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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

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A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Representatives Bennett, Solomon, Coughlin, Hull, and Shekarchi

Date Introduced: March 03, 2016

Referred To: House Health, Education & Welfare

(Dept. of Health)

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 "Uniform
2 Controlled Substances Act" is hereby amended to read as follows:

3 **21-28-3.18. 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 valid prescription by a
5 practitioner licensed by law to prescribe or administer those substances, dated and signed by the
6 person prescribing on the day when issued and bearing the full name and address of the patient to
7 whom, or of the owner of the animal for which, the substance is dispensed and the full name,
8 address, and registration number under the federal law of the person prescribing, if he or she is
9 required by that law to be registered. If the prescription is for an animal, it shall state the species
10 of the animal for which the substance is prescribed.

11 (b) When filling a hard-copy prescription for a schedule II controlled substance, the
12 apothecary filling the prescription shall sign his or her full name and shall write the date of filling
13 on the face of the prescription.

14 (c) The prescription shall be retained on file by the proprietor of the pharmacy in which
15 it was filled for a period of two (2) years so as to be readily accessible for inspection by any
16 public officer or employee engaged in the enforcement of this chapter.

17 (d) (1) Hard copy prescriptions for controlled substances in schedule II shall be filed
18 separately and shall not be refilled.

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

1 3, promulgate rules and regulations for the purpose of adopting a system for electronic data
2 transmission, including by facsimile, of prescriptions for controlled substances in schedule II, III,
3 ~~and~~ IV, and V.

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

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

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

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

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

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

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

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

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

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

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

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

29 (ii) The pharmacist must record on the prescription whether the patient is "terminally ill"
30 or an "LTCF patient." A prescription that is partially filled, and does not contain the notation
31 "terminally ill" or "LTCF patient", shall be deemed to have been filled in violation of this chapter.

32 (iii) For each partial filling, the dispensing pharmacist shall record on the back of the
33 prescription (or on another appropriate record, uniformly maintained, and readily retrievable),
34 the:

- 1 (A) Date of the partial filling;
- 2 (B) Quantity dispensed;
- 3 (C) Remaining quantity authorized to be dispensed; and
- 4 (D) Identification of the dispensing pharmacist.

5 (iv) The total quantity of schedule II controlled substances dispensed in all partial fillings
6 must not exceed the total quantity prescribed.

7 (v) Schedule II prescriptions for patients in a LTCF, or patients with a medical diagnosis
8 documenting a terminal illness, are valid for a period not to exceed sixty (60) days from the issue
9 date, unless sooner terminated by the discontinuance of medication.

10 (k) Automated data processing systems. - As an alternative to the prescription record
11 keeping provision of subsection (h) of this section, an automated data processing system may be
12 employed for the record-keeping system if the following conditions have been met:

13 (1) The system shall have the capability of producing sight-readable documents of all
14 original and refilled prescription information. The term "sight-readable" means that an authorized
15 agent shall be able to examine the record and read the information. During the course of an on-
16 site inspection, the record may be read from the CRT, microfiche, microfilm, printout, or other
17 method acceptable to the director. In the case of administrative proceedings, records must be
18 provided in a paper printout form.

19 (2) The information shall include, but not be limited to, the prescription requirements
20 and records of dispensing as indicated in subsection (h) of this section.

21 (3) The individual pharmacist responsible for completeness and accuracy of the entries
22 to the system must provide documentation of the fact that prescription information entered into
23 the computer is correct. In documenting this information, the pharmacy shall have the option to
24 either:

25 (i) Maintain a bound log book, or separate file, in which each individual pharmacist
26 involved in the dispensing shall sign a statement each day attesting to the fact that the prescription
27 information entered into the computer that day has been reviewed and is correct as shown. The
28 book or file must be maintained at the pharmacy employing that system for a period of at least
29 two (2) years after the date of last dispensing; or

30 (ii) Provide a printout of each day's prescription information. That printout shall be
31 verified, dated, and signed by the individual pharmacist verifying that the information indicated is
32 correct. The printout must be maintained at least two (2) years from the date of last dispensing.

33 (4) An auxiliary record-keeping system shall be established for the documentation of
34 refills if the automated, data-processing system is inoperative for any reason. The auxiliary

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

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

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

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

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

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

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

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

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

1 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

- 1 This act would allow for electronic system data transmission of Schedule V prescriptions.
- 2 This act would take effect upon passage.

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