

JAN 19 2007

A BILL FOR AN ACT

RELATING TO REMOTE DISPENSING PHARMACIES.

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

1 SECTION 1. The legislature finds that many individuals
2 living in underserved or remote areas need improved access to
3 medications and pharmacy services. A remote dispensing program
4 that allows for the dispensing of low-cost medications through
5 the use of a secure remote dispensing machine and patient
6 counseling via a two-way interactive videoconferencing system
7 will help to resolve the dual problem of access to prescription
8 drugs and pharmacists for low-income populations and remote
9 areas.

10 The purpose of this Act is to permit the operation of
11 remote dispensing pharmacies.

12 SECTION 2. Section 461-1, Hawaii Revised Statutes, is
13 amended by adding five new definitions to be appropriately
14 inserted and to read as follows:

15 "Remote dispensing" means the practice of dispensing drugs
16 through the use of trained personnel, telecommunications, and



1 information technologies to patients at a remote dispensing
2 pharmacy.

3 "Remote dispensing machine" means a device used for
4 dispensing unit-of-use drugs that is operated using information
5 technologies and is located in a remote dispensing pharmacy.

6 Drugs dispensed from the remote dispensing machine shall be
7 dispensed as packaged, with no changes to the drug, its
8 strength, or its unit quantity, except for the addition of water
9 for reconstitution of dry powder drugs. The remote dispensing
10 machine shall have the following features to ensure that it is
11 appropriately secure at all times and that all transactions are
12 properly documented:

- 13 (1) Secure double-locked cabinets;
- 14 (2) Bar-coding or similar technology that effectively
15 recognizes the product;
- 16 (3) A cabinet that delivers only one bar-coded unit-of-use
17 container per dispense, per prescription;
- 18 (4) A scanner and printer that, upon releasing the unit-
19 of-use container from the remote dispensing machine,
20 the container is scanned to confirm that it is in fact
21 the correct container, and with such confirmation, the



1 printer will print a patient-specific label that also
2 has a barcode that is scanned to confirm that it is
3 the correct label for the prescription; and

4 (5) A video component that allows the patient to have a
5 "face-to-face" consultation with the pharmacist at the
6 responsible pharmacy.

7 "Remote dispensing pharmacy" means the area in an
8 institutional facility located in this State that is used
9 exclusively for the storage and dispensing of pharmacy-dispensed
10 prescription drugs through the use of a remote dispensing
11 machine. Each remote dispensing machine shall operate with only
12 one responsible pharmacy. The responsible pharmacy may operate
13 with more than one remote dispensing machine. The following
14 must be conspicuously displayed at the remote dispensing
15 machine:

- 16 (1) Copy of the license of the responsible pharmacy; and
17 (2) Copy of the license of the pharmacist-in-charge of the
18 responsible pharmacy.

19 "Remote dispensing technician" means an individual who
20 assists the pharmacist in various activities specific to the
21 remote dispensing pharmacy, including the technical services of

1 preparing pharmaceuticals for final dispensing while under
2 supervision of a pharmacist.

3 "Responsible pharmacy" means a pharmacy that operates a
4 remote dispensing pharmacy located in this State and holds a
5 valid permit issued by the board pursuant to section 461-14.

6 All responsible pharmacies shall maintain, on-site at the remote
7 dispensing pharmacy and have available for inspection at all
8 times, records and documentation of the following:

- 9 (1) All prescriptions dispensed at the remote dispensing
10 pharmacy;
11 (2) All inventory movement at the remote dispensing
12 pharmacy; and
13 (3) A policies and procedures manual of the remote
14 dispensing pharmacy."

15 SECTION 3. Chapter 461, Hawaii Revised Statutes, is amended
16 by adding a new section to be appropriately designated and to
17 read as follows:

18 "§461- Remote dispensing pharmacy; operations. (a) The
19 remote dispensing pharmacy shall be connected via live computer
20 link, video link, and audio link to the responsible pharmacy.



1 (b) The remote dispensing pharmacy shall be under the
2 direct supervision of the registered pharmacist in charge of the
3 responsible pharmacy. The pharmacist in charge shall ensure
4 that the remote dispensing pharmacy is in compliance with all
5 laws and rules governing the practice of pharmacy. The
6 pharmacist in charge shall ensure that the remote dispensing
7 pharmacy is appropriately staffed by a qualified remote
8 dispensing technician.

