2013 -- H 5756 SUBSTITUTE B

LC01858/SUB B

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2013

AN ACT

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

<u>Introduced By:</u> Representatives McNamara, Azzinaro, Bennett, Corvese, and Handy <u>Date Introduced:</u> February 28, 2013 <u>Referred To:</u> House Health, Education & Welfare

It is enacted by the General Assembly as follows:

1	SECTION 1. Section	21-28-3.18 of the	General	Laws in	Chapter	21-28	entitled
2	"Uniform Controlled Substances	Act" is hereby amen	ded to rea	d as follo	ws:		

3	<u>21-28-3.18.</u> Prescriptions (a) An apothecary in good faith may sell and dispense
4	controlled substances in schedule II, III, IV and V to any person upon a written valid prescription
5	by a practitioner licensed by law to prescribe or administer those substances, dated and signed by
6	the person prescribing on the day when issued and bearing the full name and address of the
7	patient to whom, or of the owner of the animal for which the substance is dispensed and the full
8	name, address and registration number under the federal law of the person prescribing, if he or
9	she is required by that law to be registered. If the prescription is for an animal, it shall state the
10	species of the animal for which the substance is prescribed.

- (b) The When filling a hard-copy prescription for a schedule II controlled substance, the
 apothecary filling the prescription shall sign his or her full name and shall write the date of filling
 on the face of the prescription.
- (c) The prescription shall be retained on file by the proprietor of the pharmacy in which it
 was filled for a period of two (2) years so as to be readily accessible for inspection by any public
 officer or employee engaged in the enforcement of this chapter.

(d) (1) Prescriptions Hard copy prescriptions for controlled substances in schedule II shall

18 be filed separately and shall not be refilled.

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(2) The director of health may, after appropriate notice and hearing pursuant to § 42-35-3,

promulgate rules and regulations for the purpose of adopting a system for electronic data 1 2 transmission of prescriptions for controlled substances in schedule II and, III and IV.

3 (3) A practitioner may sign and transmit electronic prescriptions for controlled substances 4 and a pharmacy may dispense an electronically transmitted prescription in accordance with the code of federal regulations, title 21 part 1300, et seq. 5

(e) A prescription for a schedule II narcotic substance to be compounded for the direct 6 7 administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal 8 infusion may be transmitted by the practitioner or practitioner's agent to the pharmacy by 9 facsimile. The facsimile will serve as the original prescription.

10 (f) A prescription written for a schedule II substance for a resident of a long term care 11 facility may be transmitted by the practitioner or the practitioner's agent to the dispensing 12 pharmacy by facsimile. The facsimile serves as the original prescription.

13 (g) A prescription for a schedule II narcotic substance for a patient residing in a hospice 14 certified by Medicare under title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., or 15 licensed by the state, may be transmitted by the practitioner or practitioner's agent to the 16 dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the 17 prescription that the patient is a hospice patient. The facsimile serves as the original written 18 prescription.

19 (h) An apothecary, in lieu of a written prescription, may sell and dispense controlled 20 substances in schedules III, IV, and V to any person upon an oral prescription of a practitioner. In 21 issuing an oral prescription the prescriber shall furnish the apothecary with the same information 22 as is required by subsection (a) of this section in the case of a written prescription for controlled 23 substances in schedule II, except for the written signature of the person prescribing, and the 24 apothecary who fills the prescription, shall immediately reduce the oral prescription to writing 25 and shall inscribe the information on the written record of the prescription made. This record shall 26 be filed and preserved by the proprietor of the pharmacy in which it is filled in accordance with 27 the provisions of subsection (c) of this section. In no case may a prescription for a controlled 28 substance listed in schedules III, IV, or V be filled or refilled more than six (6) months after the 29 date on which the prescription was issued and no prescription shall be authorized to be refilled 30 more than five (5) times. Each refilling shall be entered on the face or back of the prescription 31 and note the date and amount of controlled substance dispensed, and the initials or identity of the 32 dispensing apothecary.

