H.B. NO. 2386

A BILL FOR AN ACT

RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

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

(1) By adding six new definitions to be appropriately inserted and to read as follows:

""Medical marijuana dispensary" shall have the same meaning as in section 329D-1.

"Medical marijuana production center" shall have the same meaning as in section 329D-1.

"Retail dispensing location" shall have the same meaning as in section 329D-1.

"Pharmacy delegate" means an individual employed by the pharmacy and selected by the pharmacist to act as that pharmacist's agent to whom the pharmacist has delegated the task of accessing electronic prescription accountability system information and that pharmacist takes full responsibility for the actions of that delegate.

"Practitioner delegate" means an agent or employee of a practitioner (physician, dentist, veterinarian, advanced practice registered nurse with prescriptive authority or Physician Assistant) to whom the practitioner has delegated the task of accessing electronic prescription accountability system information and that practitioner takes full responsibility for the actions of that delegate.

"Reverse distributor" means a registrant who is registered under section 329-32 to receive controlled substances acquired from another State certified controlled substance registrants for the purpose of:

(1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(2) Where necessary, processing such substances or arranging for processing such substances for disposal as authorized by the administrator."

(2) By amending the definitions of "dispense" and "locum tenens practitioner" 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[~~,~~] (of practitioner's controlled substances), 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.

"Locum tenens practitioner" means a practitioner[~~:~~ ~~(1)~~ ~~Who~~] who is licensed in this State and [~~registered under section 329-32 to administer, prescribe, or dispense a controlled substance in the course of professional practice,~~] who temporarily substitutes for another [~~registered~~] practitioner for a period not to exceed sixty days at that other practitioner's registered place of business[~~; and~~ ~~(2) Whose Drug Enforcement Administration controlled substance registration number has not been transferred to the State of Hawaii~~].

Locum tenens practitioners are not eligible to receive an oral code number as designated by section [~~+~~]328-16(k)[~~+~~]."

SECTION 2. Section 329-14, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

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

(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol (except levo-alphacetylmethadol, levomethadyl acetate, or LAAM);

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(9) Benzethidine;

(10) Betacetylmethadol;

(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

(12) Beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

(13) Betameprodine;

(14) Betamethadol;

(15) Betaprodine;

(16) Clonitazene;

(17) Dextromoramide;

(18) Diampromide;

(19) Diethylthiambutene;

(20) Difenoxin;

(21) Dimenoxadol;

(22) Dimepheptanol;

(23) Dimethylthiambutene;

(24) Dioxaphetyl butyrate;

(25) Dipipanone;

(26) Ethylmethylthiambutene;

(27) Etonitazene;

(28) Etoxeridine;

(29) Furethidine;

(30) Hydroxypethidine;

(31) Ketobemidone;

(32) Levomoramide;

(33) Levophenacylmorphan;

(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

(35) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(36) Morpheridine;

(37) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(38) Noracymethadol;

(39) Norlevorphanol;

(40) Normethadone;

(41) Norpipanone;

(42) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide;

(43) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine;

(44) Phenadoxone;

(45) Phenampromide;

(46) Phenomorphan;

(47) Phenoperidine;

(48) Piritramide;

(49) Proheptazine;

(50) Properidine;

(51) Propiram;

(52) Racemoramide;

(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

(54) Tilidine;

(55) Trimeperidine;

(56) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts, and salts of isomers; [~~and~~]

(57) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts, and salts of isomers[~~.~~]; and

(58) N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, (acetyl fentanyl) its optical, positional, and geometric isomers, salts and salts of isomers."

