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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2018

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A N A C T

RELATING TO FOOD AND DRUGS -- NALOXONE ACCESS

Introduced By: Senators Miller, Ruggerio, Goodwin, DiPalma, and Goldin

Date Introduced: May 24, 2018

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

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

3 **21-28-1.02. Definitions.**

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

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

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

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

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

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

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

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

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

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

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

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

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

16 ~~(9)~~(10) "Counterfeit substance" means a controlled substance that, or the container or
17 labeling of which, without authorization bears the trademark, trade name, or other identifying
18 mark, imprint, number, or device, or any likeness of them, of a manufacturer, distributor, or
19 dispenser, other than the person or persons who in fact manufactured, distributed, or dispensed
20 the substance and that thereby falsely purports or is represented to be the product of, or to have
21 been distributed by, the other manufacturer, distributor, or dispenser, or which substance is
22 falsely purported to be or represented to be one of the controlled substances by a manufacturer,
23 distributor, or dispenser.

24 ~~(10)~~(11) "CRT" means cathode ray tube used to impose visual information on a screen.

25 ~~(11)~~(12) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a
26 controlled substance or imitation controlled substance, whether or not there exists an agency
27 relationship.

28 ~~(12)~~(13) "Department" means the department of health of this state.

29 ~~(13)~~(14) "Depressant or stimulant drug" means:

30 (i) A drug that contains any quantity of:

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

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

1 and narcotics.

2 (ii) A drug that contains any quantity of:

3 (A) Amphetamine or any of its optical isomers;

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

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

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

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

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

19 ~~(16)~~(17) "Dispenser" is a practitioner who delivers a controlled substance to the ultimate
20 user or human research subject.

21 ~~(17)~~(18) "Distribute" means to deliver (other than by administering or dispensing) a
22 controlled substance or an imitation controlled substance and includes actual constructive, or
23 attempted transfer. "Distributor" means a person who so delivers a controlled substance or an
24 imitation controlled substance.

25 ~~(18)~~(19) "Downtime" means that period of time when a computer is not operable.

26 ~~(19)~~(20) "Drug addicted person" means a person who exhibits a maladaptive pattern of
27 behavior resulting from drug use, including one or more of the following: impaired control over
28 drug use; compulsive use; and/or continued use despite harm, and craving.

29 ~~(20)~~(21) "Drug Enforcement Administration" means the Drug Enforcement
30 Administration United States Department of Justice or its successor.

31 ~~(21)~~(22) "Federal law" means the Comprehensive Drug Abuse Prevention and Control
32 Act of 1970, (84 stat. 1236) (see generally 21 U.S.C. § 801 et seq.), and all regulations pertaining
33 to that federal act.

34 ~~(22)~~(23) "Hardware" means the fixed component parts of a computer.

1 ~~(23)~~(24) "Hospital" means an institution as defined in chapter 17 of title 23.

2 ~~(24)~~(25) "Imitation controlled substance" means a substance that is not a controlled
3 substance, that by dosage unit, appearance (including color, shape, size, and markings), or by
4 representations made, would lead a reasonable person to believe that the substance is a controlled
5 substance and, which imitation controlled substances contain substances which if ingested, could
6 be injurious to the health of a person. In those cases when the appearance of the dosage unit is not
7 reasonably sufficient to establish that the substance is an "imitation controlled substance" (for
8 example in the case of powder or liquid), the court or authority concerned should consider, in
9 addition to all other logically relevant factors, the following factors as related to "representations
10 made" in determining whether the substance is an "imitation controlled substance":

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

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

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

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

20 ~~(25)~~(26) "Immediate precursor" means a substance:

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

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

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

28 ~~(26)~~(27) "Laboratory" means a laboratory approved by the department of health as proper
29 to be entrusted with controlled substances and the use of controlled substances for scientific and
30 medical purposes and for the purposes of instruction.

31 ~~(27)~~(28) "Manufacture" means the production, preparation, propagation, cultivation,
32 compounding, or processing of a drug or other substance, including an imitation controlled
33 substance, either directly or indirectly or by extraction from substances of natural origin, or
34 independently by means of chemical synthesis or by a combination of extraction and chemical

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

5 ~~(28)~~(29) "Manufacturer" means a person who manufactures but does not include an
6 apothecary who compounds controlled substances to be sold or dispensed on prescriptions.

