

## TITLE 216 – DEPARTMENT OF HEALTH

### CHAPTER 20 – COMMUNITY HEALTH

#### SUBCHAPTER 20 – DRUGS

##### PART 5 – Opioid Overdose Prevention and Reporting

### 5.1 Authority

These rules and regulations are promulgated pursuant to the authority set forth in R.I. Gen. Laws Chapter 23-1, and establish the procedures for administration of an opioid antagonist Naloxone (Narcan) to an individual experiencing an opioid overdose or suspected overdose, and mandatory procedures for health-care professionals and hospitals to report all actual and suspected opioid-related overdoses ~~or suspected overdoses~~.

### 5.2 Definitions

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

1. “BHDDH” means the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals.

24. “Department” means the Rhode Island Department of Health.

32. “Director” means the Director of the Rhode Island Department of Health.

43. “Health-care professional” means, ~~for the purposes of these Regulations,~~ a physician, ~~any~~ physician assistant, or an advanced practice registered nurse licensed in Rhode Island, who is authorized to prescribe drugs or ~~and any pharmacies or~~ pharmacists licensed in Rhode Island ~~who are~~ authorized to dispense drugs. ~~Naloxone (Narcan).~~

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.

5. “Opioid” means any synthetic or natural opiate listed as defined in R.I. Gen. Laws § 21-28-2.08.

6. "Opioid antagonist" means a drug used to reverse the effects of opioids, such a naloxone hydrochloride, commonly referred to as naloxone or by the brand name Narcan, which is a competitive antagonist that binds to opioid receptors with higher affinity than agonists but does not activate the receptors. For the purposes of this Part, opioid antagonist does not include any drugs, such as naltrexone hydrochloride, used for addiction treatment.

76. "Opioid-related drug overdose" means, as defined in R.I. Gen. Laws § 16-21-35, 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.~~ This would include any condition for which there is a clinical suspicion for an opioid-related drug overdose (respiratory depression, unconsciousness, altered mental status) and/or for which there is either a urine toxicology screen positive for opioidsepiates or negative urine toxicology screen without other conditions to explain the clinical condition.

87. "Patient" means, ~~for the purposes of these Regulations, includes both an individual who a person who has experienced or is experiencing or is at risk of experiencing an opioid-related drug 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 § 5.2(A)(8) of this Part on the indications for and administration of Naloxone (Narcan).~~

98. "Patient information" includes but is not limited to ~~means~~ information provided to the patient on:

a. d~~D~~rug overdose prevention and recognition;

b. h~~H~~ow to perform rescue breathing and resuscitation;

c. e~~O~~pioid antidote dosage and administration;

d. t~~T~~he importance of calling 911;

e. c~~C~~are for the overdose victim after administration of the overdose antidote; and

f. e~~O~~ther issues as necessary.

10. "Person at risk of experiencing an opioid-related drug overdose" includes but is not limited to a person for whom one (1) or more of the following applies:
- a. Has ever received emergency medical care involving opioid intoxication or opioid-related drug overdose;
  - b. Has a suspected history of substance use or use disorder or non-medical opioid use, including a history of treatment or a referral for treatment;
  - c. Is prescribed methadone or buprenorphine;
  - d. Is receiving an opioid prescription for pain and one (1) or more of the following applies:
    - (1) Is given a higher dose of opioids (greater than fifty (50) mg morphine equivalent per day);
    - (2) Has rotated from one opioid to another because of possible incomplete cross tolerance;
    - (3) Has concurrent smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, or other respiratory illness or potential obstruction;
    - (4) Has pre-existing renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS;
    - (5) Has known or suspected concurrent alcohol or cocaine use;
    - (6) Has concurrent use of a benzodiazepine or other sedative prescription or who has a history of illicit benzodiazepine use;
    - (7) Is concurrently taking a prescription antidepressant.
  - e. May have difficulty accessing emergency medical services.
9. ~~"Person" means an individual, corporation, business trust, estate, trust, partnership, association, government, governmental subdivision or agency, or any other legal entity.~~
10. ~~"R.I. Gen. Laws" means the General Laws of Rhode Island, as amended.~~
11. ~~"These Regulations" means all parts of Rhode Island rules and regulations pertaining to Opioid Overdose Prevention and Reporting (216-RICR-20-20-5).~~

## **5.3 Applicability**

### **A. Scope.**

1. ~~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.~~
2. ~~These Regulations also provide for Naloxone (Narcan) to be prescribed to persons other than the individual who has the potential for overdosing on opioids.~~
3. ~~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.~~

~~B. 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.~~

~~C. 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 R.I. Gen. Laws Title 21 or any law or regulation otherwise enforceable by the Department.~~

## **5.3 Prescribing, Dispensing and Administering Opioid Antagonists**

A. Use of an opioid antagonist in accordance with this Part shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.

B. Notwithstanding any other law or Regulation, any person may lawfully possess opioid antagonists.

C. Notwithstanding any other law or Regulation, any healthcare professional may dispense opioid antagonists, consistent with the provisions of this Part.

