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A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

- 1 SECTION 1. Chapter 329, Hawaii Revised Statutes, is
- 2 amended by adding two new sections to part IV to be
- 3 appropriately designated and to read as follows:
- 4 Administrative penalties. (a) Any person who "§329-
- violates this chapter or any rule adopted by the department 5
- 6 pursuant to this chapter shall be fined not more than \$10,000
- for each separate offense. Any action taken to collect the 7
- penalty provided for in this subsection shall be considered a 8
- civil action and the fine shall be deposited into the state 9
- 10 general fund.
- 11 In addition to any other administrative or judicial
- remedy provided by this part, or by rules adopted pursuant to 12
- 13 this chapter, the director may impose by order the
- 14 administrative penalty specified in this section. Factors to be
- considered in imposing the administrative penalty include the 15
- nature and history of the violation and of any prior violation, 16
- and the opportunity, difficulty, and history of corrective 17

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



1	requireme	ents of this definition, 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 shall be appropriate
6		to the specialty training and experience of the
7		physician or the designated member of the health care
8		team, make a diagnosis and formulate a therapeutic
9		plan, or personally treat a specific injury or
10		condition;
11	(2)	Discuss with the patient the diagnosis or treatment
12		including the benefits of other treatment options; and
13	<u>(3)</u>	Ensure the availability of appropriate follow-up
14		care."
15	SECT	ION 3. Section 329-38, Hawaii Revised Statutes, is
16	amended b	y amending subsection (g) to read as follows:
17	" (g)	Prescriptions for controlled substances shall be
18	issued on	ly as follows:
19	(1)	All prescriptions for controlled substances shall
20		originate from within the State and be dated as of,
21		and signed on, the day when the prescriptions were
22		issued and shall contain:

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1	(A)	The	first	and	last	name	and	address	of	the
2		pati	lent; a	and						

The drug name, strength, dosage form, quantity (B) prescribed, and directions for use. Where a prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.

The controlled substance prescriptions shall be no larger than eight and one-half inches by eleven inches and no smaller than three inches by four inches. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to indicate the amount of controlled substance to be dispensed. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address,

1	telephone number, and registration number of the
2	practitioner. The prescriptions may be prepared by a
3	secretary or agent for the signature of the
4	practitioner, but the prescribing practitioner shall
5	be responsible in case the prescription does not
6	conform in all essential respects to this chapter and
7	any rules adopted pursuant to this chapter. <u>In</u>
8	receiving an oral prescription from a practitioner, a
9	pharmacist shall promptly reduce the oral prescription
10	to writing, which must include the following
11	information: the name, strength, and quantity of the
12	drug, in figures only, and specific directions for the
13	drug's use; the date the oral prescription was
14	received; the full name, DEA registration number, and
15	oral code number of the practitioner; and the name and
16	address of the person for whom the controlled
17	substance was prescribed or the name of the owner of
18	the animal for which the controlled substance was
19	prescribed.
20	A corresponding liability shall rest upon a
21	pharmacist who fills a prescription not prepared in
22	the form prescribed by this section. A pharmacist may

1		add a patient's missing address or change a patient's
2		address on all controlled substance prescriptions
3		after verifying the patient's identification and
4		noting the identification number on the back of the
5		prescription. The pharmacist shall not make changes
6		to the patient's name, the controlled substance being
7		prescribed, the quantity of the prescription, the
8		practitioner's DEA number, or the practitioner's
9		signature;
10 (2	!)	An intern, resident, or foreign-trained physician, or
11		a physician on the staff of a Department of Veterans
12		Affairs facility or other facility serving veterans,
13		exempted from registration under this chapter, shall
14		include on all prescriptions issued by the physician:
15		(A) The registration number of the hospital or other
16		institution; and
17		(B) The special internal code number assigned to the
18		physician by the hospital or other institution in
19		lieu of the registration number of the
20		practitioner required by this section.
21		The hospital or other institution shall forward a copy
22		of this special internal code number list to the

