ACT 159

H.B. NO. 964

A Bill for an Act Relating to Controlled Substances.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Chapter 329, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§329- Clinics.** (a)[1] Registration as a clinic is required when an outpatient 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 two 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 controlled substances must be kept separate from clinic stock and cannot be accessed by other practitioners.

The term "affiliated pharmacy" as used in this section means a licensed pharmacy which supplies and monitors the controlled substances stocked in a registered clinic.

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

The term "principal physician" means the practitioner in a clinic whose signature appears on the clinic's State of Hawaii and Drug Enforcement Administration registrations, and who is responsible for the proper maintenance, storage, and record keeping of the controlled substances ordered and centrally stocked in the clinic using the clinic Drug Enforcement Administration registration number."

SECTION 2. Chapter 329, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§329- Prohibited acts related to visits to more than one practitioner to obtain controlled substance prescriptions.** (a) It is unlawful for any person knowingly or intentionally to visit more than one practitioner and withhold information regarding previous practitioner visits for the purpose of obtaining one or more controlled substance prescriptions for quantities that:

(1) Exceed what any single practitioner would have prescribed or dispensed for the time period and legitimate medical purpose represented; and

(2) Would constitute an offense pursuant to part IV of chapter 712.

(b) Any person who violates this section is guilty of a crime which is of the grade and class identical to that imposed under part IV of chapter 712 for the same type and equivalent quantity of controlled substance."

SECTION 3. Section 329-1, Hawaii Revised Statutes, is amended by amending the definition of "administer" to read as follows:

""Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(1) A practitioner (or, in the [practitioner's] practitioner's presence or at the practitioner's direction, by a licensed or registered health care professional acting as the practitioner's authorized agent), or

(2) The patient or research subject at the direction [and] or in the presence of the practitioner."

SECTION 4. Section 329-1, Hawaii Revised Statutes, is amended by deleting the definition of "anabolic steroid".

[""Anabolic steroid" includes any of the following or any isomer, ester, salt, or derivative of the following that acts in the same manner on the human body:

(1) Clostebol;
(2) Danazol;
(3) Dromostanolone;
(4) Oxymesteron;
(5) Oxymetholone;
(6) Ethylestrenol;
(7) Mesterolone;
(8) Methenolone;
(9) Methandrostenolone;
(10) Stanozolol;
(11) Nandrolone phenpropionate;
(12) Nandrolone decanoate;
(13) Norethandrolone;
(14) Testosterone (in aqueoue suspension);
(15) Testosterone propionate (in oil);
(16) Testosterone enanthate (in oil);
(17) Testosterone cypionate (in oil);
(18) Methyltestosterone;
(19) Dehydrochlormethyl testosterone; and
(20) Fluoxymesterone."]

SECTION 5. Section 329-1, Hawaii Revised Statutes, is amended by amending the definition of "dispense" to read as follows:

""Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. A controlled substance is dispensed when:

(1) It is compounded, prepared, labeled and packaged pursuant to the lawful order of a practitioner by a licensed pharmacist acting in the usual course of his professional practice and who is either registered individually or employed in a registered pharmacy or by a registered institutional practitioner, for delivery to the ultimate user;

(2) It is compounded, prepared, labeled and packaged for delivery to the ultimate user by a practitioner acting in the usual course of his professional practice;

(3) It is prepared, labeled, and packaged pursuant to the lawful order of a practitioner by a registered health care professional acting as an agent of the practitioner for delivery to the ultimate user by the practitioner; or

(4) It is prepackaged by a pharmacist for use in an emergency facility for delivery to the ultimate user by a licensed or registered health care professional pursuant to the order of a physician."

SECTION 6. Section 329-1, Hawaii Revised Statutes, is amended by amending the definition of "practitioner" to read as follows:

""Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed[,] and registered[, or otherwise permitted] under section 329-32 to distribute, dispense, or conduct research with respect to [or to administer] a controlled substance in the course of professional practice or research in this State.

(2) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

(3) Prescribe means: to direct, designate or order the use of a formula for the preparation of a drug and medicine for a disease or illness and the manner of using them.

(4) Prescriber means: one who is authorized to issue a prescription.

(5) Prescription means: an order or formula issued by a licensed practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, for the compounding or dispensing of drugs."

SECTION 7. Section 329-16, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alfentanil;
(2) Alphaprodine;
(3) Anileridine;
(4) Bezitramide;
(5) Bulk Dextropropoxyphene (nondosage form);
(6) Carfentanil;
(7) Dihydrocodeine;
(8) Diphenoxylate;
(9) Fentanyl;
(10) Glutethimide[1]
[(10)] (11) Isomethadone;
[(11)] (12) Levomethorphan;
[(12)] (13) Levorphanol;
[(13)] (14) Metazocine;
[(14)] (15) Methadone;
[(15)] (16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

[(16)] (17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
[(17)] (18) Pethidine;
[(18)] (19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
[(19)] (20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
[(20)] (21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
[(21)] (22) Phenazocine;
[(22)] (23) Piminodine;
[(23)] (24) Racemethorphan;
[(24)] (25) Racemorphan;
[(25)] (26) Sufentanil."

