

JAN 25 2010

A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

1 SECTION 1. Section 329-14, Hawaii Revised Statutes, is
2 amended by amending subsection (d) to read as follows:

3 "(d) Any material, compound, mixture, or preparation that
4 contains any quantity of the following hallucinogenic
5 substances, their salts, isomers, and salts of isomers, unless
6 specifically excepted, whenever the existence of these salts,
7 isomers, and salts of isomers is possible within the specific
8 chemical designation:

- 9 (1) Alpha-ethyltryptamine (AET);
10 (2) 2,5-dimethoxy-4-ethylamphetamine (DOET);
11 (3) 2,5-dimethoxyamphetamine (2,5-DMA);
12 (4) 3,4-methylenedioxy amphetamine;
13 (5) 3,4-methylenedioxymethamphetamine (MDMA);
14 (6) N-hydroxy-3,4-methylenedioxyamphetamine (N-hydroxy-
15 MDA);
16 (7) 3,4-methylenedioxy-N-ethylamphetamine (MDE);
17 (8) 5-methoxy-3,4-methylenedioxy-amphetamine;
18 (9) 4-bromo-2,5-dimethoxy-amphetamine (4-bromo-2,5-DMA);

- 1 (10) 4-Bromo-2,5-dimethoxyphenethylamine (Nexus);
- 2 (11) 3,4,5-trimethoxy amphetamine;
- 3 (12) Bufotenine;
- 4 (13) 4-methoxyamphetamine (PMA);
- 5 (14) Diethyltryptamine;
- 6 (15) Dimethyltryptamine;
- 7 (16) 4-methyl-2,5-dimethoxy-amphetamine;
- 8 (17) Gamma hydroxybutyrate (GHB) (some other names include
- 9 gamma hydroxybutyric acid; 4-hydroxybutyrate; 4-
- 10 hydroxybutanoic acid; sodium oxybate; sodium
- 11 oxybutyrate);
- 12 (18) Ibogaine;
- 13 (19) Lysergic acid diethylamide;
- 14 (20) Marijuana;
- 15 (21) Parahexyl;
- 16 (22) Mescaline;
- 17 (23) Peyote;
- 18 (24) N-ethyl-3-piperidyl benzilate;
- 19 (25) N-methyl-3-piperidyl benzilate;
- 20 (26) Psilocybin;
- 21 (27) Psilocyn;
- 22 (28) 1-[1-(2-Thienyl) cyclohexyl] Pyrrolidine (TCPy);

- 1 (29) Tetrahydrocannabinols;
- 2 (30) Ethylamine analog of phencyclidine (PCE);
- 3 (31) Pyrrolidine analog of phencyclidine (PCPy, PHP);
- 4 (32) Thiophene analog of phencyclidine (TCP; TCP);
- 5 (33) Gamma-butyrolactone, including butyrolactone;
- 6 butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone
- 7 dihydro; dihydro-2(3H)-furanone; tetrahydro-2-
- 8 furanone; 1,2-butanolide; 1,4-butanolide; 4-
- 9 butanolide; gamma-hydroxybutyric acid lactone; 3-
- 10 hydroxybutyric acid lactone and 4-hydroxybutanoic acid
- 11 lactone with Chemical Abstract Service number 96-48-0
- 12 when any such substance is intended for human
- 13 ingestion;
- 14 (34) 1,4 butanediol, including butanediol; butane-1,4-diol;
- 15 1,4- butylenes glycol; butylene glycol; 1,4-
- 16 dihydroxybutane; 1,4- tetramethylene glycol;
- 17 tetramethylene glycol; tetramethylene 1,4- diol with
- 18 Chemical Abstract Service number 110-63-4 when any
- 19 such substance is intended for human ingestion;
- 20 (35) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7),
- 21 its optical isomers, salts, and salts of isomers;

- 1 (36) N-benzylpiperazine (BZP; 1-benzylpiperazine) its
2 optical isomers, salts, and salts of isomers;
- 3 (37) 1-(3-trifluoromethylphenyl)piperazine (TFMPP), its
4 optical isomers, salts, and salts of isomers;
- 5 (38) Alpha-methyltryptamine (AMT), its isomers, salts, and
6 salts of isomers; [~~and~~]
- 7 (39) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT), its
8 isomers, salts, and salts of isomers[-];
- 9 (40) Salvia divinorum;
- 10 (41) Salvinorin A; and
- 11 (42) Divinorin A."