1		department as often as necessary to update the
2		department with any additions or deletions. Failure
3		to comply with this paragraph shall result in the
4		suspension of that facility's privilege to fill
5		controlled substance prescriptions at pharmacies
6		outside of the hospital or other institution. Each
7		written prescription shall have the name of the
8		physician stamped, typed, or hand-printed on it, as
9		well as the signature of the physician;
10 (3)	An official exempted from registration shall include
11		on all prescriptions issued by the official:
12		(A) The official's branch of service or agency (e.g.,
13		"U.S. Army" or "Public Health Service"); and
14		(B) The official's service identification number, in
15		lieu of the registration number of the
16		practitioner required by this section. The
17		service identification number for a Public Health
18		Service employee shall be the employee's social
19		security identification number.
20		Each prescription shall have the name of the officer
21		stamped, typed, or handprinted on it, as well as the
22		signature of the officer; and

1	(4)	A physician assistant registered to prescribe
2		controlled substances under the authorization of a
3		supervising physician shall include on all controlled
4		substance prescriptions issued:
5		(A) The DEA registration number of the supervising
6		physician; and
7		(B) The DEA registration number of the physician
8		assistant.
9		Each written controlled substance prescription issued
10		shall include the printed, stamped, typed, or hand-
11		printed name, address, and phone number of both the
12		supervising physician and physician assistant, and
13		shall be signed by the physician assistant. The
14		medical record of each written controlled substance
15		prescription issued by a physician assistant shall be
16		reviewed and initialed by the physician assistant's
17		supervising physician within seven working days."
18	SECT	ION 4. Section 329-38, Hawaii Revised Statutes, is
19	amended by	y amending subsections (j), (k), (l), and (m) to read
20	as follow	s:
21	"(j)	A prescription for a schedule II controlled substance

may be transmitted by the practitioner or the practitioner's

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1	agent	to	a	pharmacy	by	facsimile	equipment;	provided	that	the
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- 2 original written, signed prescription is presented to the
- 3 pharmacist for review prior to the actual dispensing of the
- 4 controlled substance, except as noted in subsection (k), (l),
- 5 (m). The original prescription shall be maintained in
- 6 accordance with section 329-36. A prescription for a schedule
- 7 III, IV, or V controlled substance may be transmitted by the
- 8 practitioner or the practitioner's agent to a pharmacy by
- 9 facsimile; provided that:
- 10 (1) The information shall be communicated only between the
- prescribing practitioner or the prescriber's
- authorized agent and the pharmacy of the patient's
- choice[+]. The original prescription shall be
- 14 maintained by the practitioner in accordance with
- **15** section 329-36;
- 16 (2) The information shall be communicated in a
- 17 retrievable, recognizable format acceptable to the
- 18 intended recipient and shall include the physician's
- 19 oral code designation and the name of the recipient
- 20 pharmacy;
- 21 (3) No electronic system, software, or other intervening
- 22 mechanism or party shall alter the practitioner's



1		prescription, order entry, selection, or intended
2		selection without the practitioner's approval on a pe
3		prescription per order basis. Facsimile prescription
4		information shall not be altered by any system,
5		software, or other intervening mechanism or party
6		prior to receipt by the intended pharmacy;
7	(4)	The prescription information processing system shall
8		provide for confidentiality safeguards required by
9		federal or state law; and
10	(5)	Prescribing practitioners and pharmacists shall
11		exercise prudent and professional judgment regarding
12		the accuracy, validity, and authenticity of any
13		facsimile prescription information. The facsimile
14		shall serve as the original written prescription for
15		purposes of this section and shall be maintained in
16		accordance with section 329-36.
17	(k)	A prescription prepared in accordance with subsection
18	(g) writt	en for a narcotic listed in schedule II to be
19	compounde	d for the direct administration to a patient by
20	parentera	1, intravenous, intramuscular, subcutaneous, or
21	intraspin	al infusion, but does not extend to the dispensing of
22	oral dosa	ge units of controlled substances, may be transmitted

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

Ţ	(m) A prescription prepared in accordance with subsection
2	(g) written for a schedule II controlled substance for a
3	resident of a state-licensed long-term care facility may be
4	transmitted by the practitioner or the practitioner's agent to
5	the dispensing pharmacy by facsimile. The original prescription
6	shall be maintained by the practitioner in accordance with
7	section 329-36. The pharmacist shall note on the face of the
8	facsimile prescription in red ink "LTCF" and this facsimile
9	shall serve as the original written prescription for purposes of
10	this section and it shall be maintained in accordance with
11	section 329-36."
12	SECTION 5. Section 329-41, Hawaii Revised Statutes, is
13	amended to read as follows:
14	"§329-41 Prohibited acts Bpenalties. (a) It is
15	unlawful for any person:
16	(1) Who is subject to part III to distribute, administer,
17	prescribe, or dispense a controlled substance in
18	violation of section 329-38[+] or rules authorized
19	under section 329-31; however, a licensed manufacturer
20	or wholesaler may sell or dispense a controlled
21	substance to a master of a transpacific ship or a
22	person in charge of a transpacific aircraft upon which

