

A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

- 1 SECTION 1. Section 329-31.5, Hawaii Revised Statutes, is
- 2 amended to read as follows:
- 3 "\$329-31.5 Clinics. (a) Registration as a clinic is
- 4 required when an out-patient medical facility maintains
- 5 centralized ordering, storage, and record keeping of controlled
- 6 substances to be administered and/or dispensed to patients.
- 7 Registration of a clinic requires that:
- 8 (1) Each location where controlled substances are stocked
- 9 be registered by name, location, and designated
- 10 principal practitioner or affiliated pharmacy. The
- principal practitioner or affiliated pharmacy shall be
- responsible for the accurate maintenance of records
- which document all controlled substances ordered,
- 14 received, administered, and dispensed within the
- 15 clinic;
- 16 (2) Controlled substances stocked at a clinic under the
- 17 clinic State of Hawaii and Drug Enforcement



1		Administration registration numbers be administered to
2		clinic patients by licensed or registered health care
3		professionals under the supervision of the treating
4		practitioner;
5	(3)	Controlled substances stocked at a clinic under the
6		clinic State of Hawaii and Drug Enforcement
7		Administration registration numbers be dispensed to
8		clinic patients only by the treating practitioner for
9		emergency and urgent care, when a written prescription
10		would not be practical;
11	(4)	A centralized record signed and dated by the treating
12		practitioner which indicates the patient, controlled
13		substance, date and time of administration and/or
14		dispensing be maintained and stored with the current
15		controlled substance inventory, ordering, and receipt
16		records. These records shall be maintained for
17		five years; [and]
18	(5)	A clinic practitioner who individually maintains a
19		personal stock of controlled substances does so under
20		the practitioner's individual State and Drug
21		Enforcement Administration registration number. These

1		controlled substances shall be kept separate from
2		clinic stock and cannot be accessed by other
3		practitioners[-]; and
4	(6)	The clinic will be located at least seven hundred
5		fifty feet away from any real property comprising a
6		protected area.
7	<u>(b)</u>	[The term "affiliated pharmacy" as] As used in this
8	section <u>:</u>	
9	"Aff	iliated pharmacy" means a licensed pharmacy which
10	supplies	and monitors the controlled substances stocked in a
11	registere	ed clinic.
12	[The	term "clinic" as used in this section] "Clinic" means
13	an out-pa	tient medical facility owned and operated by a legal
14	entity th	at employs individual practitioners for the treatment
15	of patien	ts and which may or may not provide after-hours
16	emergency	or urgent care.
17	[The	term "principal physician"] "Principal physician"
18	means the	practitioner in a clinic whose signature appears on
19	the clini	c's State of Hawaii and Drug Enforcement Administration
20	registrat	ions, and who is responsible for the proper
21	maintenan	ace, storage, and record keeping of the controlled

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1 substances ordered and centrally stocked in the clinic using the 2 clinic Drug Enforcement Administration registration number. "Protected area" shall have the same meaning as in 3 4 section 712-1249.6." 5 SECTION 2. Section 329-32, Hawaii Revised Statutes, is 6 amended to read as follows: 7 "§329-32 Registration requirements. (a) Every person 8 who: 9 (1) Manufactures, distributes, prescribes, dispenses, or 10 conducts reverse distribution with any controlled 11 substance within this State; 12 (2) Proposes to engage in the manufacture, distribution, 13 prescription, dispensing, or reverse distribution of 14 any controlled substance within this State; or Dispenses or proposes to dispense any controlled 15 (3) 16 substance for use in this State by shipping, mailing, 17 or otherwise delivering the controlled substance from 18 a location outside this State; 19 shall obtain a registration issued by the department [of public 20 safety] in accordance with the department's rules. A licensed 21 or registered health care professional who acts as the

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1	authorized	agent of a	pra	actit	cioner a	and	who	adm	inisters	
2	controlled	substances	at	the	directi	lon	of t	the	practitioner	shall

- 3 not be required to obtain a registration.
- 4 (b) Persons registered by the department [of public
- 5 safety] under this chapter to manufacture, distribute,
- 6 prescribe, dispense, store, conduct research, or conduct reverse
- 7 distribution with controlled substances may possess,
- 8 manufacture, distribute, prescribe, dispense, store, or conduct
- 9 research with those substances to the extent authorized by their
- 10 registration and in conformity with this part.
- 11 (c) Except as otherwise provided by law, the following
- 12 persons shall not be required to register and may lawfully
- 13 possess controlled substances under this chapter:
- 14 (1) An agent or employee of any registered manufacturer,
- 15 distributor, or dispenser of any controlled substance,
- if the agent or employee is acting in the usual course
- of the agent's or employee's business or employment;
- 18 (2) A common or contract carrier or warehouser, or an
- employee thereof, whose possession of any controlled
- 20 substance is in the usual course of the person's
- 21 business or employment; and

