JAN 2 7 2016

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
- 3 (1) By adding six new definitions to be appropriately
- 4 inserted and to read as follows:
- 5 ""Medical marijuana dispensary" shall have the same meaning
- 6 as in section 329D-1.
- 7 "Medical marijuana production center" shall have the same
- 8 meaning as in section 329D-1.
- "Retail dispensing location" shall have the same meaning as
- 10 <u>in section 329D-1.</u>
- 11 "Pharmacy delegate" means an individual employed by the
- 12 pharmacy and selected by the pharmacist to act as that
- 13 pharmacist's agent to whom the pharmacist has delegated the task
- of accessing electronic prescription accountability system
- 15 information and that pharmacist takes full responsibility for
- 16 the actions of that delegate.

1	"Practitioner delegate" means an agent or employee of a							
2	practitioner (physician, dentist, veterinarian, advanced							
3	practice registered nurse with prescriptive authority or							
4	Physician Assistant) to whom the practitioner has delegated the							
5	task of accessing electronic prescription accountability system							
6	information and that practitioner takes full responsibility for							
7	the actions of that delegate.							
8	"Reverse distributor" means a registrant who is registered							
9	under section 329-32 to receive controlled substances acquired							
10	from another State certified controlled substance registrants							
11	for the purpose of:							
12	(1) Returning unwanted, unusable, or outdated controlled							
13	substances to the manufacturer or the manufacturer's							
14	agent; or							
15	(2) Where necessary, processing such substances or arranging	ng						
16	for processing such substances for disposal as							
17	authorized by the administrator."							
18	(2) By amending the definitions of "dispense" and "locum							
19	tenens practitioner" to read as follows:							
20	""Dispense" means to deliver a controlled substance to an							
21	ultimate user or research subject by or pursuant to the lawful							
22	order of a practitioner, including the [prescribing,]							

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1	administe	ring[$_{ au}$] (of practitioner's controlled substances),
2	packaging,	, labeling, or compounding necessary to prepare the
3	substance	for that delivery. A controlled substance is
4	dispensed	when:
5	(1)	It is compounded, prepared, labeled, and packaged
6		pursuant to the lawful order of a practitioner by a
7		licensed pharmacist acting in the usual course of his
8		professional practice and who is either registered
9		individually or employed in a registered pharmacy or
10		by a registered institutional practitioner, for
11		delivery to the ultimate user;
12	(2)	It is compounded, prepared, labeled and packaged for
13		delivery to the ultimate user by a practitioner acting
14		in the usual course of his professional practice;
15	(3)	It is prepared, labeled, and packaged pursuant to the
16		lawful order of a practitioner by a registered health
17		care professional acting as an agent of the
18		practitioner for delivery to the ultimate user by the
19		practitioner; or
20	(4)	It is prepackaged by a pharmacist for use in an

emergency facility for delivery to the ultimate user

1	by a licensed or registered health care professional
2	pursuant to the order of a physician.
3	"Locum tenens practitioner" means a practitioner[÷
4	(1) Who] who is licensed in this State and [registered
5	under section 329-32 to administer, prescribe, or
6	dispense a controlled substance in the course of
7	professional-practice, who temporarily substitutes
8	for another [registered] practitioner for a period not
9	to exceed sixty days at that other practitioner's
10	registered place of business[; and
11	(2) Whose-Drug Enforcement Administration-controlled
12	substance registration number has not been transferred
13	to-the State of Hawaii].
14	Locum tenens practitioners are not eligible to receive an oral
15	code number as designated by section [$+$]328-16(k)[$+$]."
