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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2014

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A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROLLED SUBSTANCES ACT

Introduced By: Senator Maryellen Goodwin

Date Introduced: February 27, 2014

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Sections 21-28-3.11 and 21-28-3.18 of the General Laws in Chapter 21-28
2 entitled "Uniform Controlled Substances Act" are hereby amended to read as follows:

3 **21-28-3.11. Form, delivery, and preservation of official written orders.** – (a) An
4 official written order for any controlled substance shall be signed in duplicate by the person
5 giving the order or by his or her duly authorized agent. The original shall be presented to the
6 person who sells or distributes the controlled substances named in it. In the event of the
7 acceptance of the order by that person, each party to the transaction shall preserve his or her copy
8 of the order for a period of two (2) years in such a way as to be readily accessible for inspection
9 by any public officer or employee engaged in the enforcement of this chapter. It shall be deemed
10 a compliance with this section if the parties to the transaction have complied with the federal law
11 respecting the requirements governing the use of order forms.

12 (b) Nothing in this section shall be construed as prohibiting the person giving the order,
13 or his or her duly authorized agent, from presenting said order to the person who sells or
14 distributes the controlled substances named in it by use of facsimile transmission.

15 **21-28-3.18. Prescriptions.** -- (a) An apothecary in good faith may sell and dispense
16 controlled substances in schedule II, III, IV and V to any person upon a valid prescription by a
17 practitioner licensed by law to prescribe or administer those substances, dated and signed by the
18 person prescribing on the day when issued and bearing the full name and address of the patient to
19 whom, or of the owner of the animal for which the substance is dispensed and the full name,

1 address and registration number under the federal law of the person prescribing, if he or she is
2 required by that law to be registered. If the prescription is for an animal, it shall state the species
3 of the animal for which the substance is prescribed.

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

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

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

12 (2) The director of health ~~may~~ shall, after appropriate notice and hearing pursuant to
13 section 42-35-3, promulgate rules and regulations for the purpose of adopting a system for
14 electronic data transmission, including by facsimile, of prescriptions for controlled substances in
15 schedule II, III and IV.

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

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

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

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

32 (h) An apothecary, in lieu of a written prescription, may sell and dispense controlled
33 substances in schedules III, IV, and V to any person upon an oral prescription of a practitioner. In
34 issuing an oral prescription the prescriber shall furnish the apothecary with the same information

1 as is required by subsection (a) of this section and the apothecary who fills the prescription, shall
2 immediately reduce the oral prescription to writing and shall inscribe the information on the
3 written record of the prescription made. This record shall be filed and preserved by the proprietor
4 of the pharmacy in which it is filled in accordance with the provisions of subsection (c) of this
5 section. In no case may a prescription for a controlled substance listed in schedules III, IV, or V
6 be filled or refilled more than six (6) months after the date on which the prescription was issued
7 and no prescription shall be authorized to be refilled more than five (5) times. Each refilling shall
8 be entered on the face or back of the prescription and note the date and amount of controlled
9 substance dispensed, and the initials or identity of the dispensing apothecary.

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

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

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

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

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

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

34 (2) (i) A prescription for a schedule II controlled substance written for a patient in a long

1 term care facility (LTCF), or for a patient with a medical diagnosis documenting a terminal
2 illness, may be filled in partial quantities to include individual dosage units. If there is a question
3 whether a patient may be classified as having a terminal illness, the pharmacist must contact the
4 practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing
5 practitioner have a corresponding responsibility to assure that the controlled substance is for a
6 terminally ill patient.

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

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

13 (A) Date of the partial filling;

14 (B) Quantity dispensed;

15 (C) Remaining quantity authorized to be dispensed; and

16 (D) Identification of the dispensing pharmacist.

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

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

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

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

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

33 (3) The individual pharmacist responsible for completeness and accuracy of the entries
34 to the system must provide documentation of the fact that prescription information entered into

1 the computer is correct. In documenting this information, the pharmacy shall have the option to
2 either:

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

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

11 (4) An auxiliary record keeping system shall be established for the documentation of
12 refills, if the automated data processing system is inoperative for any reason. The auxiliary
13 system shall ensure that all refills are authorized by the original prescription, and that the
14 maximum number of refills is not exceeded. When this automated data processing system is
15 restored to operation, the information regarding prescriptions filled and refilled during the
16 inoperative period, shall be entered into the automated data processing system within ninety-six
17 (96) hours.

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

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

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

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

31 (1) In prescribing controlled substances in schedule II, practitioners may write up to
32 three (3) separate prescriptions, each for up to a one-month supply, each signed and dated on the
33 date written. For those prescriptions for the second and/or third month, the practitioner must write
34 the earliest date each of those subsequent prescription may be filled, with directions to the

1 pharmacist to fill no earlier than the date specified on the face of the prescription.

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

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

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

11 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 require, rather than permit, the director of health to promulgate rules and
2 regulations for the purpose of adopting a system for electronic data transmission, including by
3 facsimile, of prescriptions for controlled substances in schedules II, III and IV.

4 This act would take effect upon passage.

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