1		no physician is regularly employed, for the actual
2		medical needs of persons on board such ship or
3		aircraft when not in port; provided schedule I or II
4		controlled substances shall be sold to the master of
5		such ship or person in charge of such aircraft only in
6		accordance with the provisions set forth in 21 Code of
7		Federal Regulations, Sections 1301, 1305, and 1307,
8		adopted pursuant to Title 21, United States Code,
9		Section 821;
10	(2)	Who is a registrant to manufacture a controlled
11		substance not authorized by the registrant's
12		registration or to distribute or dispense a controlled
13		substance not authorized by the registrant's
14		registration to another registrant or another
15		authorized person;
16	(3)	To refuse or fail to make available, keep, or furnish
17		any record, notification, order form, prescription,
18		statement, invoice, or information in patient charts
19		relating to the administration, dispensing, or
20		prescribing of controlled substances;
21	(4)	To refuse any lawful entry into any premises for any
22		inspection authorized by this chapter;

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(5)	Knowingly to keep or maintain any store, shop,
	warehouse, dwelling, building, vehicle, boat,
	aircraft, or other structure or place for the purpose
	of using these substances or which is used for keeping
	or selling them in violation of this chapter or
	chapter 712, part IV; [or]

(6) Who is a practitioner or pharmacist to dispense a controlled substance to any individual not known to the practitioner or pharmacist, without first obtaining proper identification and documenting, by signature on a log book kept by the practitioner or pharmacist, the identity of and the type of identification presented by the individual obtaining the controlled substance. If the individual does not have any form of proper identification, the pharmacist shall verify the validity of the prescription and identity of the patient with the prescriber, or their authorized agent, before dispensing the controlled substance. For the purpose of this section, "proper identification" means government-issued identification containing the photograph, printed name, and signature

1	o	f the individual obtaining the controlled
2	s	ubstance[-]; or
3	<u>(7)</u> <u>W</u>	ho is a practitioner to predate or pre-sign
4	<u>p</u>	rescriptions to facilitate the obtaining or attempted
5	<u>o</u>	btaining of controlled substances.
6	(b) I	t is unlawful for any person subject to part III of
7	this chapte	r, to administer, prescribe, or dispense any
8	controlled	substance without a bona fide physician-patient
9	relationshi	p.
10	[(b) -]	(c) Any person who violates this section is guilty
11	of a class	C felony[-]; provided that any person who violates
12	subsection	(b) shall be guilty of a crime as provided in part IV
13	of chapter	712 for the relevant type and quantity of the
14	controlled	substance administered, prescribed, or dispensed in
15	violation o	f subsection (b)."
16	SECTIO	N 6. Section 329-42, Hawaii Revised Statutes, is
17	amended by	amending subsection (a) to read as follows:
18	" (a)	It is unlawful for any person knowingly or
19	intentional	ly:
20	(1) T	o distribute as a registrant a controlled substance
21	C	lassified in schedule I or II, except pursuant to an
22	0	rder form as required by section 329-37;

1	(2)	Toju	se in the course of the manufacture [or]_
2		dist	ribution, administration, or prescribing of a
3		cont	rolled substance a registration number that is
4		fict	itious, revoked, suspended, expired, or issued to
5		anot	her person;
6	(3)	To o	btain or attempt to obtain any controlled
7		subs	tance or procure or attempt to procure the
8		ađmi	nistration of any controlled substance:
9		(A)	By fraud, deceit, misrepresentation,
10			embezzlement, theft;
11		(B)	By the forgery or alteration of a prescription or
12			of any written order;
13		(C)	By furnishing fraudulent medical information or
14			the concealment of a material fact;
15		(D)	By the use of a false name, patient
16			identification number, or the giving of false
17			address;
18		(E)	By the unauthorized use of a physician's oral
19			call-in number; or
20		(F)	By the alteration of a prescription by the
21			addition of future refills;

