

# **RULES AND REGULATIONS PERTAINING TO OPIOID OVERDOSE PREVENTION**

[R23-1-OPOID]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

**March 2014 (E)**

## **COMPILER'S NOTES:**

Proposed Additions: The proposed regulations are new in their entirety. Therefore, changes are not specifically indicated.

## ***INTRODUCTION***

These *Rules and Regulations Pertaining to Opioid Overdose Prevention* [R23-1-OPIOID] 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.

These Regulations are being promulgated as emergency regulations pursuant to the provisions of RIGL §42-35-3(b). The Department finds that there is imminent peril to the public health, safety and welfare and that these emergency regulations should be adopted to protect the public health. Specifically the Department finds that:

1. Rhode Island is in the midst of a severe prescription and street-drug overdose crisis. There have been fifty (50) opioid-related deaths since the start of 2014. Many of these deaths are directly related to the use of Fentanyl and Heroin, which are opioids. Legal prescriptions for opioids, particularly oxycodone and hydrocodone, have increased in recent years.
2. Due to the sharp increase of opioid overdose deaths in Rhode Island in 2014, expanded access to Naloxone (Narcan) has become an immediately necessary priority to save lives. Pursuant to the Rhode Island *Rules and Regulations Relating to Emergency Medical Services*, Naloxone (Narcan) is already considered a standing-order medication that can be administered to individuals for whom the medication is not specifically prescribed in an overdose situation. By expanding upon the success of this existing program, more lives could be saved if Naloxone (Narcan) were available to people with drug addiction, their families and other people and organizations likely to be in a position to assist a person at risk of an opioid-related overdose.
3. Naloxone (Narcan) is sometimes referred to as the drug-overdose antidote, and it counteracts the life-threatening depression of the central nervous system and respiratory system caused by an opioid overdose. If timely administered, Naloxone (Narcan) can prevent overdose deaths. Naloxone has reportedly reversed more than 10,000 overdoses.
4. Under these Regulations, one prescriber is now able to issue a non-patient-specific order to numerous organizations, such as police departments, allowing for increased access to the opioid antagonist Naloxone (Narcan). These Regulations will enable the person who is likely to discover an overdose victim to save their life -- a life that could otherwise be lost if the victim has to wait for an EMT to arrive to administer the Naloxone (Narcan).

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## 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, who is authorized to prescribe Naloxone (Narcan), 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 overdose that requires medical assistance.
- 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* [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 supersede and replace any and all prior regulatory requirements promulgated by the Department concerning reasonable prescribing, dispensing and administration of Naloxone (Narcan) to an individual experiencing an opioid overdose.
- 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).

#### **SECTION 4.0 SEVERABILITY**

- 4.1 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.