This example protocol is provided by the State of Ohio Board of Pharmacy and should be modified or expanded, in accordance with Ohio law, to fit the description of each Service Entity's operations.

Service Entity Protocol for Naloxone Administration

Name of Service Entity	
Date Created	
Date Last Revised	
Review Frequency	

Clinical Pharmacology of Naloxone

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

Naloxone is an essentially 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 essentially 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 (e.g., 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 Adverse Reactions

- Precautions
    - Use in Pregnancy:
        - Teratogenic Effects: no adequate or well controlled studies in pregnant women.
        - Non-teratogenic Effects: 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. Risks and benefits must be evaluated.
- Contraindications
    - Contraindicated in patients known to be hypersensitive to it or to any of the other ingredients in naloxone hydrochloride.
- Adverse reactions

- 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.

Limitations on Administration of Naloxone to Certain Individuals (if applicable)

Authorization to Administer Naloxone

Pursuant to section 4731.943 and 3707.562 of the Ohio Revised Code (ORC), the following Service Entity personnel are authorized to administer naloxone in accordance with this protocol:

Upon completion of the required training, naloxone may be administered to an individual who there is reason to believe is experiencing an opioid-related overdose.

This protocol authorizes the individuals listed above to administer the following doses of intranasal formulations of naloxone:

- Two (2) naloxone 2 mg/2 mL prefilled syringes used with mucosal atomization devices;
- One (1) NARCAN® Nasal Spray 4mg/0.1 mL FDA-approved nasal spray device; or
- Any other formulation listed below:

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

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 manufacturer's 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 stored in a separate area apart from active drug stock to prevent its use.

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.

Administrative Requirements (if applicable)

Training of Individuals Authorized to Administer Naloxone

The Service Entity shall provide training to authorized personnel that addresses, at a minimum, all of the following topics:

- Risk factors for opioid overdose
- Strategies to prevent opioid overdose
- Signs and symptoms of opioid overdose
- Response to opioid overdose, including calling 911 and administering rescue breathing
- Procedures for assembling and administering naloxone
- Information on naloxone, including possible adverse reactions
- Proper storage of naloxone

The initial training must include live demonstrations from experienced trainers to assess their 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 refresher trainings shall be conducted for all authorized personnel on an annual basis or as indicated in the "additional instructions or requirements" section of this protocol.

Any additional instructions or requirements

Physician Authorization

Physician Signature	License No.
Physician Name (please print)	Date