Illinois Opioid Overdose Reversal Agent
Standardized Procedure

This updated Opioid Overdose Reversal Agent Standardized Procedure (Procedure) (formerly limited to Naloxone only) outlines for healthcare and other trained personnel how entities, including schools, may become authorized to obtain, dispense, and administer naloxone or nalmefene for the purpose of reversing an opioid overdose This Procedure also presents the educational requirements for obtaining the Illinois Opioid Overdose Reversal Agents Standing Order and the technique for administering these reversal agents.

Introduction

In September 2015, Illinois added Section 85/19.1 to the Illinois Pharmacy Practice Act, 225 ILCS 85/19.1, 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. This statute authorizes personnel trained to dispense and/or administer reversal agents as an opioid antagonist intervention, per the instructions below.

In May 2023, nalmefene was also approved by the FDA as an opioid reversal agent, similar in mechanism to naloxone, and is therefore included in this update.

In January 2024, this Standing Order was expanded to include Illinois schools as a naloxone entity due to the need to have emergency procedures in place should persons exhibits signs of opioid overdose while on school premises. See Illinois School Code, 105 ILCS 5/22-30(e-10), (f), (f-5) and (g).

Pursuant to the Substance Use Disorder Act, 20 ILCS 301/, the Pharmacy Practice Act, and the School Code, 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 and nalmefene to persons suspected of drug overdose.

Naloxone Entity

Naloxone Entities may dispense either naloxone or nalmefene, and include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs, as discussed below:

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85) and have knowledge of this Procedure, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists shall report naloxone and nalmefene dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.

- Any non-pharmacy OEND program, except schools, must be registered with the IDHS Division of Substance Use Prevention and Recovery Drug Overdose Prevention Program (DOPP) at https://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.
- Schools registered with the Illinois State Board of Education (ISBE) and their staff members who have met the educational requirements listed below regarding the administration of reversal agents to persons suspected of potential opioid overdose.

Educational Requirement

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

- Opioid overdose prevention and recognition
- The need to quickly administer treatment to reduce the risk of severe injury or death
- The techniques for administering naloxone and nalmefene
- Trained individuals must be familiar with the product that they will be administering, including potential responses to administering the medication
- The importance of calling 911 for the care of the overdose victim
- The goal of treatment is to restore normal breathing
- For schools, the training outlined in Section 22-30(h-5) of the Illinois School Code

Signs and Symptoms of Opioid Overdose, include but are not limited to the following:

- Slowed, irregular, or no breathing
- Skin, nails turn blue
- Extreme sleepiness
- Unresponsive to sternal rub or when shaken
- Pinpoint pupils
- Generalized seizures in children not known to have epilepsy

If an individual is suspected of overdosing, an Opioid Overdose Reversal Agent must be administered as quickly as possible, because an overdose may result in death.

Naloxone Hydrochloride

Naloxone is indicated for the reversal of opioid overdose, induced by natural or synthetic opioids, as manifested by respiratory depression or unresponsiveness. **It is safe to give this medication to a child of any age or adult with symptoms of opioid overdose, even if you are not sure if they overdosed on opioids.** It should not be given to anyone known to be allergic to naloxone hydrochloride. It may be delivered to persons subcutaneously or intramuscularly using a dose appropriate auto-injector, or needle and syringe, or intranasally. **Individuals must be monitored for a recurrence of symptoms of opioid overdose after receiving naloxone, and additional doses of naloxone administered if needed.**

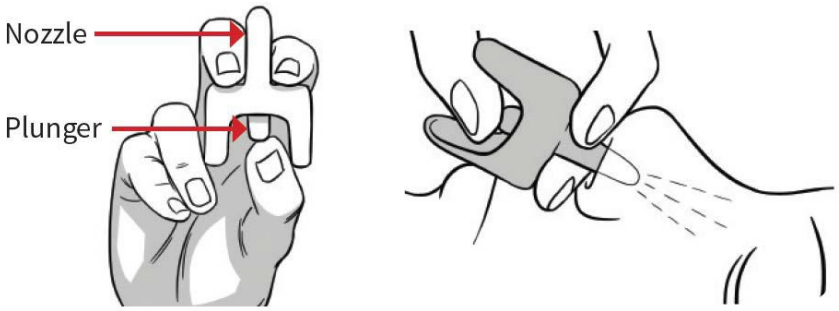
Standardized Procedure for Naloxone Administration