33 (i) In the case of an emergency situation as defined in federal law, an apothecary may 34 dispense a controlled substance listed in schedule II upon receiving an oral authorization of a 1 prescribing practitioner provided that:

2 (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the 3 patient during the emergency period and dispensing beyond the emergency period must be 4 pursuant to a written prescription signed by the prescribing practitioner.

5 (2) The prescription shall be immediately reduced to writing and shall contain all the information required in subsection (a) of this section. 6

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(3) The prescription must be dispensed in good faith in the normal course of professional 8 practice.

9 (4) Within seven (7) days after authorizing an emergency oral prescription, the 10 prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to 11 be delivered to the dispensing apothecary. The prescription shall have written on its face 12 "Authorization for emergency dispensing" and the date of the oral order. The written prescription 13 upon receipt by the apothecary shall be attached to the oral emergency prescription which had 14 earlier been reduced to writing.

15 (j) (1) The partial filling of a prescription for a controlled substance listed in schedule II 16 is permissible, if the apothecary is unable to supply the full quantity called for in a written 17 prescription or emergency oral prescription and he or she makes a notation of the quantity 18 supplied on the face of the written prescription or oral emergency prescription which has been 19 reduced to writing. The remaining portion of the prescription may be filled within seventy-two 20 (72) hours of the first partial filling, however, if the remaining portion is not, or cannot be filled 21 within seventy-two (72) hours, the apothecary shall notify the prescribing practitioner. No further 22 quantity may be supplied beyond seventy-two (72) hours without a new prescription.

23 (2) (i) A prescription for a schedule II controlled substance written for a patient in a long 24 term care facility (LTCF), or for a patient with a medical diagnosis documenting a terminal 25 illness, may be filled in partial quantities to include individual dosage units. If there is a question 26 whether a patient may be classified as having a terminal illness, the pharmacist must contact the 27 practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing 28 practitioner have a corresponding responsibility to assure that the controlled substance is for a 29 terminally ill patient.

30 (ii) The pharmacist must record on the prescription whether the patient is "terminally ill" 31 or an "LTCF patient." A prescription that is partially filled, and does not contain the notation 32 "terminally ill" or "LTCF patient", shall be deemed to have been filled in violation of this chapter. 33 (iii) For each partial filling, the dispensing pharmacist shall record on the back of the 34 prescription (or on another appropriate record, uniformly maintained, and readily retrievable),

1	the:			
2	(A) Date of the partial filling;			
3	(B) Quantity dispensed;			
4	(C) Remaining quantity authorized to be dispensed; and			
5	(D) Identification of the dispensing pharmacist.			
6	(iv) The total quantity of schedule II controlled substances dispensed in all partial fillings			
7	must not exceed the total quantity prescribed.			
8	(v) Schedule II prescriptions for patients in a LTCF, or patients with a medical diagnosis			
9	documenting a terminal illness, are valid for a period not to exceed sixty (60) days from the issue			
10	date, unless sooner terminated by the discontinuance of medication.			
11	(k) Automated data processing systems. As an alternative to the prescription record			
12	keeping provision of subsection (h) of this section, an automated data processing system may be			
13	employed for the record keeping system, if the following conditions have been met:			
14	(1) The system shall have the capability of producing sight-readable documents of all			
15	original and refilled prescription information. The term "sight-readable" means that an authorized			
16	agent shall be able to examine the record and read the information. During the course of an on-			
17	site inspection, the record may be read from the CRT, microfiche, microfilm, printout, or other			
18	method acceptable to the director. In the case of administrative proceedings, records must be			
19	provided in a paper printout form.			
20	(2) The information shall include, but not be limited to, the prescription requirements and			
21	records of dispensing as indicated in subsection (h) of this section.			
22	(3) The individual pharmacist responsible for completeness and accuracy of the entries to			
23	the system must provide documentation of the fact that prescription information entered into the			
24	computer is correct. In documenting this information, the pharmacy shall have the option to			
25	either:			
26	(i) Maintain a bound log book, or separate file, in which each individual pharmacist			
27	involved in the dispensing shall sign a statement each day, attesting to the fact that the			
28	prescription information entered into the computer that day has been reviewed and is correct as			
29	shown. The book or file must be maintained at the pharmacy employing that system for a period			
30	of at least two (2) years after the date of last dispensing; or			
31	(ii) Provide a printout of each day's prescription information. That printout shall be			

32 verified, dated, and signed by the individual pharmacist verifying that the information indicated is 33 correct. The printout must be maintained at least two (2) years from the date of last dispensing.

