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## A BILL FOR AN ACT

RELATING TO REMOTE DISPENSING.

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

1           SECTION 1. The purpose of this Act is to amend the law  
2 governing pharmacists and pharmacies to permit the operation of  
3 remote dispensing pharmacies. It is not intended to exclude the  
4 use of remote dispensing technology as practitioner dispensing.

5           SECTION 2. Chapter 461, Hawaii Revised Statutes, is  
6 amended by adding five new sections to be appropriately  
7 designated and to read as follows:

8           "§461-A Remote dispensing machine. Drugs dispensed to  
9 patients from a remote dispensing machine shall be dispensed as  
10 packaged.

11           The remote dispensing machine shall include the following  
12 safety features:

- 13           (1) Secure double-locked cabinets;  
14           (2) Bar-coding or similar technology to identify the  
15           product in each unit of use container;  
16           (3) Delivery of only one bar-coded unit of use container  
17           per dispensation per prescription;



1        (4) Technology allowing the unit of use container bar code  
 2            to be scanned upon release of the container from the  
 3            remote dispensing machine to confirm that it is the  
 4            correct container, and upon such confirmation,  
 5            producing a patient-specific label with a barcode that  
 6            is scanned to confirm that it is the correct label for  
 7            the prescription; and

8        (5) A telecommunications and live audio and video  
 9            component allowing the patient to have a face-to-face  
 10           consultation with a pharmacist of the responsible  
 11           pharmacy at the time the drug is dispensed.

12        **§461-B Remote dispensing pharmacy.** Each remote dispensing  
 13        pharmacy shall serve only one responsible pharmacy. The  
 14        responsible pharmacy may operate more than one remote dispensing  
 15        pharmacy. The following must be conspicuously displayed on the  
 16        premises of the remote dispensing pharmacy:

- 17        (1) A copy of the license of the responsible pharmacy; and
- 18        (2) A copy of the license of the pharmacist-in-charge of
- 19        the responsible pharmacy.

20        **§461-C Responsible pharmacy.** A responsible pharmacy shall  
 21        be:

- 22        (1) Physically located in this state;



- 1        (2) Be granted a permit by the board; and
- 2        (3) Maintain the following records and documentation with
- 3            respect to the remote dispensing pharmacy:
- 4            (A) Prescriptions dispensed at the remote dispensing
- 5                pharmacy;
- 6            (B) Movement of inventory at the remote dispensing
- 7                pharmacy; and
- 8            (C) Policies and procedures of the remote dispensing
- 9                pharmacy.

10        **§461-D Remote dispensing pharmacy; operations.**    (a) A  
11        remote dispensing pharmacy shall be connected via live computer  
12        link, video link, and audio link to the responsible pharmacy.

13        (b) The operations of a remote dispensing pharmacy shall  
14        be supervised by the pharmacist-in-charge of the responsible  
15        pharmacy, who shall ensure that the remote dispensing pharmacy  
16        is in compliance with all laws, including rules, governing the  
17        practice of pharmacy.

18        (c) A remote dispensing pharmacy shall be staffed by at  
19        least one remote dispensing technician.

20        (d) A remote dispensing pharmacy shall be secured at all  
21        times to prevent unauthorized access.



1       (e) A pharmacist of the responsible pharmacy shall  
2 maintain visual oversight and continuous surveillance of the  
3 remote dispensing pharmacy when the remote dispensing pharmacy  
4 is in operation.

5       (f) A remote dispensing pharmacy shall maintain an area  
6 appropriate for confidential communications between the patient  
7 and a pharmacist of the responsible pharmacy.

8       (g) A pharmacist of the responsible pharmacy shall  
9 maintain visual oversight of the final dispensing of a drug to  
10 the patient from a remote dispensing machine.

11       (h) Drugs shall not be dispensed by the remote dispensing  
12 pharmacy when the responsible pharmacy is closed.

