Illinois Naloxone Standardized Procedure

This updated Naloxone Standardized Procedure (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 Illinois Naloxone Standing Order and the technique for administering naloxone.

Introduction

In September 2015, Illinois enacted Public Act 99-0480 (Act), expanding 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 Act authorizes trained pharmacists and first responders to dispense naloxone as an opioid antagonist intervention.

Pursuant to the Act, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone.

Naloxone Entity

Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs.

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85), complete a training that meets criteria pursuant to the Act, and have knowledge of this Procedure, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists shall report naloxone dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.
- Any non-pharmacy OEND program must be registered with the IDHS Division of Substance Use Prevention and Recovery Drug Overdose Prevention Program (DOPP) at http://www.dhs.state.il.us/page.aspx?item=58142. This may include law enforcement agencies, drug treatment programs, local health departments, hospitals or urgent care facilities, or other for-profit or not-for-profit community-based organizations.

Educational Requirement

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

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

Naloxone Hydrochloride

Naloxone is indicated for the reversal of opioid overdose, induced by natural or synthetic opioids, relative to respiratory depression or unresponsiveness. 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

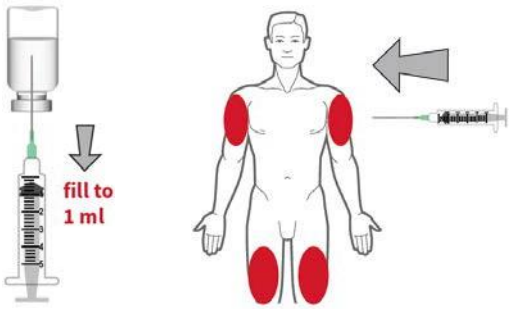
- Slowed, irregular, or no breathing
- Skin, nails turn blue
- Extreme sleepiness
- Unresponsive to sternal rub or when shaken
- Pinpoint pupils

Standardized Procedure for Naloxone Administration

1. Confirm signs and symptoms of potential opioid overdose

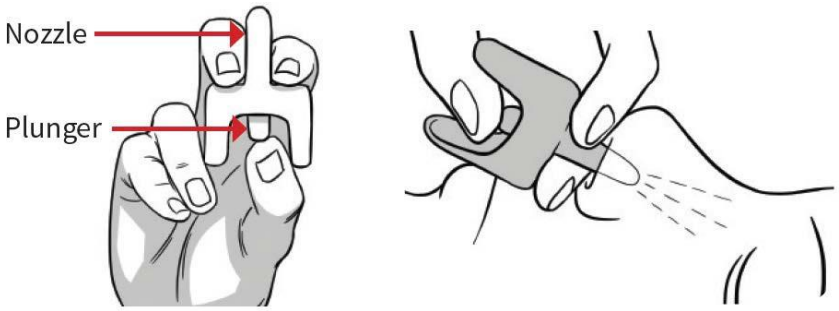
2. Call 9-1-1 and administer naloxone as follows **(select dispensed dosage form):**

   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



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. For adult and adolescent victims, responders should perform compressions and rescue breaths for opioid-associated emergencies if they are trained and have a disposable rescue breathing device or perform Hands-Only CPR if not trained to perform rescue breaths.

4. If person becomes unresponsive again, administer another dose of naloxone. Stay with the person until emergency help arrives.

Contraindications

- Patient is known to be hypersensitive to naloxone hydrochloride

Precautions

- Pre-existing cardiac disease or seizure disorder

- Person is suspected to be physically dependent on opioids including newborns of mothers with opioid dependence (Reversal of opioid effect will precipitate acute abstinence syndrome)

- Use in Pregnancy:
    1. Teratogenic Effects: Pregnancy category C, no adequate or well-controlled studies in pregnant women
    2. 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
    3. Naloxone should only be used in pregnant women with opioid dependence in situations of life-threatening overdose

- Nursing Mothers: Caution should be exercised when administering to nursing women due to transmission in human milk

- Geriatric Use**:** Caution should be exercised for potential decreased hepatic, renal and cardiac function, as well as concomitant disease and other pharmacotherapies

Adverse Reactions

- Adverse reactions are related to precipitating opioid withdrawal. They include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, 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.

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Illinois Naloxone Standing Order

This Standing Order is issued by the Chief Medical Officer of the Illinois Department of Public Health, effective on the date below. It authorizes Naloxone Entities to obtain and/or distribute naloxone, syringes, and other components of the naloxone kit to those who may assist an individual suffering opioid-related overdose. Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs. This Standing Order is made pursuant to the Substance Use Disorder Act (20 ILCS 301/5-23), and Executive Order 17-05, and should be used in conjunction with the Illinois Naloxone Procedure.

Naloxone Kits:

Intramuscular Naloxone Kits containing, at a minimum:

- Two (2) 1 ml single-use vials naloxone hydrochloride (0.4 mg/ml)(NDC 00409-1215-01, 67457-0292-02, 0641-6132-25) or one (1) 10 ml multi-use vial of naloxone hydrochloride (0.4 mg/ml)(NDC00409-1219-01)
- Two (2) 23-25 gauge, 1-1.5 inch intramuscular sterile needles with Two (2) 3 mL syringes
- One (1) case containing one (1) ZIMHI™ (naloxone HCL injection, USP) 5mg/0.5 mL single-dose, prefilled syringe
- One (1) carton containing two (2) cases, each of which contains one (1) ZIMHI™ (naloxone HCL injection, USP) 5m/.0.5 mL single-dose, prefilled syringe
- 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 (4 mg/0.1mL)(NDC 69547-353-02)
- One (1) box containing two (2) Kloxxado Nasal Spray Device (8mg/0.1mL) (ND
- Sandoz – One (1) box containing two naloxone nasal spray devices (4mg/0.1mL) (NDC 00781-7176-12)
- Teva – One (1) box containing two naloxone nasal spray devices (4mg/0.1mL) (NDC 00093-2165-68 C: 59467-679-01)
- Overdose prevention information pamphlet with step-by-step instructions for use.

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

License 036157977, NPI 1013127455

02/22/2022

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

Arti Barnes

Physician's Name (Print)

Order Effective Date: 02/24/2022

Order Expiration Date: 02/23/2023