**This sample protocol should be modified or expanded, in accordance with Ohio law, to fit the description of each pharmacy's operations.**

**This document does not bind the State of Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, or licensee.**

**Outpatient pharmacies are also encouraged to review the applicable sections of the Outpatient Pharmacy Inspection Guide, which can be accessed here: www.pharmacy.ohio.gov/OPinspect**

**Sample pharmacy educational brochures are available from the Board of Pharmacy by visiting: www.pharmacy.ohio.gov/naloxone**

# PROTOCOL FOR PHARMACIES

Protocol for Dispensing Naloxone to Individuals at Risk of Experiencing or Witnessing an Opioid-Related Overdose

| Pharmacy Name | Pharmacy TDDD License No. |
|---|---|
| Pharmacy Address | |

## 1. A Description of the 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. In the presence of physical dependence on opioids, naloxone will produce withdrawal symptoms. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and subside in about 2 hours.

## 2. 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. It may be delivered intranasally or intramuscularly with use of a needle or autoinjector.

Naloxone can be dispensed by a pharmacist or a pharmacy intern under the direct supervision of a pharmacist without a prescription in accordance with this protocol to all the following:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or

- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

Indications for dispensing naloxone are:

1. Previous opioid intoxication or overdose.
2. History of nonmedical opioid use.
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription.
5. Receiving any opioid prescription plus:
    a. Rotated from one opioid to another because of possible incomplete cross-tolerance.
    b. Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection or other respiratory illness.
    c. Renal dysfunction, hepatic disease, cardiac illness or HIV/AIDS.
    d. Known or suspected concurrent alcohol use.
    e. Concurrent benzodiazepine or other sedative prescription.
    f. Concurrent antidepressant prescription.
6. Patients who may have difficulty accessing emergency medical services (distance, remoteness).
7. Voluntary request from a family member, friend, peace officer or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

## 3. Precautions and Contraindications

*Precautions*

- Use in Pregnancy:
    - Teratogenic Effects: pregnancy category C, no adequate or well controlled studies in pregnant women.
    - Nonteratogenic 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, myalgias, diaphoresis, abdominal cramping, yawning, 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.

## 4. Assessment and Follow-up Actions by the Pharmacist or Pharmacy Intern

### Assessment

Subjective Findings:

- Individual is at risk of experiencing an opioid-related overdose or is in a position to assist a family member, friend, or other person (including a peace officer) at risk of experiencing an opioid-related overdose.

- Individual reports no known sensitivity or allergy to naloxone hydrochloride.

Objective Findings:

- Individual is oriented to person, place, and time and able to understand and learn the essential components of overdose response and naloxone administration.

- **If the pharmacist or pharmacy intern believes that the person is currently experiencing an opioid overdose, 9-1-1 should be called immediately.**

**Follow-up Actions**

- Screen individual for contraindications/precautions. If a contraindication/precaution exists, refer individual to medical provider for further evaluation.

- If applicable, inform individual that there are treatment options available for opioid addiction/dependence and provide the Ohio Department of Mental Health and Addiction Services treatment information and referral hotline (1-877-275-6364).

## 5. Authorization to Dispense Naloxone

Pursuant to section 4729.44 of the Ohio Revised Code and rules 4729:1-3-04 and 4729:2-3-04 of the Ohio Administrative Code, this protocol authorizes pharmacists employed at the location listed on Page 1 of this protocol or any of the pharmacy interns supervised by the pharmacists employed at the location listed on Page 1 of this protocol to dispense naloxone without a prescription to the following:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or

- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

Upon satisfactory assessment (see #4 of this protocol) **and** upon completion of required patient counseling pursuant to rule 4729:1-3-04 of the Ohio Administrative Code (see page 9 of this protocol), a pharmacist or pharmacy intern under the direct supervision of a pharmacist may dispense any of the following formulations of naloxone and the specified drug delivery devices without a prescription (only selected formulations are authorized):

| Naloxone Type | Authorized | Not Authorized |
|---|---|---|
| Intramuscular naloxone | ◯ | ◯ |
| Intranasal naloxone | ◯ | ◯ |

