ACT 280

S.B. NO. 846

A Bill for an Act Relating to Controlled Substances.

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

SECTION 1. Section 329-11, Hawaii Revised Statutes, is amended to read as follows:

"**§329-11 Authority to schedule controlled substances.** (a) Annually, upon the convening of each [annual] regular session of the state legislature, the department of public safety shall report to the legislature additions, deletions, or revisions in the schedules of substances[,] enumerated in sections 329-14, 329-16, 329-18, 329-20, and 329-22, and any other recommendations [which] that it deems necessary. [The] Three months prior to the convening of each regular session, the department of public safety shall [not recommend] post public notice, at the state capitol and in the office of the lieutenant governor for public inspection, of the department's recommendations to the legislature concerning any additions, deletions, or revisions in [such] these schedules [until after notice and an opportunity for a hearing is afforded all interested parties, except such hearing]; provided that the posting shall not be required if official notice has been received that the substance has been added, deleted, or rescheduled as a controlled substance under federal law. In making a determination regarding a substance, the department of public safety shall assess the degree of danger or probable danger of the substance by considering the following:

(1) The actual or probable abuse of the substance including:
    (A) Its history and current pattern of abuse;
    (B) The scope, duration, and significance of abuse; and
    (C) A judgment of the degree of actual or probable detriment [which] that may result from the abuse of the substance;
(2) The biomedical hazard of the substance including:
    (A) Its pharmacology: the effects and modifiers of effects of the substance;

(B) Its toxicology: the acute and chronic toxicity, interaction with other substances whether controlled or not, and liability to psychic or physiological dependence;
(C) Risk to public health and particular susceptibility of segments of the population; and
(D) Existence of therapeutic alternatives for substances [which] that are or may be used for medical purposes;
(3) A judgment of the probable physical and social impact of widespread abuse of the substance;
(4) Whether the substance is an immediate precursor of a substance already controlled under this part; and
(5) The current state of scientific knowledge regarding the substance.

(b) After considering the factors enumerated [above,] in subsection (a), the department of public safety shall make a recommendation to the legislature, specifying to what schedule the substance should be added, deleted, or rescheduled if it finds that the substance has a degree of danger or probable danger. The department of public safety may make [such] its recommendation to the legislature prior to the submission of its annual report, in which case the department of public safety shall publish and give notice to the public of [such] the recommendation.

(c) If the legislature designates a substance as an immediate precursor, substances [which] that are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If a substance is added, deleted, or rescheduled as a controlled substance under federal law and notice of the designation is given to the department of public safety, the department of public safety shall recommend that a corresponding change in Hawaii law be made. The department of public safety shall similarly designate the substance as added, deleted, or rescheduled under this chapter, after the expiration of thirty days from publication in the Federal Register of a final order, and [such] this change shall have the effect of law. If a substance is added, deleted, or rescheduled under this subsection, the control shall be temporary and, if the next regular session of the state legislature has not made the corresponding changes in this chapter, the temporary designation of the added, deleted, or rescheduled substance shall be nullified.

(e) The administrator may make an emergency scheduling by placing a substance into schedule I, II, III, IV, or V on a temporary basis, if the administrator determines the action is necessary to address or avoid a current or imminent danger to the health and safety of the public. If a substance is added or rescheduled under this subsection, the control shall be temporary and, if the next regular session of the state legislature has not enacted the corresponding changes in this chapter, the temporary designation of the added or rescheduled substance shall be nullified."

SECTION 2. Section 329-32, Hawaii Revised Statutes, is amended to read as follows:

"**§329-32 Registration requirements.** (a) Every person who:
(1) Manufactures, distributes, prescribes, or dispenses any controlled substance within this State;
(2) Proposes to engage in the manufacture, distribution, prescription, or dispensing of any controlled substance within this State; or
(3) Dispenses or proposes to dispense any controlled substance for use in this State by shipping, mailing, or otherwise delivering the controlled substance from a location outside this State;

shall obtain a registration issued by the department of public safety in accordance with the department's rules. A licensed or registered health care professional who

acts as the authorized agent of a practitioner and who administers controlled substances at the direction of the practitioner[,] shall not be 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 this part.

(c) Except as otherwise provided by law, the following persons shall not be required to 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 warehouser, or an employee thereof, whose possession of any controlled substance is in the usual course of the person's business or employment; and

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner.

(d) The department of public safety[, by rule,] may waive the registration or filing requirement for certain manufacturers, distributors, prescribers, or dispensers by rule if:

(1) It is consistent with the public health and safety; and

(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, 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.

(g) The department of public safety may require a registrant to submit [such] documents or written statements of fact relevant to a registration [as] that the department deems necessary to determine whether the registration should be granted or denied. The failure of the registrant to provide the documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the registrant of the opportunity to present the documents or statements for consideration by the department in granting or denying the 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."

SECTION 3. Section 329-38, Hawaii Revised Statutes, is amended to read as follows:

"**§329-38 Prescriptions.** (a) No controlled substance in [Schedule] 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] schedule II shall affix to the package a label showing [the]:

(A) The date of dispensing[, the];

(B) The name, strength, and quantity issued of the drug[, the];

(C) The dispensing practitioner's name and address[, the];

(D) The name of the patient[, the];

(E) The date the potency of the drug expires if that date is available from the manufacturer or principal labeler[, directions]; and[1]

(F) 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] schedule II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for two years. All [Schedule] 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] schedule II may be refilled.

