# A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

- SECTION 1. Chapter 329, Hawaii Revised Statutes, is
  amended by adding two new sections to part IV to be
  appropriately designated and to read as follows:

  "§329- Administrative penalties. (a) Any person who
  violates this chapter or any rule adopted by the department
- 6 pursuant to this chapter shall be fined not more than \$10,000
- 7 for each separate offense. Any action taken to collect the
- 8 penalty provided for in this subsection shall be considered a
- 9 civil action and the fine shall be deposited into the state
- 10 general fund.
- 11 (b) The director may impose by order the administrative
- 12 penalty specified in this section, in addition to any other
- 13 administrative or judicial remedy provided by this part, or by
- 14 rules adopted pursuant to this chapter. Factors to be
- considered in imposing the administrative penalty include:
- 16 (1) The nature and history of the violation;
- 17 (2) Any prior violation; and

1	(3) The opportunity, difficulty, and history of corrective								
2	action.								
3	For any judicial proceeding to recover the administrative								
4	penalty imposed, the administrator need only show that notice								
5	was given, a hearing was held or the time granted for requesting								
6	a hearing has expired without such a request, the administrative								
7	penalty was imposed, and the penalty remains unpaid.								
8	§329- Injunctive relief. The administrator may								
9	institute a civil action in any court of competent jurisdiction								
10	for injunctive relief to prevent any violation of this chapter								
11	or any rule adopted to implement this chapter. The court shall								
12	have powers to grant relief in accordance with the Hawaii rules								
13	of civil procedure."								
14	SECTION 2. Section 329-1, Hawaii Revised Statutes, is								
15	amended by adding two new definitions to be appropriately								
16	inserted and to read as follows:								
17	"Designated member of the health care team" includes								
18	physician assistants, advanced practice registered nurses, and								
19	covering physicians who are authorized under state law to								
20	prescribe drugs.								
21	"Physician-patient relationship" means the collaborative								
22	relationship between physicians and their patients. To								

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1	establish this relationship, the treating physician or the							
2	physician's designated member of the health care team, at a							
3	minimum shall:							
4	(1) Personally perform a face-to-face history and physical							
5		examination of the patient that is appropriate to the						
6		specialty training and experience of the physician or						
7	the designated member of the physician's health care							
8	team, make a diagnosis and formulate a therapeutic							
9	plan, or personally treat a specific injury or							
10		<pre>condition;</pre>						
11	(2)	Discuss with the patient the diagnosis or treatment,						
12		including the benefits of other treatment options; and						
13	(3)	Ensure the availability of appropriate follow-up						
14		care."						
15	SECT	ION 3. Section 329-18, Hawaii Revised Statutes, is						
16	amended by	y amending subsection (c) to read as follows:						
17	" (C)	Depressants. Unless listed in another schedule, any						
18	material,	compound, mixture, or preparation containing any						
19	quantity	of the following substances having a depressant effect						
20	on the ce	ntral nervous system:						