D. Any prescription for an opioid antagonist shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

### **5.3.1 Prescribing, Dispensing, and Administering Opioid Antagonists by Healthcare Professionals**

A. Opioid antagonists may lawfully be prescribed and dispensed to:

1. Any person at risk of experiencing an opioid-related overdose; and
2. Any person or persons, such as a family member or friend of a person at risk of experiencing an opioid-related overdose, who is reasonably expected by the prescriber to be in a position to respond to such person at risk of experiencing an opioid-related overdose.

B. Prescribing and dispensing healthcare professionals shall ensure that all persons prescribed and/or dispensed opioid antagonists receive the patient information specified in § 5.2(A)(9) of this Part. Provision of the patient information shall be appropriately documented. Patient information may be provided by:

1. Prescribing and dispensing healthcare professionals;
2. Community-based organizations;
3. BHDDH licensed or certified community programs offering support to individuals with a substance use diagnosis; or
4. Any other organization that has a written agreement with a healthcare professional, which agreement must include descriptions of:
  - a. How the organization will provide patient information about overdose response and use of an opioid antagonist;
  - b. How employees or volunteers providing patient information are trained; and
  - c. How patient information is documented.

C. The administering, dispensing, prescribing, purchasing, acquisition, possession, or use of an opioid antagonist by a healthcare professional shall not constitute unprofessional conduct or a violation of any statute or Regulation otherwise enforceable by the Department, provided that the healthcare professional's actions upon which the alleged unprofessional conduct or violation are based were made with reasonable care and based on a good faith effort to assist:

1. A person experiencing, or suspected to be experiencing, an opioid-related drug overdose; or
2. Any person or persons, such as a family member or friend of a person at risk of experiencing an opioid-related overdose, who is in a position to respond to such person experiencing, or suspected to be experiencing, an opioid-related drug overdose.

D. A healthcare professional who prescribes or dispenses an opioid antagonist shall not be subject to any professional disciplinary action for:

1. Prescribing or dispensing in accordance with this Part, or
2. Any outcomes resulting from the administration of an opioid antagonist in accordance with this Part.

E. All emergency medical responders (EMRs), emergency medical technicians (EMTs), Advanced EMT-Cardiac practitioners, and paramedics, licensed in Rhode Island, are authorized and permitted to administer opioid antagonists as clinically indicated.

### **5.3.2 Administration of an Opioid Antagonist (General)**

## **~~5.4 Health Care Professional Prescription of Drug Overdose Treatment Medication. Administration of Naloxone (Narcan) by an Unlicensed Person~~**

~~A. 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.~~

~~B. 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.~~

AG. Any person who is not otherwise licensed to administer Naloxone (Narcan) may in an emergency, exercising reasonable care, administer an opioid antagonist to him or herself or another person that the administering person Naloxone (Narcan) without fee if the person believes in good faith that an individual is experiencing an opioid-related drug overdose. The person administering the opioid antagonist 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 an opioid antagonist. Naloxone (Narcan). A health care professional prescribing Naloxone (Narcan) to a patient shall ensure that the patient receives the patient information specified in § 5.2(A)(8) of this Part.

1. Unless a healthcare professional or EMR, the person administering the opioid antagonist shall not bill for administering the opioid antagonist. The person administering the opioid antagonist can never bill for administering the opioid antagonist to him or herself.

~~D. 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.~~

BE. The administering, ~~dispensing, prescribing,~~ purchasing, acquisition, possession, or use of an opioid antagonist in accordance with this Part by any person, including asset forth in § 5.3.1(C) of this Part, any healthcare professional ~~Naloxone (Narcan)~~ shall not constitute unprofessional conduct or a violation of any statute or Regulation otherwise enforceable by the Department, provided that the person's actions upon which the alleged by any practitioner or person, if any allegation of unprofessional conduct or violation are based wereis made with reasonable care and based on a good faith effort to assist:

1. A ~~personn individual~~ experiencing, or suspected likely to be experiencing, an ~~opioidate~~-related drug overdose; or
2. Any person or persons, such as a family member, or friend of a ,or other person at risk of in a position to assist an individual experiencing, or likely to experience, an ~~opioidate~~-related drug overdose who is in a position to respond to such person experiencing or suspected to be experiencing an opioid-related drug overdose.

