NALOXONE

STATEWIDE PROTOCOL

Iowa Board of Pharmacy

Naloxone hydrochloride ("naloxone") is a medication indicated for reversal of opioid-related overdose in the event of a drug overdose that is the result of consumption or use of one or more opioid-related drugs causing a drug overdose event.

I. Purpose

This statewide protocol is intended to ensure that naloxone may be readily obtainable by any person ("eligible recipient") who is:

- An individual at risk of opioid-related overdose,
- A family member, friend or other person in a position to assist a person at risk of opioid-related overdose,
- A first responder employed by a law enforcement agency, fire department, or emergency service program if allowed by the first responder's scope of practice,
- A patient who is prescribed an opioid pain reliever, or
- A patient who is prescribed medication to treat opioid use disorder.

II. Authority

Pursuant to Iowa Code section 155A.46, a pharmacist may order and dispense naloxone pursuant to a protocol developed by the Iowa Board of Pharmacy ("board") in consultation with the Department of Public Health to individuals aged 18 years and older, only in accordance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification).

III. Qualification

A pharmacist shall document successful completion of a continuing education program approved by the Accreditation Council for Pharmacy Education (ACPE) of at least one-hour duration related to naloxone utilization prior to dispensing naloxone pursuant to this protocol.

IV. Authorization

This protocol is authorization for a pharmacist to order and dispense naloxone and devices for its administration solely in the forms prescribed herein.

V. Order to dispense

Upon satisfactory assessment that the person to receive naloxone is an eligible recipient pursuant to this statewide protocol, and upon completion of training regarding recognizing and responding to suspected opioid-related overdose, the pharmacist may dispense one or more naloxone products or kits identified herein. The pharmacist shall utilize an assessment form provided by the board. The assessment shall include an attestation that the recipient will make available all received training materials to any individual that may be in a position to administer the naloxone. The pharmacist shall determine the appropriate naloxone product or kit to be dispensed. In addition to the contents listed below, each naloxone product or kit dispensed shall include step-by-step instructions for administration of naloxone including the potential need for additional doses, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until emergency assistance arrives.

A. Intranasal naloxone with atomizer kits must contain a minimum of the following:
   - Two Luer-Jet Luer-lock syringes (each prefilled with 2mg/2ml naloxone hydrochloride).
   - Two mucosal atomization devices (MAD).
B. Intranasal naloxone spray kits must contain a minimum of the following:
   - One FDA-approved naloxone hydrochloride prepackaged kit containing two (2) doses.
C. Intramuscular auto-injector naloxone kits must contain a minimum of the following:
   - One FDA-approved naloxone hydrochloride prepackaged kit containing two (2) doses.
D. Intramuscular naloxone kits must contain a minimum of the following:
   - Two 1ml vials **or** one 10ml vial naloxone 0.4mg/ml
   - Two intramuscular syringes with needle

VI. Patient education required

Upon assessment and determination that the individual is eligible to receive and possess naloxone pursuant to this protocol, a pharmacist shall, prior to dispensing naloxone, provide training and education to the recipient including, but not limited to, the information identified herein. A pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified herein, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

- The signs and symptoms of opioid-related overdose as described in Section VII.

- The importance of calling 911 as soon as possible and the potential need for rescue breathing as described in Section VIII (A).
- The appropriate use and directions for administration of the naloxone to be dispensed as described in Section VIII.
- Adverse reactions of naloxone as well as reactions resulting from opioid withdrawal following administration as described in Section XII.
- The proper storage conditions, including temperature excursions, of the naloxone product being dispensed.
- The expiration date of the naloxone product being dispensed and the appropriate disposal of the naloxone product upon expiration.
- Information about substance abuse or behavior health treatment programs, if applicable.

VII. Signs and symptoms of opioid-related overdose

The following may be signs and symptoms of an individual experiencing an opioid-related overdose:

- A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
- Unresponsive or unconscious individuals.
- Not breathing or slow/shallow respirations,
- Snoring or gurgling sounds (due to partial upper airway obstruction).
- Blue lips and/or nail beds.
- Pinpoint pupils.
- Clammy skin.

Note that individuals in cardiac arrest from all causes share many symptoms with someone with a narcotic overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue skin/nail beds). If no pulse, these individuals are in cardiac arrest and require CPR.