(1) Any compound, mixture, or preparation containing

amobarbital, secobarbital, pentobarbital, or any salt

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1
               thereof and one or more other active medicinal
 2
               ingredients which are not listed in any schedule;
 3
          (2)
               Any suppository dosage form containing amobarbital,
 4
               secobarbital, pentobarbital, or any salt of any of
               these drugs and approved by the Food and Drug
 5
 6
               Administration for marketing only as a suppository;
 7
          (3)
               Any substance that contains any quantity of a
 8
               derivative of barbituric acid or any salt thereof,
9
               including the substance butalbital;
10
          (4)
               Chlorhexadol;
11
         (5)
               Embutramide (Tributame);
12
         [\frac{(5)}{(5)}] (6) Ketamine, its salts, isomers, and salts of
13
               isomers, also known as (+ or -)-2-(2-chlorophenyl)-2-
14
               (methylamino) - cyclohexanone;
15
         [(6)] (7) Lysergic acid;
16
         [\frac{7}{1}] (8) Lysergic acid amide;
17
         [(8)] (9) Methyprylon;
18
         [<del>(9)</del>] (10) Sulfondiethylmethane;
19
        [<del>(10)</del>] (11) Sulfonethylmethane;
20
        [(11)] (12) Sulfonmethane;
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1	[ <del>(12)</del> ]	(13) Tiletamine/Zolazepam (Telazol, 2-(ethylamino)-2-
2		(-thienyl)-cyclohexanone, flupyrazapon) or any salts
3		thereof; and
4	[ <del>(13)</del> ]	(14) Gamma hydroxybutyric acid and its salts, isomers
5		and salts of isomers that are contained in a drug
6		product for which an application has been approved
7		under section 505 of the federal Food, Drug, and
8		Cosmetic Act."
9	SECT	ION 4. Section 329-38, Hawaii Revised Statutes, is
10	amended a	s follows:
11	1.	By amending subsection (g) to read:
12	"(g)	Prescriptions for controlled substances shall be
13	issued on	ly as follows:
14	(1)	All prescriptions for controlled substances shall
15		originate from within the [State] state and be dated
16		as of, and signed on, the day when the prescriptions
17		were issued and shall contain:
18		(A) The first and last name and address of the
19		patient; and
20		(B) The drug name, strength, dosage form, quantity
21		prescribed, and directions for use. Where a
22		prescription is for gamma hydroxybutyric acid,

2	shall record as part of the directions for use,
3	the medical need of the patient for the
4	prescription.
5	The controlled substance prescriptions shall be no
6	larger than eight and one-half inches by eleven inches
7	and no smaller than three inches by four inches.
8	A practitioner may sign a prescription in the same
9	manner as the practitioner would sign a check or legal
10	document (e.g., J.H. Smith or John H. Smith) and shall
11	use both words and figures (e.g., alphabetically and
12	numerically as indications of quantity, such as five
13	(5)), to indicate the amount of controlled substance
14	to be dispensed. Where an oral order is not permitted,
15	prescriptions shall be written with ink or indelible
16	pencil or typed, shall be manually signed by the
17	practitioner, and shall include the name, address,
18	telephone number, and registration number of the
19	practitioner. The prescriptions may be prepared by a
20	secretary or agent for the signature of the
21	practitioner, but the prescribing practitioner shall
22	be responsible in case the prescription does not

methadone, or buprenorphine, the practitioner

conform in all essential respects to this chapter and					
any rules adopted pursuant to this chapter. <u>In</u>					
receiving an oral prescription from a practitioner, a					
pharmacist shall promptly reduce the oral prescription					
to writing, which shall include the following					
information: the drug name, strength, dosage form,					
quantity prescribed in figures only, and directions					
for use; the date the oral prescription was received;					
the full name, DEA registration number, and oral code					
number of the practitioner; and the name and address					
of the person for whom the controlled substance was					
prescribed or the name of the owner of the animal for					
which the controlled substance was prescribed.					

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

1		prescribed, the quantity of the prescription, the					
2		practitioner's DEA number, or the practitioner's					
3		signature;					
4	(2)	An intern, resident, or foreign-trained physician, or					
5		a physician on the staff of a Department of Veterans					
6		Affairs facility or other facility serving veterans,					
7		exempted from registration under this chapter, shall					
8		include on all prescriptions issued by the physician:					
9		(A) The registration number of the hospital or other					
10		institution; and					
11		(B) The special internal code number assigned to the					
12		physician by the hospital or other institution in					
13	9	lieu of the registration number of the					
14		practitioner required by this section.					
15		The hospital or other institution shall forward a copy					
16		of this special internal code number list to the					
17		department as often as necessary to update the					
18		department with any additions or deletions. Failure					
19		to comply with this paragraph shall result in the					
20		suspension of that facility's privilege to fill					
21		controlled substance prescriptions at pharmacies					
22		outside of the hospital or other institution. Each					

