

A Bill for an Act Relating to Remote Dispensing.

Be It Enacted by the Legislature of the State of Hawaii:

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

The purpose of this Act is to permit the operation of remote dispensing machines by a licensed pharmacy or pharmacist.

SECTION 2. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

“§461- Remote dispensing pharmacy; operations. (a) A remote dispensing pharmacy shall be under the direct supervision of the registered pharmacist in charge of the responsible pharmacy who shall:

- (1) Ensure that the remote dispensing pharmacy is in compliance with all laws and rules governing the practice of pharmacy and remote dispensing;
 - (2) Ensure that the remote dispensing pharmacy is appropriately staffed by a qualified remote dispensing technician; and
 - (3) Be responsible for the integrity of the drugs in the remote dispensing machine and that drugs for the remote dispensing machine are provided to the remote dispensing pharmacy only from the responsible pharmacy.
- (b) Physical set-up. A remote dispensing pharmacy shall:
- (1) Be effectively secured to prevent unauthorized access at all times, and entry to the remote dispensing pharmacy shall be limited to authorized personnel only;
 - (2) Be connected via live computer link, video link, and audio link to the responsible pharmacy and shall use the information technology system of the responsible pharmacy;
 - (3) Conspicuously display at the remote dispensing machine:
 - (A) A copy of the license of the responsible pharmacy; and
 - (B) A copy of the license of the pharmacist in charge of the responsible pharmacy; and
 - (4) Have a confidential area available for communication between the patient and the pharmacist at the responsible pharmacy.
- (c) No remote dispensing pharmacy shall operate within a five mile radius of any pharmacy as defined under section 461-1; provided that:
- (1) This subsection shall not apply to any remote dispensing pharmacy established prior to the effective date of this Act that has previously dispensed and will continue to dispense only prescription medications acquired pursuant to section 340B of the Public Health Service Act, title 42 United States Code section 256b; and
 - (2) If an appropriately designated pharmacy, as defined in section 461-1, Hawaii Revised Statutes, is established within a five mile radius of an existing remote dispensing pharmacy exempted by this subsection,

all appropriate measures shall be taken to encourage the relocation of the existing remote dispensing machine within the newly established pharmacy.

(d) Remote dispensing pharmacies shall not provide medications to patients with health insurance coverage except for patients covered by QUEST.

(e) The remote dispensing technician shall offer each patient the option of receiving counseling by a pharmacist at the responsible pharmacy for all prescriptions.

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

(g) Each remote dispensing machine shall be operated by only one responsible pharmacy. A responsible pharmacy may operate through more than one remote dispensing machine.

(h) The remote dispensing machine shall have the following features to ensure that it is appropriately secure at all times and that all transactions are properly documented:

- (1) Secure double-locked cabinets;
- (2) Bar-coding or similar technology that effectively recognizes the product;
- (3) A cabinet that delivers only one bar-coded unit-of-use container per dispense, per prescription;
- (4) A scanner and printer that, upon releasing the unit-of-use container from the remote dispensing machine, the container is scanned to confirm it is the correct container, and with that confirmation, the printer will print a patient-specific label that has a bar code which is scanned to confirm it is the correct label for the prescription; and
- (5) A video component that allows the patient to have a "face-to-face" consultation with the pharmacist at the responsible pharmacy.

(i) A pharmacist shall be in charge of the remote dispensing machine and shall ensure that:

- (1) Written policies and procedures are developed prior to using the machine that:
 - (A) Ensure the safe and effective dispensing of pharmaceutical products;
 - (B) Ensure the remote dispensing pharmacy and the remote dispensing machine is operating safely, accurately, and securely; and
 - (C) Define access to the remote dispensing machine and to medications contained within or associated with the machine, including policies that assign, discontinue, or change access to the remote dispensing machine and medications;
- (2) A pharmacist licensed in this State and employed by the responsible pharmacy has secured access to the drugs in the remote dispensing machine;
- (3) Access to the medications complies with state and federal laws, rules, and regulations;
- (4) No prescription drug is dispensed at the remote dispensing pharmacy until a pharmacist at the responsible pharmacy has verified the finished prescription;
- (5) Only one prescription is dispensed and labeled from the remote dispensing machine at a time;
- (6) All prescriptions dispensed have a label affixed to the final drug container that meets the requirements set forth in section 328-16 and includes the address of the remote dispensing pharmacy;