16	SECTION 2. Section 329-14, Hawaii Revised Statutes, is
17	amended by amending subsection (b) to read as follows:
18	"(b) Any of the following opiates, including their
19	isomers, esters, ethers, salts, and salts of isomers, esters,
20	and ethers, unless specifically excepted, whenever the existence
21	of these isomers, esters, ethers, and salts is possible within
22	the specific chemical designation:

```
Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-
1
         (1)
2
              phenethyl) -4-piperidinyl]-N-phenylacetamide);
3
         (2)
              Acetylmethadol;
              Allylprodine;
4
         (3)
5
         (4)
              Alphacetylmethadol (except levo-alphacetylmethadol,
              levomethadyl acetate, or LAAM);
6
7
         (5)
              Alphameprodine;
8
         (6)
              Alphamethadol;
9
              Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-
         (7)
              phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-
10
              2-phenylethyl)-4-(N-propanilido) piperidine);
11
12
         (8)
              Alpha-methylthiofentanyl (N-[1-methyl-2-(2-
13
              thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);
              Benzethidine;
14
         (9)
15
              Betacetylmethadol;
        (10)
16
        (11)
              Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-
              piperidinyl] -N-phenylpropanamide);
17
              Beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-
18
        (12)
              phenethyl)-3-methyl-4-piperidinyl]-N-
19
20
              phenylpropanamide);
21
              Betameprodine;
        (13)
22
              Betamethadol:
        (14)
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1
        (15)
               Betaprodine;
 2
         (16)
               Clonitazene;
 3
        (17)
               Dextromoramide;
 4
               Diampromide;
        (18)
 5
         (19)
               Diethylthiambutene;
 6
        (20)
               Difenoxin;
 7
         (21)
               Dimenoxadol;
 8
         (22)
               Dimepheptanol;
 9
         (23)
               Dimethylthiambutene;
10
         (24)
               Dioxaphetyl butyrate;
11
               Dipipanone;
        (25)
12
         (26)
               Ethylmethylthiambutene;
13
               Etonitazene;
        (27)
14
         (28)
               Etoxeridine;
15
         (29)
               Furethidine;
16
         (30)
               Hydroxypethidine;
17
               Ketobemidone;
         (31)
18
        (32)
               Levomoramide;
19
         (33)
               Levophenacylmorphan;
20
               3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-
         (34)
21
               piperidyl]-N-phenylpropanamide);
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3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl)ethyl-
1
        (35)
2
               4-piperidinyl]-N-phenylpropanamide);
              Morpheridine;
3
        (36)
              MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
4
        (37)
5
        (38)
               Noracymethadol;
              Norlevorphanol;
6
        (39)
7
        (40)
              Normethadone;
8
        (41)
              Norpipanone;
9
        (42)
               Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-
               phenethyl)-4-piperidinyl] propanamide;
10
               PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine;
11
        (43)
12
        (44)
               Phenadoxone;
               Phenampromide;
13
        (45)
               Phenomorphan;
14
        (46)
               Phenoperidine;
15
        (47)
               Piritramide;
16
        (48)
               Proheptazine;
17
        (49)
               Properidine;
18
        (50)
19
        (51)
               Propiram;
20
        (52)
               Racemoramide;
               Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-
21
        (53)
               piperidinyl]-propanamide);
22
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1	(54)	Tilidine;
2	(55)	Trimeperidine;
3	(56)	N-[1-benzyl-4-piperidyl]-N-phenylpropanamide
4		(benzylfentanyl), its optical isomers, salts, and
5		salts of isomers; [and]
6	(57)	N-[1-(2-thieny1)methyl-4-piperidyl]-N-
7		phenylpropanamide (thenylfentanyl), its optical
8		isomers, salts, and salts of isomers[-]; and
9	(58)	N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide,
10		(acetyl fentanyl) its optical, positional, and
11		geometric isomers, salts and salts of isomers."
12	SECT	ION 3. Section 329-14, Hawaii Revised Statutes, is
13	amended b	y amending subsection (g) to read as follows:
14	" (g)	Any of the following cannabinoids, their salts,
15	isomers a	nd salts of isomers, unless specifically excepted,
16	whenever	the existence of these salts, isomers and salts of
17	isomers i	s possible within the specific chemical designation:
18	(1)	Tetrahydrocannabinols; meaning tetrahydrocannabinols
19		naturally contained in a plant of the genus Cannabis
20		(cannabis plant), as well as synthetic equivalents of
21		the substances contained in the plant, or in the
22		resinous extractives of Cannabis, sp. or synthetic

substances, derivatives, and their isomers with 1 similar chemical structure and pharmacological 2 activity to those substances contained in the plant, 3 such as the following: Delta 1 cis or trans 4 tetrahydrocannabinol, and their optical isomers; Delta 5 6 cis or trans tetrahydrocannabinol, and their optical 6 isomers; and Delta 3,4 cis or trans-7 tetrahydrocannabinol, and its optical isomers (since 8 nomenclature of these substances is not 9 internationally standardized, compounds of these 10 structures, regardless of numerical designation of 11 atomic positions, are covered); 12 13 (2) Naphthoylindoles; meaning any compound containing a 3-(1-naphthoyl) indole structure with substitution at the 14 nitrogen atom of the indole ring by a alkyl, 15 haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 16 17 1-(N-methyl-2-piperidinyl) methyl or 2-(4morpholinyl) ethyl group, whether or not further 18 substituted in the indole ring to any extent and 19 whether or not substituted in the naphthyl ring to any 20 21 extent;

1	(3)	Naphthylmethylindoles; meaning any compound containing
2		a 1H-indol-3-yl-(1-naphthyl) methane structure with
3		substitution at the nitrogen atom of the indole ring
4		by a alkyl, haloalkyl, alkenyl, cycloalkylmethyl,
5		cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or
6		2-(4-morpholinyl) ethyl group whether or not further
7		substituted in the indole ring to any extent and
8		whether or not substituted in the naphthyl ring to any
9		extent;
10	(4)	Naphthoylpyrroles; meaning any compound containing a
11		3-(1-naphthoyl)pyrrole structure with substitution at
12		the nitrogen atom of the pyrrole ring by a alkyl,
