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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 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

of the registered pharmacist in charge of the responsible

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	<u>(3)</u>	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	(b)	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		only;
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
22		machine:

1		(A)	A copy of the license of the responsible
2			pharmacy; and
3		<u>(B)</u>	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		<u>betw</u>	een the patient and the pharmacist at the
8		resp	onsible pharmacy.
9	<u>(c)</u>	No r	emote dispensing pharmacy shall operate within a
10	five mile	radi	us of any pharmacy as defined under section 461-1;
11	provided	that:	
12	(1)	This	subsection shall not apply to any remote
13		disp	ensing pharmacy established prior to the effective
14		<u>date</u>	of this Act that has previously dispensed and
15		<u>will</u>	continue to dispense only prescription
16		medio	cations acquired pursuant to section 340B of the
17		Publ:	ic Health Service Act, title 42 United States Code
18		sect:	ion 256b; and
19	(2)	If an	n appropriately designated pharmacy, as defined in
20		sect:	ion 461-1, Hawaii Revised Statutes, is established
21		with:	in a five mile radius of an existing remote
22		dispe	ensing 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;

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

1		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	<u>(3)</u>	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		prescription;
12	<u>(5)</u>	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	<u>(7)</u>	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>(i)</u>	Controlled substances shall not be dispensed from any
20	remote di	spensing machine or remote dispensing pharmacy.
21	<u>(k)</u>	Drugs dispensed from the remote dispensing machine
22	shall be	dispensed as packaged, with no changes to the drug, its

I	strengtn,	or its unit quantity, except for the addition of water
2	for recon	stitution of dry powder drugs.
3	(1)	Prescription labels for the product dispensed from the
4	remote di	spensing machine shall only be generated at the remote
5	dispensin	g pharmacy.
6	<u>(m)</u>	Records of prescriptions filled at the remote
7	dispensin	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	available	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 se	ervice plan regulated under article 431-10A or 432-1
21	shall ope	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 veh	icle retrofitted for exclusive use as a medical office
11	or clinic	for medical services licensed under chapter 321."
12	SECT:	ION 3. Section 461-1, Hawaii Revised Statutes, is
13	amended by	y adding five new definitions to be appropriately
14	inserted a	and to read as follows:
15	" <u>"Re</u> r	mote 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	ote dispensing machine" means a device used for
20	dispensing	q unit-of-use drugs that are acquired pursuant to
21	section 34	40B of the Public Health Service Act, title 42 United
22	States Coo	de section 256b, that is operated using information
23	technologi	ies 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
23	made on a form to be prescribed by the board. Separate

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1	[application]	applications	shall	be	made	and	separate	permits

- 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 (c) On evidence satisfactory to the board, a permit or
- 6 notification shall be issued[, provided:]; provided that:
- 7 (1) [That the] The pharmacy for which the permit or
- 8 notification is sought is or will be[-] in full
- 9 compliance with this chapter and rules of the board;
- 10 (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
- 14 (3) [That the] The pharmacy will be under the personal and
- immediate supervision of a registered pharmacist.
- 16 (d) [No application] An application for a permit shall be
- 17 refused [except pursuant to] for noncompliance with this section
- 18 [and] but only after notice to the applicant and a full and fair
- 19 hearing.
- 20 (e) To operate a remote dispensing pharmacy, a responsible
- 21 pharmacy shall submit to the board the following information:
- 22 (1) A completed form prescribed by the board;



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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 of the responsible pharmacy;
5	(4)	The name of the institutional health care facility and
6		the address of the remote dispensing pharmacy;
7	<u>(5)</u>	A floor plan of the remote dispensing pharmacy, which
8		shall indicate the space or location of the remote
9		dispensing machine;
10	<u>(6)</u>	The date the remote dispensing pharmacy will be ready
11		for operations;
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 o	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

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- 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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Report Title:

Remote Dispensing Pharmacy; Medication

Description:

Permits the operation of remote dispensing pharmacies to uninsured patients of a health care provider and patients with QUEST coverage in certain circumstances. (CD1)