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(4)	To furnish false or fraudulent material information
	in, or omit any material information from, any
	application, report, or other document required to be
	kept or filed under this chapter, or any record
	required to be kept by this chapter;

- To make, distribute, or possess any punch, die, plate, (5) 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

1	(7) To make, distribute, possess, or sell any prescription
2	form, whether blank, faxed, computer generated,
3	photocopied, or reproduced in any other manner without
4	the authorization of the licensed practitioner."
5	SECTION 7. Section 329-52, Hawaii Revised Statutes, is
6	amended to read as follows:
7	"§329-52 Administrative inspections[and warrants]. [(a)
8	Issuance and execution of administrative inspection warrants
9	shall be as follows:
10	(1) A judge of the circuit court, or any district judge
11	within the judge's jurisdiction, and upon proper oath
12	or affirmation showing probable cause, may issue
13	warrants for the purpose of conducting administrative
14	inspections authorized by this chapter or rules
15	hereunder, and seizures of the property appropriate to
16	the inspections. For purposes of the issuance of
17	administrative inspection warrants, probable cause
18	exists upon showing a valid public interest in the
19	effective enforcement of this chapter or rules
20	hereunder, sufficient to justify administrative
21	inspection of the area, premises, building or

1		conveyance in the circumstances specified in the
2		application for the warrant;
3	(2)	A warrant shall issue only upon an affidavit of a
4		designated officer or employee having knowledge of the
5		facts alleged, sworn to before the judge and
6		establishing the grounds for issuing the warrant. If
7		the judge is satisfied that grounds for the
8		application exist or that there is probable cause to
9		believe they exist, the judge shall issue a warrant
10		identifying the area, premises, building, or
11		conveyance to be inspected, the purpose of the
12		inspection, and, if appropriate, the type of property
13		to be inspected, if any. The warrant shall:
14		(A) State the grounds for its issuance and the name
15		of each person whose affidavit has been taken in
16		support thereof;
17		(B) Be directed to a person authorized by section
18		329-51 to execute it;
19	• •	(C) Command the person to whom it is directed to
20		inspect the area, premises, building, or
21		conveyance identified for the purpose specified

1		and, if appropriate, direct the seix	ure of the
2		property specified;	
3		D) Identify the item or types of proper	ty to be
4		seized, if any;	
5		E) Direct that it be served during norm	nal business
6		hours and designate the judge to who	om it shall b
7		returned;	
8	(3)	warrant issued pursuant to this section	-must-be
9		executed and returned within ten days of	its date
10		nless, upon a showing of a need for addi	tional time,
11		the court orders otherwise. If property	is seized
12		oursuant to a warrant, a copy shall be gi	ven to the
13		erson from whom or from whose premises t	he property
14		s taken, together with a receipt for the	property
15		aken. The return of the warrant shall k	e made
16		romptly, accompanied by a written invent	ory of any
17		roperty taken. The inventory shall be r	nade in the
18		resence of the person executing the war	rant and of
19		he person from whose possession or premi	ses the
20		property was taken, if present, or in the	-presence of
21		t least one credible person other than t	the person
22		executing the warrant. A copy of the inv	entory shall

1		be delivered to the person from whom or from whose
2		premises the property was taken and to the applicant
3		for the warrant;
4	(4)	The judge who has issued a warrant shall attach
5		thereto a copy of the return and all papers returnable
6		in connection therewith and file them with the chief
7		clerk of the judicial circuit in which the inspection
8		was made.
9	(b)	The department of public safety may make
10	administr	tive inspections of controlled premises in accordance
11	with the	ollowing provisions:
12	(1)	For purposes of this section only, "controlled
13		oremises" means:
14		(A) Places where persons registered or exempted from
15		registration requirements under this chapter are
16		required to keep records; and
17		(B) Places including factories, warehouses,
18		establishments, and conveyances in which persons
19	•	registered or exempted from registration
20		requirements under this chapter are permitted to
21		hold, manufacture, compound, process, sell,

