

# Service Entity Protocol For Naloxone Administration



<b>Name of Service Entity</b>	
<b>Address</b>	
<b>Date Protocol Delivered</b>	
<b>Review Frequency</b>	Annual review by the service entity is recommended

### Physician Authorization

Physician Signature	License No. Ohio # 35.060081
Physician Name: Jon A. Elias, M.D. Medical Director, Canton City Public Health	Date:

Service Entity Protocol for Naloxone Administration established by the Board of Health, Canton City Public Health, on March 26, 2018.

### Clinical Pharmacology of Naloxone (also called Narcan®)

Naloxone hydrochloride (naloxone) prevents or reverses the effects of opioids, including respiratory depression, sedation, and hypotension.

Naloxone is a nearly pure opioid antagonist, i.e., it does not possess the "agonistic" or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits almost no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cause physical or psychological dependence. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours.

Naloxone may not reverse overdose in all cases, such as when high doses of opioids or particularly potent opioids (such as, fentanyl or carfentanil) have been consumed.

### Indications for Use of Naloxone

- ✓ Naloxone is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids.

**Precautions, Contraindications, and Side Effects**

**Use in Pregnancy**

- There are no studies that tell us if naloxone causes birth defects.
- Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms.
- Nursing mothers: caution should be exercised when administering to nursing women due to transmission in human milk.

**Contraindication Prohibition**

Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.

**Side Effects**

Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgia, diaphoresis, abdominal cramping, yawning, and sneezing.

- ✓ These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.
- ✓ The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
- ✓ Adverse effects beyond opioid withdrawal are rare.

**Authorization to Administer Naloxone**

Pursuant to section 4731.943 and 3707.562 of the Ohio Revised Code (ORC), the following Service Entity employees, volunteers, or contractors (referred to as personnel) are authorized to administer naloxone in accordance with this protocol (append additional pages if all personnel cannot be listed here):

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Upon completion of the required training, naloxone may be administered to an individual believed to be experiencing an opioid-related overdose.

This protocol authorizes the individuals listed above to administer the following doses of intranasal formulations of naloxone for which they have received the formulation-specific training:

- NARCAN® Nasal Spray, 4mg naloxone/0.1 ml FDA-approved nasal spray device  
Appended instructions are incorporated as part of this protocol for the device.

**Variation in dosage and/or formulation are permissible under the following circumstances:**

- The dose of **naloxone may be repeated every 3 minutes** if there is no reaction or improvement (that is, the person is still unconscious or unresponsive to voice or touch, or not breathing normally).

## **Labeling, storage, record-keeping, and administrative requirements**

### *Labeling*

No special labeling is required for a Service Entity authorized to administer naloxone.

### *Storage*

Naloxone must be stored in a location accessible to authorized Service Entity personnel in accordance with the manufacturers or distributor's labeling.

All doses should be checked periodically to ensure that the naloxone is not adulterated. Naloxone shall be considered adulterated when it is beyond the manufacturer's or distributor's expiration date.

Adulterated naloxone shall be removed from inventory and discarded immediately to prevent its use as instructed by the provider of the medication.

If licensed by the Board of Pharmacy, the Service Entity shall comply with all applicable state laws and rules regarding the storage of prescription drugs.

### *Record-keeping*

If licensed by the Board of Pharmacy, the Service Entity shall comply with rule 4729-9-22 of the Administrative Code.

If not licensed by the Board of Pharmacy, the Service Entity should maintain the following records:

- naloxone received by the entity;
- naloxone administration by entity personnel; and
- disposal of expired/adulterated naloxone.

## **Training of Individuals Authorized to Administer Naloxone**

Service entity employees, volunteers, and contractors who have previously completed training on the administration of naloxone are not required to repeat the training.

The Service Entity shall arrange training for authorized personnel that addresses at least the following topics:

- Signs and symptoms of opioid overdose
- Response to opioid overdose, including calling 911 and use of the recovery position
- Procedures for assembling and administering naloxone
- Information about naloxone's effects and repeat dosing
- Proper storage of naloxone

The training must include face-to-face instruction to assess the trainees understanding and ability to respond in an overdose situation. Trainings may be conducted in a variety of settings. The trainings may be in groups or conducted one-on-one.

**All authorized personnel shall be instructed to summon emergency services (9-1-1) as soon as practicable.**

### *Additional Instructions or Administrative Requirements*

1. Add names of trained employees, volunteers, and contractors to the "Authorization to Administer Naloxone" section (page 2) as they are trained to administer naloxone and as others are added to the list.
2. If not already done, please supply Canton City Public Health with the name and address of your Service Entity and a contact person's name and phone number and /or email. The information can be sent to the Director of Nursing at [dthompson@cantonhealth.org](mailto:dthompson@cantonhealth.org) or left as a phone message at 330-430-7877.