

JAN 18 2008

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.

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

7 "§461- Remote dispensing machine. Drugs dispensed to
8 patients from a remote dispensing machine shall be dispensed as
9 packaged.

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

- 12 (1) Secure double-locked cabinets;
13 (2) Bar-coding or similar technology to identify the
14 product in each unit of use container;
15 (3) Delivery of only one bar-coded unit of use container
16 per dispensation per prescription;
17 (4) Technology allowing the unit of use container bar code
18 to be scanned upon release of the container from the



1 remote dispensing machine to confirm that it is the
2 correct container, and upon such confirmation,
3 producing a patient-specific label with a bar code
4 that is scanned to confirm that it is the correct
5 label for the prescription; and

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

10 §461- Remote dispensing pharmacy. Each remote
11 dispensing pharmacy shall serve only one responsible pharmacy.
12 The responsible pharmacy may operate more than one remote
13 dispensing pharmacy. The following shall be conspicuously
14 displayed on the premises of the remote dispensing pharmacy:

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

18 §461- Responsible pharmacy. A responsible pharmacy
19 shall be:

- 20 (1) Physically located in this state;
21 (2) Granted a permit by the board; and



1 (3) Maintain the following records and documentation with
2 respect to the remote dispensing pharmacy:

3 (A) Prescriptions dispensed at the remote dispensing
4 pharmacy;

5 (B) Movement of inventory at the remote dispensing
6 pharmacy; and

7 (C) Policies and procedures of the remote dispensing
8 pharmacy.

9 §461- Remote dispensing pharmacy; operations. (a) A
10 remote dispensing pharmacy shall be secured at all times to
11 prevent unauthorized access.

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

14 (c) Controlled substances shall not be dispensed from
15 remote dispensing machines.

16 (d) A remote dispensing pharmacy shall be connected via
17 live computer link, video link, and audio link to the
18 responsible pharmacy, and shall use the information technology
19 system of the responsible pharmacy.

20 (e) The pharmacist-in-charge of the responsible pharmacy
21 shall supervise the operations of the remote dispensing pharmacy
22 and ensure that the remote dispensing pharmacy is in compliance



1 with all laws, including rules, governing the practice of
2 pharmacy.

3 (f) A pharmacist of the responsible pharmacy shall:

4 (1) Maintain visual oversight and continuous surveillance
5 of the remote dispensing pharmacy when the remote
6 dispensing pharmacy is in operation;

7 (2) Approve each prescription before it is dispensed to a
8 patient at the remote dispensing pharmacy; and

9 (3) Maintain visual oversight of the final dispensing of a
10 drug to the patient from a remote dispensing machine.

11 (g) At least one remote dispensing technician shall staff
12 the remote dispensing pharmacy. The remote dispensing
13 technician shall offer the patient counseling by a pharmacist
14 for each prescription to be filled at the remote dispensing
15 pharmacy. The remote dispensing pharmacy shall maintain an area
16 appropriate for confidential communications between the patient
17 and a pharmacist of the responsible pharmacy.

18 (h) Each unit of use container dispensed by a remote
19 dispensing machine shall have a label affixed to the container
20 that meets the requirements set forth in section 328-16 and
21 includes the address of the remote dispensing pharmacy. Labels
22 shall be generated at the remote dispensing pharmacy.



1 (i) Records of prescriptions filled at the remote
2 dispensing pharmacy shall be maintained at the responsible
3 pharmacy and shall be distinguishable from the records of
4 prescriptions filled at the responsible pharmacy.

