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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. 2018

A N A C T

RELATING TO FOOD AND DRUGS -- NALOXONE ACCESS

Introduced By: Representatives Bennett, Diaz, Craven, Giarrusso, and Hull

Date Introduced: June 13, 2018

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Section 21-28-1.02 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby amended to read as follows:

21-28-1.02. Definitions.

Unless the context otherwise requires, the words and phrases as defined in this section are used in this chapter in the sense given them in the following definitions:

(1) "Administer" refers to the direct application of controlled substances to the body of a patient or research subject by:

(i) A practitioner, or, in his or her presence by his or her authorized agent; or

(ii) The patient or research subject at the direction and in the presence of the practitioner whether the application is by injection, inhalation, ingestion, or any other means.

(2) "Agent" means an authorized person who acts on behalf of, or at the direction of, a manufacturer, wholesaler, distributor, or dispenser; except that these terms do not include a common or contract carrier or warehouse operator, when acting in the usual and lawful course of the carrier's or warehouse operator's business.

(3) "Apothecary" means a registered pharmacist as defined by the laws of this state and, where the context requires, the owner of a licensed pharmacy or other place of business where controlled substances are compounded or dispensed by a registered pharmacist; and includes registered assistant pharmacists as defined by existing law, but nothing in this chapter shall be construed as conferring on a person who is not registered as a pharmacist any authority, right, or

privilege that is not granted to him or her by the pharmacy laws of the state.

(4) "Automated data processing system" means a system utilizing computer software and hardware for the purposes of record keeping.

(5) "Certified law enforcement prescription drug diversion investigator" means a certified law enforcement officer assigned by his or her qualified law enforcement agency to investigate prescription drug diversion.

(6) "Computer" means programmable electronic device capable of multi-functions, including, but not limited to: storage, retrieval, and processing of information.

(7) "Control" means to add a drug or other substance or immediate precursor to a schedule under this chapter, whether by transfer from another schedule or otherwise.

(8) "Controlled substance" means a drug, substance, immediate precursor, or synthetic drug in schedules I -- V of this chapter. The term shall not include distilled spirits, wine, or malt beverages, as those terms are defined or used in chapter 1 of title 3, nor tobacco.

(9) "Co-prescribing" means issuing a prescription for an opioid antagonist along with a prescription for an opioid analgesic.

~~(9)~~(10) "Counterfeit substance" means a controlled substance that, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness of them, of a manufacturer, distributor, or dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed the substance and that thereby falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser, or which substance is falsely purported to be or represented to be one of the controlled substances by a manufacturer, distributor, or dispenser.

~~(10)~~(11) "CRT" means cathode ray tube used to impose visual information on a screen.

~~(11)~~(12) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a controlled substance or imitation controlled substance, whether or not there exists an agency relationship.

~~(12)~~(13) "Department" means the department of health of this state.

~~(13)~~(14) "Depressant or stimulant drug" means:

(i) A drug that contains any quantity of:

(A) Barbituric acid or derivatives, compounds, mixtures, or preparations of barbituric acid; and

(B) "Barbiturate" or "barbiturates" includes all hypnotic and/or somnifacient drugs, whether or not derivatives of barbituric acid, except that this definition shall not include bromides

and narcotics.

(ii) A drug that contains any quantity of:

(A) Amphetamine or any of its optical isomers;

(B) Any salt of amphetamine and/or desoxyephedrine or any salt of an optical isomer of amphetamine and/or desoxyephedrine, or any compound, mixture, or preparation of them.

(iii) A drug that contains any quantity of coca leaves. "Coca leaves" includes cocaine, or any compound, manufacture, salt, derivative, mixture, or preparation of coca leaves, except derivatives of coca leaves, that do not contain cocaine, ecgonine, or substance from which cocaine or ecgonine may be synthesized or made.

(iv) Any other drug or substance that contains any quantity of a substance that the attorney general of the United States, or the director of health, after investigation, has found to have, or by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system.

~~(14)~~(15) "Director" means the director of health.

~~(15)~~(16) "Dispense" means to deliver, distribute, leave with, give away, or dispose of a controlled substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

~~(16)~~(17)"Dispenser" is a practitioner who delivers a controlled substance to the ultimate user or human research subject.