9 (c) The remote dispensing pharmacy shall be effectively
10 secured to prevent unauthorized access at all times. There
11 shall be visual oversight and continuous surveillance of the
12 remote dispensing pharmacy by a pharmacist in the responsible
13 pharmacy while the remote dispensing pharmacy is in operation.

14 (d) The remote dispensing pharmacy shall have a
15 confidential area available for communication between the
16 patient and the pharmacist at the responsible pharmacy.

17 (e) There shall be visual oversight of the final
18 dispensing activity from the remote dispensing machine and
19 remote dispensing pharmacy to the patient.



1 (f) Drugs shall not be dispensed from the remote
2 dispensing machine and the remote dispensing pharmacy when the
3 responsible pharmacy is closed.

4 (g) The remote dispensing pharmacy shall use the
5 information technology system of the responsible pharmacy.

6 (h) Prescription labels for the product from the remote
7 dispensing machine must be generated at the remote dispensing
8 pharmacy.

9 (i) All prescriptions distributed at the remote dispensing
10 pharmacy must have a label that meets the requirements set forth
11 in section 328-16 affixed to the final drug container. The
12 label shall list the address of the remote dispensing pharmacy.

13 (j) Prescription records filled at the remote dispensing
14 pharmacy shall be maintained at the responsible pharmacy and
15 shall be distinguishable from those records filled at the
16 responsible pharmacy.

17 (k) A pharmacist at the responsible pharmacy shall approve
18 each prescription before it is dispensed to the patient.



1 (1) An offer to counsel the patient by a pharmacist shall
2 be made by the remote dispensing technician for all
3 prescriptions.

4 (m) Controlled substances shall not be dispensed from any
5 remote dispensing machine or remote dispensing pharmacy.

6 (n) The pharmacist in charge of the remote dispensing
7 machine shall ensure that:

8 (1) Written policies and procedures are developed, prior
9 to utilizing the machine, that ensures the safe and
10 effective dispensing of pharmaceutical products;

11 (2) No prescription drug is dispensed at the remote
12 dispensing pharmacy until a pharmacist at the
13 responsible pharmacy has verified the finished
14 prescription drug using the live computer link, video
15 link, and audio link;

16 (3) Only one prescription is dispensed and labeled from
17 the remote dispensing machine at a time;

18 (4) The patient is present when the drug is dispensed from
19 the remote dispensing machine;



- 1 (5) The remote dispensing machine and the remote
2 dispensing pharmacy are operating safely, accurately,
3 and securely;
- 4 (6) Access to the remote dispensing machine and to
5 medications contained within or associated with the
6 machine, including policies that assign, discontinue,
7 or change access to the remote dispensing machine and
8 medications, is defined;
- 9 (7) A pharmacist licensed in this State, employed by the
10 responsible pharmacy, has secured access to the drugs
11 in the remote dispensing machine;
- 12 (8) Access to the medications complies with state and
13 federal laws, rules, and regulations;
- 14 (9) If a patient refuses the prescription drug at the time
15 it is dispensed, the prescription drug is locked in a
16 secured cabinet and accessible only by a pharmacist of
17 the responsible pharmacy;
- 18 (10) There is proper inventory control at the remote
19 dispensing pharmacy and only a registered pharmacist
20 of the responsible pharmacy shall stock the remote
21 dispensing machine;



- 1 (11) A reconciliation of the physical inventory of the
2 remote dispensing pharmacy is conducted at least
3 annually;
- 4 (12) All personnel who operate the remote dispensing
5 machine at the remote dispensing pharmacy are properly
6 trained. Training shall ensure the competence and
7 ability of all personnel who operate any component of
8 the remote dispensing machine and the remote
9 dispensing pharmacy. Documentation of training shall
10 be kept by the responsible pharmacy;
- 11 (13) The remote dispensing machine is stocked accurately
12 and in accordance with established written policies
13 and procedures. The pharmacist shall check the
14 accuracy of the product supplied for stocking the
15 remote dispensing machine; and
- 16 (14) Entry to the remote dispensing pharmacy is limited to
17 authorized personnel only.
- 18 (o) The pharmacist of the responsible pharmacy is
19 responsible for the integrity of the drugs in the remote
20 dispensing machine and that drugs for machine are provided to
21 the remote dispensing pharmacy only from the responsible
22 pharmacy."