12 SECTION 2. Section 329-16, Hawaii Revised Statutes, is
13 amended by amending subsection (c) to read as follows:

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

- 18 (1) Alfentanil;
- 19 (2) Alphaprodine;
- 20 (3) Anileridine;
- 21 (4) Bezitramide;
- 22 (5) Bulk Dextropropoxyphene (nondosage form);

- 1 (6) Carfentanil;
- 2 (7) Dihydrocodeine;
- 3 (8) Diphenoxylate;
- 4 (9) Fentanyl;
- 5 (10) Isomethadone;
- 6 (11) Levo-alphaacetylmethadol (LAAM);
- 7 (12) Levomethorphan;
- 8 (13) Levorphanol;
- 9 (14) Metazocine;
- 10 (15) Methadone;
- 11 (16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-
- 12 dphenyl butane;
- 13 (17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-
- 14 diphenyl-propane-carboxylic acid;
- 15 (18) Pethidine (Meperidine);
- 16 (19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-
- 17 phenylpiperidine;
- 18 (20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-
- 19 carboxylate;
- 20 (21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-
- 21 4-carboxylic acid;
- 22 (22) Phenazocine;

- 1 (23) Piminodine;
- 2 (24) Racemethorphan;
- 3 (25) Racemorphan;
- 4 (26) Remifentanil; [~~and~~]
- 5 (27) Sufentanil [~~-~~]; and
- 6 (28) Tapentadol."

7 SECTION 3. Section 329-20, Hawaii Revised Statutes, is
8 amended by amending subsection (b) to read as follows:

9 "(b) Depressants. Any material, compound, mixture, or
10 preparation which contains any quantity of the following
11 substances, including its salts, isomers, esters, ethers, and
12 salts of isomers, whenever the existence of these isomers,
13 esters, ethers, and salts is possible within the specific
14 chemical designation, that has a degree of danger or probable
15 danger associated with a depressant effect on the central
16 nervous system:

- 17 (1) Alprazolam;
- 18 (2) Barbital;
- 19 (3) Bromazepam;
- 20 (4) Butorphanol;
- 21 (5) Camazepam;
- 22 (6) Carisoprodol;

- 1 (7) Chloral betaine;
- 2 (8) Chloral hydrate;
- 3 (9) Chlordiazepoxide;
- 4 (10) Clobazam;
- 5 (11) Clonazepam;
- 6 (12) Clorazepate;
- 7 (13) Clotiazepam;
- 8 (14) Cloxazolam;
- 9 (15) Delorazepam;
- 10 (16) Dichloralphenazone (Midrin);
- 11 (17) Diazepam;
- 12 (18) Estazolam;
- 13 (19) Ethchlorvynol;
- 14 (20) Ethinamate;
- 15 (21) Ethyl loflazepate;
- 16 (22) Fludiazepam;
- 17 (23) Flunitrazepam;
- 18 (24) Flurazepam;
- 19 (25) Fospropofol (Lusedra);
- 20 [~~25~~] (26) Halazepam;
- 21 [~~26~~] (27) Haloxazolam;
- 22 [~~27~~] (28) Ketazolam;

- 1 [~~(28)~~] (29) Loprazolam;
- 2 [~~(29)~~] (30) Lorazepam;
- 3 [~~(30)~~] (31) Lormetazepam;
- 4 [~~(31)~~] (32) Mebutamate;
- 5 [~~(32)~~] (33) Medazepam;
- 6 [~~(33)~~] (34) Meprobamate;
- 7 [~~(34)~~] (35) Methohexital;
- 8 [~~(35)~~] (36) Methylphenobarbital (mephobarbital);
- 9 [~~(36)~~] (37) Midazolam;
- 10 [~~(37)~~] (38) Nimetazepam;
- 11 [~~(38)~~] (39) Nitrazepam;
- 12 [~~(39)~~] (40) Nordiazepam;
- 13 [~~(40)~~] (41) Oxazepam;
- 14 [~~(41)~~] (42) Oxazolam;
- 15 [~~(42)~~] (43) Paraldehyde;
- 16 [~~(43)~~] (44) Petrichloral;
- 17 [~~(44)~~] (45) Phenobarbital;
- 18 [~~(45)~~] (46) Pinazepam;
- 19 [~~(46)~~] (47) Prazepam;
- 20 [~~(47)~~] (48) Quazepam;
- 21 [~~(48)~~] (49) Temazepam;
- 22 [~~(49)~~] (50) Tetrazepam;

- 1 [~~(50)~~] (51) Triazolam;
- 2 [~~(51)~~] (52) Zaleplon;
- 3 [~~(52)~~] (53) Zolpidem; and
- 4 [~~(53)~~] (54) Zopiclone (Lunesta)."