13		haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl,
14		1-(N-methyl-2-piperidinyl)methyl or 2-(4-
15		morpholinyl)ethyl group whether or not further
16		substituted in the pyrrole ring to any extent, whether
17		or not substituted in the naphthyl ring to any extent;
18	(5)	Naphthylmethylindenes; meaning any compound containing
19		a naphthylideneindene structure with substitution at
20		the 3-position of the indene ring by a alkyl,
21		haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl,
22		1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl)

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1		ethyl group whether or not further substituted in the
2		indene ring to any extent, whether or not substituted
3		in the naphthyl ring to any extent;
4	(6)	Phenylacetylindoles; meaning any compound containing a
5		3-phenylacetylindole structure with substitution at
6		the nitrogen atom of the indole ring by a alkyl,
7		haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl,
8		1-(N-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl)
9		ethyl group whether or not further substituted in the
10		indole ring to any extent, whether or not substituted
11	,	in the phenyl ring to any extent;
12	(7)	Cyclohexylphenols; meaning any compound containing a
13		2-(3-hydroxycyclohexyl) phenol structure with
14		substitution at the 5-position of the phenolic ring by
15		a alkyl, haloalkyl, alkenyl, cycloalkylmethyl,
16		cycloalkylethyl, 1-(N-methyl-2-piperidinyl) methyl or
17		2-(4-morpholinyl) ethyl group whether or not
18		substituted in the cyclohexyl ring to any extent;
19	(8)	Benzoylindoles; meaning any compound containing a 3-
20		(benzoyl) indole structure with substitution at the
21		nitrogen atom of the indole ring by a alkyl, aloalkyl,
22		alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-

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methyl-2-piperidinyl) methyl or 2-(4-morpholinyl)
1
2
               ethyl group whether or not further substituted in the
3
               indole ring to any extent and whether or not
4
               substituted in the phenyl ring to any extent; and
5
               2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)
          (9)
6
               pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-
7
               napthalenylmethanone (another trade name is WIN
8
               55,212-2);
9
         (10)
               (6a, 10a) - 9 - (hydroxymethyl) - 6, 6 - dimethyl - 3 - (2 - a)
10
               methyloctan-2-yl)-6a,7,10,10a-
11
               tetrahydrobenzo[c]chromen-1-ol (other trade names are:
12
               HU-210/HU-211);
13
         (11)
               Tetramethylcyclopropanoylindoles; meaning any compound
14
               containing a 3-tetramethylcyclopropanoylindole
15
               structure with substitution at the nitrogen atom of
16
               the indole ring by an alkyl, haloalkyl, cyanoalkyl,
               alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-
17
18
               methyl-2-piperidinyl) methyl, 2-(4-morpholinyl) ethyl,
19
               1-(N-methyl-2-pyrrolidinyl) methyl, 1-(N-methyl-3-
              morpholinyl) methyl, or tetrahydropyranylmethyl group,
20
21
               whether or not further substituted in the indole ring
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1
              to any extent and whether or not substituted in the
2
              tetramethylcyclopropyl ring to any extent.
              N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide,
3
        (12)
               its optical, positional, and geometric isomers, salts
4
               and salts of isomers. (Other names: APINACA, AKB48);
5
              Ouinolin-8-yl 1-pentyl-1H-indole-3-carboxylate, its
6
        (13)
               optical, positional, and geometric isomers, salts and
7
               salts of isomers (Other names: PB-22; QUPIC);
8
              Ouinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-
9
        (14)
               carboxylate, its optical, positional, and geometric
10
               isomers, salts and salts of isomers (Other names: 5-
11
               fluoro-PB-22; 5F-PB-22);
12
13
         (15)
              N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-amino-3-methyl-1-oxobutan-2-yl)
               fluorobenzyl)-1H-indazole-3-carboxamide, its optical,
14
               positional, and geometric isomers, salts and salts of
15
16
               isomers (Other names: AB-FUBINACA);
17
         (16)
               N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-
               indazole-3-carboxamide, its optical, positional, and
18
               geometric isomers, salts and salts of isomers (Other
19
20
               names: ADB-PINACA);
21
               N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-
         (17)
               (cyclohexylmethyl) -1H-indazole-3-carboxamide, its
22
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optical, positional, and geometric isomers, salts and
1
              salts of isomers (Other names: AB-CHMINACA);
2
3
              N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-
        (18)
              indazole-3-carboxamide, and geometric isomers, salts
4
5
              and salts of isomers (Other names: AB-PINACA);
6
        (19)
              [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-
              yl) methanone, and geometric isomers, salts and salts
7
              of isomers (Other names: THJ-2201);
8
9
              Methyl (1-(4-fluorobenzyl)-1 H-indazole-3-carbonyl)-L-
        (20)
10
              valinate, and geometric isomers, salts and salts of
11
               isomers (Other names: FUB-AMB);
12
        (21)
              (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-
               carboxamido) - 3-methylbutanoate, and geometric isomers,
13
14
               salts and salts of isomers (Other names: 5-fluoro-
15
              AMB, 5-fluoro-AMP);
              N-((3s, 5s, 7s) - adamantan - 1 - yl) - 1 - (5 - fluoropentyl) - 1H-
16
        (22)
               indazole-3-carboxamide, and geometric isomers, salts
17
18
               and salts of isomers (Other names: AKB48 N-(5-
               fluoropentyl) analog, 5F-AKB48, APINACA 5-fluoropentyl
19
20
               analog, 5F-APINACA);
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1	(23)	N-adamantyl-1-fluoropentylindole-3-Carboxamide, and
2		geometric isomers, salts and salts of isomers (Other
3		names: STS-135, 5F-APICA; 5-fluoro-APICA); [and]
4	(24)	Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-
5		carboxylate, and geometric isomers, salts and salts of
6		isomers (Other names: NM2201)[-]; and
7	(25)	N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-
8		(cyclohexylmethyl)-1H-indazole-3-carboxamide, and
9		geometric isomers, salts and salts of isomers (Other
10		names: MAB-CHMINACA and ADB-CHMINACA)."