1		deliver, or otherwise dispose of any controlled
2		substance.
3	(2)	When authorized by an administrative inspection
4		warrant issued pursuant to subsection (a) an officer
5		or employee designated by the department of public
6		safety, upon presenting the warrant and appropriate
7		credentials to the owner, operator, or agent in
8		charge, may enter controlled premises for the purpose
9		of conducting an administrative inspection.
10	(3)	When authorized by an administrative inspection
11		warrant, an officer or employee designated by the
12		department of public safety may:
13		(A) Inspect and copy records required by this chapter
14		to be kept;
15		(B) Inspect, within reasonable limits and in a
16		reasonable manner, controlled premises and all
17		pertinent equipment, finished and unfinished
18		material, containers and labeling found therein,
19		and, except as provided in subsection (b) (5), all
20		other things therein, including records, files,
21		papers, processes, controls, and facilities
22		bearing on violation of this chapter; and

1		(C)	Inventory any stock of any controlled substance
2			therein and obtain samples thereof.
3	(4)	This	section does not prevent the inspection without a
4		warr	ant of books and records pursuant to an
5		admi	nistrative subpoena issued in accordance with law,
6		nor	does it prevent entries and administrative
7		insp	ections, including scizures of property, without a
8		warr	ant:
9		(A)	If the owner, operator, or agent in charge of the
10			controlled premises consents;
11		(B)	In situations presenting imminent danger to
12			health or safety;
13		(C)	In situations involving inspection of conveyances
14			if there is reasonable cause to believe that the
15			mobility of the conveyance makes it impracticable
16			to obtain a warrant;
17		(D)	In any other exceptional or emergency
18			circumstance where time or opportunity to apply
19			for a warrant is lacking; or
20		(E)	In all other situations in which a warrant is not
21			constitutionally required.

1	(5) An	inspection authorized by this section shall not
2	e xi	tend to financial data, sales data, other than
3	sh :	ipment data, or pricing data unless the owner,
4	өрө	erator, or agent in charge of the controlled
5	pre	emises consents in writing.]
6	(a) The adm:	inistrator or any of the administrator's agents may
7	make administ	trative inspections of controlled premises upon
8	presenting ap	opropriate credentials to the registrant or persons
9	subject to pa	art III, IV, VIII, and IX of this chapter or their
10	agents in acc	cordance with the following provisions:
11	<u>(1)</u> <u>For</u>	purposes of this section only, "controlled
12	pre	emises" means:
13	(A)	Places where persons registered or exempted from
14		registration requirements under this chapter are
15		required to keep records; and
16	<u>(B)</u>	Places including factories, warehouses,
17		establishments, and conveyances in which persons
18		registered or exempted from registration
19		requirements under this chapter are permitted to
20		hold, manufacture, compound, process, sell,
21		dispense, deliver, or otherwise dispose of any

1		controlled substance or regulated chemical
2		designated under 329-61.
3	(2)	Inspections shall be at reasonable times and within
4		reasonable limits and in a reasonable manner of
5		controlled premises and vehicles in which persons
6		registered or exempted from registration requirements
7		under this chapter are permitted to hold, manufacture,
8		compound, process, sell, dispense, deliver, or
9		otherwise dispose of any controlled substance or
10	•	regulated chemical designated under 329-61 and all
11		pertinent equipment, finished and unfinished
12		materials, containers, and labeling therein to
13		determine if this chapter is being violated;
14	(3)	The administrator or any of the administrator's agents
15		shall have access to and may copy any and all records,
16		books, logs, or documents pertaining to the
17		administering, prescribing, dispensing, or sale of
18		controlled substances or regulated chemicals
19		designated under this chapter without a warrant; and
20	(4)	The administrator or any of the administrator's agents
21		may inventory any stock of any controlled substance or
22		regulated chemical designated under 329-61 and secure

1		samples or specimens of any drug, device, or chemical
2		not seized as evidence by paying or offering to pay
3		for the sample. The administrator shall make or cause
4		to be made examinations of samples secured under this
5		section to determine whether or not this chapter is
6		being violated.
7	<u>(b)</u>	An inspection of records authorized by this section
8	shall not	extend to financial data, data relating to pricing of
9	items, oth	her than shipment and sale amounts, unless the owner,
10	operator,	or agent in charge of the controlled premises consents
11	in writing	g."
12	SECT	ION 8. Statutory material to be repealed is bracketed
13	and stric	ken. New statutory material is underscored.
14	SECT	ION 9. This Act shall take effect on July 1, 2007.
15		
		INTRODUCED BY: Tranne Chun Cakland

16

Report Title:

Controlled Substances

Description:

Prohibits pre-signed and predated prescriptions. Clarifies how the narcotic enforcement division administrator shall conduct inspections at pharmacies.