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- (3) An ultimate user or a person in possession of any
 controlled substance pursuant to a lawful order of a
 practitioner.
- 4 (d) The department [of public safety] may waive the
 5 registration or filing requirement for certain manufacturers,
 6 distributors, prescribers, or dispensers by rule if:
- 7 (1) It is consistent with the public health and safety;
 8 and
- 9 (2) The department [of public safety] states the specific reasons for the waiver and the time period for which the waiver is to be valid.
 - (e) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, prescribes, dispenses, or conducts reverse distribution with controlled substances, except an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

- 4 The department [of public safety] may require a 5 registrant to submit documents or written statements of fact 6 relevant to a registration that the department deems necessary 7 to determine whether the registration should be granted or 8 denied. The failure of the registrant to provide the documents 9 or statements within a reasonable time after being requested to 10 do so shall be deemed to be a waiver by the registrant of the 11 opportunity to present the documents or statements for 12 consideration by the department in granting or denying the 13 registration.
- (h) The failure to renew the controlled substance
 registration on a timely basis or to pay the applicable fees or
 payment with a check that is dishonored upon first deposit shall
 cause the registration to be automatically forfeited.
- (i) No registration shall be issued or renewed under this section to any person, applicant, or registrant, and no registration shall be waived under subsection (d) for any person or applicant, for a methadone clinic or substance use disorder

1	services clinic if the clinic is within seven hundred fifty feet
2	of a protected area, as defined in section 712-1249.6."
3	SECTION 3. Section 329-33, Hawaii Revised Statutes, is
4	amended to read as follows:
5	"§329-33 Registration. (a) The department [of public
6	safety] shall register an applicant to manufacture, dispense,
7	prescribe, distribute, or conduct reverse distribution with
8	controlled substances included in sections 329-14, 329-16,
9	329-18, 329-20, and 329-22 unless [$\pm t$] the department determines
10	that the issuance of that registration would be inconsistent
11	with the public interest. In determining the public interest,
12	the department [of public safety] shall consider the following
13	factors:
14	(1) Maintenance of effective controls against diversion of
15	controlled substances into other than legitimate
16	medical, scientific, or industrial channels;
17	(2) Compliance with applicable state and local [law;]
18	laws;
19	(3) Any convictions of the applicant under any federal and
20	state laws relating to any controlled substance;

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1	(4)	Past experience in the manufacture or distribution of
2		controlled substances, and the existence in the
3		applicant's establishment of effective controls
4		against diversion;

- (5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
- (6) Suspension, revocation, or surrender of the applicant's federal registration to manufacture, distribute, prescribe, or dispense controlled substances as authorized by federal law; and
- 11 (7) Any other factor relevant to and consistent with the public health and safety.
 - (b) Registration under subsection (a) does not entitle a registrant to manufacture, dispense, prescribe, and distribute controlled substances in schedule I or II other than those specified in the registration.
- (c) Practitioners shall be registered to dispense or to

 prescribe any controlled substances or to conduct research with

 controlled substances in schedules II through V if they are

 authorized to dispense or to prescribe or conduct research under

 the law of this State. The department [of public safety] need

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- 1 not require separate registration under this part for
- 2 practitioners engaging in research with nonnarcotic controlled
- 3 substances in schedules II through V where the registrant is
- 4 already registered under this part in another capacity.
- 5 Practitioners registered under federal law to conduct research
- 6 with schedule I substances may conduct research with schedule I
- 7 substances within this State upon furnishing the department of
- 8 public safety evidence of that federal registration.
- 9 (d) Compliance by manufacturers and distributors with the
- 10 provisions of the federal law respecting registration (excluding
- 11 fees) entitles them to be registered under this chapter.
- (e) No registration under this section shall be issued to
- 13 any applicant for a methadone clinic or substance use disorder
- 14 services clinic that will be located within seven hundred fifty
- 15 feet of a protected area, as defined in section 712-1249.6."
- 16 SECTION 4. Section 329-34, Hawaii Revised Statutes, is
- 17 amended by amending subsection (a) to read as follows:
- 18 "(a) A registration under section 329-33 to manufacture,
- 19 distribute, dispense, or conduct reverse distribution with a
- 20 controlled substance may be suspended or revoked by the