SECTION 3. Section 329-14, Hawaii Revised Statutes, is amended by amending subsection (g) to read as follows:

"(g) Any of the following cannabinoids, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Tetrahydrocannabinols; meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic

substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following: Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers; Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; and Delta 3,4 cis or trans-tetrahydrocannabinol, and its optical isomers (since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions, are covered);

(2) Naphthoylindoles; meaning any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl,cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(3) Naphthylmethylindoles; meaning any compound containing a 1H-indol-3-yl-(1-naphthyl) methane structure with substitution at the nitrogen atom of the indole ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl) ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(4) Naphthoylpyrroles; meaning any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent;

(5) Naphthylmethylindenes; meaning any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl)

ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent;

(6) Phenylacetylindoles; meaning any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl) ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent;

(7) Cyclohexylphenols; meaning any compound containing a 2-(3-hydroxycyclohexyl) phenol structure with substitution at the 5-position of the phenolic ring by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl) ethyl group whether or not substituted in the cyclohexyl ring to any extent;

(8) Benzoylindoles; meaning any compound containing a 3-(benzoyl) indole structure with substitution at the nitrogen atom of the indole ring by a alkyl, aloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-

methyl-2-piperidinyl) methyl or 2-(4-morpholinyl) ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent; and

(9) 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl) pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-napthalenylmethanone (another trade name is WIN 55,212-2);

(10) (6a,10a)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (other trade names are: HU-210/HU-211);

(11) Tetramethylcyclopropanoylindoles; meaning any compound containing a 3-tetramethylcyclopropanoylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, or tetrahydropyranylmethyl group, whether or not further substituted in the indole ring

to any extent and whether or not substituted in the tetramethylcyclopropyl ring to any extent.

(12) N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. (Other names: APINACA, AKB48);

(13) Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: PB-22; QUPIC);

(14) Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 5-fluoro-PB-22; 5F-PB-22);

(15) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: AB-FUBINACA);

(16) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ADB-PINACA);

(17) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its

optical, positional, and geometric isomers, salts and salts of isomers (Other names: AB-CHMINACA);

(18) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, and geometric isomers, salts and salts of isomers (Other names: AB-PINACA);

(19) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, and geometric isomers, salts and salts of isomers (Other names: THJ-2201);

(20) Methyl (1-(4-fluorobenzyl)-1 H-indazole-3-carbonyl)-L-valinate, and geometric isomers, salts and salts of isomers (Other names: FUB-AMB);

(21) (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, and geometric isomers, salts and salts of isomers (Other names: 5-fluoro-AMB, 5-fluoro-AMP);

(22) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, and geometric isomers, salts and salts of isomers (Other names: AKB48 N-(5-fluoropentyl) analog, 5F-AKB48, APINACA 5-fluoropentyl analog, 5F-APINACA);

(23) N-adamantyl-1-fluoropentylindole-3-Carboxamide, and geometric isomers, salts and salts of isomers (Other names: STS-135, 5F-APICA; 5-fluoro-APICA); [~~and~~]

(24) Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, and geometric isomers, salts and salts of isomers (Other names: NM2201)[~~.~~]; and

(25) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, and geometric isomers, salts and salts of isomers (Other names: MAB-CHMINACA and ADB-CHMINACA)."

SECTION 4. Section 329-20, Hawaii Revised Statutes, is amended by amending subsection (e) to read as follows:

"(e) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its [~~salts: Pentazocine.~~] optical isomers and its salts, isomers, and salts of isomers:

(1) Pentazocine; and

(2) Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid."

SECTION 5. Section 329-23, Hawaii Revised Statutes, is amended to read as follows:

"**§329-23 Republishing** [~~**and distribution**~~] **of schedules.** [~~(a)~~] The department of public safety shall [~~republish~~] make available to the public on the department's website the schedules annually or more often, as may be necessary to update the schedules.

[~~(b) The department of public safety shall publicly announce and, in addition, shall make available to the public copies of any changes to the schedules as such changes are made.~~]"

SECTION 6. Section 329-31, Hawaii Revised Statutes, is amended to read as follows:

"**§329-31 Rules.** The department of public safety may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, [~~prescription, and~~] prescribing, dispensing [~~of~~], storage, conducting research, reverse distribution, or chemical analysis with controlled substances within this State."

