A BILL FOR AN ACT

RELATING TO CONTROLLED SUBSTANCES.

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

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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	"§329- Administrative penalties. (a) Any person who
5	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.

- (b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this chapter, the director may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the
- 16 nature and history of the violation and of any prior violation,
- 17 and the opportunity, difficulty, and history of corrective



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- 1 action. For any judicial proceeding to recover the administrative penalty imposed, the administrator need only show 2 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 or any rule adopted to implement this chapter. The court shall 10 11 have powers to grant relief in accordance with the Hawaii rules of civil procedure." 12 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 16 17 physician assistants, advanced practice registered nurses, and 18 covering physicians. 19 "Physician-patient relationship" means the collaborative
- relationship between physicians and their patients. The health
 and well being of patients depends upon a collaborative
 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,	must:
4	<u>(1)</u>	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	(3)	Ensure the availability of appropriate follow-up
14		care."
15	SECT	ION 3. Section 329-38, Hawaii Revised Statutes, is
16	amended by	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	patient; and
3	(B) The drug name, strength, dosage form, quantity
4	prescribed, and directions for use. Where a
5	prescription is for gamma hydroxybutyric acid,
6	methadone, or buprenorphine, the practitioner
7	shall record as part of the directions for use,
8	the medical need of the patient for the
9	prescription.
10	The controlled substance prescriptions shall be no
11	larger than eight and one-half inches by eleven inches
12	and no smaller than three inches by four inches.
13	A practitioner may sign a prescription in the same
14	manner as the practitioner would sign a check or legal
15	document (e.g., J.H. Smith or John H. Smith) and shall
16	use both words and figures (e.g., alphabetically and
17	numerically as indications of quantity, such as five
18	(5)), to indicate the amount of controlled substance
19	to be dispensed. Where an oral order is not
20	permitted, prescriptions shall be written with ink or
21	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 pharmacist
21	who fills a prescription not prepared in the form
22	prescribed by this section. A pharmacist may add a

1	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

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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	SECTION 4. Section 329-38, Hawaii Revised Statutes, is
19	amended by amending subsections (j), (k), (l), and (m) to read
20	as follows:
21	"(j) A prescription for a schedule II controlled substance
22	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
2	original	written, signed prescription is presented to the
3	pharmacis	t for review prior to the actual dispensing of the
4	controlle	d substance, except as noted in subsection (k), (1),
5	(m). The	original prescription shall be maintained in
6	accordanc	e with section 329-36. A prescription for a schedule
7	III, IV,	or V controlled substance may be transmitted by the
8	practitio	ner or the practitioner's agent to a pharmacy by
9	facsimile	; provided that:
10	(1)	The information shall be communicated only between the
11		prescribing practitioner or the prescriber's
12		authorized agent and the pharmacy of the patient's
13		choice[+]. The original prescription shall be
14		maintained by the practitioner in accordance with
15		<u>section 329-36;</u>
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

mechanism or party shall alter the practitioner's

1		prescription, order entry, selection, or intended
2		selection without the practitioner's approval on a per
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) writte	en for a narcotic listed in schedule II to be
19	compounded	d for the direct administration to a patient by
20	parentera	l, 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.

1	(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

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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; [ox]

(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		of the individual obtaining the controlled
2		substance[-];
3	(7)	Who is a practitioner to predate or pre-sign
4		prescriptions to facilitate the obtaining or attempted
5		obtaining of controlled substances; or
6	(8)	Who is a practitioner to facilitate the issuance or
7		distribution of a written prescription or to issue an
8		oral prescription for a controlled substance when not
9		physically in the state.
10	(b)	It is unlawful for any person subject to part III of
11	this chap	ter, to administer, prescribe, or knowingly dispense
12	any contr	olled substance without a bona fide physician-patient
13	relations	hip.
14	[-(b)] (c) Any person who violates this section is guilty
15	of a clas	s C felony[-]; provided that any person who violates
16	subsection	n (b) shall be guilty of a crime as provided in part IV
17	of chapte	r 712 for the relevant type and quantity of the
18	controlle	d substance administered, prescribed, or dispensed in
19	violation	of subsection (b)."
20	SECT	ION 6. Section 329-42, Hawaii Revised Statutes, is
21	amended by	y amending subsection (a) to read as follows:

1	"(a)	It is unlawful for any person knowingly or
2	intentiona	ally:
3	(1)	To distribute as a registrant a controlled substance
4		classified in schedule I or II, except pursuant to an
5		order form as required by section 329-37;
6	(2)	To use in the course of the manufacture [or],
7		distribution, administration, or prescribing of a
8		controlled substance a registration number that is
9		fictitious, revoked, suspended, expired, or issued to
10		another person;
11	(3)	To obtain or attempt to obtain any controlled
12		substance or procure or attempt to procure the
13	•	administration of any controlled substance:
14	((A) By fraud, deceit, misrepresentation, embezzlement,
15		theft;
16	((B) By the forgery or alteration of a prescription or
17		of any written order;
18	((C) By furnishing fraudulent medical information or
19		the concealment of a material fact;
20	((D) By the use of a false name, patient identification
21		number, or the giving of false address;