7 ~~(29)~~(30) "Marijuana" means all parts of the plant cannabis sativa L., whether growing or
8 not; the seeds of the plant; the resin extracted from any part of the plant; and every compound,
9 manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not
10 include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the
11 seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of
12 mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the
13 plant which is incapable of germination.

14 ~~(30)~~(31) "Narcotic drug" means any of the following, whether produced directly or
15 indirectly by extraction from substances of vegetable origin, or independently by means of
16 chemical synthesis or by a combination of extraction and chemical synthesis:

17 (i) Opium and opiates.

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

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

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

25 ~~(31)~~(32) "Official written order" means an order written on a form provided for that
26 purpose by the Drug Enforcement Administration under any laws of the United States making
27 provision for an official form, if order forms are authorized and required by federal law, and if no
28 order form is provided then on an official form provided for that purpose by the director of health.

29 ~~(32)~~(33) "Opiate" means any substance having an addiction-forming or addiction-
30 sustaining liability similar to morphine or being capable of conversion into a drug having
31 addiction-forming or addiction-sustaining liability.

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

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

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

5 ~~(33)~~(36) "Opium poppy" means the plant of the species papaver somniferum L., except
6 the seeds of the plant.

7 ~~(34)~~(37) "Ounce" means an avoirdupois ounce as applied to solids and semi-solids, and a
8 fluid ounce as applied to liquids.

9 ~~(35)~~(38) "Person" means any corporation, association, partnership, or one or more
10 individuals.

11 ~~(36)~~(39) "Physical dependence" means a state of adaptation that is manifested by a drug
12 class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose
13 reduction, decreasing blood level of the drug, and/or administration of an antagonist.

14 ~~(37)~~(40) "Poppy straw" means all parts, except the seeds, of the opium poppy, after
15 mowing.

16 ~~(38)~~(41) "Practitioner" means:

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

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

24 ~~(39)~~(42) "Printout" means a hard copy produced by computer that is readable without the
25 aid of any special device.

26 ~~(40)~~(43) "Production" includes the manufacture, planting, cultivation, growing, or
27 harvesting of a controlled substance.

28 ~~(41)~~(44) "Qualified law enforcement agency" means the U.S. Food and Drug
29 Administration, Drug Enforcement Administration, Federal Bureau of Investigation, Office of
30 Inspector General of the U.S. Department of Health & Human Services, or the Medicaid Fraud
31 and Patient Abuse Unit in the Office of the Attorney General.

32 ~~(42)~~(45) "Researcher" means a person authorized by the director of health to conduct a
33 laboratory as defined in this chapter.

34 ~~(43)~~(46) "Sell" includes sale, barter, gift, transfer, or delivery in any manner to another,

1 or to offer or agree to do the same.

2 ~~(44)~~(47) "Software" means programs, procedures and storage of required information
3 data.

4 ~~(45)~~(48) "Synthetic drugs" means any synthetic cannabinoids or piperazines or any
5 synthetic cathinones as provided for in schedule I.

6 ~~(46)~~(49) "Ultimate user" means a person who lawfully possesses a controlled substance
7 for his or her own use or for the use of a member of his or her household, or for administering to
8 an animal owned by him or her or by a member of his or her household.

9 ~~(47)~~(50) "Wholesaler" means a person who sells, vends, or distributes at wholesale, or as
10 a jobber, broker agent, or distributor, or for resale in any manner in this state any controlled
11 substance.

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

14 **21-28-3.20. Authority of practitioner to prescribe, administer, and dispense.**

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

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

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

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

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

1 abuse or opioid dependence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

30 (2) Ensuring that opioid antagonists that are distributed in a non-pharmacy setting are
31 eligible for reimbursement from any health insurance carrier, as defined under chapters 18, 19,
32 20, and 41 of title 27, and the Rhode Island medical assistance program, as defined under chapter
33 7.2 of title 42.

34 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

- 1 This act would require the director of the department of health to develop best practices
- 2 for co-prescribing opioid antagonists to patients who are prescribed opioid analgesics.
- 3 This act would take effect upon passage.

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