5 SECTION 4. Section 329-22, Hawaii Revised Statutes, is
6 amended by amending subsection (d) to read as follows:

7 "(d) Depressants. Unless specifically exempted or excluded
8 or unless listed in another schedule, any material, compound,
9 mixture, or preparation that contains any quantity of the
10 following substances having a depressant effect on the central
11 nervous system, including its salts, isomers, and salts of
12 isomers:

13 (1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-
14 propionamide], (Vimpat); and

15 [~~(1)~~] (2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic
16 acid]."

17 SECTION 5. Section 329-35, Hawaii Revised Statutes, is
18 amended to read as follows:

19 "**§329-35 Order to show cause.** (a) [~~Before denying,~~
20 ~~suspending, or revoking a registration, or refusing a renewal of~~
21 ~~registration, the department of public safety shall serve upon~~
22 ~~the applicant or registrant an order to show cause why~~

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1 ~~registration should not be denied, revoked, or suspended, or why~~
2 ~~the renewal should not be refused. The order to show cause~~
3 ~~shall contain a statement of the basis therefor and shall call~~
4 ~~upon the applicant or registrant to appear before the department~~
5 ~~of public safety at a time and place not less than thirty days~~
6 ~~after the date of service of the order, but in the case of a~~
7 ~~denial or renewal of registration the show cause order shall be~~
8 ~~served not later than thirty days before the expiration of the~~
9 ~~registration. These proceedings shall be conducted in~~
10 ~~accordance with chapter 91 without regard to any criminal~~
11 ~~prosecution or other proceeding. Proceedings to refuse renewal~~
12 ~~of registration shall not abate the existing registration which~~
13 ~~shall remain in effect pending the outcome of the administrative~~
14 ~~hearing.] If, upon examination of the application for~~
15 ~~registration from any applicant and other information gathered~~
16 ~~by the department regarding the applicant, the administrator is~~
17 ~~unable to make the determinations required by the applicable~~
18 ~~provisions of sections 329-32 and 329-33 and applicable rules to~~
19 ~~register the applicant, the administrator shall serve upon the~~
20 ~~applicant an order to show cause why the registration should not~~
21 ~~be denied.~~

1 (b) If, upon information gathered by the department
2 regarding any registrant, the administrator determines that the
3 registration of such registrant is subject to suspension or
4 revocation pursuant to section 329-34 or applicable rules, the
5 department shall serve upon the registrant an order to show
6 cause why the registration should not be revoked or suspended.

7 (c) The order to show cause shall call upon the applicant
8 or registrant to appear before the department at a time and
9 place stated in the order, which shall not be less than thirty
10 days after the date of receipt of the order. The order to show
11 cause shall also contain a statement of the legal basis for such
12 hearing and for the denial, revocation, or suspension of
13 registration and a summary of the matters of fact and law
14 asserted.

15 (d) Upon receipt of an order to show cause, the applicant
16 or registrant must, (if the registrant or applicant desires a
17 hearing) file a request for a hearing with the department within
18 thirty days after service of the order to show cause. Failure
19 to request a hearing will result in the automatic termination of
20 the registrant's registration and in the case of a new
21 application or renewal the unprocessed application will be
22 returned to the applicant.

1 [~~(b)~~] (e) The department of public safety may suspend any
2 registration simultaneously with the institution of proceedings
3 under section 329-34, or where renewal of registration is
4 refused, if it finds that there is an imminent danger to the
5 public health or safety which warrants this action. The
6 suspension shall continue in effect until the conclusion of the
7 proceedings, including judicial review thereof, unless sooner
8 withdrawn by the department of public safety or dissolved by a
9 court of competent jurisdiction.

