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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2019

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:

SECTION 1. Section 21-28-3.18 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby amended to read as follows:

21-28-3.18. Prescriptions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Date of the partial filling;

(B) Quantity dispensed;

(C) Remaining quantity authorized to be dispensed; and

(D) Identification of the dispensing pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Prescriptions in schedule III cannot be written for more than one hundred (100) dosage units and not more than one hundred (100) dosage units may be dispensed at one time. Provided, however, manufacturer prepackaged steroids and hormones in schedule III shall be exempt from this subsection.

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

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

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

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

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

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

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

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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

This act would take effect upon passage.

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