## EXECUTIVE CHAMBERS

HONOLULU

LINDA LINGLE GOVERNOR

July 3, 2008

The Honorable Colleen Hanabusa, President and Members of the Senate Twenty-Fourth State Legislature State Capitol, Room 409 Honolulu, Hawaii 96813

Dear Madam President and Members of the Senate:

This is to inform you that on July 3, 2008, the following bill was signed into law:

SB2459 SD2 HD1 CD1

A BILL FOR AN ACT RELATING TO REMOTE DISPENSING. (ACT 212)

Sincerely,

LINDA LINGLE

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Approved by the Governor on JUL 3 2008

THE SENATE TWENTY-FOURTH LEGISLATURE, 2008 STATE OF HAWAII ACT 212
S.B. NO. 2459
S.D. 2
H.D. 1
C.D. 1

## A BILL FOR AN ACT

RELATING TO REMOTE DISPENSING.

## 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.
- 9 The purpose of this Act is to permit the operation of remote
- 10 dispensing machines by a licensed pharmacy or pharmacist.
- 11 SECTION 2. Chapter 461, Hawaii Revised Statues, is amended
- 12 by adding a new section to be appropriately designated and to
- 13 read as follows:
- 14 "§461- Remote dispensing pharmacy; operations. (a) A
- 15 remote dispensing pharmacy shall be under the direct supervision
- 16 of the registered pharmacist in charge of the responsible
- 17 pharmacy who shall:

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1	(1)	Ensure that the remote dispensing pharmacy is in
2		compliance with all laws and rules governing the
3		practice of pharmacy and remote dispensing;
4	(2)	Ensure that the remote dispensing pharmacy is
5		appropriately staffed by a qualified remote dispensing
6		technician; and
7	(3)	Be responsible for the integrity of the drugs in the
8		remote dispensing machine and that drugs for the
9		remote dispensing machine are provided to the remote
10		dispensing pharmacy only from the responsible
11		pharmacy.
12	<u>(b)</u>	Physical set-up. A remote dispensing pharmacy shall:
13	(1)	Be effectively secured to prevent unauthorized access
14		at all times, and entry to the remote dispensing
15		pharmacy shall be limited to authorized personnel
16		<pre>only;</pre>
17	(2)	Be connected via live computer link, video link, and
18		audio link to the responsible pharmacy and shall use
19		the information technology system of the responsible
20		pharmacy;
21	(3)	Conspicuously display at the remote dispensing

1		(A)	A copy of the license of the responsible
2			pharmacy; and
3		(B)	A copy of the license of the pharmacist in charge
4			of the responsible pharmacy;
5		and	
6	(4)	<u>Have</u>	a confidential area available for communication
7		betwe	een the patient and the pharmacist at the
8		respo	onsible pharmacy.
9	<u>(c)</u>	No re	emote dispensing pharmacy shall operate within a
10	five mile	radiu	as of any pharmacy as defined under section 461-1;
11	provided	that:	
12	(1)	This	subsection shall not apply to any remote
13		dispe	ensing pharmacy established prior to the effective
14		date	of this Act that has previously dispensed and
15		will	continue to dispense only prescription
16		medic	ations acquired pursuant to section 340B of the
17		<u>Publi</u>	c Health Service Act, title 42 United States Code
18		secti	on 256b; and
19	(2)	If an	appropriately designated pharmacy, as defined in
20		<u>secti</u>	on 461-1, Hawaii Revised Statutes, is established
21		withi	n a five mile radius of an existing remote
22		dispe	nsing pharmacy exempted by this subsection, all

1	appropriate measures shall be taken to encourage the
2	relocation of the existing remote dispensing machine
3	within the newly established pharmacy.
4	(d) Remote dispensing pharmacies shall not provide
5	medications to patients with health insurance coverage except
6	for patients covered by QUEST.
7	(e) The remote dispensing technician shall offer each
8	patient the option of receiving counseling by a pharmacist at the
9	responsible pharmacy for all prescriptions.
10	(f) A pharmacist at the responsible pharmacy shall approve
11	each prescription before it is dispensed to the patient.
12	(g) Each remote dispensing machine shall be operated by
13	only one responsible pharmacy. A responsible pharmacy may
14	operate through more than one remote dispensing machine.
15	(h) The remote dispensing machine shall have the following
16	features to ensure that it is appropriately secure at all times
17	and that all transactions are properly documented:
18	(1) Secure double-locked cabinets;
19	(2) Bar-coding or similar technology that effectively
20	recognizes the product;
21	(3) A cabinet that delivers only one bar-coded unit-of-use
22	container per dispense, per prescription;