11	SECT	ION 4. Section 329-20, Hawaii Revised Statutes, is
12	amended b	y amending subsection (e) to read as follows:
13	"(e)	Other substances. Unless specifically excepted or
14	unless li	sted in another schedule, any material, compound,
15	mixture,	or preparation which contains any quantity of the
16	following	substances, including its [salts: Pentazocine.]
17	optical i	somers and its salts, isomers, and salts of isomers:
18	(1)	Pentazocine; and
19	(2)	Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-
20		2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-
21		<pre>imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic</pre>
22		acid."

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1 SECTION 5. Section 329-23, Hawaii Revised Statutes, is 2 amended to read as follows: "§329-23 Republishing [and distribution] of schedules. 3 4 [(a)] The department of public safety shall [republish] make available to the public on the department's website the 5 schedules annually or more often, as may be necessary to update 6 7 the schedules. 8 [(b) The department of public safety shall publicly 9 announce and, in addition, shall make available to the public **10** copies of any changes to the schedules as such changes are 11 made.]" 12 SECTION 6. Section 329-31, Hawaii Revised Statutes, is amended to read as follows: 13 "§329-31 Rules. The department of public safety may 14 promulgate rules and charge reasonable fees relating to the 15 registration and control of the manufacture, distribution, 16 [prescription, and] prescribing, dispensing [of], storage, 17 conducting research, reverse distribution, or chemical analysis 18 with controlled substances within this State." 19 SECTION 7. Section 329-32, Hawaii Revised Statutes, is 20 21 amended to read as follows:

1	"§32	9-32 Registration requirements. (a) Every person
2	who:	
3	(1)	Manufactures, distributes, prescribes, [or] dispenses,
4		stores, conducts research, conducts reverse
5		distribution, or chemical analysis with any controlled
6		substance within this State;
7	(2)	Proposes to engage in the manufacture, distribution,
8		prescription, [er] dispensing, storage, research,
9		reverse distribution, or chemical analysis of any
10		controlled substance within this State; or
11	(3)	Dispenses or proposes to dispense any controlled
12		substance for use in this State by shipping, mailing,
13		or otherwise delivering the controlled substance from
14		a location outside this State;
15	shall obt	ain a registration issued by the department of public
16	safety in	accordance with the department's rules. A licensed or
17	registere	d health care professional who acts as the authorized
18	agent of	a practitioner and who administers controlled
19	substance	s at the direction of the practitioner shall not be
20	required	to obtain a registration.
21	(b)	Persons registered by the department of public safety
22	under thi	s chapter to manufacture, distribute, prescribe,

20

practitioner.

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dispense,	store, [or] conduct research, conduct reverse									
distribut	ion, or chemical analysis with controlled substances									
may possess, manufacture, distribute, prescribe, dispense,										
store, [er] 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 sl	hall 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									
	distribut: may posses store, [es substances conformity (c) persons si possess co (1)									

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The department of public safety may waive the 1 2 registration or filing requirement for certain manufacturers, 3 distributors, prescribers, or dispensers by rule if: It is consistent with the public health and safety; 4 5 and (2) 6 The department of public safety states the specific 7 reasons for the waiver and the time period for which 8 the waiver is to be valid. 9 (e) A separate registration shall be required at each 10 principal place of business or professional practice where the 11 applicant manufactures, distributes, prescribes, [or] dispenses, stores, conducts research, conducts reverse distribution, or 12 13 chemical analysis with controlled substances, except an office 14 used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither 15 16 administered nor otherwise dispensed as a regular part of the **17** professional practice of the practitioner at such office, and 18 where no supplies of controlled substances are maintained. 19 The department of public safety may inspect the establishment of a registrant or applicant for registration in 20 21 accordance with the department's rule.