10 [~~(e)~~] (f) The department of public safety may subpoena and
11 examine witnesses under oath upon all such charges as may be
12 [~~preferred~~] referred before it [~~, and the circuit court of the~~
13 ~~circuit in which the hearing is held shall enforce by~~
14 ~~appropriate order the attendance and testimony of witnesses so~~
15 ~~subpoenaed]."~~

16 SECTION 6. Section 329-64, Hawaii Revised Statutes, is
17 amended by amending subsection (a) to read as follows:

18 "(a) The requirements imposed by sections 329-62 [~~7~~] and
19 329-63(a) [~~7~~ ~~and 329-67~~] of this part shall not apply to any of
20 the following:

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- 1 (1) Any pharmacist or other authorized person who sells or
2 furnishes a substance upon the prescription of a
3 physician, dentist, podiatrist, or veterinarian;
- 4 (2) Any physician, dentist, podiatrist, or veterinarian
5 who administers or furnishes a substance to patients;
- 6 (3) Any manufacturer or wholesaler licensed by the State
7 who sells, transfers, or otherwise furnishes a
8 substance to a licensed pharmacy, physician, dentist,
9 podiatrist, or veterinarian;
- 10 (4) Any sale, transfer, furnishing, or receipt of any drug
11 that contains pseudoephedrine or norpseudoephedrine
12 that is lawfully sold, transferred, or furnished over
13 the counter without a prescription pursuant to the
14 federal Food, Drug, and Cosmetic Act (21 United States
15 Code Sec. 301 et seq.) or regulations adopted
16 thereunder as long as it complies with the
17 requirements of sections 329-73, 329-74, and 329-75 [7
18 and]
- 19 ~~(5) Any "dietary supplement" as defined by the federal~~
20 ~~Food, Drug, and Cosmetic Act (21 United States Code~~
21 ~~Sec. 301) containing ephedrine alkaloids extracted~~

1 ~~from any species of Ephedra that meets all of the~~
2 ~~following criteria:~~

3 ~~(A) It contains, per dosage unit or serving, not more~~
4 ~~than twenty five milligrams of ephedrine~~
5 ~~alkaloids and its labeling does not suggest or~~
6 ~~recommend a total daily intake of more than one~~
7 ~~hundred milligrams of ephedrine alkaloids;~~

8 ~~(B) It contains no hydrochloride or sulfate salts of~~
9 ~~ephedrine alkaloids; and~~

10 ~~(C) It is packaged with a prominent label securely~~
11 ~~affixed to each package that states all of the~~
12 ~~following:~~

13 ~~(i) The amount in milligrams of ephedrine~~
14 ~~alkaloids in a dosage unit or serving;~~

15 ~~(ii) The amount of the dietary supplement that~~
16 ~~constitutes a dosage unit or serving; and~~

17 ~~(iii) The maximum recommended dosage of ephedrine~~
18 ~~alkaloids for a healthy adult human is not~~
19 ~~more than one hundred milligrams in a~~
20 ~~twenty four hour period]."~~

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

1 "(f) [~~Intentional or knowing failure~~] Failure to transmit
2 any information as required by this section (to include request
3 by the designated state agency for data corrections) shall be a
4 misdemeanor, may incur administrative fines and shall result in
5 the immediate suspension of that pharmacy or practitioner's
6 ability to dispense controlled substances in the State until
7 authorized by the administrator."

8 SECTION 8. Section 329-104, Hawaii Revised Statutes, is
9 amended to read as follows:

10 "**§329-104 Confidentiality of information; disclosure of**
11 **information.** (a) The information collected under this part
12 shall not be available to the public or used for any commercial
13 purpose. Ownership of all data collected shall reside with the
14 State.

15 (b) Responsibility for limiting access to information in
16 the system is vested in the administrator. Access to the
17 information collected at the central repository pursuant to this
18 part shall be confidential, and access to the information shall
19 be limited to[+

20 ~~(1) Personnel]~~ personnel of the designated state agency[+
21 and

1 ~~(2) The Drug Enforcement Administration diversion group~~
2 ~~supervisor].~~

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

5 (1) Law enforcement officers, investigative agents of
6 federal, state, or county law enforcement agencies,
7 United States attorneys, county prosecuting attorneys,
8 or the attorney general; provided that the
9 administrator has reasonable grounds to believe that
10 the disclosure of any information collected under this
11 part is in furtherance of an ongoing criminal or
12 regulatory investigation or prosecution;

13 (2) Registrants authorized under chapters 448, 453, and
14 463E who are registered to administer, prescribe, or
15 dispense controlled substances; provided that the
16 information disclosed relates only to the registrant's
17 own patient;

18 (3) Pharmacists, employed by a pharmacy registered under
19 section 329-32, who request prescription information
20 about a customer relating to a violation or possible
21 violation of this chapter; or

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1 (4) Other state-authorized governmental prescription-
 2 monitoring programs.
 3 Information disclosed to a registrant, pharmacist, or authorized
 4 government agency under this section shall be transmitted by a
 5 secure means determined by the designated agency.