13       (i) A remote dispensing pharmacy shall use the information  
14 technology system of the responsible pharmacy.

15       (j) Each unit of use container dispensed by a remote  
16 dispensing machine shall have a label affixed to the container  
17 that meets the requirements set forth in section 328-16 and  
18 includes the address of the remote dispensing pharmacy.

19       Labels shall be generated at the remote dispensing  
20 pharmacy.

21       (k) Prescription records filled at the remote dispensing  
22 pharmacy shall be maintained at the responsible pharmacy and



1 shall be distinguishable from the prescription records filled at  
2 the responsible pharmacy.

3 (l) A pharmacist of the responsible pharmacy shall approve  
4 each prescription before it is dispensed to a patient at the  
5 remote dispensing pharmacy.

6 (m) The remote dispensing technician shall offer the  
7 patient counseling by a pharmacist for each prescription to be  
8 filled at a remote dispensing pharmacy.

9 (n) Controlled substances shall not be dispensed from  
10 remote dispensing machines.

11 **§461-E Responsible pharmacy; duties, responsibilities, and**  
12 **requirements.** (a) The responsible pharmacy shall:

13 (1) Develop written policies and procedures prior to using  
14 a remote dispensing machine that ensure the following:

15 (A) The safe and effective dispensing of  
16 pharmaceutical products to the correct patient,  
17 including ensuring that a prescription drug shall  
18 not be dispensed at the remote dispensing  
19 pharmacy until a pharmacist of the responsible  
20 pharmacy has verified the finished prescription  
21 drug using the live computer, video, or audio  
22 link;



- 1           (B) Patient confidentiality;
- 2           (C) That only one prescription shall be dispensed  
3           from and labeled by the remote dispensing machine  
4           before another prescription is released from the  
5           remote dispensing machine;
- 6           (D) The physical presence of the patient when the  
7           drug is dispensed from the remote dispensing  
8           machine;
- 9           (E) The safety, accuracy, and security of the remote  
10           dispensing machine and remote dispensing  
11           pharmacy;
- 12           (F) Defined access to the remote dispensing machine  
13           and to medications contained within or associated  
14           with the remote dispensing machine, including but  
15           not limited to policies that assign, discontinue,  
16           or change access to the remote dispensing machine  
17           and medications; provided that a pharmacist of  
18           the responsible pharmacy shall have secured  
19           access to the drugs in the remote dispensing  
20           machine;
- 21           (G) Compliance with all state and federal laws and  
22           regulations;





1           (A) In a manner that ensures the competence and  
2           ability of all personnel who operate any  
3           component of the remote dispensing pharmacy and  
4           the remote dispensing machine; and

5           (B) With documentation of such training to be  
6           retained by the responsible pharmacy;

7           (3) Ensure that the remote dispensing machine is stocked  
8           accurately and in accordance with the established  
9           written policies and procedures, including ensuring  
10           that a pharmacist of the responsible pharmacy checks  
11           the accuracy of the product supplied for stocking the  
12           remote dispensing machine;

13           and

14           (4) Ensure that entry to the remote dispensing pharmacy is  
15           limited to authorized personnel.

16           (b) The pharmacist-in-charge of the responsible pharmacy  
17           shall be responsible for ensuring the meeting of the  
18           requirements in subsection (a)."

19           SECTION 3. Chapter 461-1 is amended by adding the following  
20           definitions to be appropriately inserted and to read as follows:

21           "Remote dispensing" means the dispensing of drugs by a  
22           responsible pharmacy at a location other than that of the



1 responsible pharmacy through the use of a remote dispensing  
2 machine.

3 "Remote dispensing machine" means a machine that contains  
4 unit of use drugs for dispensing that is operated using  
5 information technologies and connected to the responsible  
6 pharmacy by telecommunications and live audio and video  
7 technology.