1 The department of public safety may require a registrant to submit documents or written statements of fact 2 3 relevant to a registration that the department deems necessary 4 to determine whether the registration should be granted or 5 denied. The failure of the registrant to provide the documents 6 or statements within a reasonable time after being requested to 7 do so shall be deemed to be a waiver by the registrant of the 8 opportunity to present the documents or statements for 9 consideration by the department in granting or denying the 10 registration. 11 The failure to renew the controlled substance 12 registration on a timely basis or to pay the applicable fees or 13 payment with a check that is dishonored upon first deposit shall 14 cause the registration to be automatically forfeited." 15 SECTION 8. Section 329-33, Hawaii Revised Statutes, is 16 amended to read as follows: **17** "§329-33 Registration. (a) The department of public 18 safety shall register an applicant to manufacture, dispense, 19 prescribe, [or] distribute, store, conduct research, conduct 20 reverse distribution, or chemical analysis with controlled substances included in sections 329-14, 329-16, 329-18, 329-20, 21 22 and 329-22 unless it determines that the issuance of that

1	registrat	ion would be inconsistent with the public interest. In
2	determini	ng the public interest, the department of public safety
3	shall con	sider the following factors:
4	(1)	Maintenance of effective controls against diversion of
5		controlled substances into other than legitimate
6		medical, scientific, or industrial channels;
7	(2)	Compliance with applicable state and local law;
8	(3)	Any convictions of the applicant under any federal and
9		state laws relating to any controlled substance;
10	(4)	Past experience in the manufacture or distribution of
11		controlled substances, and the existence in the
12		applicant's establishment of effective controls
13		against diversion;
14	(5)	Furnishing by the applicant of false or fraudulent
15		material in any application filed under this chapter;
16	(6)	Suspension, revocation, or surrender of the
17		applicant's federal registration to manufacture,
18		distribute, prescribe, or dispense controlled
19		substances as authorized by federal law; and
20	(7)	Any other factor relevant to and consistent with the
21		public health and safety.

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(b) Registration under subsection (a) does not entitle a 1 registrant to manufacture, dispense, prescribe, and distribute 2 controlled substances in schedule I or II other than those 3 specified in the registration. 4 5 Practitioners must be registered to dispense or to prescribe any controlled substances or to conduct research with 6 7 controlled substances in schedules II through V if they are 8 authorized to dispense or to prescribe or conduct research under the law of this State. The department of public safety need not 9 require separate registration under this part for practitioners 10 11 engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already 12 registered under this part in another capacity. [Practitioners 13 14 registered under federal law to conduct research with schedule I 15 substances may conduct research with schedule I substances within this State upon furnishing the department of public 16 17 safety evidence of that federal registration. 18 Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding 19 fees) entitles them to be registered under this chapter." 20 SECTION 9. Section 329-34, Hawaii Revised Statutes, is 21 amended by amending subsection (a) to read as follows: 22

1	(a)	A registration under section 329-33 to manufacture,
2	distribut	e, [or] dispense, store, conduct research, conduct
3	reverse d	istribution, or chemical analysis with a controlled
4	substance	may be suspended or revoked by the department of
5	public sa	fety upon a finding that the registrant:
6	(1)	Has furnished false or fraudulent material information
7		in any application filed under this chapter;
8	(2)	Has been convicted of a felony or has been granted a
9		motion for the deferral of acceptance of a guilty plea
10		or a nolo contendere plea to a felony, pursuant to
11		chapter 853 and under any state or federal law
12		relating to any controlled substance;
13	(3)	Has had the registrant's federal registration
14		suspended or revoked to manufacture, distribute,
15		prescribe, [or] dispense, store, conduct research,
16		conduct reverse distribution, or chemical analysis
17		with controlled substances; or
18	(4)	Has had the registrant's state license to practice the
19		registrant's profession suspended or revoked by the
20		applicable governing state board."
21	SECT	ION 10. Section 329-36, Hawaii Revised Statutes, is
22	amended t	o read as follows:

1 "§329-36 Records of registrants. Persons registered to manufacture, distribute, prescribe, [or] dispense, store, 2 conduct research, conduct reverse distribution, or chemical 3 4 analysis with controlled substances under this chapter shall 5 keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with 6 7 any additional rules the department of public safety issues." 8 SECTION 11. Section 329-37, Hawaii Revised Statutes, is amended to read as follows: 9 10 "§329-37 Filing requirements. All persons registered to 11 manufacture, distribute, conduct reverse distribution or 12 dispense controlled substances and all persons who transport, 13 warehouse, or otherwise handle controlled substances, shall file 14 with the department of public safety on forms and within the 15 time and manner prescribed by the department of public safety, 16 copies of order, receipt and distribution of schedule I and 17 schedule II controlled substances and other controlled substances designated by the department of public safety, 18 19 showing the amounts of such controlled substances ordered, 20 received, distributed, transported, warehoused, or otherwise 21 handled."