SECTION 7. 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, stores, conducts research, conducts reverse distribution, or chemical analysis with any controlled substance within this State;

(2) Proposes to engage in the manufacture, distribution, prescription, [~~or~~] dispensing, storage, research, reverse distribution, or chemical analysis 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, conduct reverse distribution, or chemical analysis with controlled substances may possess, manufacture, distribute, prescribe, dispense, store, [~~or~~] conduct research, or chemical analysis 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 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, stores, conducts research, conducts reverse distribution, or chemical analysis with controlled substances, except an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(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 documents or written statements of fact relevant to a registration 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 8. Section 329-33, Hawaii Revised Statutes, is amended to read as follows:

"**§329-33 Registration.** (a) The department of public safety shall register an applicant to manufacture, dispense, prescribe, [~~or~~] distribute, store, conduct research, conduct reverse distribution, or chemical analysis with controlled substances included in sections 329-14, 329-16, 329-18, 329-20, and 329-22 unless it determines that the issuance of that

registration would be inconsistent with the public interest. In determining the public interest, the department of public safety shall consider the following factors:

(1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable state and local law;

(3) Any convictions of the applicant under any federal and state laws relating to any controlled substance;

(4) Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

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

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

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

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

(c) Practitioners must be registered to dispense or to prescribe any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or to prescribe or conduct research under the law of this State. The department of public safety need not require separate registration under this part for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this part in another capacity. [~~Practitioners registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this State upon furnishing the department of public safety evidence of that federal registration.~~]

(d) Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this chapter."

SECTION 9. Section 329-34, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) A registration under section 329-33 to manufacture, distribute, [~~or~~] dispense, store, conduct research, conduct reverse distribution, or chemical analysis with a controlled substance may be suspended or revoked by the department of public safety upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this chapter;

(2) Has been convicted of a felony or has been granted a motion for the deferral of acceptance of a guilty plea or a nolo contendere plea to a felony, pursuant to chapter 853 and under any state or federal law relating to any controlled substance;

(3) Has had the registrant's federal registration suspended or revoked to manufacture, distribute, prescribe, [~~or~~] dispense, store, conduct research, conduct reverse distribution, or chemical analysis with controlled substances; or

(4) Has had the registrant's state license to practice the registrant's profession suspended or revoked by the applicable governing state board."

SECTION 10. Section 329-36, Hawaii Revised Statutes, is amended to read as follows:

"§329-36 **Records of registrants.** Persons registered to manufacture, distribute, prescribe, [~~or~~] dispense, store, conduct research, conduct reverse distribution, or chemical analysis with controlled substances under this chapter shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with any additional rules the department of public safety issues."

SECTION 11. Section 329-37, Hawaii Revised Statutes, is amended to read as follows:

"§329-37 **Filing requirements.** All persons registered to manufacture, distribute, conduct reverse distribution or dispense controlled substances and all persons who transport, warehouse, or otherwise handle controlled substances, shall file with the department of public safety on forms and within the time and manner prescribed by the department of public safety, copies of order, receipt and distribution of schedule I and schedule II controlled substances and other controlled substances designated by the department of public safety, showing the amounts of such controlled substances ordered, received, distributed, transported, warehoused, or otherwise handled."

SECTION 12. 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 the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization from a prescribing practitioner; provided that:

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner);

(B) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the prescribing practitioner using the phone number

in the telephone directory or other good faith efforts to identify the prescriber; and

(C) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this subsection, the prescription shall have written on its face "Authorization for Emergency Dispensing". The written prescription may be delivered to the pharmacist in person or by mail, and if by mail, the prescription shall be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the administrator if the prescribing practitioner fails to deliver a written prescription to the pharmacy within the allotted time. Failure of the pharmacist to do so shall void the authority

conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. Any practitioner who fails to deliver a written prescription within the seven-day period shall be in violation of section 329-41(a)(1);

(2) No schedule II narcotic controlled substance may be prescribed or dispensed for more than a thirty-day supply;

[~~(2)~~] (3) 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:

(A) The date of dispensing;

(B) The name, strength, and quantity of the drug dispensed;

(C) The dispensing practitioner's name and address;

(D) The name of the patient;

(E) The "use by" date for the drug, which shall be:

(i) The expiration date on the manufacturer's or principal labeler's container; or

(ii) One year from the date the drug is dispensed, whichever is earlier; and

(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 II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for five years. 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; or

(3) In the case of an electronic prescription, a pharmacist may dispense a controlled substance listed in schedule II upon receiving an electronic prescription."