1		(E) By the unauthorized use of a physician's oral
2		call-in number; or
3		(F) By the alteration of a prescription by the
4		addition of future refills;
5	(4)	To furnish false or fraudulent material information
6		in, or omit any material information from, any
7		application, report, or other document required to be
8		kept or filed under this chapter, or any record
9		required to be kept by this chapter;
10	(5)	To make, distribute, or possess any punch, die, plate,
11		stone, or other thing designed to print, imprint, or
12		reproduce the trademark, trade name, or other
13		identifying mark, imprint, or device of another or any
14		likeness of any of the foregoing upon any drug or
15		container or labeling thereof so as to render the drug
16		a counterfeit substance;
17	(6)	To misapply or divert to the person's own use or other
18		unauthorized or illegal use or to take, make away
19		with, or secrete, with intent to misapply or divert to
20		the person's own use or other unauthorized or illegal
21		use, any controlled substance that shall have come

into the person's possession or under the person's

1		care as a registrant or as an employee of a registrant
2		who is authorized to possess controlled substances or
3		has access to controlled substances by virtue of the
4		person's employment; or
5	(7)	To make, distribute, possess, or sell any prescription
6		form, whether blank, faxed, computer generated,
7	,	photocopied, or reproduced in any other manner without
8		the authorization of the licensed practitioner."
9	SECT	ION 7. Section 329-52, Hawaii Revised Statutes, is
10	amended to	o read as follows:
11	"§32:	9-52 Administrative inspections[-and-warrants]. [-(a)-
12	Issuance d	and execution of administrative inspection warrants
13	shall be	as follows:
14	(1)	A judge of the circuit court, or any district judge
15		within the judge's jurisdiction, and upon proper oath
16		or affirmation showing probable cause, may issue
17		warrants for the purpose of conducting administrative
18		inspections authorized by this chapter or rules
19		hereunder, and seizures of the property appropriate to
20		the inspections. For purposes of the issuance of
21		administrative inspection warrants, probable cause
22		exists upon showing a valid public interest in the

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

1	(c) command the person to whom it is directed to
2	inspect the area, premises, building, or
3	conveyance identified for the purpose specified
4	and, if appropriate, direct the seizure of the
5	property specified;
6	(D) Identify the item or types of property to be
7	seized, if any;
8	(E) Direct that it be served during normal business
9	hours and designate the judge to whom it shall be
10	returned;
11	(3) A warrant issued pursuant to this section must be
12	executed and returned within ten days of its date
13	unless, upon a showing of a need for additional time,
14	the court orders otherwise. If property is seized
15	pursuant to a warrant, a copy shall be given to the
16	person from whom or from whose premises the property
17	is taken, together with a receipt for the property
18	taken. The return of the warrant shall be made
19	promptly, accompanied by a written inventory of any
20	property taken. The inventory shall be made in the
21	presence of the person executing the warrant and of
22	the person from whose possession or premises the

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

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

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

1	(E) In all other situations in which a warrant is not
2	constitutionally required.
3	(5) An inspection authorized by this section shall not
4	extend to financial data, sales data, other than
5	shipment data, or pricing data unless the owner,
6	operator, or agent in charge of the controlled
7	premises consents in writing.]
8	(a) The administrator or any of the administrator's agents may
9	make administrative inspections of controlled premises upon
10	presenting appropriate credentials to the registrant or persons
11	subject to part III, IV, VIII, and IX of this chapter or their
12	agents in accordance with the following provisions:
13	(1) For purposes of this section only, "controlled
14	<pre>premises means:</pre>
15	(A) Places where persons registered or exempted from
16	registration requirements under this chapter are
17	required to keep records; and
18	(B) Places including factories, warehouses,
19	establishments, and conveyances in which persons
20	registered or exempted from registration
21	requirements under this chapter are permitted to
22	hold, manufacture, compound, process, sell,

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

1		regulated chemical designated under 329-61 and secure
2		samples or specimens of any drug, device, or chemical
3		not seized as evidence by paying or offering to pay
4		for the sample. The administrator shall make or cause
5		to be made examinations of samples secured under this
6	•	section to determine whether or not this chapter is
7		being violated.
8	(b)	An inspection of records authorized by this section
9	shall not	extend to financial data, data relating to pricing of
10	items, ot	her than shipment and sale amounts, unless the owner,
11	operator,	or agent in charge of the controlled premises consents
12	in writing	g."
13	SECT	ION 8. Statutory material to be repealed is bracketed
14	and stric	ken. New statutory material is underscored.
15	SECT:	ION 9. This Act shall take effect on July 1, 2007.

Report Title:

Controlled Substances

Description:

Prohibits pre-signed and predated prescriptions. Clarifies how the narcotic enforcement division administrator shall conduct inspections at pharmacies. (SD1)