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(4) An auxiliary record keeping system shall be established for the documentation of

refills, if the automated data processing system is inoperative for any reason. The auxiliary 1 2 system shall ensure that all refills are authorized by the original prescription, and that the 3 maximum number of refills is not exceeded. When this automated data processing system is 4 restored to operation, the information regarding prescriptions filled and refilled during the 5 inoperative period, shall be entered into the automated data processing system within ninety-six (96) hours. 6

7 (5) Any pharmacy using an automated data processing system must comply with all 8 applicable state and federal laws and regulations.

9 (6) A pharmacy shall make arrangements with the supplier of data processing services or 10 materials to ensure that the pharmacy continues to have adequate and complete prescription and 11 dispensing records if the relationship with the supplier terminates for any reason. A pharmacy 12 shall ensure continuity in the maintenance of records.

13 (7) The automated data processing system shall contain adequate safeguards for security 14 of the records, to maintain the confidentiality and accuracy of the prescription information. 15 Safeguards against unauthorized changes in data after the information has been entered and 16 verified by the registered pharmacist shall be provided by the system.

17 (1) Prescriptions for controlled substances as found in schedules II, will become void 18 unless dispensed within ninety (90) days of the original date of the prescription, and in no event 19 shall more than a thirty (30) day supply be dispensed at any one time.

20 (1) In prescribing controlled substances in schedule II, practitioners may write up to three 21 (3) separate prescriptions, each for up to a one-month supply, each signed and dated on the date 22 written. For those prescriptions for the second and/or third month, the practitioner must write the 23 earliest date each of those subsequent prescription may be filled, with directions to the pharmacist 24 to fill no earlier than the date specified on the face of the prescription.

25 (m) The prescriptions in schedules III, IV, and V will become void unless dispensed 26 within one hundred eighty (180) days of the original date of the prescription. For purposes of this 27 section, a "dosage unit" shall be defined as a single capsule, tablet or suppository, or not more 28 than one five (5) ml. of an oral liquid.

29 (1) Prescriptions in Schedule III cannot be written for more than one hundred (100) 30 dosage units and not more than one hundred (100) dosage units may be dispensed at one time.

31 (2) Prescriptions in Schedule IV and V may be written for up to a ninety (90) day supply 32 based on directions. No more than three hundred and sixty (360) dosage units may be dispensed 33 at one time.

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SECTION 1. Chapter 21-28 of the General Laws entitled "Uniform Controlled

- Substances Act" is hereby amended by adding thereto the following section:
- 1 2 21-28-3.32. Electronic prescription database. -- (a) The information contained in any 3 prescription drug monitoring database maintained by the department of health pursuant to section 4 3.18 of this chapter shall be disclosed only: 5 (1) To a practitioner who certifies that the requested information is for the purpose of evaluating the need for or providing medical treatment for a current patient to whom the 6 7 practitioner is prescribing or considering prescribing a controlled substance; 8 (2) To a pharmacist who certifies that the requested information is for a current client to 9 whom the pharmacist is dispensing or considering dispensing a controlled substance; 10 (3) Pursuant to a valid search warrant based on probable cause to believe a violation of 11 federal or state criminal law has occurred and that specified information contained in the database 12 would assist in the investigation of the crime; 13 (4) To a patient who requests his or her own prescription information, or the parent or 14 legal guardian of a minor child who requests the minor child's prescription information; 15 (5) To a health professional regulatory board that documents, in writing, that the 16 requested information is necessary for an investigation related to licensure, renewal or 17 disciplinary action involving the applicant, licensee or registrant to whom the requested 18 information pertains; 19 (6) To any vendor or contractor with whom the department has contracted to establish or 20 maintain the electronic system of the prescription drug monitoring database; or 21 (7) To public or private entities for statistical, research, or educational purposes, after 22 removing the patient and prescriber information that could be used to identify individual patients. 23 This shall not include entities receiving a waiver from the institutional review board. 24 (b) Information stored in the prescription drug monitoring database shall include only the 25 following: 26 (1) Patient's first and last name, and/or patient identification number; provided, however, 27 the patient's social security number shall not be recorded in whole or in part, patient sex, patient date of birth, and patient address; 28 29 (2) Prescribing practitioner's name and drug enforcement administration prescriber 30 information number; 31 (3) Prescribing practitioner's office or hospital contact information; 32 (4) Prescription name, prescription number, prescription species code, national drug code 33 number, prescription dosage, prescription quantity, days' supply, new-refill code, number of
- refills authorized, date the prescription was written, date the prescription was filled, payment 34