5 §461- Responsible pharmacy; duties, responsibilities,
6 and requirements. (a) The responsible pharmacy shall:

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

9 (A) The safe and effective dispensing of
10 pharmaceutical products to the correct patient,
11 including ensuring that a prescription drug shall
12 not be dispensed at the remote dispensing
13 pharmacy until a pharmacist of the responsible
14 pharmacy has verified the finished prescription
15 drug using the live computer, video, or audio
16 link;

17 (B) Patient confidentiality;

18 (C) That only one prescription shall be dispensed
19 from and labeled by the remote dispensing machine
20 before another prescription is released from the
21 remote dispensing machine;



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



1 (I) Proper inventory control at the remote dispensing
2 pharmacy, including the following:

3 (i) Only a pharmacist of the responsible
4 pharmacy shall stock the remote dispensing
5 machine;

6 (ii) A pharmacist of the responsible pharmacy is
7 responsible for maintaining the integrity of
8 the drugs in the remote dispensing machine;

9 (iii) Drugs for the remote dispensing machine are
10 provided to the remote dispensing pharmacy
11 only from the responsible pharmacy; and

12 (iv) A reconciliation of the physical inventory
13 of the remote dispensing pharmacy shall be
14 conducted at least annually;

15 (2) Train all personnel who operate the remote dispensing
16 machine at the remote dispensing pharmacy:

17 (A) In a manner that ensures the competence and
18 ability of all personnel who operate any
19 component of the remote dispensing pharmacy and
20 the remote dispensing machine; and

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



1 (3) Ensure that the remote dispensing machine is stocked
2 accurately and in accordance with the established
3 written policies and procedures, including ensuring
4 that a pharmacist of the responsible pharmacy checks
5 the accuracy of the product supplied for stocking the
6 remote dispensing machine; and

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

9 (b) The pharmacist-in-charge of the responsible pharmacy
10 shall be responsible for ensuring the meeting of the
11 requirements in subsection (a)."

12 SECTION 3. Section 461-1 is amended by adding six new
13 definitions to be appropriately inserted and to read as follows:

14 "Remote dispensing" means the dispensing of drugs by a
15 responsible pharmacy at a location other than that of the
16 responsible pharmacy through the use of a remote dispensing
17 machine.

18 "Remote dispensing machine" means a machine that contains
19 unit of use drugs for dispensing that is operated using
20 information technologies and connected to the responsible
21 pharmacy by telecommunications and live audio and video
22 technology.



1 "Remote dispensing pharmacy" means the area in an
2 institutional health care facility located in this state that is
3 used exclusively for the storage and dispensing of pharmacy-
4 dispensed prescription drugs through the use of one or more
5 remote dispensing machines.

6 "Remote dispensing technician" means an individual who
7 assists the pharmacist in operating a remote dispensing pharmacy
8 by providing services that include technical assistance in the
9 preparation of pharmaceuticals for remote dispensing while under
10 the supervision of a pharmacist.

11 "Responsible pharmacy" means the pharmacy that operates the
12 remote dispensing pharmacy.

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

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

17 "§461-9 Pharmacist in charge; pharmacy personnel. (a) A
18 registered pharmacist shall be in personal and immediate charge
19 of the pharmacy and personnel employed in the pharmacy.
20 Temporary absences of the registered pharmacist shall be
21 unlawful except for periods of time and under circumstances as
22 authorized under the rules of the board. During any absence of



1 the registered pharmacist, prescriptions may not be filled,
2 compounded, or received by telephone and no drugs shall be sold;
3 provided that this shall not preclude the sale at those times of
4 things that might be sold were the pharmacy a store not subject
5 to this chapter. No person other than a registered pharmacist
6 or a pharmacy intern under the registered pharmacist's immediate
7 supervision shall fill or compound prescriptions except as
8 provided by subsection (c).

9 (b) No person shall practice as a pharmacy intern without
10 having first obtained a permit from the board. The board shall
11 adopt rules pursuant to chapter 91 defining the functions of a
12 pharmacy intern, establishing the requirements to be met by an
13 applicant for a pharmacy intern permit, and specifying the
14 duration of the permit and the procedures for the immediate
15 supervision of the pharmacy intern by a registered pharmacist.

