

Iowa Harm Reduction Coalition Naloxone Standardized Procedure

This updated Naloxone Standardized Procedure outlines how entities may become authorized to obtain, dispense, and administer naloxone hydrochloride for the purpose of reversing an opioid overdose. This Procedure also presents the educational requirements for obtaining the Iowa Harm Reduction Coalition (IHRC) Naloxone Standing Order and the technique for administering naloxone.

Introduction

This standing order is issued pursuant to Iowa Code sections 147A.18 and 135.190 which permits a pharmacist to dispense naloxone under the authority of the authorizing physician and permits the possession and administration of opioid antagonist medications by certain eligible recipients, including service organizations such as IHRC, in order to expand access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. The law authorizes a licensed pharmacist to dispense naloxone, under the guidance of a standing order, to persons in a position to assist.

Pursuant to the Act, the Iowa Department of Public Health on Nov. 3, 2017 – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone.

Naloxone Entity

Educational Requirement

Under this standardized procedure, eligible entities must complete training in opioid overdose reversal, which includes the following:

- Opioid overdose recognition and prevention
- Naloxone administration techniques
- The importance of calling 911 for the care of the overdose victim after naloxone administration

The name of the person being trained to distribute naloxone, the date of the training, and the name of the trainer should be recorded and reported to the Iowa Harm Reduction Coalition (IHRC)

Naloxone Hydrochloride

Naloxone is indicated for the reversal of opioid overdose. It is used to reverse the respiratory depression or unresponsiveness that can be induced by natural or synthetic opioids. It should not be given to anyone known to be allergic to naloxone hydrochloride.

It may be delivered subcutaneously or intramuscularly using an auto-injector, or needle and syringe, or intranasally.

Signs of Symptoms of Opioid Overdose

- Slowed, irregular, or no breathing
- Skin, nails turn blue
- Extreme sleepiness
- Unresponsive to sternal rub or when shaken
- Pinpoint pupils

Standardized Procedure for Naloxone Administration

1. Confirm signs and symptoms of potential opioid overdose
2. Administer naloxone as follows (**select dispensed dosage form**):

Intramuscular Naloxone:

- Uncap the naloxone vial and uncap the muscle needle-syringe
- Insert the muscle needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 ml of naloxone liquid, and withdraw the needle
- 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
- Repeat the injection if there is no response after three minutes

Multi-Step Intranasal Naloxone:

- Pop off two colored caps from the delivery syringe and one from the naloxone vial
- Screw the naloxone vial gently into the delivery syringe
- Screw the mucosal atomizer device onto the top of the syringe
- Spray half (1 mL) of naloxone in one nostril and the other half (1 mL) in the other
- Repeat if there is no response after three minutes

Single-Step Intranasal Naloxone:

- Peel back the package to remove the device
- Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle
- Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose
- Press the plunger firmly to release the dose into the patient's nose
- Repeat if there is no response after 3 minutes

Auto-injector Naloxone:

- Pull auto-injector from outer case and pull off red safety guard

- Place the black end of the auto-injector against the outer thigh, through clothing if needed, press firmly and hold in place for 5 seconds
 - Repeat if there is no response after 3 minutes
3. **Provide rescue breathing** using a disposable rescue breathing device, chest compressions, or full cardiopulmonary resuscitation (CPR) based on the training and abilities of the responder.
 4. **Call 9-1-1.** Follow the directions of the dispatcher.
 5. **If person becomes unresponsive again, administer another dose of naloxone.**

Contraindications

Patient is known to be allergic/hypersensitive to naloxone hydrochloride

Precautions

A. Drug dependence

Those who may be chronically taking opioids are more likely to experience adverse reactions from naloxone. (See adverse reactions under section “X” below). Additionally, after administration, they may awaken disoriented. Being disoriented can sometimes lead to highly combative behavior, including physical violence, especially if naloxone is given by someone unfamiliar.

B. Respiratory depression due to other drugs

Naloxone is not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and contact 911.

C. Pain crisis

In patients taking an opioid medication for a painful illness such as cancer, administration of naloxone can cause a pain crisis, which is an intense increase in the experience of pain as the naloxone neutralizes the pain-relieving effect of the opioid medication. Comfort the patient as much as possible and contact 911 as the patient may need advanced medical treatment to ease the pain crisis.

Use in pregnancy (Teratogenic effects: Pregnancy Category C)

Based on animal studies, no definitive evidence of birth defects in pregnant or nursing women exists to date. There also have not been adequate studies in humans to make a

determination. Based on this limited evidence, the benefit of giving naloxone to a pregnant patient who has overdosed outweighs the risks, and it should be given.

Adverse reactions

A. Opioid withdrawal

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may cause an acute withdrawal syndrome.

The acute withdrawal syndrome may include the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, yawning, weakness, shivering or trembling, nervousness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and fast heart beat.

While the symptoms of acute withdrawal are uncomfortable they are rarely life-threatening. Sometimes, however, they may be severe enough to require advanced medical attention.