1	SECT	ION 1	2. S	ection	329-3	8,	Hawa	ii :	Revis	sed S	tatut	tes,	is
2	amended by	y ame	nding	subse	ction	(a)	to	rea	d as	foll	.ows:		
3	"(a)	No	contr	olled	substa	nce	in	sch	edule	e II	may b	oe -	
4	dispensed	with	out a	writt	en pre	scr	ipti	on	of a	prac	titic	oner,	
5	except:												
6	(1)	In t	he ca	se of a	an eme	rge	ncy	sit	uatio	on, a	a pha:	rmacis	st
7		may	dispe	nse a (contro	lle	d su	bst	ance	list	ed i	n sche	edule
8		II u	pon r	eceivi	ng ora	.l a	utho	riz	ation	n fro	om a		
9		pres	cribi	ng pra	ctitio	ner	; pr	ovi	ded t	chat:			
10		(A)	The	quanti	ty pre	scr	ibed	an	d dis	spens	sed is	s lim:	ited
11	;		to t	he amo	unt ad	lequ	ate	to	treat	: the	e pat.	ient	
12			duri	ng the	emerg	enc	y pe	rio	d (d:	Lsper	nsing	beyo	nd
13			the	emerge	ncy pe	rio	d mu	st	be pı	ırsua	ant to	оа	
14			writ	ten pr	escrip	tio	n si	gne	d by	the	pres	cribi	ng
15			prac	tition	er);								
16		(B)	If t	he pre	scribi	.ng	prac	tit	ione	r is	not	known	to
17			the]	pharma	cist,	the	pha	rma	cist	shal	ll ma	ke a	
18			reas	onable	effor	t t	o de	ter	mine	that	the	oral	
19			auth	orizat	ion ca	ıme	from	ı a	regi	stere	ed		
20			prac	tition	er, wh	ich	may	, in	clud	e a c	callb	ack t	o the
21			pres	cribin	g prac	tit	ione	r u	sing	the	phon	e num!	ber

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in the telephone directory or other good faith 1 efforts to identify the prescriber; and 2 Within seven days after authorizing an emergency 3 (C) oral prescription, the prescribing practitioner 4 shall cause a written prescription for the 5 emergency quantity prescribed to be delivered to 6 the dispensing pharmacist. In addition to 7 8 conforming to the requirements of this subsection, the prescription shall have written 9 on its face "Authorization for Emergency 10 Dispensing". The written prescription may be 11 delivered to the pharmacist in person or by mail, 12 13 and if by mail, the prescription shall be postmarked within the seven-day period. Upon 14 receipt, the dispensing pharmacist shall attach 15 this prescription to the oral emergency 16 17 prescription, which had earlier been reduced to writing. The pharmacist shall notify the 18 administrator if the prescribing practitioner 19 fails to deliver a written prescription to the 20 pharmacy within the allotted time. Failure of 21 the pharmacist to do so shall void the authority 22

1	conferred by this paragraph to dispense without a
2	written prescription of a prescribing individual
3	practitioner. Any practitioner who fails to
4	deliver a written prescription within the seven-
5	day period shall be in violation of section 329-
6	41(a)(1);
7	(2) No schedule II narcotic controlled substance may be
8	prescribed or dispensed for more than a thirty-day
9	supply;
10	$[\frac{(2)}{(3)}]$ When dispensed directly by a practitioner, other
11	than a pharmacist, to the ultimate user. The
12	practitioner in dispensing a controlled substance in
13	schedule II shall affix to the package a label
14	showing:
15	(A) The date of dispensing;
16	(B) The name, strength, and quantity of the drug
17	dispensed;
18	(C) The dispensing practitioner's name and address;
19	(D) The name of the patient;
20	(E) The "use by" date for the drug, which shall be:
21	(i) The expiration date on the manufacturer's or
22	principal labeler's container; or

1		(ii) One year from the date the drug is
2		dispensed, whichever is earlier; and
3		(F) Directions for use, and cautionary statements, if
4		any, contained in the prescription or as required
5		by law.
6		A complete and accurate record of all schedule II
7		controlled substances ordered, administered,
8		prescribed, and dispensed shall be maintained for five
9		years. Prescriptions and records of dispensing shall
10		otherwise be retained in conformance with the
11		requirements of section 329-36. No prescription for a
12		controlled substance in schedule II may be refilled;
13		or
14	(3)	In the case of an electronic prescription, a
15		pharmacist may dispense a controlled substance listed
16		in schedule II upon receiving an electronic
17	•	prescription."