1		written prescription shall have the name of the
2		physician stamped, typed, or hand-printed on it, as
3		well as the signature of the physician;
4	(3)	An official exempted from registration shall include on
5		all prescriptions issued by the official:
6		(A) The official's branch of service or agency (e.g.,
7		"U.S. Army" or "Public Health Service"); and
8		(B) The official's service identification number, in
9		lieu of the registration number of the
10		practitioner required by this section. The
11		service identification number for a Public Health
12		Service employee shall be the employee's social
13		security or other government issued
14		identification number.
15		Each prescription shall have the name of the officer
16		stamped, typed, or handprinted on it, as well as the
17		signature of the officer; and
18	(4)	A physician assistant registered to prescribe
19		controlled substances under the authorization of a
20		supervising physician shall include on all controlled
21		substance prescriptions issued:

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1	(A) The DEA registration number of the supervising
2	physician; and
3	(B) The DEA registration number of the physician
4	assistant.
5	Each written controlled substance prescription issued
6	shall include the printed, stamped, typed, or hand-
7	printed name, address, and phone number of both the
8	supervising physician and physician assistant, and
9	shall be signed by the physician assistant. The
10	medical record of each written controlled substance
11	prescription issued by a physician assistant shall be
12	reviewed and initialed by the physician assistant's
13	supervising physician within seven working days."
14	2. By amending subections (j), (k), (1), and (m) to read
15	as follows:
16	"(j) A prescription for a schedule II controlled substance
17	may be transmitted by the practitioner or the practitioner's
18	agent to a pharmacy by facsimile equipment; provided that the
19	original written, signed prescription is presented to the
20	pharmacist for review prior to the actual dispensing of the
21	controlled substance, except as noted in [subsection]
22	subsections (k), (l), $[\Theta r]$ and (m). The original prescription

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2	prescription for a schedule III, IV, or V controlled substance								
3	may be transmitted by the practitioner or the practitioner's								
4	agent to a pharmacy by facsimile; provided that:								
5	(1)	The information shall be communicated only between the							
6		prescribing practitioner or the prescriber's							
7		authorized agent and the pharmacy of the patient's							
8		choice[+]. The original prescription shall be							
9		maintained by the practitioner in accordance with							
10		section 329-36;							
11	(2)	The information shall be communicated in a							
12		retrievable, recognizable format acceptable to the							
13		intended recipient and shall include the physician's							
14		oral code designation and the name of the recipient							
15		pharmacy;							

shall be maintained in accordance with section 329-36.

16 (3) No electronic system, software, or other intervening
17 mechanism or party shall alter the practitioner's
18 prescription, order entry, selection, or intended
19 selection without the practitioner's approval on a per
20 prescription per order basis. Facsimile prescription
21 information shall not be altered by any system,

1		software, or other intervening mechanism or party
2		prior to receipt by the intended pharmacy;
3	(4)	The prescription information processing system shall
4		provide for confidentiality safeguards required by
5		federal or state law; and
6	(5)	Prescribing practitioners and pharmacists shall
7		exercise prudent and professional judgment regarding
8		the accuracy, validity, and authenticity of any
9		facsimile prescription information. The facsimile
10		shall serve as the original written prescription for
11		purposes of this section and shall be maintained in
12		accordance with section 329-36.
13	(k)	A prescription prepared in accordance with subsection
14	(g) writt	en for a narcotic listed in schedule II to be
15	compounde	d for the direct administration to a patient by
16	parentera	l, intravenous, intramuscular, subcutaneous, or
17	intraspin	al infusion, but does not extend to the dispensing of
18	oral dosa	ge units of controlled substances, may be transmitted
19	by the pr	actitioner or the practitioner's agent to the pharmacy
20	by facsim	ile. The original prescription shall be maintained by
21	the pract	itioner in accordance with section 329-36. The
22	pharmacis	t shall note on the face of the facsimile prescription