(b) The transfer of original prescription information for a controlled substance listed in [Schedules] schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis, subject to the following requirements:

(1) The transfer shall be communicated directly between two licensed pharmacists, and the transferring pharmacist shall:

(A) Write or otherwise place the word "VOID" on the face of the invalidated prescription;

(B) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and

(C) Record the date of the transfer and the name of the pharmacist transferring the information;

(2) The pharmacist receiving the transferred prescription information shall:

(A) Write or otherwise place the word "transfer" on the face of the transferred prescription;

(B) Record all information required to be on a prescription, including:

(i) The date of issuance of original prescription;

(ii) The original number of refills authorized on original prescription;

(iii) The date of original dispensing;

(iv) The number of valid refills remaining and date of last refill;

(v) The pharmacy's name, address, DEA registration number, and original prescription number from which the prescription information was transferred; and

(vi) The name of transferor pharmacist;

(3) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill; and

(4) The procedure allowing the transfer of prescription information for refill purposes is permissible only between pharmacies located on the same island in this State.

Failure to comply with [the provisions of] this subsection shall void the authority of the pharmacy to transfer prescriptions or receive a transferred prescription to or from another pharmacy.

(c) No controlled substance in [Schedule] schedule III, IV, or V may be dispensed without a written or oral prescription of a practitioner, except when a controlled substance is dispensed directly by a practitioner, other than a pharmacist, to an ultimate user. The practitioner, in dispensing a controlled substance in [Schedule] schedule III, IV, or V, shall affix to the package a label showing:

(1) The date of dispensing;
(2) The name, strength, and quantity issued of the drug;
(3) The dispensing practitioner's name and business address;
(4) The name of the patient;
(5) The date the potency of the drug expires, if that date is available from the manufacturer or the principal labeler;
(6) Directions for use; and
(7) Cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all [Schedule] schedule III, IV, and V controlled substances administered, prescribed, and dispensed shall be maintained for two years. Prescriptions and records of dispensing shall be retained in conformance with the requirements of section 329-36 unless otherwise provided by law. Prescriptions may not be filled or refilled more than three months after the date of the prescription or be refilled more than two times after the date of the prescription, unless the prescription is renewed by the practitioner.

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

(1) A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or for legitimate and authorized research shall not be deemed a prescription within the meaning and intent of this section, and the person who knowingly fills such a purported prescription, as well as the person who issues the prescription, shall be subject to the penalties provided for violations of this chapter;
(2) A prescription may not be issued to allow 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 the purpose of "detoxification treatment" or "maintenance treatment"[; and]. Nothing in this section shall prohibit a physician or authorized hospital staff from administering or dispensing narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction; and
(4) An individual practitioner may not prescribe or dispense a substance included in [Schedule] schedule II, III, IV, or V for that individual practitioner's personal use, except in a medical emergency.

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

(1) All prescriptions for controlled substances shall be dated as of, and signed on, the day when the prescriptions were issued and shall bear [the]:
   (A) The full name and address of the patient[,]; and [the]
   (B) The name, address, and registration number of the practitioner.

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 by typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared 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. A corresponding liability shall rest upon a pharmacist who fills a prescription not prepared in the form prescribed by this section;

(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.

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

(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 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.

(f) A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

(g) Partial filling of controlled substance prescriptions shall be determined as follows:

(1) The partial filling of a prescription for a controlled substance listed in schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling; provided that if the remaining portion is not or cannot be filled within the seventy-two-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity shall be supplied beyond seventy-two hours without a new prescription; and

(2) The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible; provided that:

(A) Each partial filling is recorded in the same manner as a refilling;
(B) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;
(C) No dispensing occurs more than three months after the date on which the prescription was issued; and
(D) The prescription is refilled no more than two times after the initial date of the prescription, unless the prescription is renewed by the practitioner."

SECTION 4. 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 [Schedules] 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 of a controlled substance a registration number [which] that 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;
(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] 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, photo copied, or reproduced in any other manner without the authorization of the licensed practitioner."

SECTION 5. Section 329-54, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) A practitioner engaged in medical [practice or] research is not required or compelled to furnish the name or identity of a [patient or] research subject to the department of public safety, nor may the practitioner be compelled in any state or local civil, criminal, administrative, legislative, or other proceedings to furnish the name or identity of [an individual] any research subject that the practitioner is obligated to keep confidential."

SECTION 6. Section 329-101, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

''(c) The information required by this section shall be transmitted: on an electronic device that is compatible with the receiving device of the central repository; or by computer diskette, magnetic tape, or pharmacy universal claim form that meets the specifications provided in the rules of the designated state agency. [Effective no later than six months after June 18, 1996, the] The information to be transmitted under subsection (b) shall include at least the following for each dispensation:

(1) The patient's name;
(2) The patient's identification number;
(3) The patient's date of birth;
(4) The eight-digit national drug code number of the substance dispensed;
(5) The date of dispensation;
(6) The quantity and number of refills authorized;
(7) The practitioner's Drug Enforcement Administration registration number;
(8) The pharmacy's National Association of Boards of Pharmacy number and location; and
(9) The practitioner's practice specialty and subspecialties, as determined by the applicable licensure boards.''

SECTION 7. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun, before its effective date.

SECTION 8. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 9. This Act shall take effect upon its approval.

(Approved June 21, 1997.)

Note

1. Should be underscored.