18	SECT	ION 13. Section 329-49, Hawaii Revised Statutes, is
19	amended b	y amending subsection (a) to read as follows:
20	"(a)	Any person who violates this chapter or any rule
21	adopted b	y the department pursuant to this chapter shall be
22	fined not	more than \$10,000 for each separate offense. Any

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1	action taken to collect the penalty provided for in this
2	subsection shall be considered a civil action and the fine shall
3	be deposited into the [state general fund.] controlled substance
4	registration revolving fund pursuant to section 329-59."
5	SECTION 14. Section 329-52, Hawaii Revised Statutes, is
6	amended by amending subsection (c) to read as follows:
7	"(c) For purposes of this section, "controlled premises"
8	means:
9	(1) Places where persons registered or exempted from
10	registration requirements under this chapter are
11	required to keep records; and
12	(2) Places, including factories, warehouses,
13	establishments, and conveyances in which persons
14	registered or exempted from registration requirements
15	under this chapter are permitted to hold, manufacture,
16	compound, process, sell, dispense, deliver, conduct
17	chemical analysis or otherwise dispose of any
18	controlled substance or regulated chemical designated
19	under section 329-61."
20	SECTION 15. Section 329-54, Hawaii Revised Statutes, is
21	amended by amending subsection (c) to read as follows:

"(c) A practitioner engaged in medical research is not 1 required or compelled to furnish the name or identity of a 2 research subject to the department of public safety, nor may the 3 practitioner be compelled in any state or local civil, criminal, 4 administrative, legislative, or other proceedings to furnish the 5 name or identity of any research subject that the practitioner 6 is obligated to keep confidential [-] unless the subject violates 7 8 sections 329-41 or 329-46 or commits an offense pursuant to part 9 IV of chapter 712." SECTION 16. Section 329-59, Hawaii Revised Statutes, is 10 amended by amending subsection (b) to read as follows: 11 12 The fund shall consist of all moneys derived from 13 fees collected pursuant to sections 329-31 and 329-67 [and], legislative appropriations [-], and fines collected pursuant to 14 section 329-49. All fees collected pursuant to sections 329-31 15 and 329-67 and fines collected pursuant to section 329-49 shall 16 17 be deposited in the controlled substance registration revolving 18 fund." Section 329-74, Hawaii Revised Statutes, is 19 SECTION 17. amended by amending subsection (a) to read as follows: 20 "(a) A person commits the offense of unlawful transport of 21 22 pseudoephedrine if the person transports more than three

packages of any product the sale of which is restricted by 1 section 329-75 [without a permit issued from the department]." 2 3 SECTION 18. Section 329-101, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows: 4 5 The designated state agency shall determine those 6 schedules of controlled substances, classes of controlled 7 substances, and specific controlled substances that are 8 purportedly being misused and abused in the State. As part of 9 the controlled substance registration process all practitioners 10 and pharmacies shall be registered with the department to utilize the electronic prescription accountability system. 11 identified controlled substances may be dispensed unless 12 information relevant to the dispensation of the substance is 13 14 reported electronically or by means indicated by the designated state agency to the central repository established under section 15 16 329-102, in accordance with rules adopted by the department." SECTION 19. Section 329-104, Hawaii Revised Statutes, is **17** 18 amended to read as follows: 19 "§329-104 Confidentiality of information; disclosure of 20 information. (a) The information collected under this part 21 shall not be available to the public or used for any commercial

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2	State.
3	(b) Responsibility for limiting access to information in
4	the system is vested in the administrator. Access to the
5	information collected at the central repository pursuant to this
6	part shall be confidential, and access to the information shall
7	be limited to personnel of the designated state agency.
8	(c) This section shall not prevent the disclosure, at the
9	discretion of the administrator, of investigative information
10	to:
11	(1) Law enforcement officers, investigative agents of
12	federal, state, or county law enforcement or
13	regulatory agencies, United States attorneys, county
14	prosecuting attorneys, or the attorney general;
15	provided that the administrator has reasonable grounds
16	to believe that the disclosure of any information
17	collected under this part is in furtherance of an
18	ongoing criminal or regulatory investigation or
19	prosecution;
20	(2) Registrants authorized under chapters 448, 453, and
21	463E who are registered to administer, prescribe, or
22	dispense controlled substances and their practitioner

1 purpose. Ownership of all data collected shall reside with the

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1		delegate; provided that the information disclosed
2		relates only to the registrant's own patient;
3	(3)	Pharmacists[7] or pharmacist delegates, employed by a
4		pharmacy registered under section 329-32, who request
5		prescription information about a customer relating to
6		a violation or possible violation of this chapter;
7		[or]
8	(4)	Other state-authorized governmental prescription-
9		monitoring programs[-];
10	(5)	The chief medical examiner or licensed physician
11		designee who requests information and certifies the
12		request is for the purpose of investigating the death
13		of an individual;
14	<u>(6)</u>	Qualified personnel for the purpose of bona fide
15		research or education; however, data elements that
16		would reasonably identify a specific recipient,
17		prescriber, or dispenser must be deleted or redacted
18		from such information prior to disclosure; and further
19		provided that, release of the information may be made
20		only pursuant to a written agreement between qualified
21		personnel and the administrator in order to ensure
22		compliance with this subsection; and

1	(7) Other entities or individuals authorized by the
2	Administrator to assist the program with projects that
3	enhance the prescription accountability system.