Ţ	departmen	t (of public safety) upon a finding that the
2	registran	t:
3	(1)	Has furnished false or fraudulent material information
4		in any application filed under this chapter;
5	(2)	Has been convicted of a felony or has been granted a
6		motion for the deferral of acceptance of a guilty plea
7		or a nolo contendere plea to a felony, pursuant to
8		chapter 853 and under any state or federal law
9		relating to any controlled substance;
10	(3)	Has had the registrant's federal registration
11		suspended or revoked to manufacture, distribute,
12		prescribe, dispense, or conduct reverse distribution
13		with controlled substances; [or]
14	(4)	Has had the registrant's state license to practice the
15		registrant's profession suspended or revoked by the
16		applicable governing state board[-]; or
17	(5)	Is a registrant for a methadone clinic or substance
18		use disorder services clinic that has located or
19		relocated within seven hundred fifty feet of a
20		protected area, as defined in section 712-1249.6."

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1 SECTION 5. Section 329-40, Hawaii Revised Statutes, is 2 amended to read as follows: 3 "§329-40 Methadone treatment programs. (a) 4 Notwithstanding any other provision of law to the contrary, 5 methadone may be administered or dispensed or both as part of a state-registered and federal Substance Abuse and Mental Health 6 7 Services Administration approved methadone treatment program by 8 a practitioner who is licensed and registered under state and 9 federal law to administer and dispense methadone for patients or 10 by an agent of the practitioner, supervised by and under the 11 order of the practitioner. The agent must be a pharmacist, 12 registered nurse, or licensed practical nurse. The licensed 13 practitioner shall be responsible for the amounts of methadone 14 administered or dispensed in accordance with Substance Abuse and 15 Mental Health Services Administration regulations and shall 16 record, approve, and countersign all changes in dosage 17 schedules.

(b) Registration of a methadone treatment program requires

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that:

1	(1)	The methadone treatment program obtain a controlled
2		substance registration from the State of Hawaii and
3		the Drug Enforcement Administration;
4	(2)	The medical director of a methadone treatment program
5		obtain a controlled substance registration from the
6		State of Hawaii and the Drug Enforcement
7		Administration at the location of the program;
8	(3)	Admission to a methadone treatment program be limited
9		to the narcotic-dependent persons as defined in this
10		chapter;
11	(4)	Unless otherwise stated in this chapter, admission to
12		a methadone treatment program be in accordance with
13		Title 21 Code of Federal Regulations Part 291 and
14		Title 42 Code of Federal Regulations Part 8;
15	(5)	All medical orders including initial medication
16		orders, all subsequent medication order changes, all
17		changes in the frequency of take-home medication, and
18		the prescription of additional take-home medication
19		for emergency situations be authorized by a licensed
20		registered physician employed by the program;

1	(6)	Only the medical director or other designated program
2		physician authorize a patient's admission for
3		treatment in accordance with Title 21 Code of Federal
4		Regulations Part 291 and Title 42 Code of Federal
5		Regulations Part 8; [and]
6	(7)	Take-home doses of methadone be dispensed to patients
7		in accordance with Title 21 Code of Federal
8		Regulations Part 291 and Title 42 Code of Federal
9		Regulations Part 8, but shall not exceed a fourteen-
10		day supply at any given time nor more than the maximum
11		amount of take-homes for Levo-alphacetylmethadol
12		(LAAM/Orlamm) that would allow a patient to be away
13		from the clinic for dosing for more than two weeks
14		unless authorized by the state authority[$ extstyle au$
15	The	term "methadone treatment program" as]; and
16	(8)	The methadone treatment program be located at least
17		seven hundred fifty feet away from a protected area.
18	(c)	As used in this section:
19	"Met	hadone treatment program" means an organization or a
20	person [+], including a private physician[) that], who
21	administe	rs or dispenses methadone to a narcotic-dependent



1 person for maintenance or detoxification treatment and who 2 provides the medical and rehabilitative services required by 3 Title 21 Code of Federal Regulations Part 291 or Title 42 Code 4 of Federal Regulations Part 8 and is approved to do so by the 5 State and by the United States Substance Abuse and Mental Health 6 Services Administration, and who holds a controlled substance 7 registration as required by this chapter and the United States Drug Enforcement Administration to use methadone for the 8 9 treatment of narcotic-dependent persons. 10 [The term "narcotic-dependent person" as used in this section] "Narcotic-dependent person" means an individual who 11 12 physiologically needs heroin or a morphine-like drug to prevent 13 the onset of signs of withdrawal. 14 [The term "state authority" as used in this section] "Protected area" shall have the same meaning as in 15 16 section 712-1249.6. 17 "State authority" means the agency within the State which 18 exercises the responsibility for governing the treatment of 19 narcotic-dependent persons with the narcotic drug methadone." 20 SECTION 6. Section 712-1249.6, Hawaii Revised Statutes, is

amended to read as follows:

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1	"§ 71 :	2-1249.6 Promoting a controlled substance in, on, or
2	near [sch	ools, school vehicles, public parks, or public housing
3	projects	or complexes.] a protected area. (1) A person commits
4	the offen	se of promoting a controlled substance in, on, or near
5	[schools,	school vehicles, public parks, or public housing
6	projects (or complexes] a protected area if the person knowingly:
7	(a)	Distributes or possesses with intent to distribute a
8		controlled substance in any amount in or on the real
9		property comprising a [school, public park, or public
10		housing project or complex; protected area;
11	(b)	Distributes or possesses with intent to distribute a
12		controlled substance in any amount within seven
13		hundred [and] fifty feet of the real property
14		comprising a [school, public park, or public housing
15		<pre>project or complex;] protected area;</pre>
16	(c)	Distributes or possesses with intent to distribute a
17		controlled substance in any amount while on any school
18		vehicle, or within ten feet of a parked school vehicle
19		during the time that the vehicle is in service for or
20		waiting to transport school children; or

(d)	Manufactures methamphetamine or any of its salts,
	isomers, and salts of isomers, within seven hundred
	[and] fifty feet of the real property comprising a
	[school, public park, or public housing project or
	complex.] protected area.
(2)	A person who violates subsection (1)(a), (b), or (c)
is guilty	of a class C felony. A person who violates
subsection	(1)(d) is guilty of a class A felony.
(3)	Any person with prior conviction or convictions under
subsection	(1)(a), (b), or (c) is punishable by a term of
imprisonme	ent of not less than two years and not more than
ten years.	
(4)	Any individual convicted under subsection (3) of this
section sh	nall not be eligible for parole until the individual
has served	d the minimum sentence required by such subsection.
(5)	For the purposes of this section[, "school vehicle"
means eve	sy school vehicle as defined in section 286-181 and any
regulation	ns adopted pursuant to that section.
(6)	For purposes of this section, "school" means any
public or	private preschool, kindergarten, elementary,
	(2) is guilty subsection (3) subsection imprisonmenten years. (4) section shas served (5) means even regulation (6)

intermediate, middle secondary, or high school.



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1 (7) For purposes of this section, "public housing-project 2 or complex" means a housing project directly controlled, owned, 3 developed, or managed by the Hawaii public housing authority 4 pursuant to the federal or state low-rent public housing 5 program.]: 6 "Group child care center" shall have the same meaning as in 7 section 346-151. 8 "Group child care home" shall have the same meaning as in 9 section 346-151. 10 "Protected area" means a school, public park, public 11 housing project or complex, group child care center, group child 12 care home, public recreation center, or youth services center. 13 "Public housing project or complex" means a housing project 14 directly controlled, owned, developed, or managed by the Hawaii 15 public housing authority pursuant to the federal or state low-16 rent public housing program. "School" means any public or private preschool, 17 18 kindergarten, elementary, intermediate, middle, secondary, or 19 high school.

1	"School vehicle" means every school vehicle, as defined in
2	section 286-181, and any regulations adopted pursuant to that
3	section.
4	"Youth services center" refers to a youth services center
5	established under section 352D-7."
6	SECTION 7. Statutory material to be repealed is bracketed
7	and stricken. New statutory material is underscored.
8	SECTION 8. This Act shall take effect upon its approval;
9	provided that any organization or person who was registered as a
10	clinic under section 329-31.5, Hawaii Revised Statutes, or
11	registered to manufacture, distribute, prescribe, dispense, or
12	conduct reverse distribution with any controlled substance at a
13	methadone clinic or substance use disorder services clinic prior
14	to the effective date of this Act shall have one year from the
15	effective date of this Act to comply with this Act.
16	INTRODUCED BY. OCHE, BRILL
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Report Title:

Controlled Substances; Methadone Clinics; Substance Use Disorder Services Clinics; Registration; Protected Areas

Description:

Expands the prohibition on promoting a controlled substance in, on, or near schools, school vehicles, public parks, and public housing projects or complexes to include group child care centers, group child care homes, public recreation centers, and youth services centers, collectively as protected areas. Requires the registration and registration renewal of methadone clinics and substance use disorder services clinics as clinics and for handling controlled substances to be contingent upon location at least 750 feet away from protected areas. Gives methadone clinics and substance use disorder services clinics one year from the effective date of this Act to comply with this Act.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.