~~(17)~~(18) "Distribute" means to deliver (other than by administering or dispensing) a controlled substance or an imitation controlled substance and includes actual constructive, or attempted transfer. "Distributor" means a person who so delivers a controlled substance or an imitation controlled substance.

~~(18)~~(19) "Downtime" means that period of time when a computer is not operable.

~~(19)~~(20) "Drug addicted person" means a person who exhibits a maladaptive pattern of behavior resulting from drug use, including one or more of the following: impaired control over drug use; compulsive use; and/or continued use despite harm, and craving.

~~(20)~~(21) "Drug Enforcement Administration" means the Drug Enforcement Administration United States Department of Justice or its successor.

~~(21)~~(22) "Federal law" means the Comprehensive Drug Abuse Prevention and Control Act of 1970, (84 stat. 1236) (see generally 21 U.S.C. § 801 et seq.), and all regulations pertaining to that federal act.

~~(22)~~(23) "Hardware" means the fixed component parts of a computer.

~~(23)~~(24) "Hospital" means an institution as defined in chapter 17 of title 23.

~~(24)~~(25) "Imitation controlled substance" means a substance that is not a controlled substance, that by dosage unit, appearance (including color, shape, size, and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance and, which imitation controlled substances contain substances which if ingested, could be injurious to the health of a person. In those cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(i) Statement made by an owner, possessor, transferor, recipient, or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(ii) Statements made by the owner, possessor, or transferor, to the recipient that the substance may be resold for substantial profit.

(iii) Whether the substance is packaged in a manner reasonably similar to packaging of illicit controlled substances.

(iv) Whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the non-controlled substance.

~~(25)~~(26) "Immediate precursor" means a substance:

(i) That the director of health has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(ii) That is an immediate chemical intermediary used or likely to be used in the manufacture of those controlled substances; and

(iii) The control of which is necessary to prevent, curtail, or limit the manufacture of that controlled substance.

~~(26)~~(27) "Laboratory" means a laboratory approved by the department of health as proper to be entrusted with controlled substances and the use of controlled substances for scientific and medical purposes and for the purposes of instruction.

~~(27)~~(28) "Manufacture" means the production, preparation, propagation, cultivation, compounding, or processing of a drug or other substance, including an imitation controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical

synthesis and includes any packaging or repackaging of the substance or labeling or relabeling of its container in conformity with the general laws of this state except by a practitioner as an incident to his or her administration or dispensing of the drug or substance in the course of his or her professional practice.

~~(28)~~(29) "Manufacturer" means a person who manufactures but does not include an apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

~~(29)~~(30) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.

~~(30)~~(31) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium and opiates.

(ii) A compound, manufacture, salt, derivative, or preparation of opium or opiates.

(iii) A substance (and any compound, manufacture, salt, derivative, or preparation of it) that is chemically identical with any of the substances referred to in paragraphs (i) and (ii) of this subdivision.

(iv) Any other substance that the attorney general of the United States, or his or her successor, or the director of health, after investigation, has found to have, and by regulation designates as having, a potential for abuse similar to opium and opiates.

~~(31)~~(32) "Official written order" means an order written on a form provided for that purpose by the Drug Enforcement Administration under any laws of the United States making provision for an official form, if order forms are authorized and required by federal law, and if no order form is provided then on an official form provided for that purpose by the director of health.

~~(32)~~(33) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(34) "Opioid analgesics" means and includes, but is not limited to, the medicines buprenophine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, pentazocine, propoxyphene as well

as their brand names, isomers, and combinations, or other medications approved by the department.

(35) "Opioid antagonist" means naloxone hydrochloride and any other drug approved by the United States Food and Drug Administration for the treatment of opioid overdose.

~~(33)~~(36) "Opium poppy" means the plant of the species papaver somniferum L., except the seeds of the plant.

~~(34)~~(37) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a fluid ounce as applied to liquids.

~~(35)~~(38) "Person" means any corporation, association, partnership, or one or more individuals.

~~(36)~~(39) "Physical dependence" means a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.

~~(37)~~(40) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

~~(38)~~(41) "Practitioner" means:

(i) A physician, osteopath, dentist, chiropodist, veterinarian, scientific investigator, or other person licensed, registered or permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(ii) A pharmacy, hospital, or other institution licensed, registered or permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

~~(39)~~(42) "Printout" means a hard copy produced by computer that is readable without the aid of any special device.

