



## **Naloxone Standardized Procedures Illinois Departments of DFPR, DPH & DHS Opioid Antagonist Initiative**

### **Background:**

In September 2015, Illinois passed a new law, PA99-0480, expanding access to the opioid antagonist Naloxone. Naloxone may be used to reverse overdoses to narcotic medications, such as certain prescription pain medications and heroin. As a result of the new law, a trained pharmacist can follow standardized procedures to dispense Naloxone for opioid antagonist intervention.

With these standardized procedures, trained pharmacists may provide this antagonist to those who might benefit from it the most, including:

- A family member, friend or other person in a position to assist a person at risk of overdose;
- A trained first responder;
- An individual at risk of overdose;
- A trained school nurse.

Based upon PA99-0480, IDFPR may approve standardized procedures for dispensing Naloxone developed in accordance with the Departments of Public Health and Human Services by pharmacists trained in the use of Naloxone for opioid antagonist intervention.

### **Continuing Education (CE):**

Under these standardized procedures, eligible pharmacists who have completed a certificate training program in opioid overdose prevention and who are CPR certified, may dispense Naloxone and educate patients or concerned entities, based upon their demonstrated knowledge of:

- Opioid overdose prevention;
- Reducing the risk of prescription opioid abuse;
- Safe use of opioids for the management of chronic pain;
- Use of screening tools to detect opioid abuse or dependency and management of difficult patients;
- Preventing diversion of prescribed opioid medications;
- Naloxone administration techniques;
- Knowledge of Protocol for Naloxone Standing Order for Opioid Antagonist Initiative.

**Standardized Procedures:**

Pharmacies who have pharmacists with certified Naloxone Antagonist Training, and who wish to participate in the Illinois Naloxone Antagonist overdose prevention program, can contact ILPMP at: [ILPMP.org](http://ILPMP.org) to request a copy of the Standardized Procedures for Naloxone Opioid Overdose.



**Illinois Departments of DFPR, DPH & DHS  
Standard Procedures for Naloxone Distribution for Overdose Prevention  
January 2016**

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 intramuscularly with an Auto-injector, a needle and syringe or intranasally with a mucosal atomizer device.

This standard procedure covers the possession and dispensing of Naloxone Kits, to include Naloxone Hydrochloride, intramuscular syringes, injection supplies, nasal atomizers, or commercial Naloxone auto-injections.

This standardized procedure authorizes trained pharmacists at \_\_\_\_\_pharmacy in the state of Illinois to maintain supplies of Naloxone Kits for the purpose of dispensing them, in accordance with the attached Protocol, to any of the following:

- A person at risk of experiencing an opiate-related overdose;
- A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose;
- A trained first responder;
- A trained school nurse.

**Pharmacist Standardized Procedure to Dispense Naloxone**

Dispense one Naloxone Kit to identified individual who is approved to receive the medication. Unlimited refills are authorized.

Individual is approved to receive Naloxone by meeting the criteria outlined in the standardized procedures.

1. Individual is a person at risk of experiencing an opiate-related overdose or a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.
2. Individual has received counseling by a pharmacist trained in the use of Naloxone regarding the recognizing and responding to suspected opioid overdose. The mandatory counseling shall also cover the proper use of the dosage forms listed below:

Intramuscular Naloxone Kits contain the following, at a minimum:

- Two (2) single-use 1 ml vials Naloxone Hydrochloride (0.4mg/ml)
- Two (2) intramuscular needle syringes
- Overdose prevention information pamphlet with step by step instructions for use.

Intranasal Naloxone Kits containing, at a minimum:

- Two 2 ml Luer-Jet Luer-lock syringes prefilled with Naloxone Hydrochloride (2mg/2ml)
- Two mucosal atomization devices
- Overdose prevention information pamphlet with step by step instructions for use.

Auto-injector Kits Containing the following:

- Naloxone HCL 0.4 mg/ml pre-packaged kits (Evzio, NDC 60842-030-01)
- Containing 2 auto-injectors with audio instructions and 1 training device and step by step instructions for administration of Naloxone by auto-injector.

**Standardized Procedures for Naloxone Distribution for Overdose Prevention**  
**Directions for Use:**

1. Evaluate the individual for signs and symptoms of potential Opioid or Heroin Over dose.
2. If individual is not breathing, start rescue breathing using a disposable rescue breathing device.
3. **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.

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

Auto-injector Naloxone:

- 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 three minutes
- 4. Call 911 as soon as possible for a person suspected of an opioid overdose with respiratory depression or unresponsiveness.
- 5. Continue rescue breathing and monitor respiration and responsiveness of the Naloxone recipient until emergency help arrives.

## **Counseling Protocol for Naloxone Standardized Procedures**

### **Indications and Usage:**

Naloxone is indicated for the complete or partial reversal of opioid overdose induced by natural or synthetic opioids and exhibited by respiratory depression or unresponsiveness.

### **Assessment:**

#### Subjective Findings

- Individual is at risk of experiencing an opiate-related overdose or is in a position to assist a family member, friend, or other person at risk of experiencing an opiate-related overdose.
- Individual reports no known sensitivity or allergy of the intended recipient to Naloxone Hydrochloride.

#### Objective Findings

- In the pharmacist's judgement, the client is oriented to person, place, and time and able to understand and learn the essential components of overdose response and Naloxone administration.

### **Provider Actions:**

- Screen individual for contraindications / precautions to dispensing Naloxone.
- If a contraindication / precaution exist, refer individual to medical provider for evaluation.
- Provide Opioid overdose training information which covers at least the following:
  1. Risk factors for opioid overdose and possible prevention actions;
  2. Recognition of opioid overdose;

3. Calling 911;
  4. Rescue breathing, Using a disposable rescue breathing device.
  5. Administration of Naloxone as described within the Standardized Procedures.
- Upon the successful counseling session, the pharmacist will dispense the Naloxone kit and explain contents to individual
  - The pharmacy is to report dispensed kits to the ILPMP with daily reporting of dispensed controlled substances.
  - As part of the mandatory counseling function, the pharmacist shall provide information and /or referral for substance abuse or behavioral health treatment options.

**Follow Up Requirements:**

- The pharmacist shall instruct individual/parent/guardian to call medical provider if questions, concerns or problems arise
- The pharmacist shall, instruct individual/parent/guardian to return for refill as needed, subject to use and expiration of Naloxone (approx. 18 months)
- The pharmacist shall encourage opioid user or other concerned individual to communicate with primary care provider regarding overdose, use of Naloxone, and availability of behavioral health services.

**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 narcotic dependence. (Reversal of narcotic 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 as well.

- Nursing Mothers: Caution should be exercised when administering to nursing women due to transmission in human milk. Risk and benefits must be evaluated.
- Geriatric Use: Choose lower range dose taking precautions for potential decreased hepatic, renal and cardiac function, as well as, concomitant disease and other pharmacotherapies.

### **Adverse Reactions:**

- Adverse reactions are related to reversing dependency and precipitating withdrawal and includes fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, yawning, sneezing.
  1. These symptoms may appear within minutes of Naloxone administration and subside in approximately 2 hours.
  2. 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.