16 (c) A pharmacy technician may be employed to assist the
17 registered pharmacist under rules adopted by the board pursuant
18 to chapter 91 that define the qualifications and functions of
19 the pharmacy technician and provide the procedures for control
20 and supervision by a registered pharmacist.



1 (d) A pharmacist of the responsible pharmacy shall
2 supervise at all times any remote dispensing technicians at the
3 remote dispensing pharmacy."

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

6 "§461-14 Permits for operation of pharmacy~~[]~~;
7 notification of remote dispensing pharmacy. (a) It shall be
8 unlawful for any person to operate, maintain, open, change
9 location, or establish any pharmacy or remote dispensing
10 pharmacy within the [~~State~~] state without [~~first~~] having first
11 obtained a permit or prior notification from the board.

12 (b) Application for permits and notifications shall be
13 made on a form to be prescribed by the board. Separate
14 [~~application~~] applications shall be made and separate permits
15 and notifications issued for each separate place at which is
16 carried on any of the operations for which a permit or
17 notification is required.

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

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



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

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

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

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

13 (1) A completed form prescribed by the board;

14 (2) The name, address, and permit number of the
15 responsible pharmacy;

16 (3) The name and license number of the pharmacist-in-
17 charge of the responsible pharmacy;

18 (4) The name of the institutional health care facility and
19 the address of the remote dispensing pharmacy;

20 (5) A floor plan of the remote dispensing pharmacy, which
21 shall indicate the space or location of the remote
22 dispensing machine;



1 (6) The date the remote dispensing pharmacy will be ready
2 for operations;

3 (7) A description of the security system;

4 (8) A description of the computer link, video link, and
5 audio link; and

6 (9) Photographs of the remote dispensing pharmacy area,
7 including but not limited to the remote dispensing
8 machine, the security system, computer link, video
9 link, audio link, confidential-communications area,
10 and locked cabinet.

11 A remote dispensing pharmacy's failure to notify the board
12 in writing within thirty days of any changes to the information
13 described in paragraphs (1) to (9) or failure to comply with
14 this chapter shall be considered a violation of this chapter and
15 shall result in disciplinary action against the pharmacist-in-
16 charge and the responsible pharmacy.

17 (f) Permits and licenses issued under this section and
18 section 461-15 may be closed upon written request from the
19 holder of the permit or license. The board shall approve all
20 requests by the holder for closure of a permit or license. Once
21 the closure is approved, the holder of the closed permit or



1 license shall be required to reapply as a new applicant to
2 conduct business where a permit or license is required."

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

5 "§461-16 Fees for permits and licenses; renewal. (a) The
6 board shall collect application, license, and permit fees for
7 each permit to operate a pharmacy or for each license to operate
8 as a wholesale prescription drug distributor and a fee for the
9 issuance of a permit in accordance with section 461-15(a)(1),
10 (5), (6), and (7).

11 (b) Permits issued under sections 461-14 and 461-15 and
12 licenses issued under section 461-8.6 shall be conspicuously
13 displayed in the place for which the permit or license was
14 granted. The permits and licenses shall not be transferable,
15 shall expire on December 31 of each odd-numbered year following
16 the date of issuance, and shall be renewed biennially.

17 (c) The holder of an expired permit or an expired license
18 to operate as a wholesale prescription drug distributor may have
19 the same restored within three years of the date of expiration
20 upon due application therefor and payment of the delinquent fees
21 and a penalty fee; provided that in the case of an expired



1 permit, the holder of the expired permit meets the requirements
2 for the renewal of permits.

3 (d) 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 or 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 7. Statutory material to be repealed is bracketed
11 and stricken. New statutory material is underscored.

12 SECTION 8. This Act shall take effect upon its approval.

13

INTRODUCED BY: *Therese Chun Caliland*



Report Title:

Remote Dispensing Pharmacies

Description:

Provides for the establishment of remote dispensing pharmacies.