8 "Remote dispensing pharmacy" means the area in an  
9 institutional health care facility located in this state that is  
10 used exclusively for the storage and dispensing of pharmacy-  
11 dispensed prescription drugs through the use of one or more  
12 remote dispensing machines.

13 "Remote dispensing technician" means an individual who  
14 assists the pharmacist in operating a remote dispensing pharmacy  
15 by providing services that include technical assistance in the  
16 preparation of pharmaceuticals for remote dispensing while under  
17 the supervision of a pharmacist.

18 "Responsible pharmacy" means the pharmacy that operates the  
19 remote dispensing pharmacy.

20 "Unit of use" means drugs packed in a container in  
21 separate, one-dose units."



1 SECTION 4. Section 461-9, Hawaii Revised Statutes, is  
2 amended to read as follows:

3 **"§461-9 Pharmacist in charge; pharmacy personnel.** (a) A  
4 registered pharmacist shall be in personal and immediate charge  
5 of the pharmacy and personnel employed in the pharmacy.  
6 Temporary absences of the registered pharmacist shall be  
7 unlawful except for periods of time and under circumstances as  
8 authorized under the rules of the board. During any absence of  
9 the registered pharmacist, prescriptions may not be filled,  
10 compounded, or received by telephone and no drugs shall be sold;  
11 provided that this shall not preclude the sale at those times of  
12 things that might be sold were the pharmacy a store not subject  
13 to this chapter. No person other than a registered pharmacist  
14 or a pharmacy intern under the registered pharmacist's immediate  
15 supervision shall fill or compound prescriptions except as  
16 provided by subsection (c).

17 (b) No person shall practice as a pharmacy intern without  
18 having first obtained a permit from the board. The board shall  
19 adopt rules pursuant to chapter 91 defining the functions of a  
20 pharmacy intern, establishing the requirements to be met by an  
21 applicant for a pharmacy intern permit, and specifying the



1 duration of the permit and the procedures for the immediate  
2 supervision of the pharmacy intern by a registered pharmacist.

3 (c) A pharmacy technician may be employed to assist the  
4 registered pharmacist under rules adopted by the board pursuant  
5 to chapter 91 that define the qualifications and functions of  
6 the pharmacy technician and provide the procedures for control  
7 and supervision by a registered pharmacist.

8 (d) A pharmacist of the responsible pharmacy shall  
9 supervise at all times any remote dispensing technicians at the  
10 remote dispensing pharmacy."

11 SECTION 5. Section 461-14, Hawaii Revised Statutes, is  
12 amended to read as follows:

13 "**§461-14 Permits for operation of pharmacy**~~[.]~~**;**  
14 **notification of remote dispensing pharmacy.** (a) It shall be  
15 unlawful for any person to operate, maintain, open, change  
16 location, or establish any pharmacy or remote dispensing  
17 pharmacy within the [~~State~~] state without [~~first~~] having first  
18 obtained a permit or prior notification from the board.

19 (b) Application for permits and notifications shall be  
20 made on a form to be prescribed by the board. Separate  
21 [~~application~~] applications shall be made and separate permits  
22 and notifications issued for each separate place at which is



1 carried on any of the operations for which a permit or  
2 notification is required.

3 (c) On evidence satisfactory to the board, a permit or  
4 notification shall be issued~~[, provided:]~~; provided that:

5 (1) ~~[That the]~~ The pharmacy for which the permit or  
6 notification is sought is or will be~~[,]~~ in full  
7 compliance with this chapter and rules of the board;

8 (2) ~~[That the]~~ The location and appointments of the  
9 pharmacy are such that it can be operated and  
10 maintained without endangering the public health or  
11 safety; and

12 (3) ~~[That the]~~ The pharmacy will be under the personal and  
13 immediate supervision of a registered pharmacist.

14 (d) ~~[No application]~~ An application for a permit shall be  
15 refused ~~[except pursuant to]~~ for noncompliance with this section  
16 ~~[and]~~ but only after notice to the applicant and a full and fair  
17 hearing.

