ACT 186 S.B. NO. 1487

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 two new sections to part IV to be appropriately designated and to read as follows:

"**§329- Administrative penalties.** (a) Any person who violates this chapter or any rule adopted by the department pursuant to this chapter shall be fined not more than $10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action and the fine shall be deposited into the state general fund.

(b) The director may impose by order the administrative penalty specified in this section, in addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this chapter. Factors to be considered in imposing the administrative penalty include:

(1) The nature and history of the violation;
(2) Any prior violation; and
(3) The opportunity, difficulty, and history of corrective action.

For any judicial proceeding to recover the administrative penalty imposed, the administrator need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and the penalty remains unpaid.

§329- Injunctive relief. The administrator may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this chapter or any rule adopted to implement this chapter. The court shall have powers to grant relief in accordance with the Hawaii rules of civil procedure."

SECTION 2. Section 329-1, Hawaii Revised Statutes, is amended by adding two new definitions to be appropriately inserted and to read as follows:

""Designated member of the health care team" includes physician assistants, advanced practice registered nurses, and covering physicians who are authorized under state law to prescribe drugs.

"Physician-patient relationship" means the collaborative relationship between physicians and their patients. To establish this relationship, the treating physician or the physician's designated member of the health care team, at a minimum shall:

(1) Personally perform a face-to-face history and physical examination of the patient that is appropriate to the specialty training and experience of the physician or the designated member of the physician's health care team, make a diagnosis and formulate a therapeutic plan, or personally treat a specific injury or condition;
(2) Discuss with the patient the diagnosis or treatment, including the benefits of other treatment options; and
(3) Ensure the availability of appropriate follow-up care."

SECTION 3. Section 329-18, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) Depressants. Unless listed in another schedule, any material, compound, mixture, or preparation containing 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 that contains any quantity of a derivative of barbituric acid or any salt thereof, including the substance butalbital;

(4) Chlorhexadol;

(5) Embutramide (Tributame);

[~~(5)~~] (6) Ketamine, its salts, isomers, and salts of isomers, also known as (+ or -)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone;

[~~(6)~~] (7) Lysergic acid;

[~~(7)~~] (8) Lysergic acid amide;

[~~(8)~~] (9) Methyprylon;

[~~(9)~~] (10) Sulfondiethylmethane;

[~~(10)~~] (11) Sulfonethylmethane;

[~~(11)~~] (12) Sulfonmethane;

[~~(12)~~] (13) Tiletamine/Zolazepam (Telazol, 2-(ethylamino)-2-(-thienyl)-cyclohexanone, flupyrazapon) or any salts thereof; and

[~~(13)~~] (14) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers that are contained in a drug product for which an application has been approved under section 505 of the federal Food, Drug, and Cosmetic Act."

SECTION 4. Section 329-38, Hawaii Revised Statutes, is amended as follows:

1. By amending subsection (g) to read:

"(g) Prescriptions for controlled substances shall be issued only as follows:

(1) All prescriptions for controlled substances shall originate from within the [~~State~~] state and be dated as of, and signed on, the day when the prescriptions were issued and shall contain:

(A) The first and last name and address of the patient; and

(B) The drug name, strength, dosage form, quantity prescribed, and directions for use. Where a prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.

The controlled substance prescriptions shall be no larger than eight and one-half inches by eleven inches and no smaller than three inches by four inches. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to indicate the amount of controlled substance to be dispensed. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address, telephone number, and registration number of the practitioner. The prescriptions may be pre-

pared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner shall be responsible in case the prescription does not conform in all essential respects to this chapter and any rules adopted pursuant to this chapter. In receiving an oral prescription from a practitioner, a pharmacist shall promptly reduce the oral prescription to writing, which shall include the following information: the drug name, strength, dosage form, quantity prescribed in figures only, and directions for use; the date the oral prescription was received; the full name, DEA registration number, and oral code number of the practitioner; and the name and address of the person for whom the controlled substance was prescribed or the name of the owner of the animal for which the controlled substance was prescribed.

