

RULES AND REGULATIONS PERTAINING TO OPIOID OVERDOSE PREVENTION AND REPORTING

[R23-1-OPOID]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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INTRODUCTION

These *Rules and Regulations Pertaining to Opioid Overdose Prevention and Reporting* [R23-1-OPIOID]¹ are promulgated pursuant to the authority set forth in RIGL Chapter 23-1, and establish the procedures for administration of Naloxone (Narcan) to an individual experiencing an opioid overdose or suspected overdose, and mandatory procedures for health care professionals and hospitals to report all opioid overdoses or suspected overdoses.

Pursuant to the provisions of RIGL § 42-35-3(a)(3) and § 42-35.1-4, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulation; and (3) significant economic impact on small business. Based on the available information, no known alternative approach, duplication or overlap was identified.

Upon promulgation of these amendments, these Regulations shall supersede all previous *Rules and Regulations Pertaining to Opioid Overdose Prevention* and *Rules and Regulations Pertaining to Opioid Overdose Reporting* promulgated by the Rhode Island Department of Health and filed with the Secretary of State.

¹ Prior to the October 2014 edition, these Regulations were promulgated as emergency regulations under the title *Rules and Regulations Pertaining to Opioid Overdose Prevention*. In addition, these Regulations also incorporate requirements previously promulgated as emergency regulations under the title *Rules and Regulations Pertaining to Opioid Overdose Reporting*.

TABLE OF CONTENTS

	<i>Page</i>
INTRODUCTION	i
1.0 Definitions	1
2.0 Applicability	2
3.0 Health Care Professional Prescription of Drug Overdose Treatment Medication. Administration Of Naloxone (Narcan) by an Unlicensed Person	2
4.0 Reporting Requirements	5
5.0 Severability	5

SECTION 1.0 *Definitions*

Wherever used in these Regulations, the following terms shall be construed as follows:

- 1.1 **"Department"** means the Rhode Island Department of Health.
- 1.2 **"Director"** means the means the Director of the Rhode Island Department of Health.
- 1.3 **"Health care professional"** for the purposes of these Regulations, includes a physician, any physician assistant, or an advanced practice registered nurse licensed in Rhode Island, and any pharmacies or pharmacists licensed in Rhode Island who are authorized to dispense Naloxone (Narcan).
- 1.4 **"Naloxone (Narcan)"** means a particular drug which is a competitive antagonist that binds to the opioid receptors with higher affinity than agonists but does not activate the receptors, effectively blocking the receptor, preventing the human body from making use of opiates and endorphins. The brand and generic terms of this drug are used interchangeably in these Regulations.
- 1.5 **"Opioid"** means an opiate as defined in RIGL § 21-28-2.08.
- 1.6 **"Opioid-related drug overdose"** means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid, or another substance with which an opioid was combined, or that a layperson would reasonably believe to be an opioid-related drug. This would include an overdose that requires medical assistance, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status) and either a urine toxicology screen positive for opiates or negative urine toxicology screen without other conditions to explain the clinical condition.
- 1.7 **"Patient"**, for the purposes of these Regulations, includes both an individual who is at risk of opioid overdose and a person who is not at risk of opioid overdose but who, in the judgment of the physician, may be in a position to assist another individual during an overdose and who has received patient information as required in § 1.8 of these Regulations on the indications for and administration of Naloxone (Narcan).
- 1.8 **"Patient information"** includes information provided to the patient on drug overdose prevention and recognition; how to perform rescue breathing and resuscitation; opioid antidote dosage and administration; the importance of calling 911; care for the overdose victim after administration of the overdose antidote; and other issues as necessary.
- 1.9 **"Person"** means an individual, corporation, business trust, estate, trust, partnership, association, government, governmental subdivision or agency, or any other legal entity.
- 1.10 **"RIGL"** means the General Laws of Rhode Island, as amended.
- 1.11 **"These Regulations"** mean all parts of Rhode Island *Rules and Regulations Pertaining to Opioid Overdose Prevention and Reporting* [R23-1-OPIOID]