- (7) If a patient refuses the prescription drug at the time it is dispensed, the prescription drug is locked in a secured cabinet;
- (8) There is proper inventory control at the remote dispensing pharmacy and only a registered pharmacist or a remote dispensing technician assigned by the pharmacist in charge of the responsible pharmacy shall stock the remote dispensing machine;
- (9) A reconciliation of the physical inventory of the remote dispensing pharmacy is conducted at least annually;
- (10) All personnel who operate the remote dispensing machine at the remote dispensing pharmacy are properly trained. Training shall ensure the competence and ability of all personnel who operate any component of the remote dispensing machine and the remote dispensing pharmacy. Documentation of training shall be kept by the responsible pharmacy; and
- (11) The remote dispensing machine is stocked accurately and in accordance with established written policies and procedures. The pharmacist shall check the accuracy of the product supplied for stocking the remote dispensing machine.
 - (j) Controlled substances shall not be dispensed from any remote dispensing machine or remote dispensing pharmacy.
 - (k) Drugs dispensed from the remote dispensing machine shall be dispensed as packaged, with no changes to the drug, its strength, or its unit quantity, except for the addition of water for reconstitution of dry powder drugs.
 - (l) Prescription labels for the product dispensed from the remote dispensing machine shall only be generated at the remote dispensing pharmacy.
 - (m) Records of prescriptions filled at the remote dispensing pharmacy shall be maintained at the responsible pharmacy and shall be distinguishable from those records filled at the responsible pharmacy. All responsible pharmacies shall maintain, on-site at the remote dispensing pharmacy and have available for inspection at all times, records and documentation of the following:
 - (1) All prescriptions dispensed at the remote dispensing pharmacy;
 - (2) All inventory movement at the remote dispensing pharmacy; and
 - (3) A policies and procedures manual of the remote dispensing pharmacy.
 - (n) No health insurance provider group, hospital, or medical service plan regulated under article 431-10A or 432-1 shall operate a remote dispensing pharmacy.
 - (o) This section shall not apply to:
 - (1) Mobile medical clinics, provided that no such clinic shall operate in counties with a population less than 100,000; or
 - (2) Federally qualified health centers, provided that no remote dispensing pharmacy shall operate within a five mile radius of any pharmacy as defined under section 461-1, except for those federally qualified health centers that are exempt under section 461- (c)(2).

As used in this subsection, "mobile medical clinic" means a motor vehicle retrofitted for exclusive use as a medical office or clinic for medical services licensed under chapter 321."

SECTION 3. Section 461-1, Hawaii Revised Statutes, is amended by adding five new definitions to be appropriately inserted and to read as follows:

"Remote dispensing" means the practice of dispensing drugs through the use of trained personnel, telecommunications, and information technologies to patients at a remote dispensing pharmacy.

"Remote dispensing machine" means a device used for dispensing unit-of-use drugs that are acquired pursuant to section 340B of the Public Health Service

Act, title 42 United States Code section 256b, that is operated using information technologies and is located in a remote dispensing pharmacy.

“Remote dispensing pharmacy” means the area in an institutional facility, including a federally qualified health center, providing outpatient medical care in any county, by dispensing prescription drugs that are acquired pursuant to section 340B of the Public Health Service Act, title 42 United States Code section 256b, through the use of a remote dispensing machine.

“Remote dispensing technician” means an individual who assists the pharmacist in various activities specific to the remote dispensing pharmacy.

“Responsible pharmacy” means a pharmacy that operates a remote dispensing machine located in this State and holds a valid permit issued by the board pursuant to section 461-14.”

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

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

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

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

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

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

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

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

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

(1) A completed form prescribed by the board;

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

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

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

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

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

(7) A description of the security system;

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

(9) Photographs of the remote dispensing pharmacy area, including but not limited to the remote dispensing machine, the security system, comput-

er link, video link, audio link, confidential-communications area, and locked cabinet.

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

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

SECTION 5. The department of commerce and consumer affairs shall submit an annual report to the legislature no later than twenty days prior to the convening of the regular legislative session, beginning with the regular session of 2009 and ending with the regular session of 2013. The report shall include information on the use of the remote dispensing machines.

SECTION 6. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.¹

SECTION 7. This Act shall take effect upon its approval and shall be repealed on January 1, 2013.

(Approved July 3, 2008.)

Note

1. Edited pursuant to HRS §23G-16.5.