A corresponding liability shall rest upon a pharmacist who fills a prescription not prepared in the form prescribed by this section. A pharmacist may add a patient's missing address or change a patient's address on all controlled substance prescriptions after verifying the patient's identification and noting the identification number on the back of the prescription. The pharmacist shall not make changes to the patient's name, the controlled substance being prescribed, the quantity of the prescription, the practitioner's DEA number, or the practitioner's signature;

(2) An intern, resident, or foreign-trained physician, or a physician on the staff of a Department of Veterans Affairs facility or other facility serving veterans, exempted from registration under this chapter, shall include on all prescriptions issued by the physician:
   (A) The registration number of the hospital or other institution; and
   (B) The special internal code number assigned to the physician by the hospital or other institution in lieu of the registration number of the practitioner required by this section.

   The hospital or other institution shall forward a copy of this special internal code number list to the department as often as necessary to update the department with any additions or deletions. Failure to comply with this paragraph shall result in the suspension of that facility's privilege to fill controlled substance prescriptions at pharmacies outside of the hospital or other institution. Each written prescription shall have the name of the physician stamped, typed, or hand-printed on it, as well as the signature of the physician;

(3) An official exempted from registration shall include on all prescriptions issued by the official:
   (A) The official's branch of service or agency (e.g., "U.S. Army" or "Public Health Service"); and
   (B) The official's service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee shall be the employee's social security or other government issued identification number.

   Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer; and

(4) A physician assistant registered to prescribe controlled substances under the authorization of a supervising physician shall include on all controlled substance prescriptions issued:
   (A) The DEA registration number of the supervising physician; and
   (B) The DEA registration number of the physician assistant.

   Each written controlled substance prescription issued shall include the printed, stamped, typed, or hand-printed name, address, and phone

number of both the supervising physician and physician assistant, and shall be signed by the physician assistant. The medical record of each written controlled substance prescription issued by a physician assistant shall be reviewed and initialed by the physician assistant's supervising physician within seven working days."

2. By amending subections (j), (k), (l), and (m) to read as follows:

"(j) A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment; provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in [~~subsection~~] subsections (k), (l), [~~or~~] and (m). The original prescription shall be maintained in accordance with section 329-36. A prescription for a schedule III, IV, or V controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile; provided that:

(1) The information shall be communicated only between the prescribing practitioner or the prescriber's authorized agent and the pharmacy of the patient's choice[~~;~~]. The original prescription shall be maintained by the practitioner in accordance with section 329-36;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient and shall include the physician's oral code designation and the name of the recipient pharmacy;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval on a per prescription per order basis. Facsimile prescription information shall not be altered by any system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy;

(4) The prescription information processing system shall provide for confidentiality safeguards required by federal or state law; and

(5) Prescribing practitioners and pharmacists shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any facsimile prescription information. The facsimile shall serve as the original written prescription for purposes of this section and shall be maintained in accordance with section 329-36.

(k) A prescription prepared in accordance with subsection (g) written for a narcotic listed in schedule II to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, but does not extend to the dispensing of oral dosage units of controlled substances, may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red ink "Home Infusion/IV" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

(l) A prescription prepared in accordance with subsection (g) written for a schedule II substance for a patient enrolled in a hospice care program certified or paid for by medicare under Title XVIII or a hospice program that is licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The practitioner or practitioner's agent shall note on the prescription that the patient is a hospice patient. The pharmacist shall note on the face of the facsimile prescription in red ink "HOSPICE" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

(m) A prescription prepared in accordance with subsection (g) written for a schedule II controlled substance for a resident of a state-licensed long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red ink "LTCF" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36."