SECTION 2.0 *Applicability*

2.1 **Scope.**

- (a) These Regulations authorize health care professionals who have a current license to prescribe or dispense medications to prescribe or dispense Naloxone (Narcan) to an individual who either abuses opioids or who does not abuse opioids but in is in a position to assist another individual during an overdose. These Regulations provide protections against any professional disciplinary action resulting from such prescribing.
 - (b) These Regulations also provide for Naloxone (Narcan) to be prescribed to persons other than the individual who has the potential for overdosing on opioids.
 - (c) These Regulations require health care professionals and hospitals to report all opioid-related overdoses or suspected overdoses to the Department within a forty-eight (48) hour time period.
- 2.2 These Regulations expand a health care professional's authority to prescribe, dispense, and distribute Naloxone (Narcan) directly or by non-patient-specific order to an individual at risk of experiencing an opioid-related overdose and to a family member, friend, or other person in a position to assist an individual at risk of experiencing an opioid-related overdose.
- 2.3 These Regulations allow a person acting under a non-patient-specific order to store and dispense an opioid antagonist without being subject to otherwise applicable provisions of RIGL Title 21 or any law or regulation otherwise enforceable by the Department.

SECTION 3.0 *Health Care Professional Prescription of Drug Overdose Treatment Medication. Administration of Naloxone (Narcan) by an Unlicensed Person*

- 3.1 A health care professional who is licensed in Rhode Island to prescribe Naloxone (Narcan) and who in good faith, either directly or by standing order, prescribes or dispenses Naloxone (Narcan) to a patient who, in the judgment of the health care professional, is capable of administering the drug in an emergency, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under any statute or regulation otherwise enforceable by the Department.
- 3.2 A health care professional who is licensed in Rhode Island to dispense Naloxone (Narcan) and who in good faith, either directly or pursuant to standing order, dispenses Naloxone (Narcan) to a patient who, in the judgment of the health care professional, is capable of administering the drug in an emergency, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under any statute or regulation otherwise enforceable by the Department

- 3.3 A person who is not otherwise licensed to administer Naloxone (Narcan) may in an emergency administer Naloxone (Narcan) without fee if the person believes in good faith that an individual is experiencing a drug overdose. The person shall not, as a result of his or her acts or omissions, be liable for any violation of any statute or regulations enforceable by the Department, and shall not be considered to be engaged in the unauthorized practice of medicine or the unlawful possession of Naloxone (Narcan). A health care professional prescribing Naloxone (Narcan) to a patient shall ensure that the patient receives the patient information specified in § 1.8 of these Regulations.
- 3.4 Patient information may be provided by the health care professional or a community-based organization, substance abuse program, or other organization with which the health care professional establishes a written agreement that includes a description of how the organization will provide patient information, how employees or volunteers providing information will be trained. Provision of patient information shall be documented in the patient's medical record or through similar means as determined by agreement between the health care professional and the organization.
- 3.5 The administering, dispensing, prescribing, purchasing, acquisition, possession, or use of Naloxone (Narcan) shall not constitute unprofessional conduct or a violation of any statute or regulation otherwise enforceable by the Department by any practitioner or person, if any allegation of unprofessional conduct or violation is made based on a good faith effort to assist:
- (a) An individual experiencing, or likely to be experiencing, an opiate-related overdose; or
 - (b) A family member, friend, or other person in a position to assist an individual experiencing, or likely to experience, an opiate-related overdose.
- 3.6 Naloxone (Narcan) may lawfully be prescribed and dispensed to an individual at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose. Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.
- 3.7 (a) A person who, acting in good faith and with reasonable care, administers Naloxone (Narcan) to an individual who appears to be suffering an opioid-related drug overdose shall be immune from sanction under any professional licensing statute, in addition to immunity already granted in RIGL Chapter 21-28.8.
- (b) A health care professional who, acting in good faith and with reasonable care, prescribes or dispenses Naloxone (Narcan) shall not be subject to any professional disciplinary action for:
 - (1) Such prescribing or dispensing, or
 - (2) Any outcomes resulting from the eventual administration of Naloxone (Narcan).
 - (c) Every Emergency Medical Technician licensed in Rhode Island shall be authorized and permitted to administer Naloxone (Narcan) as clinically indicated.