SECTION 8. Section 329-18, Hawaii Revised Statutes, is amended to read as follows:

"**§329-18 Schedule III.** (a) The controlled substances listed in this section are included in Schedule III.

(b) Stimulants. Unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including [its] their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation.

(1) Those compounds, mixtures, or [preparation] preparations in dosage unit form containing any stimulant substance listed in Schedule II, and any other drug of the quantitative composition or which is the same except that it contains a lesser quantity of controlled substances;
(2) Benzphetamine;
(3) Chlorphentermine;
(4) Clortermine;
(5) Mazindol;
(6) Phendimetrazine.

(c) Depressants. Unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;
(2) Any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;
(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof;
(4) Chlorexadol;
[(5) Glutethimide;]
[(6)] (5) Lysergic acid;
[(7)] (6) Lysergic acid amide;
[(8)] (7) Methyprylon;
[(9)] (8) Sulfondiethylmethane;
[(10)] (9) Sulfonethylmethane;
[(11)] (10) Sulfonmethane;
[(12)] (11) Tiletamine/Zolazepam (Telazol).

(d) Nalorphine.

(e) Any material, compound, mixture, or preparation containing limited quantities or any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) Not more than 300 milligrams of dihydrocodeinone, or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) Not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) Not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) The department of public safety may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) and (c) from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

(g) Any anabolic steroid. The term "anabolic steroid" means any drug or hormonal substance chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(1) Boldenone;

(2) Chlorotestosterone;

(3) Clostebol;

(4) Dehydrochlormethylestosterone;

(5) Dihydrotestosterone;

(6) Dromostanolone;

(7) Ethylestrenol;

(8) Fluoxymesterone;

(9) Formebolone;

(10) Mesterolone;
(11) Methandrenone;
(12) Methandranone;
(13) Methandriol;
(14) Methandrostenolone;
(15) Methenolone;
(16) Methyltestosterone;
(17) Mibolerone;
(18) Nandrolone;
(19) Norethandrolone;
(20) Oxandrolone;
(21) Oxymesterone;
(22) Oxymetholone;
(23) Stanolone;
(24) Stanozolol;
(25) Testolactone;
(26) Testosterone;
(27) Trenobolone;
(28) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

(h) Penalties applied to anabolic steroids as a Schedule III drug are not applicable to anabolic steroids that are expressly intended for administration through implants to cattle or other nonhuman species, and that are approved by the United States Food and Drug Administration for such use."

SECTION 9. Section 329-32, Hawaii Revised Statutes, is amended to read as follows:

"[[]§329-32[]] **Registration requirements.** (a) Every person who manufactures, distributes, prescribes, or dispenses any controlled substance within this State or who proposes to engage in the manufacture, distribution, prescription, or dispensing of any controlled substance within this State, must obtain annually a registration issued by the department of public safety in accordance with its rules. A licensed or registered health care professional acting as the authorized agent of a practitioner who administers controlled substances at the direction of a practitioner is not required to obtain a registration.

(b) Persons registered by the department of public safety under this chapter to manufacture, distribute, prescribe, dispense, store, or conduct research with controlled substances may possess, manufacture, distribute, prescribe, dispense, store, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this part.

(c) Except as otherwise provided, the following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any registered manufacturer, 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;
(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;
(3) An ultimate user or person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

(d) The department of public safety may waive by rule the requirement for registration or filing of certain manufacturers, distributors, prescribers, or dispensers if it is consistent with the public health and safety and if the department of public safety states the specific reasons for such waiver and the time period for which it is to be valid.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, prescribes, or dispenses controlled substances.

(f) The department of public safety may inspect the establishment of a registrant or applicant for registration in accordance with the department's rule."

SECTION 10. Section 329-38, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) No controlled substance in Schedule II may be dispensed without a written prescription of a practitioner, except:

(1) In an emergency situation, those drugs may be dispensed upon oral prescription of a practitioner, provided that promptly thereafter the prescription is reduced to writing by the practitioner and filed by the pharmacy; or

(2) When dispensed directly by a practitioner, other than a pharmacist, to the ultimate user. The practitioner in dispensing a controlled substance in Schedule II shall affix to the package a label showing the date of dispensing, the name, strength, and quantity issued of the drug, the dispensing practitioner's name and address, the name of the patient, the date the potency of the drug expires if that date is available from the manufacturer or principal labeler, directions for use, and cautionary statements, if any, contained in the prescription or as required by law. A complete and accurate record of all Schedule II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for two years. All Schedule II prescriptions shall be written by the practitioner in duplicate. Prescriptions and records of dispensing shall otherwise be retained in conformance with the requirements of section 329-36. No prescription for a controlled substance in Schedule II may be refilled."

