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LC000431/SUB A
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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2019

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A N A C T

RELATING TO FOOD AND DRUGS - UNIFORM CONTROL SUBSTANCES ACT

Introduced By: Senators Archambault, Sheehan, DiPalma, Paolino, and Raptakis

Date Introduced: January 24, 2019

Referred To: Senate Health & Human Services

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.**

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

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

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

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

1 (2) The director of health shall, after appropriate notice and hearing pursuant to § 42-35-
2 3, promulgate rules and regulations for the purpose of adopting a system for electronic data
3 transmission of prescriptions for controlled substances in schedules II, III, IV, and V. Opioid
4 antagonists, including, but not limited to, naloxone, as may be further determined by rules and
5 regulations, shall be transmitted with controlled substances in schedules II, III, IV, and V.
6 Provided, information collected regarding dispensing of opioid antagonists shall be for statistical,
7 research, or educational purposes only. The department's rules and regulations shall require the
8 removal of patient, recipient, or prescriber information that could be used to identify individual
9 patients or recipients of opioid antagonists.

10 (3) A practitioner shall sign and transmit electronic prescriptions for controlled
11 substances in schedules II, III, IV, and V to a pharmacy in accordance with rules and regulations
12 as shall be promulgated by the department and which shall require electronic transmission no
13 sooner than January 1, 2020, and a pharmacy may dispense an electronically transmitted
14 prescription for these controlled substances in accordance with the code of federal regulations, 21
15 C.F.R., pt. 1300, et seq.

16 (e) Subject to the rules and regulations promulgated by the department pursuant to
17 subsection (d)(3) of this section, a prescription for a schedule II narcotic substance to be
18 compounded for the direct administration to a patient by parenteral, intravenous, intramuscular,
19 subcutaneous, or intraspinal infusion may be transmitted by the practitioner, or practitioner's
20 agent, to the pharmacy by facsimile. The facsimile will serve as the original prescription.

21 (f) Subject to the rules and regulations promulgated by the department pursuant to
22 subsection (d)(3) of this section, a prescription for a schedule II substance for a resident of a long-
23 term-care facility may be transmitted by the practitioner, or the practitioner's agent, to the
24 dispensing pharmacy by facsimile. The facsimile serves as the original prescription.

25 (g) Subject to the rules and regulations promulgated by the department pursuant to
26 subsection (d)(3) of this section, a prescription for a schedule II narcotic substance for a patient
27 residing in a hospice certified by Medicare under title XVIII of the Social Security Act, 42 U.S.C.
28 § 1395 et seq., or licensed by the state, may be transmitted by the practitioner, or practitioner's
29 agent, to the dispensing pharmacy by facsimile. The practitioner, or the practitioner's agent, will
30 note on the prescription that the patient is a hospice patient. The facsimile serves as the original,
31 written 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).

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 that had earlier
25 been reduced to writing.

26 (j)(1) The partial filling of a prescription for a controlled substance listed in schedule II is
27 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 that 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 and
32 records of dispensing as indicated in subsection (h) of this section.

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

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

3 (i) Maintain a bound logbook, 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 prescription
5 information entered into the computer that day has been reviewed and is correct as shown. The
6 book or file must be maintained at the pharmacy employing that system for a period of at least
7 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 schedule II will become void unless
29 dispensed within ninety (90) days of the original date of the prescription and in no event shall
30 more than a thirty-day (30) supply be dispensed at any one time.

31 (1) In prescribing controlled substances in schedule II, practitioners may write up to three
32 (3) separate prescriptions, each for up to a one-month supply, each signed and dated on the date
33 written. For those prescriptions for the second and/or third month, the practitioner must write the
34 earliest date each of those subsequent prescriptions 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 Provided, however, manufacturer prepackaged steroids and hormones in schedule III shall be
9 exempt from this subsection.

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

13 (n) A pharmacy shall transmit prescription information to the prescription-monitoring
14 database at the department of health within one business day following the dispensing of an
15 opioid prescription.

16 (o) The pharmacist shall inform patients verbally or in writing about the proper disposal
17 of expired, unused, or unwanted medications, including the location of local disposal sites as
18 listed on the department of health website.

19 (p) The pharmacist shall inform patients verbally or in writing in the proper use of any
20 devices necessary for the administration of controlled substances.

21 (q)(1) A health care professional authorized to issue prescriptions shall, prior to issuing
22 an initial prescription for an opioid drug, and upon the second refill and/or upon the third
23 prescription specifically discuss with the patient who is eighteen (18) years of age or older, or the
24 patient's parent or guardian if the patient is under eighteen (18) years of age, the risks of
25 developing a dependence or addiction to the prescription opioid drug and potential of overdose or
26 death; the adverse risks of concurrent use of alcohol or other psychoactive medications and the
27 patient's or the minor patient's parent or guardian's responsibility to safeguard all medications;
28 and, if the prescriber deems it appropriate, discuss such alternative treatments as may be
29 available. For patients in recovery from substance dependence, education shall be focused on
30 relapse risk factors. This discussion shall be noted in the patient's record.

31 (2) The director of the department of health shall develop and make available to
32 prescribers guidelines for the discussion required pursuant to this subsection.

33 (3) The discussion required under this subsection shall not be required prior to issuing a
34 prescription to any patient who is currently receiving hospice care from a licensed hospice.

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 CONTROL SUBSTANCES ACT

1 This act would require that professionals authorized to prescribe opioid drugs discuss
2 addiction risks and when appropriate alternative treatments with patients prior to the third time
3 the opioid drug is provided by prescription or refill of a prescription.

4 This act would take effect upon passage.

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