- 3.8 (a) A person may administer Naloxone (Narcan) to an individual if:
- (1) He or she, in good faith, believes the individual is experiencing a drug overdose; or
 - (2) He or she acts with reasonable care in administering the drug to the individual.
- (b) A person who administers Naloxone (Narcan) to an individual pursuant to these Regulations shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug.
- 3.9 Notwithstanding any other law or regulation, a health care professional who is licensed to prescribe Naloxone (Narcan) may, directly or by standing order, prescribe or dispense Naloxone (Narcan), as the case may be, to:
- (a) An individual at risk of experiencing an opioid-related overdose, and/or
 - (b) To a family member, friend, or other person reasonably expected to be in a position to assist an individual at risk of experiencing an opioid-related overdose.
- 3.10 Notwithstanding any other law or regulation, a health care professional who is licensed to dispense Naloxone (Narcan) may, directly or pursuant to standing order, dispense Naloxone (Narcan), as the case may be, to:
- (a) An individual at risk of experiencing an opioid-related overdose, and/or
 - (b) To a family member, friend, or other person reasonably expected to be in a position to assist an individual at risk of experiencing an opioid-related overdose.
- 3.11 Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.
- 3.12 Notwithstanding any other law or regulation, a person possessing an order issued by a health care professional who is otherwise authorized to prescribe Naloxone (Narcan) may store and dispense Naloxone (Narcan) regardless of usual drug storage requirements in RIGL Title 21. Health care professionals shall comply with the drug storage requirements of RIGL Title 21 while Naloxone (Narcan) remains in their possession prior to administering or dispensing to a patient.
- 3.13 Use of Naloxone (Narcan) pursuant to these Regulations shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.
- 3.14 Notwithstanding any other law or regulation, any person may lawfully possess Naloxone (Narcan).

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SECTION 4.0 *Reporting Requirements*

- 4.1 (a) A health care professional who attends or treats, or who is requested to attend or treat, an opioid-related drug overdose or the administrator, or other person in charge of a hospital in which an opioid-related drug overdose is attended or treated or in which the attention or treatment is requested, shall report the case within forty-eight (48) hours to the Department using the reporting format approved by the Department.
- (b) Reports regarding an opioid-related drug overdose shall be submitted utilizing the Department's Drug Overdose Prevention website:
<http://health.ri.gov/healthrisks/drugoverdose/reporting/>.
- 4.2 The health care professional or hospital making the report shall provide demographic information concerning the person attended or treated or for whom treatment was sought but may not disclose the person's name or address or any other information concerning the person's identity.
- 4.3 (a) In accordance with § 811.2(f) of the *Rules and Regulations Pertaining to Medical Examiner System*, the health care professional or hospital shall, where feasible, draw one blood specimen (full 10 cc red top tube) from any victim of a chemical overdose who is a potential fatality referable to the Medical Examiner, and label it "Medical Examiner".
- (b) Such blood specimen shall be discarded by the hospital laboratory for those patients discharged alive. In the event a patient dies of a drug overdose, the health care professional or hospital shall immediately send the above described ante mortem blood sample to the Office of the State Medical Examiner in the full amount drawn.
- 4.4 A health care professional or hospital that makes a report under § 4.1 and provides an ante mortem blood specimen as described in § 4.3 of these Regulations, is not subject to civil or criminal liability for damages arising out of the report or delivery of ante mortem blood to the Office of the State Examiner. An individual who makes a good-faith report under these Regulations is not subject to civil or criminal liability for damages arising out of the report.
- 4.5 All opioid overdose reports submitted pursuant to these Regulations shall be handled in accordance with all applicable state and federal statutes and regulations pertaining to confidentiality of health care information.

SECTION 5.0 *Severability*

- 5.1 If any provisions of these Regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.