VIII. Appropriate use and directions

A. ***Call 911 as soon as possible*** for a person suspected of an opioid-related overdose with respiratory depression or unresponsiveness and initiate rescue breathing. Naloxone is a short-acting reversal medication which *may require additional doses* if the person relapses into respiratory depression or unresponsiveness prior to the arrival of emergency assistance.

B. Administer naloxone as follows (pharmacist to indicate to the recipient which set of instructions to follow based upon the form of naloxone being dispensed):

1. Intranasal naloxone with syringe and atomizer:

- 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 tip of the syringe.
- Spray half (1ml) of the naloxone in one nostril and the other half (1ml) in the other nostril.
- ***Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.***

2. Intranasal naloxone with FDA-approved nasal spray:

- Deliver one spray into one nostril. (Do not "prime" or test the spray device before spraying it into the nostril, as this will waste the medicine.)
- ***Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.***
- If these administration instructions differ from those provided by the manufacturer, the pharmacy shall provide the patient with the manufacturer's administration instructions.

3. Intramuscular naloxone with FDA-approved auto-injector:

- Pull auto-injector from outer case.
- 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, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.***
- If these administration instructions differ from those provided by the manufacturer, the pharmacy shall provide the patient with the manufacturer's administration instructions.

4. Intramuscular naloxone with syringe and needle:

- Remove the plastic cap from the vial and remove the cap from the needle on the syringe.
- Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1ml (1cc) of naloxone liquid, and withdraw the needle.
- Insert the needle into the muscle of the upper arm or thigh of the victim, through the clothing if needed, and push the plunger to inject all of the naloxone.

- ***Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.***

C. Continue to monitor respiration and responsiveness of the victim, and continue to provide rescue breathing as necessary until emergency assistance arrives. Upon arrival of emergency assistance, report to first responder that naloxone has been administered.
D. Contact medical provider with questions, concerns, or problems.
E. Return for additional supply as needed, following use or expiration of naloxone.
F. Encourage opioid user to communicate with primary care provider regarding overdose, use of naloxone, and availability of behavioral health services.

IX. Contraindications

Do not administer naloxone to a person with known hypersensitivity to naloxone or to any of the other ingredients contained in the package insert for naloxone.

X. 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 XII 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.

XI. 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.

XII. Adverse reactions

A. Opioid-induced respiratory depression

Abrupt reversal of opioid-induced respiratory depression may result in nausea, vomiting, sweating, abnormal heart beat, fluid development in the lungs and opioid acute withdrawal syndrome (see part B below), increased blood pressure, shaking, shivering, seizures and hot flashes. Additional doses of naloxone may be required if the victim does not respond to a dose within 3 minutes or relapses back into respiratory depression or unresponsiveness prior to the arrival of emergency assistance.

B. Opioid dependence

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

Acute withdrawal syndrome may include, but not be limited to, 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 heartbeat.

Reactions resulting from administration of naloxone may appear within minutes of naloxone administration and subside in approximately 2 hours. Additionally, the opioid-related adverse reactions may subside within minutes of naloxone administration; the reactions may reappear in approximately 90 minutes, so it is imperative that the person experiencing an opioid-related overdose receive emergency medical care following naloxone administration.

Most often the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.

Adverse reactions beyond opioid-related overdose are rare.

XIII. Labeling

A prescription label shall be affixed to the naloxone product as required in Iowa Administrative Code rule 657—6.10, except that the expiration date of the product shall

not be rendered illegible. The prescription shall be dispensed in the name of the eligible recipient.

XIV. Records and reporting

Each pharmacy shall maintain the original record of each assessment, regardless of the eligibility determination following assessment, and dispensing of naloxone to each eligible recipient. These records shall be available for inspection or copying by the board or its authorized agent for at least two (2) years from the date of assessment or the date of dispensing, whichever is later. Naloxone dispensing shall be reported to the Iowa Prescription Monitoring Program pursuant to rule 657—37.2(124). As soon as reasonably possible, the pharmacist shall notify the recipient's primary health care provider of the naloxone product dispensed to the recipient. If the recipient does not have a primary health care provider, the pharmacist shall provide the recipient with a written record of the naloxone product dispensed and shall advise the recipient to consult a physician.

XV. Effective date

This protocol is effective June 28, 2022 and shall be in effect for a period of one year and shall automatically renew for subsequent one year periods unless otherwise amended or terminated by the board.