drug
13 importation program for federal certification, the department of
14 health shall ensure that:
15 (1) The department of health contracts with a licensed
16 wholesaler for the purpose of seeking federal



- 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 has a process in place to sample the
6 purity, chemical composition, and potency of imported
7 prescription drugs;
- 8 (4) The program only imports those prescription drugs that
9 are expected to generate substantial savings for
10 consumers;
- 11 (5) Imported prescription drugs shall not be distributed,
12 dispensed, or sold outside of the borders of the
13 State;
- 14 (6) Pharmacies and health care providers do not charge
15 individual consumers and health plans more than the
16 actual acquisition cost of the dispensed, imported
17 prescription drug;
- 18 (7) Health plan payments of the prescription drug
19 component of pharmacy and health care provider billing
20 do not reimburse more than the actual acquisition cost
21 of the dispensed, imported prescription drug;



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



1 Act (P.L. 113-54) to the extent practical and feasible
2 before imported prescription drugs come into
3 possession of the state wholesaler, and complies fully
4 after imported prescription drugs are in the
5 possession of the state wholesaler;

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

10 (15) The program includes an audit function to ensure that:

11 (A) The department of health has a sound methodology
12 by which to determine the most cost-effective
13 prescription drugs to include on an ongoing basis
14 in the prescription drug importation program;

15 (B) The department of health has processes in place
16 to select Canadian suppliers of high quality and
17 performance that are in full compliance with
18 Canadian law and regulation;

19 (C) Imported prescription drugs under the state
20 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 are not charging 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 up to date with all
11 relevant aspects of the wholesale prescription
12 drug importation program;

13 (G) Participating health plans base patient
14 coinsurance and other cost sharing upon the
15 actual acquisition cost of covered, imported
16 prescription drugs;

17 (H) Participating health plans reimburse
18 participating pharmacies and administering
19 providers the actual acquisition cost for
20 dispensed, imported 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 the wholesale
13 prescription drug importation program.

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

20 § -4 **Implementation and additional administrative**
21 **requirements.** Upon certification and approval by the Secretary



1 of the United States Department of Health and Human Services,
2 the department of health shall begin implementation of the
3 wholesale prescription drug importation program and have the
4 program operational within six months of the date of the
5 Secretary's certification. As part of the implementation
6 process, the department of health shall:

- 7 (1) Contract with a licensed wholesaler;
- 8 (2) Contract with a state-licensed distributor or
9 distributors;
- 10 (3) Contract with licensed or regulated Canadian
11 suppliers;
- 12 (4) Engage health plans, employers, pharmacies, providers,
13 and consumers;
- 14 (5) Develop a registration process in which health plans,
15 pharmacies, and administering providers are willing to
16 participate;
- 17 (6) Create a publicly available source for listing prices
18 of imported prescription drugs that will be available
19 to all participating entities and consumers;
- 20 (7) Create an outreach and marketing plan to generate
21 program awareness;



- 1 (8) Create and staff a hotline to answer questions from
2 any affected sector starting in the weeks before the
3 program becomes operational, which can address the
4 needs and questions of consumers, employers, plans,
5 pharmacies, and providers;
- 6 (9) Establish an audit function and a two-year audit work
7 plan cycle; and
- 8 (10) Conduct any other activities determined to be
9 important to successful implementation as determined
10 by the department of health.
- 11 **§ -5 Report to the governor and the legislature.** The
12 department of health shall provide an annual report to the
13 governor and the legislature that includes:
- 14 (1) The prescription drugs covered in the wholesale
15 prescription drug importation program;
- 16 (2) The number of participating pharmacies, providers, and
17 health plans;
- 18 (3) The number of prescriptions dispensed under the
19 program in the reporting period;



- 1 (4) The estimated savings to consumers, health plans, and
- 2 employers that resulted from the program in the
- 3 reporting period;
- 4 (5) During the first three reporting periods, information
- 5 on the implementation of the audit plan and audit
- 6 findings for the reporting period; and
- 7 (6) Any other information as determined by the department
- 8 of health."

9 SECTION 2. This Act shall take effect on July 1, 2050.



Report Title:

DOH; Prescription Drugs; Wholesale Importation

Description:

Authorizes the Department of Health to implement a program for wholesale importation of prescription drugs. Requires the Department to contract with a licensed wholesaler to seek federal certification and approval for the program. Effective 7/1/2050. (HD2)

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