**<u>Intramuscular naloxone</u>:**

- Naloxone 0.4 mg/ml single dose vial, 2 vials (NDC No. 0409-1215-01)
- SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.
- Syringe 3 ml 25G ×1 inch No. 2
- SIG: Use as directed for naloxone administration

Directions for Use:

1. Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness, and initiate rescue breathing.
2. Uncap the naloxone vial and uncap the syringe.
3. Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1cc of naloxone, and withdraw the needle.
4. Insert the needle into the muscle of the upper arm or thigh of the victim, through clothing if needed, and push on the plunger to inject the naloxone.
5. Repeat the injection if there is no response after 2-3 minutes.
6. Continue rescue breathing and monitor respiration and responsiveness of the naloxone recipient until emergency help arrives.

**Intranasal naloxone (NARCAN Nasal Spray):**

- Naloxone 4mg FDA approved nasal spray device, 2 doses per unit (NDC No. 69547-353-02)

- SIG: Administer a single spray intranasally into one nostril. Call 911. May repeat ×1.

Directions for Use:

1. Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness, and initiate rescue breathing.

2. Peel back the tab with the circle to open the nasal spray.

3. Hold the device with your thumb on the bottom of the red plunger and your first and middle fingers on either side of the nozzle. Do not apply any pressure until you are ready to give the dose.

4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.

5. Press the red plunger firmly to give the dose of the medication. Remove the device from the nostril after giving the dose.

6. Repeat if there is no response after 2-3 minutes, give in the other nostril.

7. Continue rescue breathing and monitor respiration and responsiveness of the naloxone recipient until emergency help arrives.

**Intranasal naloxone (KLOXXADO):**

- Naloxone 8mg FDA approved nasal spray device, 2 doses per unit (NDC No. 59467-679-01)

- SIG: Administer a single spray intranasally into one nostril. Call 911. May repeat ×1.

Directions for Use:

1. Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness, and initiate rescue breathing.

2. Peel back the tab with the black triangle to open the nasal spray.

3. Hold the device with your thumb on the bottom of the red plunger and your first and middle fingers on either side of the nozzle. Do not apply any pressure until you are ready to give the dose.

4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.

5. Press the red plunger firmly to give the dose of the medication. Remove the device from the nostril after giving the dose.

6. Repeat if there is no response after 2-3 minutes, give in the other nostril.

7. Continue rescue breathing and monitor respiration and responsiveness of the naloxone recipient until emergency help arrives.

**Required Patient Training (OAC 4729:1-3-04)***

- A pharmacist or pharmacy intern who dispenses naloxone shall instruct the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

- A pharmacist/pharmacy intern (or an appropriately trained designee of the pharmacist) shall personally provide in-person training and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed including, but not limited to, the following:

    1. Risk factors of opioid overdose;
    2. Strategies to prevent opioid overdose;
    3. Signs of opioid overdose;
    4. Steps in responding to an overdose;
    5. Information on naloxone, including possible adverse reactions;
    6. Procedures for administering naloxone;
    7. Proper storage and expiration of naloxone product dispensed; and
    8. Information on where to obtain a referral for substance abuse treatment.

*Patient training is not required if the patient has previously received training and all the following apply:

(1) The patient is offered training and refuses;

(2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months;

(3) A pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

**6. Any patient instructions in addition to the counseling required in OAC 4729:1-3-04.**

**7. Any additional instructions or requirements.**

## Physician Authorization

| | |
|---|---|
| Physician Signature | License Number |
| Physician Name (print) | Date |

## Pharmacy Responsible Person Authorization

| | |
|---|---|
| Responsible Person Signature | License Number |
| Responsible Person Name (print) | Date |