1. Confirm signs and symptoms of potential opioid overdose.

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

Single-Step Intranasal Naloxone:

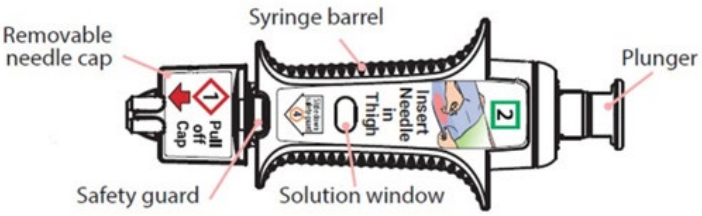
- The device is ready to use, no assembly required.
- Peel back the package to remove the device.
- Do not test the nasal spray. It has only one dose and cannot be reused.
- Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.
- Place and hold the tip of the nozzle 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, using the alternate nostril, if there is no response after 2 - 3 minutes using a new nasal spray.



- If there is still no response and additional doses are available, administer additional doses of nasal spray every 2 - 3 minutes until emergency medical assistance arrives. Use a new nasal spray in alternate nostrils with each dose.

Auto-injector Naloxone:

- ZIMHI is intended to be administered by individuals 12 years of age or older. Younger individuals or those with limited hand strength may find the device difficult to use.
- Place the individual on their back.



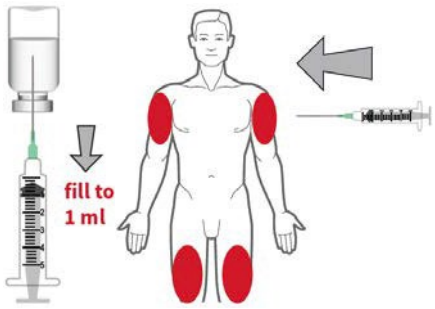
- Pull auto-injector from outer case and pull off red safety guard.
- Place the black end of the auto-injector against the outer thigh, through clothing if needed, press firmly, and hold in place for 5 seconds.

- Immediately after injection, using one hand with fingers behind the needle, slide the safety guard over the needle. Do not use two hands to activate the safety guard.

- Place the individual on their side (recovery position).
- Repeat, if there is no response after 3 minutes.
- Tell the EMS personnel that you administered an injection of naloxone and show them where the injection was administered.

Intramuscular Naloxone (single or multi-dose vials):

- Uncap the naloxone vial and uncap the intramuscular (IM) needle (23-25 gauge) and syringe (3mL).
- Insert the IM 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.



3. For all 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.

Contraindications

There are no absolute contraindications to the use of naloxone in an emergency. The only relative contraindication is known hypersensitivity to naloxone.

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.
- Some individuals may display responses not related to withdrawal such as temporary amnesia, physical discomfort or aggression when an opioid overdose is treated.
- **Adverse effects beyond opioid withdrawal are rare.**

Nalmefene Hydrochloride

Nalmefene nasal spray is an opioid antagonist indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids, as manifested by respiratory and/or central nervous system depression. It is safe to give this medication to adults and pediatric patients aged 12 years and older, with symptoms of opioid overdose, even if you are not sure if they overdosed on opioids.