- 1 in red ink "Home Infusion/IV" and this facsimile shall serve as
- 2 the original written prescription for purposes of this section
- 3 and it shall be maintained in accordance with section 329-36.
- 4 (1) A prescription prepared in accordance with subsection
- 5 (g) written for a schedule II substance for a patient enrolled
- 6 in a hospice care program certified or paid for by medicare
- 7 under Title XVIII or a hospice program that is licensed by the
- 8 State may be transmitted by the practitioner or the
- 9 practitioner's agent to the dispensing pharmacy by facsimile.
- 10 The original prescription shall be maintained by the
- 11 practitioner in accordance with section 329-36. The
- 12 practitioner or practitioner's agent shall note on the
- 13 prescription that the patient is a hospice patient. The
- 14 pharmacist shall note on the face of the facsimile prescription
- 15 in red ink "HOSPICE" and this facsimile shall serve as the
- 16 original written prescription for purposes of this section and
- 17 it shall be maintained in accordance with section 329-36.
- 18 (m) A prescription prepared in accordance with subsection
- 19 (g) written for a schedule II controlled substance for a
- 20 resident of a state-licensed long-term care facility may be
- 21 transmitted by the practitioner or the practitioner's agent to
- 22 the dispensing pharmacy by facsimile. The original prescription

- 1 shall be maintained by the practitioner in accordance with
- 2 section 329-36. The pharmacist shall note on the face of the
- 3 facsimile prescription in red ink "LTCF" and this facsimile
- 4 shall serve as the original written prescription for purposes of
- 5 this section and it shall be maintained in accordance with
- 6 section 329-36."
- 7 SECTION 5. Section 329-41, Hawaii Revised Statutes, is
- 8 amended to read as follows:
- 9 "§329-41 Prohibited acts B--penalties. (a) It is unlawful
- 10 for any person:
- 11 (1) Who is subject to part III to distribute, administer,
- 12 prescribe, or dispense a controlled substance in
- violation of section 329-38[+] or rules authorized
- under section 329-31; however, a licensed manufacturer
- or wholesaler may sell or dispense a controlled
- substance to a master of a transpacific ship or a
- 17 person in charge of a transpacific aircraft upon which
- 18 no physician is regularly employed, for the actual
- 19 medical needs of persons on board such ship or
- 20 aircraft when not in port; provided schedule I or II
- 21 controlled substances shall be sold to the master of
- such ship or person in charge of such aircraft only in

1		accordance with the provisions set forth in 21 Code of
2		Federal Regulations, Sections 1301, 1305, and 1307,
3		adopted pursuant to Title 21, United States Code,
4		Section 821;
5	(2)	Who is a registrant to manufacture a controlled
6		substance not authorized by the registrant's
7		registration or to distribute or dispense a controlled
8		substance not authorized by the registrant's
9		registration to another registrant or another
10		authorized person;
11	(3)	To refuse or fail to make available, keep, or furnish
12		any record, notification, order form, prescription,
13		statement, invoice, or information in patient charts
14		relating to the administration, dispensing, or
15		prescribing of controlled substances;
16	(4)	To refuse any lawful entry into any premises for any
17		inspection authorized by this chapter;
18	(5)	Knowingly to keep or maintain any store, shop,
19		warehouse, dwelling, building, vehicle, boat,
20		aircraft, or other structure or place for the purpose
21		of using these substances or which is used for keeping

L	or	selling	them	in	violation	of	this	chapter	or
2	cha	apter 712	2, par	rt :	IV; [ <del>or</del> ]				

- 3 (6) Who is a practitioner or pharmacist to dispense a 4 controlled substance to any individual not known to 5 the practitioner or pharmacist, without first 6 obtaining proper identification and documenting, by 7 signature on a log book kept by the practitioner or 8 pharmacist, the identity of and the type of 9 identification presented by the individual obtaining 10 the controlled substance. If the individual does not 11 have any form of proper identification, the pharmacist 12 shall verify the validity of the prescription and identity of the patient with the prescriber, or their 13 14 authorized agent, before dispensing the controlled 15 substance. For the purpose of this section, "proper identification" means government-issued identification 16 17 containing the photograph, printed name, and signature 18 of the individual obtaining the controlled 19 substance[-];
  - (7) Who is a practitioner to predate or pre-sign