18 (e) To operate a remote dispensing pharmacy, a responsible  
19 pharmacy shall submit to the board the following information:

20 (1) A form prescribed by the board;

21 (2) The name, address, and permit number of the  
22 responsible pharmacy;



- 1       (3) The name and license number of the pharmacist-in-  
2       charge of the responsible pharmacy;
- 3       (4) The name of the institutional health care facility and  
4       the address of the remote dispensing pharmacy;
- 5       (5) A floor plan of the remote dispensing pharmacy, which  
6       shall indicate the space or location of the remote  
7       dispensing machine;
- 8       (6) The date the remote dispensing pharmacy will be ready  
9       for operations;
- 10      (7) A description of the security system;
- 11      (8) A description of the computer link, video link, and  
12      audio link; and
- 13      (9) Photographs of the remote dispensing pharmacy area,  
14      including but not limited to the remote dispensing  
15      machine, the security system, computer link, video  
16      link, audio link, confidential-communications area,  
17      and locked cabinet.

18       A remote dispensing pharmacy's failure to notify the board  
19      in writing within thirty days of any changes to the information  
20      described in paragraphs (1) to (9) or failure to comply with  
21      this chapter shall be considered a violation of this chapter and



1 shall result in disciplinary action against the pharmacist-in-  
2 charge and the responsible pharmacy.

3 (f) Permits and licenses issued under sections 461-14 and  
4 461-15 may be closed upon written request from the holder of the  
5 permit or license. The board shall approve all requests by the  
6 holder for closure of a permit of license. Once the closure is  
7 approved, the holder of the closed permit or license shall be  
8 required to reapply as a new applicant to conduct business where  
9 a permit or license is required."

10 SECTION 6. Section 461-16, Hawaii Revised Statutes, is  
11 amended to read as follows:

12 "**§461-16 Fees for permits and licenses; renewal.** (a) The  
13 board shall collect application, license, and permit fees for  
14 each permit to operate a pharmacy or for each license to operate  
15 as a wholesale prescription drug distributor and a fee for the  
16 issuance of a permit in accordance with section 461-15(a)(1),  
17 (5), (6), and (7).

18 (b) Permits issued under sections 461-14 and 461-15 and  
19 licenses issued under section 461-8.6 shall be conspicuously  
20 displayed in the place for which the permit or license was  
21 granted. The permits and licenses shall not be transferable,



1 shall expire on December 31 of each odd-numbered year following  
2 the date of issuance, and shall be renewed biennially.

3 (c) The holder of an expired permit or an expired license  
4 to operate as a wholesale prescription drug distributor may have  
5 the same restored within three years of the date of expiration  
6 upon due application therefor and payment of the delinquent fees  
7 and a penalty fee; provided that in the case of an expired  
8 permit, the holder of the expired permit meets the requirements  
9 for the renewal of permits.

10 (d) Permits and licenses issued under sections 461-14 and  
11 461-15 may be closed upon written request from the holder of the  
12 permit or license. The board shall approve all requests by the  
13 holder for closure of a permit of license. Once the closure is  
14 approved, the holder of the closed permit or license shall be  
15 required to reapply as a new applicant to conduct business where  
16 a permit or license is required."

17 SECTION 7. In codifying the new sections added by section  
18 2 of this Act, the revisor of statutes shall substitute  
19 appropriate section numbers for the letters used in designating  
20 the new sections in this Act.

21 SECTION 8. Statutory material to be repealed is bracketed  
22 and stricken. New statutory material is underscored.



# H.B. NO. 370

1 SECTION 9. This act shall take effect upon approval.

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INTRODUCED BY:

Marilyn B. Lee

*MW*

*Paul N. ...*

*Paul N. ...*

*[Signature]*

JAN 18 2007



**Report Title:**

Remote dispensing pharmacies

**Description:**

Provides for the establishment of remote dispensing pharmacies.