~~F. 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.~~

CG. A person who, acting in good faith and with reasonable care, administers an opioid antagonist to a person experiencing or suspected to be experiencing ~~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 R.I. Gen. Laws Chapter 21-28.9.

- ~~H. 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).~~
- ~~I. Every Emergency Medical Technician licensed in Rhode Island shall be authorized and permitted to administer Naloxone (Narcan) as clinically indicated.~~
- ~~J. 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.~~
  - ~~3. 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.~~
- ~~K. 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:~~
- ~~1. An individual at risk of experiencing an opioid-related overdose, and/or~~
  - ~~2. 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.~~
- ~~L. 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:~~
- ~~1. An individual at risk of experiencing an opioid-related overdose, and/or~~
  - ~~2. 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.~~
- ~~M. Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.~~



- ~~N. 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 R.I. Gen. Laws Title 21. Health care professionals shall comply with the drug storage requirements of R.I. Gen. Laws Title 21 while Naloxone (Narcan) remains in their possession prior to administering or dispensing to a patient.~~
- ~~O. 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.~~
- ~~P. Notwithstanding any other law or regulation, any person may lawfully possess Naloxone (Narcan).~~

## **5.45 Reporting Requirements**

- ~~A. A health care professional who attends or treats, or who is requested to attend or treat, Hospitals in which medical care for an opioid-related drug overdose is provided or sought to be provided 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 opioid-related drug overdose case within forty-eight (48) hours to the Department using the reporting format approved by the Department, within forty-eight (48) hours of initial contact with the patient. Such report shall include any results of drug screening/testing performed on a patient who experienced an opioid-related drug overdose. Any additional pertinent information, including patient's name, date of birth, address, and any retrospective data not previously provided, which is requested by the Department after the initial reported case, shall be reported to the Department promptly upon request.~~
- ~~1. Reports regarding an opioid-related drug overdose shall be submitted utilizing a secure means of data transfer determined by the Departmentthe Department's Drug Overdose Prevention website:  
<http://health.ri.gov/healthrisks/drugoverdose/reporting/>.~~
  - ~~2. Data collected under § 5.4(A) of this Part may be used by the Department for the purposes of conducting program and policy evaluation, and research as approved by the Department's Institutional Review Board. Data collected pursuant to § 5.4(A) of this Part may be linked to other data accessible to the Department for those purposes.~~
  - ~~3. Data under § 5.4(A) of this Part shall not be shared with law enforcement.~~
  - ~~4. Data collected under § 5.4(A) of this Part shall not be shared with third party payers, or other entities outside of the Department for activities outside of Department approved evaluation, surveillance and research.~~

a. Exception. Data shall be shared with the Director of BHDDH or his or her designee in accordance with the inter-agency memorandum of understanding.

5. Data collected under § 5.4(A) of this Part are not public information. The collection, storage, use, or sharing of any data obtained pursuant to this Part shall be in accordance with all applicable State and Federal law, including the Confidentiality of Health Care Information Act (R. I. Gen. Laws §§ 5-37.3-1 *et seq.*), the Health Insurance Portability and Accountability Act (including all effective Regulations promulgated thereunder), the Identify Theft Protection Act of 2015 (R. I. Gen. Laws §§ 11-49.3-1 *et seq.*), and all other applicable laws. Any transfer of these data must meet State data encryption policy.

~~B. 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.~~

~~BG. In addition to complying with the provisions of accordance with § 60-10-1.104.11(H)(6) of this Title, pertaining to the Medical Examiner System (216-RIGR-60-10-1), the health care professional or hospital shall, where feasible, hospitals shall submit residual biological samples (e.g., blood, urine) obtained in the course of hospitalization of patients who experienced an opioid related drug overdose which resulted in whole or in part, in current hospitalization. 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". Such biological specimen shall be submitted to the Department's laboratory in accordance with Department guidance.~~

~~1. 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.~~

~~CD. Any health care professional or hospital or agent thereof, that makes a report under § 5.45(A) of this Part and provides an ante mortem a blood specimen as described in § 5.45(BG) of this Part, is not subject to civil or criminal liability for damages arising out of the report or provisional delivery of the biological specimen ante mortem blood to the Office of the State Examiner. An individual who makes a good-faith report or provision under these Regulations is not subject to civil or criminal liability for damages arising out of such act~~the report~~.~~

~~DE. All opioid-related drug 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.~~

## **5.56 Severability**

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