SECTION 11. Section 329-38, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) No controlled substance in Schedule III or IV may be dispensed without a written or oral prescription of a practitioner, except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user. The practitioner in dispensing a controlled substance in Schedule III and IV shall affix to the package a label showing the date of dispensing, the name, strength, and quantity issued of the drug, the dispensing practitioner's name and address, the name of the patient, the date the potency of the drug expires if that date is available from the manufacturer or the principal labeler, directions for use, and cautionary statements, if any, contained in the prescription or as required by law. A complete and accurate record of all Schedule III, IV, and V controlled substances administered, prescribed, and dispensed shall be maintained for two years. Prescriptions and records of dispensing shall otherwise be retained in conformance with the requirements of section 329-36. [Those prescriptions] Prescriptions may not be

filled or refilled more than three months after the date thereof or be refilled more than two times after the date of the prescription unless renewed by the practitioner."

SECTION 12. Section 329-38, Hawaii Revised Statutes, is amended by amending subsection (e) to read as follows:

"(e) The effectiveness of a prescription for the purposes of this section shall be determined as follows:

(1) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of this section, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of the law relating to controlled substances[.];

(2) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients[.];

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment"[.]; and

(4) An individual practitioner may not prescribe or dispense a substance included in Schedule II, III, or IV for that individual practitioner's personal use except in a medical emergency."

SECTION 13. Section 329-40, Hawaii Revised Statutes, is amended to read as follows:

"[[]§329-40[]] **[Administration and dispensing of methadone in registered and approved treatment programs.]** **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 Food and Drug Administration approved methadone treatment program by a practitioner who is licensed and registered under state and federal law to administer, prescribe, 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 Federal Food and Drug Administration regulations and shall record, approve, and countersign all changes in dosage schedules.

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

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

(2) The medical director of a methadone treatment program obtain a controlled substance registration from the State of Hawaii and the Drug Enforcement Administration at the location of the program;

(3) Admission to a methadone treatment program be limited to the Narcotic Dependent Persons as defined in this chapter;

(4) Unless otherwise stated in this chapter, admission to a methadone treatment program be in accordance with 21 C.F.R. Part 291;

(5) All medical orders including initial medication orders, all subsequent medication order changes, all changes in the frequency of take-home medication, and the prescription of additional take-home medication for emergency situations be authorized by a licensed 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 21 C.F.R. Part 291; and

(7) Take-home doses of methadone be dispensed to patients in accordance with 21 C. F. R. Part 291.

The term "methadone treatment program" as used in this section means an organization or a person (including a private physician) that administers or dispenses methadone to a narcotic-dependent person for maintenance or detoxification treatment and who provides the medical and rehabilitative services required by 21 C.F.R. part 291 and is approved to do so by the State and by the United States Food and Drug Administration, and who holds a controlled substance registration as required by this chapter and the United States Drug Enforcement Administration to use methadone for the treatment of narcotic-dependent persons.

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

The term "State authority" as used in this section means the agency within the State which exercises the responsibility for governing the treatment of narcotic dependent persons with the narcotic drug methadone."

SECTION 14. Section 329-42, Hawaii Revised Statutes, is amended to read as follows:

"[[]§329-42[]] **Prohibited acts C-penalties.** (a) It is unlawful for any person knowingly or intentionally:

(1) To distribute as a registrant a controlled substance classified in Schedules I or II, except pursuant to an order form as required by section 329-37;

(2) To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;

(4) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter; [or]

(5) To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance[.]; or

(6) To misapply or divert to the person's own use or other unauthorized or illegal use or to take, make away with, or secrete, with intent to

misapply or divert to the person's own use or other unauthorized or illegal use, any controlled substance which shall have come into the person's possession or under the person's care as a registrant or as an employee of a registrant who is authorized to possess controlled substances or has access to controlled substances by virtue of the person's employment.

(b) Any person who violates this section is guilty of a [crime and upon conviction may be imprisoned for not more than five years, or fined not more than $5,000, or both.] class C felony."

SECTION 15. Section 329-45, Hawaii Revised Statutes is repealed.

SECTION 16. Statutory material to be repealed is bracketed. New statutory material is underscored.[2]

SECTION 17. This Act shall take effect upon its approval.

(Approved May 23, 1991.)

Notes

1. So in original.
2. Edited pursuant to HRS §23G-16.5.