
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
11 principal practitioner or affiliated pharmacy shall be
12 responsible for the accurate maintenance of records
13 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 five
17 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 school.

6 (b) [The term "affiliated pharmacy" as] As used in this
7 section:

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

11 ~~[The term "clinic" as used in this section]~~ "Clinic" means
12 an out-patient medical facility owned and operated by a legal
13 entity that employs individual practitioners for the treatment
14 of patients and which may or may not provide after-hours
15 emergency or urgent care.

16 ~~[The term "principal physician"]~~ "Principal physician"
17 means the practitioner in a clinic whose signature appears on
18 the clinic's State of Hawaii and Drug Enforcement Administration
19 registrations, and who is responsible for the proper
20 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 "School" shall have the same meaning as in section 712-
4 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 warehouse, 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 law enforcement~~] 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 school, 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, 329-
9 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;



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 (5) Furnishing by the applicant of false or fraudulent
6 material in any application filed under this chapter;

7 (6) Suspension, revocation, or surrender of the
8 applicant's federal registration to manufacture,
9 distribute, prescribe, or dispense controlled
10 substances as authorized by federal law; and

11 (7) Any other factor relevant to and consistent with the
12 public health and safety.

13 (b) Registration under subsection (a) does not entitle a
14 registrant to manufacture, dispense, prescribe, and distribute
15 controlled substances in schedule I or II other than those
16 specified in the registration.

17 (c) Practitioners shall be registered to dispense or to
18 prescribe any controlled substances or to conduct research with
19 controlled substances in schedules II through V if they are
20 authorized to dispense or to prescribe or conduct research under
21 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 school, as defined in section 712-1249.6."

16 SECTION 4. Section 329-34, Hawaii Revised Statutes, is
17 amended to read as follows:

18 **"§329-34 Revocation and suspension of registration. (a)**
19 A registration under section 329-33 to manufacture, distribute,
20 dispense, or conduct reverse distribution with a controlled



1 substance may be suspended or revoked by the department [~~of~~
2 ~~public safety~~] upon a finding that the 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 school,
20 as defined in section 712-1249.6.



1 (b) The department [~~of public safety~~] may limit revocation
2 or suspension of a registration to the particular controlled
3 substance with respect to which grounds for revocation or
4 suspension exist.

5 (c) If the department [~~of public safety~~] suspends or
6 revokes a registration, all controlled substances owned or
7 possessed by the registrant at the time of suspension or the
8 effective date of the revocation order may be placed under seal.
9 No disposition may be made of substances under seal until the
10 time for taking an appeal has elapsed or until all appeals have
11 been concluded unless a court, upon application therefor, orders
12 the sale of perishable substances and the deposit of the
13 proceeds of the sale with the court. Upon a revocation order
14 becoming final, all controlled substances may be forfeited to
15 the State.

16 (d) The department [~~of public safety~~] shall promptly
17 notify the Bureau of all orders suspending or revoking
18 registration and all forfeitures of controlled substances."

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



1 **"§329-40 Methadone treatment programs. (a)**

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

16 (b) Registration of a methadone treatment program requires
17 that:

18 (1) The methadone treatment program obtain a controlled
19 substance registration from the State of Hawaii and
20 the Drug Enforcement Administration;



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



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

12 ~~The term "methadone treatment program" as]; and~~
13 (8) The methadone treatment program be located at least
14 seven hundred fifty feet away from a school.

15 (c) As used in this section:
16 "Methadone treatment program" means an organization or a
17 person [~~(+)~~], including a private physician[~~(+)~~ that], who
18 administers or dispenses methadone to a narcotic-dependent
19 person for maintenance or detoxification treatment and who
20 provides the medical and rehabilitative services required by
21 Title 21 Code of Federal Regulations Part 291 or Title 42 Code

1 of Federal Regulations Part 8 and is approved to do so by the
2 State and by the United States Substance Abuse and Mental Health
3 Services Administration, and who holds a controlled substance
4 registration as required by this chapter and the United States
5 Drug Enforcement Administration to use methadone for the
6 treatment of narcotic-dependent persons.

7 ~~[The term "narcotic-dependent person" as used in this~~
8 ~~section]~~ "Narcotic-dependent person" means an individual who
9 physiologically needs heroin or a morphine-like drug to prevent
10 the onset of signs of withdrawal.

11 ~~[The term "state authority" as used in this section]~~
12 "School" shall have the same meaning as in section 712-
13 1249.6.

14 "State authority" means the agency within the State which
15 exercises the responsibility for governing the treatment of
16 narcotic-dependent persons with the narcotic drug methadone."

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 provided that any organization or person who was registered as a
21 clinic under section 329-31.5, Hawaii Revised Statutes, or



H.B. NO. 378

Report Title:

Methadone Clinics; Substance Use Disorder Services Clinics;
Registration; Restrictions

Description:

Requires the registration and registration renewal for methadone clinics and substance use disorder services clinics to be deemed a clinic and for the handling of controlled substances to be contingent upon its location being at least 750 feet away from a school. 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.