I	(4)	A scanner and printer that, upon releasing the unit-
2		of-use container from the remote dispensing machine,
3		the container is scanned to confirm it is the correct
4		container, and with that confirmation, the printer
5		will print a patient-specific label that has a bar
6		code which is scanned to confirm it is the correct
7		label for the prescription; and
8	<u>(5)</u>	A video component that allows the patient to have a
9		"face-to-face" consultation with the pharmacist at the
10		responsible pharmacy.
11	<u>(i)</u>	A pharmacist shall be in charge of the remote
12	dispensin	g machine and shall ensure that:
13	<u>(1)</u>	Written policies and procedures are developed prior to
14		using the machine that:
15		(A) Ensure the safe and effective dispensing of
16		pharmaceutical products;
17		(B) Ensure the remote dispensing pharmacy and the
18		remote dispensing machine is operating safely,
19		accurately, and securely; and
20		(C) Define access to the remote dispensing machine
21		and to medications contained within or associated
22		with the machine, including policies that assign,

I		discontinue, or change access to the remote
2		dispensing machine and medications;
3	(2)	A pharmacist licensed in this State and employed by
4		the responsible pharmacy has secured access to the
5		drugs in the remote dispensing machine;
6	(3)	Access to the medications complies with state and
7		federal laws, rules, and regulations;
8	(4)	No prescription drug is dispensed at the remote
9		dispensing pharmacy until a pharmacist at the
10		responsible pharmacy has verified the finished
11		<pre>prescription;</pre>
12	(5)	Only one prescription is dispensed and labeled from
13		the remote dispensing machine at a time;
14	<u>(6)</u>	All prescriptions dispensed have a label affixed to
15		the final drug container that meets the requirements
16		set forth in section 328-16 and includes the address of
17		the remote dispensing pharmacy;
18	(7)	If a patient refuses the prescription drug at the time
19		it is dispensed, the prescription drug is locked in a
20		secured cabinet;
21	(8)	There is proper inventory control at the remote
22		dispensing pharmacy and only a registered pharmacist

1		or a remote dispensing technician assigned by the
2		pharmacist in charge of the responsible pharmacy shall
3		stock the remote dispensing machine;
4	(9)	A reconciliation of the physical inventory of the
5		remote dispensing pharmacy is conducted at least
6		annually;
7	(10)	All personnel who operate the remote dispensing
8		machine at the remote dispensing pharmacy are properly
9		trained. Training shall ensure the competence and
10		ability of all personnel who operate any component of
11		the remote dispensing machine and the remote
12		dispensing pharmacy. Documentation of training shall
13		be kept by the responsible pharmacy; and
14	(11)	The remote dispensing machine is stocked accurately
15		and in accordance with established written policies
16		and procedures. The pharmacist shall check the
17		accuracy of the product supplied for stocking the
18		remote dispensing machine.
19	<u>(j)</u>	Controlled substances shall not be dispensed from any
20	remote dis	spensing machine or remote dispensing pharmacy.
21	<u>(k)</u>	Drugs dispensed from the remote dispensing machine
22	shall be d	lispensed as packaged, with no changes to the drug, its



I	Screnden	, of its unit quantity, except for the addition of water
2	for reco	nstitution of dry powder drugs.
3	(1)	Prescription labels for the product dispensed from the
4	<u>remote di</u>	spensing machine shall only be generated at the remote
5	dispensir	ng pharmacy.
6	<u>(m)</u>	Records of prescriptions filled at the remote
7	dispensir	g pharmacy shall be maintained at the responsible
8	pharmacy	and shall be distinguishable from those records filled
9	at the re	sponsible pharmacy. All responsible pharmacies shall
10	maintain,	on-site at the remote dispensing pharmacy and have
11	<u>available</u>	for inspection at all times, records and documentation
12	of the fo	llowing:
13	(1)	All prescriptions dispensed at the remote dispensing
14		pharmacy;
15	(2)	All inventory movement at the remote dispensing
16		pharmacy; and
17	(3)	A policies and procedures manual of the remote
18		dispensing pharmacy.
19	<u>(n)</u>	No health insurance provider group, hospital, or
20	medical s	ervice plan regulated under article 431-10A or 432-1
21	shall oper	rate a remote dispensing pharmacy.
22	(0)	This section shall not apply to:

1	<u>(1)</u>	Mobile medical clinics, provided that no such clinic
2		shall operate in counties with a population less than
3		100,000; or
4	(2)	Federally qualified health centers, provided that no
5		remote dispensing pharmacy shall operate within a five
6		mile radius of any pharmacy as defined under section
7		461-1, except for those federally qualified health
8		centers that are exempt under section 461- (c)(2).
9	As used in	n this subsection, "mobile medical clinic" means a
10	motor vehi	icle retrofitted for exclusive use as a medical office
11	or clinic	for medical services licensed under chapter 321."
12	SECTI	ON 3. Section 461-1, Hawaii Revised Statutes, is
13	amended by	adding five new definitions to be appropriately
14	inserted a	and to read as follows:
15	""Ren	note dispensing means the practice of dispensing drugs
16	through th	ne use of trained personnel, telecommunications, and
17	informatio	on technologies to patients at a remote dispensing
18	pharmacy.	
19	"Remo	te dispensing machine" means a device used for
20	dispensing	unit-of-use drugs that are acquired pursuant to
21	section 34	OB of the Public Health Service Act, title 42 United
22	States Cod	e section 256b, that is operated using information
23	technologi	es and is located in a remote dispensing pharmacy.
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1	"Remote dispensing pharmacy" means the area in an
2	institutional facility, including a federally qualified health
3	center, providing outpatient medical care in any county, by
4	dispensing prescription drugs that are acquired pursuant to
5	section 340B of the Public Health Service Act, title 42 United
6	States Code section 256b, through the use of a remote dispensing
7	machine.
8	"Remote dispensing technician" means an individual who
9	assists the pharmacist in various activities specific to the
10	remote dispensing pharmacy.
11	"Responsible pharmacy" means a pharmacy that operates a
12	remote dispensing machine located in this State and holds a valid
13	permit issued by the board pursuant to section 461-14."
14	SECTION 4. Section 461-14, Hawaii Revised Statutes, is
15	amended to read as follows:
16	"§461-14 Permits for operation of pharmacy[-]:
17	notification of remote dispensing pharmacy. (a) It shall be
18	unlawful for any person to operate, maintain, open, change
19	location, or establish any pharmacy or remote dispensing
20	pharmacy within the State without [first] having first obtained
21	a permit or prior notification from the board.
22	(b) Application for permits and notifications shall be

made on a form to be prescribed by the board. Separate 2008-2622 SB2459 CD1 SMA.doc

1	[ <del>application</del> ]	applications	shall	be	made	and	separate	permits
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- 2 and notifications issued for each separate place at which is
- 3 carried on any of the operations for which a permit or
- 4 notification is required.
- 5 On evidence satisfactory to the board, a permit or
- notification shall be issued[- provided:]; provided that: 6
- 7 (1)[That the] The pharmacy for which the permit or
- 8 notification is sought is or will be[7] in full
- 9 compliance with this chapter and rules of the board;
- [That the] The location and appointments of the 10 (2)
- pharmacy are such that it can be operated and 11
- 12 maintained without endangering the public health or
- safety; and 13
- [That the] The pharmacy will be under the personal and 14 (3)
- immediate supervision of a registered pharmacist. 15
- 16 (d) [No application] An application for a permit shall be
- refused [except pursuant to] for noncompliance with this section 17
- 18 [and] but only after notice to the applicant and a full and fair
- 19 hearing.
- 20 To operate a remote dispensing pharmacy, a responsible
- pharmacy shall submit to the board the following information: 21
- A completed form prescribed by the board; 22 (1)

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1	(2)	The name, address, and permit number of the
2		responsible pharmacy;
3	<u>(3)</u>	The name and license number of the pharmacist in
4		charge of the responsible pharmacy;
5	(4)	The name of the institutional health care facility and
6		the address of the remote dispensing pharmacy;
7	(5)	A floor plan of the remote dispensing pharmacy, which
8		shall indicate the space or location of the remote
9		dispensing machine;
10	(6)	The date the remote dispensing pharmacy will be ready
11		<pre>for operations;</pre>
12	<u>(7)</u>	A description of the security system;
13	(8)	A description of the computer link, video link, and
14		audio link; and
15	(9)	Photographs of the remote dispensing pharmacy area,
16		including but not limited to the remote dispensing
17		machine, the security system, computer link, video
18		link, audio link, confidential-communications area,
19		and locked cabinet.
20	A remote d	dispensing pharmacy's failure to notify the board in
21	writing wi	thin thirty days of any changes to the information
22	described	in paragraphs (1) to (9) or failure to comply with

- 1 this chapter shall be considered a violation of this chapter and
- 2 shall result in disciplinary action against the pharmacist in
- 3 charge and the responsible pharmacy.
- 4 (f) Permits and licenses issued under this section and
- 5 section 461-15 may be closed upon written request from the
- 6 holder of the permit or license. The board shall approve all
- 7 requests by the holder for closure of a permit or license. Once
- 8 the closure is approved, the holder of the closed permit or
- 9 license shall be required to reapply as a new applicant to
- 10 conduct business where a permit or license is required."
- 11 SECTION 5. The department of commerce and consumer affairs
- 12 shall submit an annual report to the legislature no later than
- 13 twenty days prior to the convening of the regular legislative
- 14 session, beginning with the regular session of 2009 and ending
- 15 with the regular session of 2013. The report shall include
- 16 information on the use of the remote dispensing machines.
- 17 SECTION 6. Statutory material to be repealed is bracketed
- 18 and stricken. New statutory material is underscored.
- 19 SECTION 7. This Act shall take effect upon its approval
- 20 and shall be repealed on January 1, 2013.

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S.B. NO.

APPROVED this

day of JUL , 2008

GOVERNOR OF THE STATE OF HAWAII

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