216-RICR-20-20-5

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 to an individual experiencing an opioid overdose or suspected overdose, and mandatory procedures for hospitals to report all actual and suspected opioid-related 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.

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

3. "Director" means the Director of the Rhode Island Department of Health.

4. “Healthcare professional” means a physician, physician assistant, or an advanced practice registered nurse licensed in Rhode Island, who is authorized to prescribe drugs or any pharmacists licensed in Rhode Island authorized to dispense drugs.

5. “Opioid” means any synthetic or natural opiate listed 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.

7. “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 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 opioids or negative urine toxicology screen without other conditions to explain the clinical condition.

8. "Patient" means a person who has experienced or is experiencing or is at risk of experiencing an opioid-related drug overdose.

9. "Patient information" includes but is not limited to information provided to the patient on:

    a. Drug overdose prevention and recognition;

    b. How to perform rescue breathing and resuscitation;

    c. Opioid antidote dosage and administration;

    d. The importance of calling 911;

    e. Care for the overdose victim after administration of the overdose antidote; and

    f. Other 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.

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)

A. Any person may in an emergency, exercising reasonable care, administer an opioid antagonist to him or herself or another person that the administering person believes in good faith 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.

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.

B. The administering, 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 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 unprofessional conduct or violation are based were made with reasonable care and 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 drug overdose who is in a position to respond to such person experiencing or suspected to be experiencing an opioid-related drug overdose.

C. A person who, acting in good faith and with reasonable care, administers an opioid antagonist to a person experiencing or suspected to be experiencing 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.

5.4 Reporting Requirements

A. Hospitals in which medical care for an opioid-related drug overdose is provided or sought to be provided, shall report the opioid-related drug overdose 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 Department

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. In addition to complying with the provisions of § 60-10-1.10(H)(6) of this Title, 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. Such biological specimen shall be submitted to the Department's laboratory in accordance with Department guidance.

C. Any hospital or agent thereof, that makes a report under § 5.4(A) of this Part or provides a blood specimen as described in § 5.4(B) of this Part, is not subject to civil or criminal liability for damages arising out of the report or provision of the

biological specimen. 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.

D. 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 healthcare information.

5.5 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.

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