Withdrawal symptoms resulting from administration of naloxone may appear within minutes of naloxone administration and usually subside in 1-2 hours.

B. Pulmonary edema (fluid in the lungs)

Abrupt reversal of opioid effects has been associated with development of fluid in the lungs (pulmonary edema). This has also been seen in people who use opioids who did not receive naloxone, so it is unclear whether it is a direct effect of the naloxone. Patients experiencing pulmonary edema will have difficulty breathing. This requires immediate medical care.

C. Naloxone has a relatively short duration of effect compared to many opioids and the signs of opioid overdose may reappear after 60-90 minutes and may require additional naloxone. It is recommended that the person experiencing an opioid-related overdose receive emergency medical care following naloxone administration.

D. Adverse reactions to naloxone unrelated to the opioid-related effects mentioned above are rare.

Labeling and storage

A prescription label shall be affixed to the naloxone product as required in Iowa Administrative Code rule 657—6.10. The proper storage conditions, including temperature excursions, shall be discussed with the recipient.

Reporting

The appropriate documentation noting the date of dispensation, the amount dispensed, and any reversals, as required by the Iowa Harm Reduction Coalition, shall be properly completed and submitted, either electronically or in paper format by entities that dispense each dose of naloxone.

Records

The Iowa Harm Reduction Coalition shall maintain a record of each training and dispensation of naloxone. All records of dispensations of naloxone will also be maintained. These records shall be available for inspection or copying by the State of Iowa or its authorized agent for at least two (2) years from the date of assessment or the date of dispensing, whichever is later.

Iowa Harm Reduction Coalition Naloxone Standing Order to Dispense

This Standing Order is issued by the Medical Director of the Iowa Harm Reduction Coalition, effective on the date below. This standing order authorizes the IHRC to maintain supplies of naloxone kits. The naloxone is purchased from a licensed wholesaler by IHRC under the authority of the Medical Director and will be dispensed by a licensed pharmacist associated with IHRC. In accordance with Iowa Code sections 147A.18 and 135.190, this pharmacist will dispense the naloxone to a person at risk of experiencing an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

Upon satisfactory assessment that the person to receive the naloxone kit is a person in a position to assist a person at risk of experiencing an opioid-related overdose, and upon completion of training regarding recognizing and responding to suspected opioid overdose, this Standing Order authorizes Naloxone Entities to obtain and/or distribute naloxone. The person or entity receiving the naloxone must agree that if they further distribute the naloxone to others they will also provide this training with the distribution. Naloxone may be provided via mucosal atomizer devices, syringes, and other components of the naloxone kit. Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution programs. This Standing Order is made pursuant to the Iowa Code sections 147A.18 and 135.190.

Naloxone Kits:

Intramuscular Naloxone Kits containing, at a minimum:

- Two (2) 1 ml single-use vials naloxone hydrochloride or one (1) 10 ml multi-use vial of naloxone hydrochloride (0.4 mg/ml)
- Two (2) 23-25 gauge, 1-1.5 inch intramuscular sterile needles with two (2) syringes
- Overdose prevention information pamphlet with step-by-step instructions for use

Multi-step Intranasal Naloxone Kits containing, at a minimum:

- Two (2) Luer-Jet luer-lock sterile syringes prefilled with naloxone hydrochloride (2gm/2ml)
- Two (2) mucosal atomization devices
- Overdose prevention information pamphlet with step-by-step instructions for use.

Single-step Intranasal Naloxone Kits containing, at minimum

- One (1) box containing two (2) Narcan® Nasal Spray Devices (4mg) OR one (1) box containing four (4) , Narcan® Nasal Spray Devices (2gm)
- Overdose prevention information pamphlet with step-by-step instructions for use.

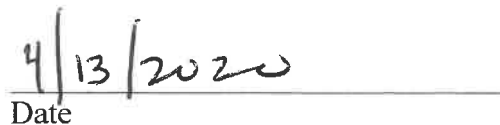
Auto-injector Kits Containing the following:

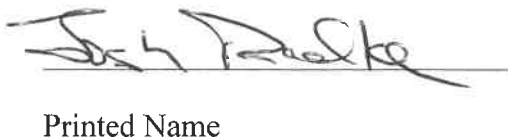
- One (1) box containing two (2) Evzio® naloxone HCl injection 2 mg/0.4 ml pre-packaged kits containing two (2) auto-injectors with audio instructions and one (1) training device
- Overdose prevention information pamphlet with step-by-step instructions for use.

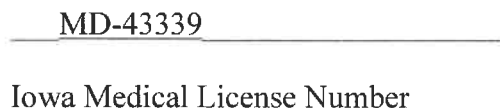
Dispense at minimum one (1) naloxone kit to the Naloxone Entity trained to receive the medication in accordance to the Naloxone Standardized Protocol. Unlimited refills are authorized.

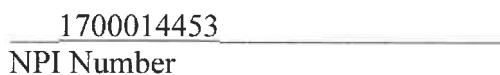
Physician's Signature and License No. and NPI No.


Signature


Date


Printed Name


Iowa Medical License Number


NPI Number