

JAN 21 2022

A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

SECTION 1. Section 329-31.5, Hawaii Revised Statutes, is amended to read as follows:

"§329-31.5 Clinics. (a) Registration as a clinic is required when an out-patient medical facility maintains centralized ordering, storage, and record keeping of controlled substances to be administered and/or dispensed to patients.

Registration of a clinic requires that:

(1) Each location where controlled substances are stocked be registered by name, location, and designated 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, received, administered, and dispensed within the clinic;

(2) Controlled substances stocked at a clinic under the clinic State of Hawaii and Drug Enforcement



Administration registration numbers be administered to clinic patients by licensed or registered health care professionals under the supervision of the treating practitioner;

(3) Controlled substances stocked at a clinic under the clinic State of Hawaii and Drug Enforcement Administration registration numbers be dispensed to clinic patients only by the treating practitioner for emergency and urgent care, when a written prescription would not be practical;

(4) A centralized record signed and dated by the treating practitioner which indicates the patient, controlled substance, date and time of administration and/or dispensing be maintained and stored with the current controlled substance inventory, ordering, and receipt records. These records shall be maintained for five years; ~~and~~

(5) A clinic practitioner who individually maintains a personal stock of controlled substances does so under the practitioner's individual State and Drug 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 (b) ~~[The term "affiliated pharmacy" as]~~ As used in this
8 section:

9 "Affiliated pharmacy" means a licensed pharmacy which
10 supplies and monitors the controlled substances stocked in a
11 registered clinic.

12 ~~[The term "clinic" as used in this section]~~ "Clinic" means
13 an out-patient medical facility owned and operated by a legal
14 entity that employs individual practitioners for the treatment
15 of patients 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 clinic's State of Hawaii and Drug Enforcement Administration
20 registrations, and who is responsible for the proper
21 maintenance, storage, and record keeping of the controlled



1 substances ordered and centrally stocked in the clinic using the
2 clinic Drug Enforcement Administration registration number.

3 "Protected area" shall have the same meaning as in
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

15 (3) Dispenses or proposes to dispense any controlled
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



1 authorized agent of a practitioner and who administers
2 controlled substances at the direction of 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,
16 if the agent or employee is acting in the usual course
17 of the agent's or employee's business or employment;

18 (2) A common or contract carrier or warehouser, or an
19 employee thereof, whose possession of any controlled
20 substance is in the usual course of the person's
21 business or employment; and



1 (3) An ultimate user or a person in possession of any
2 controlled substance pursuant to a lawful order of a
3 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
10 reasons for the waiver and the time period for which
11 the waiver is to be valid.

12 (e) A separate registration shall be required at each
13 principal place of business or professional practice where the
14 applicant manufactures, distributes, prescribes, dispenses, or
15 conducts reverse distribution with controlled substances, except
16 an office used by a practitioner (who is registered at another
17 location) where controlled substances are prescribed but neither
18 administered nor otherwise dispensed as a regular part of the
19 professional practice of the practitioner at such office, and
20 where no supplies of controlled substances are maintained.



1 (f) The department [~~of public safety~~] may inspect the
2 establishment of a registrant or applicant for registration in
3 accordance with the department's rule.

4 (g) 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.

14 (h) The failure to renew the controlled substance
15 registration on a timely basis or to pay the applicable fees or
16 payment with a check that is dishonored upon first deposit shall
17 cause the registration to be automatically forfeited.

18 (i) No registration shall be issued or renewed under this
19 section to any person, applicant, or registrant, and no
20 registration shall be waived under subsection (d) for any person
21 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 [~~it~~] 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;



(4) Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls 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

(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



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.

12 (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



1 department [~~of public safety~~] upon a finding that the
2 registrant:

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."



SECTION 5. Section 329-40, Hawaii Revised Statutes, is amended to read as follows:

"§329-40 Methadone treatment programs. (a)

Notwithstanding any other provision of law to the contrary, methadone may be administered or dispensed or both as part of a state-registered and federal Substance Abuse and Mental Health Services Administration approved methadone treatment program by a practitioner who is licensed and registered under state and federal law to administer and dispense methadone for patients or by an agent of the practitioner, supervised by and under the order of the practitioner. The agent must be a pharmacist, registered nurse, or licensed practical nurse. The licensed practitioner shall be responsible for the amounts of methadone administered or dispensed in accordance with Substance Abuse and Mental Health Services Administration regulations and shall record, approve, and countersign all changes in dosage schedules.

(b) Registration of a methadone treatment program requires 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;



(6) Only the medical director or other designated program physician authorize a patient's admission for treatment in accordance with Title 21 Code of Federal Regulations Part 291 and Title 42 Code of Federal Regulations Part 8; ~~and~~

(7) Take-home doses of methadone be dispensed to patients in accordance with Title 21 Code of Federal Regulations Part 291 and Title 42 Code of Federal Regulations Part 8, but shall not exceed a fourteen-day supply at any given time nor more than the maximum amount of take-homes for Levo-alphaacetylmethadol (LAAM/Orlamm) that would allow a patient to be away from the clinic for dosing for more than two weeks unless authorized by the state authority[~~-~~

~~The term "methadone treatment program" as]; and~~

(8) The methadone treatment program be located at least seven hundred fifty feet away from a protected area.

(c) As used in this section:

"Methadone treatment program" means an organization or a person [~~+~~], including a private physician[~~-that~~], who administers 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
8 Drug Enforcement Administration to use methadone for the
9 treatment of narcotic-dependent persons.

10 ~~[The term "narcotic-dependent person" as used in this~~
11 ~~section]~~ "Narcotic-dependent person" means an individual who
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]~~

15 "Protected area" shall have the same meaning as in
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
21 amended to read as follows:



1 "§712-1249.6 Promoting a controlled substance in, on, or
2 near [~~schools, school vehicles, public parks, or public housing~~
3 ~~projects or complexes.~~] a protected area. (1) A person commits

4 the offense 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 ~~project or complex;~~] protected area;

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



1 (d) Manufactures methamphetamine or any of its salts,
2 isomers, and salts of isomers, within seven hundred
3 ~~[and]~~ fifty feet of the real property comprising a
4 ~~[school, public park, or public housing project or~~
5 ~~complex.]~~ protected area.

6 (2) A person who violates subsection (1)(a), (b), or (c)
7 is guilty of a class C felony. A person who violates
8 subsection (1)(d) is guilty of a class A felony.

9 (3) Any person with prior conviction or convictions under
10 subsection (1)(a), (b), or (c) is punishable by a term of
11 imprisonment of not less than two years and not more than
12 ten years.

13 (4) Any individual convicted under subsection (3) of this
14 section shall not be eligible for parole until the individual
15 has served the minimum sentence required by such subsection.

16 (5) For the purposes of this section~~["school vehicle"~~
17 ~~means every school vehicle as defined in section 286-181 and any~~
18 ~~regulations adopted pursuant to that section.~~

19 ~~(6) For purposes of this section, "school" means any~~
20 ~~public or private preschool, kindergarten, elementary,~~
21 ~~intermediate, middle secondary, or high school.~~



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.

17 "School" means any public or private preschool,
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: _____

Karl N. N. N.



S.B. NO. 2742

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.