SECTION 13. Section 329-49, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(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.~~] controlled substance registration revolving fund pursuant to section 329-59."

SECTION 14. Section 329-52, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) For purposes of this section, "controlled premises" means:

(1) Places where persons registered or exempted from registration requirements under this chapter are required to keep records; and

(2) Places, including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this chapter are permitted to hold, manufacture, compound, process, sell, dispense, deliver, conduct chemical analysis or otherwise dispose of any controlled substance or regulated chemical designated under section 329-61."

SECTION 15. Section 329-54, Hawaii Revised Statutes, is amended by amending subsection (c) to read as follows:

"(c) A practitioner engaged in medical research is not required or compelled to furnish the name or identity of a 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 any research subject that the practitioner is obligated to keep confidential[~~.~~] unless the subject violates sections 329-41 or 329-46 or commits an offense pursuant to part IV of chapter 712."

SECTION 16. Section 329-59, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) The fund shall consist of all moneys derived from fees collected pursuant to sections 329-31 and 329-67 [~~and~~]~~,~~ legislative appropriations[~~.~~], and fines collected pursuant to section 329-49. All fees collected pursuant to sections 329-31 and 329-67 and fines collected pursuant to section 329-49 shall be deposited in the controlled substance registration revolving fund."

SECTION 17. Section 329-74, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) A person commits the offense of unlawful transport of pseudoephedrine if the person transports more than three

packages of any product the sale of which is restricted by section 329-75 [~~without a permit issued from the department~~]."

SECTION 18. Section 329-101, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(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. As part of the controlled substance registration process all practitioners and pharmacies shall be registered with the department to utilize the electronic prescription accountability system. No identified controlled substances may be dispensed unless information relevant to the dispensation of the substance is reported electronically or by means indicated by the designated state agency to the central repository established under section 329-102, in accordance with rules adopted by the department."

SECTION 19. Section 329-104, Hawaii Revised Statutes, is amended to read as follows:

"**§329-104 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 personnel of the designated state agency.

(c) This section shall not prevent the disclosure, at the discretion of the administrator, of investigative information to:

(1) Law enforcement officers, investigative agents of federal, state, or county law enforcement or regulatory agencies, United States attorneys, county prosecuting attorneys, or the attorney general; 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 criminal or regulatory investigation or prosecution;

(2) Registrants authorized under chapters 448, 453, and 463E who are registered to administer, prescribe, or dispense controlled substances and their practitioner

delegate; provided that the information disclosed relates only to the registrant's own patient;

(3) Pharmacists[~~,~~] or pharmacist delegates, employed by a pharmacy registered under section 329-32, who request prescription information about a customer relating to a violation or possible violation of this chapter; [~~or~~]

(4) Other state-authorized governmental prescription-monitoring programs[~~.~~];

(5) The chief medical examiner or licensed physician designee who requests information and certifies the request is for the purpose of investigating the death of an individual;

(6) Qualified personnel for the purpose of bona fide research or education; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser must be deleted or redacted from such information prior to disclosure; and further provided that, release of the information may be made only pursuant to a written agreement between qualified personnel and the administrator in order to ensure compliance with this subsection; and

(7) Other entities or individuals authorized by the Administrator to assist the program with projects that enhance the prescription accountability system.

Information disclosed to a registrant, pharmacist, or authorized government agency under this section shall be transmitted by a secure means determined by the designated agency.

(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 five 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 20. Section 329-31.5, Hawaii Revised Statutes, is repealed.

~~["**§329-31.5 Clinics.** Registration as a clinic is required when an out-patient 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 five 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 shall 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 21. Section 329-73, Hawaii Revised Statutes, is repealed.