1 type; provided, however, no credit card number shall be recorded in whole or in part; and

- 2 (5) The drug enforcement administration pharmacy number of the pharmacy filling the
 3 prescription.
- 4 (c) The department shall disclose any information relating to a patient maintained in the 5 prescription drug monitoring database to that patient, at no cost to the patient, within thirty (30) business days after the department receives a written request from the patient for the information. 6 7 This information shall include the records maintained by the department pursuant to subsection 8 (e). Notwithstanding the above, the department may, at the request of the law enforcement 9 agency, withhold for up to sixty (60) days following the conclusion of a law enforcement 10 investigation, the disclosure to the patient that information has been obtained pursuant to 11 subdivision (a)(3). 12 (d) A patient may request from the dispensing pharmacy correction of any inaccurate 13 information contained within the prescription drug monitoring database in accordance with the 14 procedure specified by subsection 5-37.3-5(c). 15 (e) The department shall, for the period of time that prescription information is 16 maintained, maintain records of the information disclosed through the prescription drug 17 monitoring database, including, but not limited to: 18 (1) The identity of each person who requests or receives information from the 19 prescription drug monitoring database and the organization, if any, the person represents; 20 (2) The information released to each person or organization and the basis for its release 21 under subsection (a); and 22 (3) The dates the information was requested and provided. 23 (f) Prescription information contained within the prescription drug monitoring database 24 shall be removed no later than five (5) years from the date the information is entered into the 25 database. Records in existence prior to the enactment of this section shall be removed no later 26 than ten (10) years from the date the information is entered into the database. 27 (g) The department shall promptly notify any affected individual of an improper 28 disclosure of information from the prescription drug monitoring database or a breach in the 29 security of the prescription drug monitoring database that poses a significant risk of disclosure of 30 patient information to an unauthorized individual. 31 (h) At the time of signing a prescription which is required by the department to be entered 32 into the prescription drug monitoring database, the prescribing practitioner shall inform the 33 patient in writing of the existence of the prescription drug monitoring database, the patient's right
- 34 to access their own prescription information, and the name and contact information of the agency

- 1 <u>operating the program.</u>
- 2 (i) No person shall access information in the prescription monitoring database except to
- 3 the extent and for the purposes authorized by subsection (a).
- 4 (j) In any civil action allowing a violation of this chapter, the court may award damages,
- 5 including punitive damages, and reasonable attorneys' fees and costs to a prevailing plaintiff, and
- 6 <u>injunctive and any other appropriate relief.</u>
- 7 (k) Any pharmacist who, in his or her professional judgment, refuses to fill a prescription
- 8 <u>based on information contained within the prescription drug monitoring database shall inform the</u>
- 9 prescribing physician within twenty-four (24) hours.
- 10 SECTION 2. This act shall take effect upon passage.

LC01858/SUB B

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

AN ACT

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

1 This act would require the director of the department of health, after appropriate notice 2 and hearing, to promulgate rules and regulations for the purpose of adopting a system for 3 electronic data transmission of prescriptions for controlled substances in schedule II, III and IV. 4 This act would take effect upon passage.

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