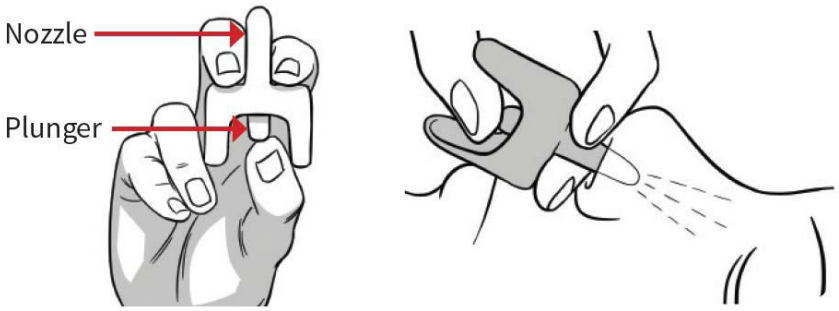
Following nalmefene administration individuals must be monitored for signs of a recurrence of symptoms of opioid overdose, and an additional dose of nalmefene administered if needed.

Standardized Procedure for Nalmefene Administration

1. Confirm signs and symptoms of potential opioid overdose

2. Call 9-1-1 and administer nalmefene as follows:

   <u>Single-Step Intranasal nalmefene</u>:
   - The device is ready to use, no assembly required.
   - Peel back the package to remove the device.
   - Do not test the nasal spray. It has only one dose and cannot be reused.
   - 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, using the alternate nostril, if there is no response after 2 - 5 minutes using a new nasal spray.



   - If there is still no response and additional doses are available, administer additional doses of nasal spray every 2 - 5 minutes until emergency medical assistance arrives. Use a new nasal spray in alternate nostrils with each dose.

3. For all 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.

Contraindications

There are no absolute contraindications to the use of nalmefene in an emergency. The only relative contraindication is known hypersensitivity to nalmefene.

Adverse Reactions

- The safety and tolerability of nalmefene is similar to naloxone.
- In studies most individuals (82%) did not experience adverse reactions.
- The main side effects are related to (non-severe, not life-threatening) opioid withdrawal: nausea, vomiting, rapid heart rate, hypertension, pain, fever, and dizziness.
- Some individuals may display responses not related to withdrawal such as temporary amnesia, physical discomfort, or aggression when an opioid overdose is treated.

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
69 West Washington Street, Suite 3500 • Chicago, Illinois 60602-3027 • www.dph.illinois.gov

Illinois Opioid Reversal Agent Standing Order

This Standing Order is issued by the Director of the Illinois Department of Public Health, effective on the date below. It authorizes Naloxone Entities to obtain and/or distribute opioid reversal agents, syringes, and other components of the naloxone or nalmefene kit to those who may assist an individual suffering opioid-related overdose. Naloxone Entities may include pharmacies, pharmacists, opioid overdose education and naloxone distribution (OEND) programs, or schools registered with the Illinois State Board of Education (ISBE). 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 Opioid Reversal Agent Standardized Procedure.

Intramuscular Naloxone Kits containing, at a minimum (links to package insert):

- Two (2) 1 ml single-use vials naloxone hydrochloride (0.4 mg/ml) 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) 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 (links to package inserts):

- One (1) box containing two (2) NARCAN® Nasal Spray Devices (4 mg/0.1mL)
- One (1) box containing two (2) KLOXXADO™ Nasal Spray Devices (8mg/0.1mL)
- One (1) box containing two Sandoz (generic) naloxone nasal spray devices (4mg/0.1mL)
- One (1) box containing two Teva (generic) naloxone intranasal spray devices (4mg/0.1mL)
- Overdose prevention information pamphlet with step-by-step instructions for use

- Single-step Internasal Nalmefene Kits containing, at minimum (links to package insert):
- One (1) box containing two (2) OPVEE® Nasal Spray Devices (3 mg/0.1mL)
- Overdose prevention information pamphlet with step-by-step instructions for use

Standing Order

Dispense at minimum two (2) naloxone or nalmefene kits to the entity trained to receive the medication in accordance with the Illinois Opioid Overdose Reversal Agent Standardized Procedure. Unlimited refills are authorized.

License: 036135164
NPI: 1841585783

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

Sameer Vohra, MD, JD, MA
Physician's Name (Print):

Order Effective Date: 02/09/2024
Revision Date(s): 01/15/2024
Order Expiration Date: 02/08/2025