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 or remote dispensing technician
4 may be employed to assist the registered pharmacist under rules
5 adopted by the board pursuant to chapter 91 that define the
6 qualifications and functions of the pharmacy technician or the
7 remote dispensing technician and provide the procedures for
8 control and supervision by a registered pharmacist.

9 (d) A remote dispensing technician shall be directly
10 responsible to the responsible pharmacy and shall be under
11 continuous supervision at the remote dispensing pharmacy by a
12 registered pharmacist at the responsible pharmacy."

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

15 "§461-14 Permits for operation of pharmacy[+];
16 notifications for operation of remote dispensing pharmacy. (a)

17 It shall be unlawful for any person to operate, maintain, open,
18 change location, or establish any pharmacy or remote dispensing
19 pharmacy within the State without first having obtained a permit
20 or prior notification from the board.

21 (b) [~~Application~~] Applications for permits and
22 notifications shall be made on a form to be prescribed by the



1 board. Separate [~~application~~] applications shall be made and
2 separate permits and notifications shall be issued for each
3 separate [~~place at which is carried on any of the~~] location
4 where operations [~~for which~~] require a permit [~~is required~~]
5 pursuant to this section.

6 (c) On evidence satisfactory to the board, a permit or
7 notification shall be issued, provided:

8 (1) That the pharmacy for which the permit or notification
9 is sought is or will be, in full compliance with this
10 chapter and rules of the board;

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

14 (3) That the pharmacy will be under the personal and
15 immediate supervision of a registered pharmacist.

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

20 (e) To operate a remote dispensing pharmacy, the following
21 information shall be submitted to the board:

22 (1) A form prescribed by the board;



- 1 (2) The name, address, and permit number of the
- 2 responsible pharmacy;
- 3 (3) The name and license number of the pharmacist in
- 4 charge;
- 5 (4) The name and address of the institutional facility
- 6 where the remote dispensing pharmacy is located;
- 7 (5) The floor plan of the remote dispensing pharmacy,
- 8 including a diagram of the space or location of the
- 9 remote dispensing machine;
- 10 (6) The date the remote dispensing pharmacy will be ready
- 11 for operation;
- 12 (7) A description of the security system;
- 13 (8) A description of the computer, video, and audio link;
- 14 and
- 15 (9) Photographs of the remote dispensing pharmacy area,
- 16 including the remote dispensing machine, the security
- 17 system, computer, counseling area, and locked cabinet.
- 18 Failure to comply with this section shall be considered a
- 19 violation of this chapter and shall result in disciplinary
- 20 action against the pharmacist in charge and the responsible
- 21 pharmacy.



1 (f) Permits, notifications, and licenses issued under this
2 section and section 461-15 may be closed upon written request
3 from the permit holder or licensee. The board shall approve all
4 requests for closure of a permit or license. Once approved, the
5 holder of the closed permit or license shall re-apply as a new
6 applicant in order to conduct business where a permit or license
7 is required."

8 SECTION 6. Section 461-16, Hawaii Revised Statutes, is
9 amended by amending the title and subsections (a) and (b) to
10 read as follows:

11 **"§461-16 Fees for permits, notifications, and licenses;**
12 **renewal. (a) The board shall collect application, license,**
13 **notification, and permit fees for each permit to operate a**
14 **pharmacy or for each license to operate as a wholesale**
15 **prescription drug distributor and a fee for the issuance of a**
16 **permit in accordance with section 461-15(a)(1), (5), (6) and**
17 **(7).**

18 (b) Permits and notifications issued under sections 461-14
19 and 461-15 and licenses issued under section 461-8.6 shall be
20 conspicuously displayed in the place for which the permit or
21 license was granted. The permits and licenses shall not be
22 transferable, shall expire on December 31 of each odd-numbered



1 year following the date of issuance, and shall be renewed
2 biennially."

3 SECTION 7. There is appropriated out of the general
4 revenues of the State of Hawaii the sum of \$, or so
5 much thereof as may be necessary for fiscal year 2007-2008, and
6 the same sum as may be necessary for fiscal year 2008-2009, to
7 carry out the purposes of this Act.

8 The sums appropriated shall be expended by the department
9 of health for the purposes of this Act.

10 SECTION 8. Statutory material to be repealed is bracketed
11 and stricken. New statutory material is underscored.

12 SECTION 9. This Act shall take effect upon approval.

13

INTRODUCED BY: Shiranne Chun Oakland



Report Title:

Remote Dispensing Pharmacy; Medication

Description:

Permits the operation of remote dispensing pharmacies.

