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# A BILL FOR AN ACT

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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 either becomes a licensed  
16               wholesaler or licenses an entity to become a  
17               wholesaler for the purpose of seeking federal



# H.B. NO. 14

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



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



# H.B. NO. 14

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;



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

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

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

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

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

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

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

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





- 1 (5) Audit findings for the reporting period including,  
2 during the first three reporting periods, information  
3 on the implementation of the audit plan; and  
4 (6) Any other information as determined by the department  
5 of health."

6 SECTION 2. This Act shall take effect upon approval.  
7

INTRODUCED BY:



JAN 20 2021



# H.B. NO. 14

**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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