~~(40)~~(43) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

~~(41)~~(44) "Qualified law enforcement agency" means the U.S. Food and Drug Administration, Drug Enforcement Administration, Federal Bureau of Investigation, Office of Inspector General of the U.S. Department of Health & Human Services, or the Medicaid Fraud and Patient Abuse Unit in the Office of the Attorney General.

~~(42)~~(45) "Researcher" means a person authorized by the director of health to conduct a laboratory as defined in this chapter.

~~(43)~~(46) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another,

or to offer or agree to do the same.

~~(44)~~(47) "Software" means programs, procedures and storage of required information data.

~~(45)~~(48) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in schedule I.

~~(46)~~(49) "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household.

~~(47)~~(50) "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled substance.

SECTION 2. Section 21-28-3.20 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby amended to read as follows:

21-28-3.20. Authority of practitioner to prescribe, administer, and dispense.

(a) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances, or he or she may cause the controlled substances to be administered by a nurse or intern under his or her direction and supervision.

(b) The prescription-monitoring program shall be reviewed prior to starting any opioid. A prescribing practitioner, or designee as authorized by § 21-28-3.32(a)(3), shall review the prescription-monitoring program prior to refilling or initiating opioid therapy with an intrathecal pump. For patients the prescribing practitioner is maintaining on continuous opioid therapy for pain for three (3) months or longer, the prescribing practitioner shall review information from the prescription-monitoring program at least every three (3) months. Documentation of that review shall be noted in the patient's medical record.

(c) The director of health shall develop regulations for prescribing practitioners on appropriate limits of opioid use in acute pain management. Initial prescriptions of opioids for acute pain management of outpatient adults shall not exceed thirty (30) morphine milligram equivalents (MMEs) total daily dose per day for a maximum total of twenty (20) doses, and, for pediatric patients, the appropriate opioid dosage maximum per the department of health.

(d) For the purposes of this section, acute pain management shall not include chronic pain management, pain associated with a cancer diagnosis, palliative or nursing home care, or other exception in accordance with department of health regulations.

(e) Subsection (c) shall not apply to medications designed for the treatment of substance

abuse or opioid dependence.

(f) On or before September 1, 2018, the director of health shall develop, and make available to health care practitioners, information on best practices for co-prescribing opioid antagonists to patients. The best practices information shall identify situations in which co-prescribing an opioid antagonist may be appropriate, including, but not limited to:

(1) In conjunction with a prescription for an opioid medication, under circumstances in which the health care practitioner determines the patient is at an elevated risk for an opioid drug overdose;

(2) In conjunction with medications prescribed pursuant to a course of medication therapy management for the treatment of a substance use disorder involving opioids; or

(3) Under any other circumstances in which a health care practitioner identifies a patient as being at an elevated risk for an opioid drug overdose.

(g) The best practices information developed pursuant to subsection (f) of this section shall include guidelines for determining when a patient is at an elevated risk for an opioid drug overdose, including, but not limited to, situations in which the patient:

(1) Meets the criteria provided in the opioid overdose toolkit published by the federal substance abuse and mental health service administration;

(2) Is receiving high-dose, extended release, or long-acting opioid medications;

(3) Has a documented history of an alcohol or substance use disorder, or a mental health disorder;

(4) Has a respiratory ailment or other co-morbidity that may be exacerbated by the use of opioid medications;

(5) Has a known history of intravenous drug use or misuse of prescription opioids;

(6) Has received emergency medical care or been hospitalized for an opioid overdose; or

(7) Uses opioids with antidepressants, benzodiazepines, alcohol, or other drugs.

(h) On or before September 1, 2018, the director of health and the secretary of the office of health and human services shall develop strategies that include:

(1) Allowing practitioners in non-pharmacy settings to prescribe and dispense opioid antagonists; and

(2) Ensuring that opioid antagonists that are distributed in a non-pharmacy setting are eligible for reimbursement from any health insurance carrier, as defined under chapters 18, 19, 20, and 41 of title 27, and the Rhode Island medical assistance program, as defined under chapter 7.2 of title 42.

SECTION 3. 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 -- NALOXONE ACCESS

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This act would require the director of the department of health to develop best practices for co-prescribing opioid antagonists to patients who are prescribed opioid analgesics.

This act would take effect upon passage.

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