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

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

16 SECTION 9. Statutory material to be repealed is bracketed
 17 and stricken. New statutory material is underscored.

18 SECTION 10. This Act shall take effect upon its approval.

19

20

21

INTRODUCED BY:

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BY REQUEST

Report Title:
Controlled Substances

Description:
Makes Hawaii's controlled substance laws consistent with that of federal law and clarifies sections of chapter 329 relating to controlled substances.

JUSTIFICATION SHEET

DEPARTMENT: Public Safety

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

PURPOSE: Update chapter 329, Hawaii Revised Statutes (HRS), to include emergency scheduling as designated under section 329-11 and amendments made to the federal Controlled Substance Act; amend section 329-35 relating to the order to show cause; amend section 329-64 relating to exemptions for the requirements of precursor chemicals; and amend sections 329-101 and 329-104 relating to the Department's electronic prescription monitoring program.

MEANS: Amend sections 329-14(d), 329-16(c), 329-20(b), 329-22(d), 329-35, 329-64(a), 329-101(f), and 329-104, Hawaii Revised Statutes.

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

- (1) Amend Hawaii's Uniform Controlled Substances Act, chapter 329, HRS, in accordance with the requirements of section 329-11, by adding the hallucinogenic substance Salvia Divinorum and/or Salvinorin A to Schedule I as required by section 329-11(e), HRS.
- (2) Update Hawaii's Uniform Controlled Substance Act, chapter 329, HRS, with a change made to the federal Controlled Substance Act, title 21, code of federal regulations, part 1308.12 by adding the narcotic drugs Tapentadol to Schedule II as required by section 329-11(d), HRS.
- (3) Update Hawaii's Uniform Controlled Substance Act, chapter 329, HRS, with a change made to the federal Controlled Substance Act, title 21, code of federal regulations, part 1308.14 by adding the depressants drug Fospropofol (Lusedra) to Schedule IV as required by section 329-11(d), HRS.

- (4) Update Hawaii's Uniform Controlled Substance Act, chapter 329, HRS, with a change made to the federal Controlled Substance Act, title 21, code of federal regulations, part 1308.15 by adding the depressants drug Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide] to Schedule V as required by section 329-11(d), HRS.
- (5) Update section 329-35, HRS, to be consistent with federal language listed in the federal Controlled Substance Act, title 21, code of federal regulations, part 1301.37 relating to the "order to show cause."
- (6) Amend section 329-64, HRS, relating to exemptions to the requirements imposed by sections 329-62, 329-63(a), and 329-67 relating to the sales of precursor chemicals requiring that all individuals and entities that conduct retail sales of pseudoephedrine containing products obtain a precursor chemical permit. Section 329-64 is also amended to delete the exemption for the retail sales of dietary supplements that contain ephedrine. Ephedrine was designated as a drug to be dispensed by prescription only by Act 171, section 2, Session Laws of Hawaii 2006.
- (7) Amend section 329-101(f) to clarify the language relating to the penalty for failure to transmit controlled substance prescription data to the Department due to non-compliance by pharmacies.
- (8) Amend section 329-104(e) by deleting the requirement for the designated state agency to purge the patient identification number data on all controlled substance prescriptions after 3 years. Due to administrative, civil and regulatory investigations lasting longer than three years the department feels that it is necessary to permanently maintain the patient identification number with the rest of the data as a means of better identifying patients with the same name.

Impact on the public: This bill is intended to protect the public by updating Hawaii's controlled substance schedules as well as assist pharmacists and physicians in better serving their patients by streamlining the requirements for dispensing controlled substances.

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
DESIGATION: PSD 502.

OTHER AFFECTED
AGENCIES: Department of Health, Food and Drug
Branch.

EFFECTIVE DATE: Upon approval.