ACT 268 H.B. NO. 2636

A Bill for an Act Relating to Controlled Substances.

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

SECTION 1. The legislature finds that:

(1) The inappropriate, nonmedical use of illicit prescription drugs is a serious public health concern;

(2) According to the 1990 National Household Survey on Drug Abuse, an estimated 8,500,000 people twelve years or older used controlled seda-

tives, tranquilizers, stimulants, or analgesics for nonmedical reasons at least once during the preceding year;

(3) According to the National Institute on Drug Abuse sponsored Drug Abuse Research Survey of drug treatment facilities around the country, of the principal drugs being abused, approximately ten per cent were drugs that may be prescribed;

(4) In fiscal year 1995-1996, the narcotics enforcement division of the department of public safety investigated five hundred and seventy-one reported cases directly related to pharmaceutical controlled substances;

(5) The Drug Enforcement Administration has estimated that the illegal diversion of legal controlled substances constitutes a $25,000,000,000 a year market;

(6) Drug use is straining the health care system. In 1993, almost 500,000 drug-related emergencies occurred across the nation;

(7) A federal health and human services inspector general has reported that roughly one out of sixteen seniors—between 1,500,000 and 2,000,000 people—are addicted or at risk of addiction to benzodiazapenes (i.e., tranquilizers such as Valium, Librium, Xanax, and Halcion). This addiction has been referred to as "America's other drug problem";

(8) It is the policy of this State that any retail monitoring system, in order not to impede the appropriate prescribing and use of prescription drugs, must not be unduly burdensome to prescribing physicians, and must fully protect the legitimate confidentiality concerns of patients; and

(9) A controlled substance electronic accountability prescription system will efficiently and effectively detect and reduce the use of retail prescription practices to obtain prescription drugs for improper purposes.

The purpose of this Act is to improve the State's ability to stop the illegal diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate prescribing of pain-killing and other prescription drugs and to ensure the full protection of patients' interest in preserving the confidentiality of sensitive medical information.

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

"**PART . ELECTRONIC PRESCRIPTION ACCOUNTABILITY SYSTEM**

§329-A Reporting of dispensation of controlled substances; electronic prescription accountability system; requirements; penalty. (a) A controlled substance electronic accountability prescription system shall be established within six months of the effective date of this part.

(b) The designated state agency shall determine those schedules of controlled substances, classes of controlled substances, and specific controlled substances that are purportedly being misused and abused in the State. No identified controlled substances may be dispensed unless information relevant to the dispensation of the substance is reported electronically or by universal claim form to the central repository established under section 329-B, in accordance with rules adopted by the department.

(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 the effective date of this part, 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 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.

(d) Under the system:

(1) Information shall be reported in numerical format, not less than once every seven days, on the filling of prescriptions for designated controlled substances and the dispensing of drug samples by a licensed practitioner; and
(2) Each dispenser shall maintain a record of such filled prescriptions, including all information described in subsection (c), for a period of two years. Each dispenser shall keep these records available for inspection and copying by the designated state agency.

(e) The system shall provide for the use of a central repository in accordance with section 329-B. The operation of the system shall be overseen by the designated state agency. The system shall include provisions to protect the confidentiality of information in the system, in accordance with section 329-D.

(f) Intentional or knowing failure to transmit any information as required by this section shall be a misdemeanor.

§329-B Central repository. (a) Except as provided in subsection (b), the transmittal of information under this section shall be made: through an electronic transmitting device that is compatible with the receiving device of the central repository; or by computer diskette, magnetic tape, or other appropriate electronic means that meets the specifications provided by rules of the designated state agency.

(b) The administrator may exempt individual dispensing entities from the electronic information reporting requirements of subsection (a) if:

(1) The imposition of the requirement would result in financial hardship for a particular pharmacy; and
(2) The pharmacy agrees to provide the information to the designated state agency through use of a pharmacy universal claim form.

(c) The administrator, in consultation with the state pharmacist membership organizations and applicable licensure boards, shall develop policies that account for the transmission of data fields in section 329-A that include unintentional data errors. Data errors collected by the designated state agency shall be presumed to be accidental in nature, unless a pattern of transmission errors occurs as determined by the agency.

(d) The system shall provide for the maintenance of information collected in a central repository that meets the following requirements:

(1) The central repository shall be a data processing system maintained by, or under contract with, the designated state agency. The system shall be capable of aggregating and displaying the collected information in

formats required by the designated state agency, including reports showing controlled substances by the:

(A) Practitioner's name, practice specialty and subspecialties, and identifying number or numbers as specified by the designated state agency, including the practitioner's Drug Enforcement Administration registration number;

(B) Pharmacy's name, National Association of Boards of Pharmacy number, and registration number;

(C) Patient's name, identification number, and date of birth; and

(D) Eight-digit national drug code number, frequency of use, quantity, number of refills, and whether new or refill prescription;

(2) The central repository shall provide the designated state agency with continual, twenty-four hour per day, on-line access to information;

(3) The central repository shall secure the information against access by unauthorized persons and shall be subject to review and oversight by the administrator or the administrator's designee, to ensure the security of the information and the system;

(4) If the central repository is not operated by the designated state agency, the vendor-repository:

(A) Shall provide information in response to the designated state agency's inquiries within twenty-four hours and shall provide routine reports on a regular schedule to be specified by the designated state agency; and

(B) Shall not withhold access to the collected information for any reason other than failure of the designated state agency to pay agreed fees and charges for the use of the central repository; and

(5) If the relationship between the designated state agency and the vendor-repository is terminated, the vendor-repository shall provide to the designated state agency within thirty days all collected information, the database maintained by the vendor-repository, and such software as is needed to access the information and the database.