4	Information disclosed to a registrant, pharmacist, or authorized
5	government agency under this section shall be transmitted by a
6	secure means determined by the designated agency.
7	(d) No person shall knowingly disclose or attempt to
8	disclose, or use or attempt to use, information in the system in
9	violation of this section. Any person who violates this section
10	is guilty of a class C felony.
11	(e) The designated state agency shall purge or cause to be
12	purged from the central repository system, no later than five
13	years after the date a patient's prescription data are made
14	available to the designated state agency, the identification
15	number of the patient, unless the information is part of an
16	active investigation."
17	SECTION 20. Section 329-31.5, Hawaii Revised Statutes, is
18	repealed.
19	[" §329-31.5 Clinics. Registration as a clinic is required
20	when an out-patient medical facility maintains centralized
21	ordering, storage, and record keeping of controlled substances

1	to be adm	inistered-and/or dispensed to patients Registration
2	of a clin	ic requires that:
3	(1)	Each location where controlled substances are stocked
4		be registered by name, location, and designated
5		principal practitioner or affiliated pharmacy. The
6		principal practitioner or affiliated pharmacy shall be
7		responsible for the accurate maintenance of records
8		which document all-controlled substances ordered,
9		received, administered, and dispensed within the
10		clinic;
11	(2)	Controlled substances stocked at a clinic under the
12		clinic State of Hawaii and Drug Enforcement
13		Administration registration numbers be administered to
14		clinic patients by licensed or registered health care
15		professionals under the supervision of the treating
16		practitioner;
17	(3)	Controlled substances stocked at a clinic under the
18		clinic-State of Hawaii-and Drug Enforcement
19		Administration registration numbers be dispensed to
20		clinic patients only by the treating practitioner for
21		emergency and urgent care, when a written prescription
22		would not be-practical;

1	(4) ·	A centralized record signed and dated by the treating
2		practitioner which indicates the patient, controlled
3		substance, date and time of administration and/or
4		dispensing-be maintained and stored with the current
5		controlled substance inventory, ordering, and receipt
6		records. These records shall be maintained for five
7		years; and
8	-(5) -	A clinic practitioner who individually maintains a
9		personal stock of controlled substances does so under
10		the practitioner's individual State and Drug
11		Enforcement Administration registration number. These
12		controlled substances shall be kept separate from
13		clinic-stock and cannot be accessed by other
14		practitioners.
15	The -	term "affiliated pharmacy" as used in this section
16	means a-l	icensed pharmacy-which supplies and monitors the
17	controlle	d substances-stocked-in a registered clinic.
18	The -	term "clinic" as used in this section means an out-
19	patient m	edical facility owned and operated by a legal entity
20	that empl	oys individual practitioners for the treatment of
21	patients-	and which may or may not provide after hours emergency
22	or urgent	- care.

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The term "principal-physician" means the practitioner in-a 1 2 clinic whose signature appears on the clinic's State of Hawaii and Drug-Enforcement Administration registrations, and who is 3 4 responsible for the proper maintenance, storage, and record 5 keeping of the controlled substances ordered and centrally 6 stocked in the clinic using the clinic Drug Enforcement 7 Administration registration-number."] 8 SECTION 21. Section 329-73, Hawaii Revised Statutes, is 9 repealed. 10 ["[\$329-73] Pseudoephedrine permit. (a)—Beginning January 1, 2006, any person transporting by any means more than 11 12 three packages of any product the sale of which is restricted by 13 section 329-75-shall obtain a pseudoephedrine permit. (b)—The requirements imposed by [subsection] (a)—shall-not 14 15 apply to persons registered with the department under section 329-67. A pseudoephedrine permit-shall be-issued-by the 16 department in a form and manner as prescribed by the department 17 by rule. A pseudoephedrine permit shall be valid for one year 18 19 and renewable annually."] SECTION 22. Statutory material to be repealed is bracketed 20 and stricken. New statutory material is underscored. 21 22 SECTION 23. This Act shall take effect upon its approval.

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1	
2	INTRODUCED BY:
3	BY REOUEST

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.

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.

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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.

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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.