["~~**[§329-73] Pseudoephedrine permit.** (a) Beginning January 1, 2006, any person transporting by any means more than three packages of any product the sale of which is restricted by section 329-75 shall obtain a pseudoephedrine permit.~~

~~(b) The requirements imposed by [subsection] (a) shall not apply to persons registered with the department under section 329-67. A pseudoephedrine permit shall be issued by the department in a form and manner as prescribed by the department by rule. A pseudoephedrine permit shall be valid for one year and renewable annually.~~"]

SECTION 22. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 23. This Act shall take effect upon its approval.

H.B. NO. 2386

INTRODUCED BY: _____

BY REQUEST

JAN 2 5 2016

H.B. NO. 2386

Report Title:
Uniform Controlled Substances Act

Description:
Updates chapter 329, Hawaii Revised Statutes, to make it consistent with amendments in federal controlled substances law as required under section 329-11; amends section 329-1 to clarify existing definitions to be consistent with Federal controlled substance law; deletes definitions no longer utilized under federal law; adds new definitions to allow the use of "delegates" by practitioners and pharmacists to access the electronic prescription accountability system; clarify that individuals storing, conducting research, reverse distribution and analytical analysis with controlled substances must register with the Department and follow appropriate controlled substance statutes and rules; amend 329-23 to take advantage of technology in the posting of updates to Hawaii's drug schedules on the department's website; amend section 329-38 to be consistent with Federal limitations on the prescribing of Schedule II narcotic controlled substances; mandate that the collections of fines under section 329-49 be deposited into the State controlled substance registration revolving fund under section 329-59 to support the program; delete the requirement for a pseudoephedrine permit for transporting over 3 grams of pseudoephedrine as required under sections 329-73 and 329-74; amends chapter 329, part VIII ELECTRONIC PRESCRIPTION ACCOUNTABILITY SYSTEM, Hawaii Revised Statutes, by adding language to mandate the requirement that all practitioners and pharmacies register to utilize the electronic prescription accountability system when they obtain a controlled substance registration; authorize the Department of Public Safety Narcotics Enforcement Division Administrator to allow access to state, county, or federal regulatory agencies to the database when conducting joint regulatory investigations.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

HB 2386

JUSTIFICATION SHEET

DEPARTMENT: Public Safety

TITLE: A BILL FOR AN ACT RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

PURPOSE: Updates chapter 329, Hawaii Revised Statutes (HRS), to make it consistent with amendments in federal controlled substances law as required under section 329-11; amends section 329-1 to clarify existing definitions to be consistent with Federal controlled substance law and add new definitions under section 329D; deletes definitions no longer utilized under federal law; adds new definitions to allow the use of "delegates" by practitioners and pharmacist to access the electronic prescription accountability system; clarify that individuals storing, conducting research, reverse distribution and analytical analysis with controlled substances must register with the Department and follow appropriate controlled substance statutes and rules; amend 329-23 to take advantage of technology in the posting of updates to Hawaii's drug schedules on the department's website; amend section 329-38 to be consistent with Federal limitations on the prescribing of Schedule II narcotic controlled substances; mandate that the collections of fines under section 329-49 be deposited into the State controlled substance registration revolving fund under section 329-59 to support the program; delete the requirement for a pseudoephedrine permit for transporting over 3 grams of pseudoephedrine as required under sections 329-73 and 329-74; amends sections 329-101 and 329-104, relating to Hawaii's Electronic Prescription Accountability System, by adding language to authorize the Department of Public Safety Narcotics Enforcement Division Administrator to allow access to State, County or Federal regulatory Agencies to the database when conducting joint regulatory investigations.

MEANS: Amend sections 329-1, 329-14(b) and (g), 329-20(e), 329-23, 329-31, 329-32, 329-33, 329-34(a), 329-36, 329-37, 328-38(a), 329-49(a), 329-52(c), 329-54(c), 329-59(b), 329-74(a), 329-101(b), and 329-104, HRS, and repeal sections 329-31.5 and 329-73, HRS.