(e) The administrator shall select the most overall cost-effective and efficient computerization system, and automatic data processing services and equipment, to ensure the successful implementation of the system. The administrator may enter into a contract with a vendor to implement the central repository. The repository may include an existing system, such as the State's medicaid management information system, or other existing computerization systems and automated data processing services available to the designated state agency.

(f) All prescriptions for schedule II 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.

§329-C Designated state agency. The designated state agency shall:

(1) Oversee and administer the collection of information under the system;

(2) Control access to the information in the system; and

(3) Produce exception reports as defined in section 329-1.

§329-D Confidentiality of information; disclosure of information. (a) The information collected under this part shall not be available to the public or used for any commercial purpose. Ownership of all data collected shall reside with the State.

(b) Responsibility for limiting access to information in the system is vested in the administrator. Access to the information collected at the central repository pursuant to this part shall be confidential, and access to the information shall be limited to:

(1) Personnel of the designated state agency; and

(2) The Drug Enforcement Administration diversion group supervisor.

(c) This section shall not prevent the disclosure, at the discretion of the administrator, of investigative information to: law enforcement officers; investigative agents of federal, state, or county law enforcement agencies; prosecuting attorneys; or the attorney general, in furtherance of criminal investigations or prosecutions within their respective jurisdictions; provided that the administrator has reasonable grounds to believe that the disclosure of any information collected under this part is in furtherance of an ongoing investigation.

(d) No person shall knowingly disclose or attempt to disclose, or use or attempt to use, information in the system in violation of this section. Any person who violates this section is guilty of a class C felony.

(e) The designated state agency shall purge or cause to be purged from the central repository system, no later than three years after the date a patient's prescription data are made available to the designated state agency, the identification number of the patient, unless the information is part of an active investigation."

SECTION 3. Chapter 329, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§329- Controlled substance registration revolving fund; established.** (a) There is established within the state treasury the controlled substance registration revolving fund. The fund shall be expended at the discretion of the director of public safety for the purpose of:

(1) Offsetting the cost of the electronic prescription accountability system and the registration and control of the manufacture, distribution, prescription, and dispensation of controlled substances within the State; and

(2) Funding positions authorized by the legislature by law.

(b) The fund shall consist of all moneys derived from fees collected pursuant to section 329-31 and legislative appropriations. All fees collected pursuant to section 329-31 shall be deposited in the controlled substance registration revolving fund."

SECTION 4. Section 329-1, Hawaii Revised Statutes, is amended by adding eight new definitions to be appropriately inserted and to read as follows:

"<u>"Administrator" means the administrator of the narcotics enforcement division of the department of public safety.</u>

<u>"Central repository" means a central repository established under section 329-B.</u>

<u>"Department" means the department of public safety.</u>

<u>"Designated state agency" means the narcotics enforcement division, department of public safety.</u>

<u>"Drug Enforcement Administration registration number" means the practitioner's Drug Enforcement Administration controlled substance registration number.</u>

<u>"Exception report" means an output of data indicating schedule II controlled substances dispensation that is outside expected norms for a practitioner</u>

practicing a particular specialty or field of health care, for a dispenser doing business in a particular location, or for a patient.

"Identification number" means, with respect to a patient:

(1) The unique, valid driver's license number of the patient, followed by the two-digit United States Postal Service code for the state issuing the driver's license or, if the patient is a foreign patient, the patient's passport number. If the patient does not have a driver's license, the "identification number" means the patient's social security number, followed by the patient's state of residency code. If the patient is less than eighteen years old and has no such identification, the identification number means the unique number contained on the valid driver's license of the patient's parent or guardian; or

(2) If the controlled substance is obtained for an animal, the unique number described in paragraph (1) of the animal's owner.

"System" means an electronic prescription accountability system as described in part ___."

SECTION 5. There is appropriated out of the controlled substance registration revolving fund established in section 3 the sum of $170,000 or so much thereof as may be necessary for fiscal year 1996-1997 to provide for two full-time equivalent (2.00 FTE) investigator V positions and other current expenses to carry out the purposes of this Act. The sum appropriated shall be expended by the department of public safety.

SECTION 6. In codifying the new part added to chapter 329, Hawaii Revised Statutes, by section 2 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in the designation of the new sections in this Act.

SECTION 7. New statutory material is underscored.[1]

SECTION 8. This Act shall take effect upon its approval; provided that section 5 shall take effect on July 1, 1996.

(Approved June 18, 1996.)

Note

1. Edited pursuant to HRS §23G-16.5.