SECTION 5. Section 329-41, Hawaii Revised Statutes, is amended to read as follows:

"**§329-41 Prohibited acts B—penalties.** (a) It is unlawful for any person:

(1) Who is subject to part III to distribute, administer, prescribe, or dispense a controlled substance in violation of section 329-38[~~;~~] or rules authorized under section 329-31; however, a licensed manufacturer or wholesaler may sell or dispense a controlled substance to a master of a transpacific ship or a person in charge of a transpacific aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft when not in port; provided schedule I or II controlled substances shall be sold to the master of such ship or person in charge of such aircraft only in accordance with the provisions set forth in 21 Code of Federal Regulations, Sections 1301, 1305, and 1307, adopted pursuant to Title 21, United States Code, Section 821;

(2) Who is a registrant to manufacture a controlled substance not authorized by the registrant's registration or to distribute or dispense a controlled substance not authorized by the registrant's registration to another registrant or another authorized person;

(3) To refuse or fail to make available, keep, or furnish any record, notification, order form, prescription, statement, invoice, or information in patient charts relating to the administration, dispensing, or prescribing of controlled substances;

(4) To refuse any lawful entry into any premises for any inspection authorized by this chapter;

(5) Knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place for the purpose of using these substances or which is used for keeping or selling them in violation of this chapter or chapter 712, part IV; [~~or~~]

(6) Who is a practitioner or pharmacist to dispense a controlled substance to any individual not known to the practitioner or pharmacist, without first obtaining proper identification and documenting, by signature on a log book kept by the practitioner or pharmacist, the identity of and the type of identification presented by the individual obtaining the controlled substance. If the individual does not have any form of proper identification, the pharmacist shall verify the validity of the prescription and identity of the patient with the prescriber, or their authorized agent, before dispensing the controlled substance. For the purpose of this section, "proper identification" means government-issued identification containing the photograph, printed name, and signature of the individual obtaining the controlled substance[~~.~~];

(7) Who is a practitioner to predate or pre-sign prescriptions to facilitate the obtaining or attempted obtaining of controlled substances; or

(8) Who is a practitioner to facilitate the issuance or distribution of a written prescription or to issue an oral prescription for a controlled substance when not physically in the State.

(b) It shall be unlawful for any person subject to part III of this chapter except a pharmacist, to administer, prescribe, or dispense any controlled substance without a bona fide physician-patient relationship.

[~~(b)~~] (c) Any person who violates this section is guilty of a class C felony."

SECTION 6. Section 329-42, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) It is unlawful for any person knowingly or intentionally:

(1) To distribute as a registrant a controlled substance classified in schedule 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, administration, or prescribing of a controlled substance a registration number that is fictitious, revoked, suspended, expired, or issued to another person;

(3) To obtain or attempt to obtain any controlled substance or procure or attempt to procure the administration of any controlled substance:
   (A) By fraud, deceit, misrepresentation, embezzlement, theft;
   (B) By the forgery or alteration of a prescription or of any written order;
   (C) By furnishing fraudulent medical information or the concealment of a material fact;
   (D) By the use of a false name, patient identification number, or the giving of false address;
   (E) By the unauthorized use of a physician's oral call-in number; or
   (F) By the alteration of a prescription by the addition of future refills;

(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;

(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;

(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 that 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; or

(7) To make, distribute, possess, or sell any prescription form, whether blank, faxed, computer generated, photocopied, or reproduced in any other manner without the authorization of the licensed practitioner."

SECTION 7. Section 329-101, Hawaii Revised Statutes, is amended by amending subsection (f) to read as follows:

"(f) Intentional or knowing failure to transmit any information as required by this section shall be a misdemeanor[~~.~~] and shall result in the immediate suspension

of that pharmacy or practitioner's ability to dispense controlled substance in the state until authorized by the administrator."

SECTION 8. Section 329-102, Hawaii Revised Statutes, is amended by amending subsection (f) to read as follows:

"(f) All prescriptions for [~~schedule~~] controlled substances in schedules II through V and other controlled substances designated by the designated state agency that are processed by an out-of-state pharmacy shall conform to reporting and registration requirements adopted by the State, and to any additional rules the department adopts."

SECTION 9. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.[1]

SECTION 10. This Act shall take effect on July 1, 2008.

(Approved June 17, 2008.)

Note

1. Edited pursuant to HRS §23G-16.5.