    prescriptions to facilitate the obtaining or attempted

    obtaining of controlled substances; or

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22

1	(8)	Who is a practitioner to facilitate the issuance or				
2		distribution of a written prescription or to issue an				
3		oral prescription for a controlled substance when not				
4		physically in the State.				
5	(b)	It shall be unlawful for any person subject to part				
6	III of th	III of this chapter except a pharmacist, to administer,				
7	prescribe	, or dispense any controlled substance without a bona				
8	fide phys	ician-patient relationship.				
9	( <del>d)</del> ]	] (c) Any person who violates this section is guilty				
10	of a clas	s C felony."				
11	SECT	ION 6. Section 329-42, Hawaii Revised Statutes, is				
12	amended by amending subsection (a) to read as follows:					
13	"(a) It is unlawful for any person knowingly or					
14	intentionally:					
15	(1)	To distribute as a registrant a controlled substance				
16		classified in schedule I or II, except pursuant to an				
17		order form as required by section 329-37;				
18	(2)	To use in the course of the manufacture [or]				
19		distribution, administration, or prescribing of a				
20		controlled substance a registration number that is				
21		fictitious, revoked, suspended, expired, or issued to				
22		another person;				

1	(3)	.1.0 C	obtain or attempt to obtain any controlled
2		subs	tance or procure or attempt to procure the
3		admi	nistration of any controlled substance:
4		(A)	By fraud, deceit, misrepresentation,
5			embezzlement, theft;
6		(B)	By the forgery or alteration of a prescription or
7			of any written order;
8		(C)	By furnishing fraudulent medical information or
9			the concealment of a material fact;
10		(D)	By the use of a false name, patient
11			identification number, or the giving of false
12			address;
13		(E)	By the unauthorized use of a physician's oral
14			call-in number; or
15		(F)	By the alteration of a prescription by the
16			addition of future refills;
17	(4)	To f	urnish false or fraudulent material information
18		in,	or omit any material information from, any
19		app1	ication, report, or other document required to be
20		kept	or filed under this chapter, or any record
21		requ	dired to be kept by this chapter;

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(5)	To make, distribute, or possess any punch, die, plate,
	stone, or other thing designed to print, imprint, or
	reproduce the trademark, trade name, or other
	identifying mark, imprint, or device of another or any
	likeness of any of the foregoing upon any drug or
	container or labeling thereof so as to render the drug
	a counterfeit substance;

- (6) To misapply or divert to the person's own use or other unauthorized or illegal use or to take, make away with, or secrete, with intent to misapply or divert to the person's own use or other unauthorized or illegal use, any controlled substance that shall have come into the person's possession or under the person's care as a registrant or as an employee of a registrant who is authorized to possess controlled substances or has access to controlled substances by virtue of the person's employment; or
- (7) To make, distribute, possess, or sell any prescription form, whether blank, faxed, computer generated, photocopied, or reproduced in any other manner without the authorization of the licensed practitioner."

- 1 SECTION 7. Section 329-101, Hawaii Revised Statutes, is
- 2 amended by amending subsection (f) to read as follows:
- 3 "(f) Intentional or knowing failure to transmit any
- 4 information as required by this section shall be a
- 5 misdemeanor  $[\cdot]$  and shall result in the immediate suspension of
- 6 that pharmacy or practitioner's ability to dispense controlled
- 7 substance in the state until authorized by the administrator."
- 8 SECTION 8. Section 329-102, Hawaii Revised Statutes, is
- 9 amended by amending subsection (f) to read as follows:
- "(f) All prescriptions for [schedule] controlled substances
- 11 in schedules II through V and other controlled substances
- 12 designated by the designated state agency that are processed by an
- 13 out-of-state pharmacy shall conform to reporting and registration
- 14 requirements adopted by the State, and to any additional rules the
- 15 department adopts."
- 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 on July 1, 2008.

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### Report Title:

Controlled Substances

### Description:

Makes Hawaii's controlled substance laws consistent with that of federal law. (CD1)