Naloxone Standing Order

Iowa Department of Public Health

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 standing order 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, or
- A first responder employed by a service program, law enforcement agency, or fire department.

II. Authority

This standing order is issued pursuant to Iowa Code sections 147A.18 and 135.190 which permits the possession and administration of opioid antagonist medications by certain eligible recipients and allows the distribution of such medications by pharmacists pursuant to standing order or collaborative agreement. A pharmacist shall engage in naloxone dispensing pursuant to this standing order only when the pharmacist has complied with the rules of the Iowa Board of Pharmacy ("board").

III. Authorization

This standing order may be used as a prescription to obtain naloxone from a pharmacy in the event there is an inability to obtain naloxone or a prescription for naloxone from an eligible recipient's regular health care provider or another source. This order is authorization for a pharmacist to dispense naloxone and devices for its administration solely in the forms prescribed herein.

IV. Order to dispense

Upon satisfactory assessment that the person to receive naloxone is an eligible recipient pursuant to this standing order, and upon completion of training regarding recognizing and responding to suspected opioid-related overdose, the pharmacist may dispense no

more than five (5) naloxone kits identified herein to any single eligible recipient at one time, unless the pharmacist has made the determination that a greater quantity is reasonable and justified. The pharmacist shall utilize an assessment form provided by the Iowa Board of Pharmacy. 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 to be dispensed. If the eligible recipient is a minor, a parent or guardian shall provide consent.

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).
   - Step-by-step instructions for administration of intranasal naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.
B. Intranasal naloxone spray kits must contain a minimum of the following:
   - One FDA-approved naloxone hydrochloride prepackaged kit containing two (2) doses, such as Narcan® or KLOXXADO™.
   - Step-by-step instructions for administration of intranasal naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.
C. Intramuscular auto-injector naloxone kits must contain a minimum of the following:
   - One FDA-approved naloxone hydrochloride prepackaged kit containing two (2) doses, such as Evzio ®.
   - Step-by-step instructions for administration of intramuscular naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.

V. 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.

VI. 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.
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 with the second nasal spray device in the opposite nostril if there is no response after 2-3 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 with the second auto-injector if 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.

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.

VII. 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.

VIII. 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.

IX. 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.

X. Adverse reactions

A. Opioid depression

Abrupt reversal of opioid 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.

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 heart beat.

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.

XI. Expiration and review

This standing order will automatically expire one year from the date of authorization, or the date naloxone may be approved as an over-the-counter medication, whichever occurs first. It may be reissued annually at the discretion of the medical director. This standing order will be reviewed, and may be updated, if there is relevant new science about naloxone administration.

XII. Labeling and storage

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. The proper storage conditions, including temperature excursions, shall be discussed with the recipient.

XIII. Reporting

A copy of the assessment form shall be submitted to the medical director that has authorized this standing order, via facsimile to 515-725-4098, within seven (7) days of dispensing naloxone. When eligibility has been denied, a copy of the assessment form shall be submitted to the medical director that has authorized this standing order, via facsimile to 515-725-4098, within seven (7) days of the denial.

XIV. Records

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 of pharmacy or its authorized agent for at least two (2) years from the date of assessment or the date of dispensing, whichever is later.

/s/ Caitlin Pedati — September 21, 2021

Caitlin Pedati, MD, MPH, FAAP — Date
Medical Director and State Epidemiologist
Iowa Department of Public Health

Authorized pharmacists in compliance with the requirements of this standing order and board rules sign below:

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