JUSTIFICATION: Proposed amendments to chapter 329, HRS, will accomplish the following:

(1) Update Hawaii's Uniform Controlled Substance Act, chapter 329, HRS, with changes made to the Federal Controlled Substance Act, Federal Register Volume 80, Number 137 FR Doc No: 2015-17563, by adding N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, (acetyl fentanyl) its optical, positional, and geometric isomers, salts and salts of isomers to schedule I in accordance with section 329-11(d), HRS.

(2) Update Hawaii's Uniform Controlled Substances Act, chapter 329, HRS, with changes made to the Federal Controlled Substance Act, Federal Register Volume 80, Number 179 FR Doc No: 2015-23198, by adding N-(1-amino-3,3-demethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric simoers, salts and salts of isomers-7032 (Other names: MAB-CHIMINACA; ADB-CHMINACA) to schedule I in accordance with section 329-11(d), HRS.

(3) Update Hawaii's Uniform Controlled Substances Act, chapter 329 HRS, with changes made to the Federal Controlled Substance Act, Federal Register Volume 80, Number 154 FR Doc No: 2015-19655, by adding the drug classified as other substances Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid to schedule IV as required by section 329-11(d) HRS.

(4) Update Hawaii's Uniform Controlled Substances Act to be consistent with Federal law by adding and deleting definitions to sections 329-1, 329-31, 329-31.5, 329-32, 329-33, 329-34,329-36, 329-37 and 329-52 to clarify that registrants that manufacture, distribute, prescribe, dispense, store, reverse distribute, conduct research, or chemical analysis with controlled substances. This bill also proposes to add the definition of practitioner and pharmacist "delegates" to increase access to NED's electronic prescription accountability system.

(5) This bill also proposes to add the definitions of "medical marijuana dispensary", "medical marijuana production center", and "retail dispensing location" in accordance with section 329D-1. Section 329-33 is also amended to include the requirement of obtaining licensure from the Department of Health under sections 329D-2 and 329D-8 prior to applying for controlled substance certification.

(6) Amends section 329-23(a), HRS, by clarifying that the department would make available to the public an electronic copy of the controlled substance schedules on its website.

(7) Amends section 329-38 (a) by adding language to limit the quantity of schedule II narcotic controlled substance prescriptions to a thirty-day supply due to the abuse and over prescribing of these drugs. Presently Hawaii does not have a quantity limit on schedule II drugs unlike some of the other states and many insurance carriers that have already implemented limits on the quantity of controlled substance dispensed to a 30-day supply.

(8) Amends section 329-49 to transfer the deposit of the funds collected from administrative fines of registrants to the controlled substance registration revolving fund under section 329-59. These funds will be utilized to pay for compliance inspections, investigations and prevention programs for controlled substance registrants.

(9) Deletes section 329-73 and amends section 329-74 relating to Pseudoephedrine permits. Since the inception of this law in 2006 the NED has not issued a single pseudoephedrine permit for persons transporting pseudoephedrine in excess of 3 grams. Most retailers or registrants are already in possession of a regulated chemical permit. Section 329-73 is not necessary and should be deleted.

(10) Amends section 329-101 to require that as part of NED's controlled substance registration program that all registrants requesting a controlled substance certification shall register for to access the electronic prescription accountability system.

(11) Amends section 328-104 relating to Hawaii's Electronic Prescription Accountability System, by adding language to authorize the NED Administrator to allow access to State, County or Federal regulatory Agencies conducting joint regulatory investigations with NED, pharmacist and practitioner delegates, chief medical examiner, researchers (limited access) and other entities authorized by the NED Administrator.

Impact on the public: This bill is intended to protect the public by updating Hawaii's controlled substance schedules with that of Federal law.

Impact on the department and other agencies: These proposed amendments would assist the Department's Narcotics Enforcement Division in clarifying regulations of the Uniform Controlled Substances Act.

GENERAL FUND: None.

OTHER FUNDS: None.

PPBS PROGRAM DESIGNATION: PSD 502.

OTHER AFFECTED AGENCIES: Department of Health Food and Drug Branch, Federal State and County law enforcement.

EFFECTIVE DATE: Upon approval.