

KEY INFORMATION

1. If you believe, someone is experiencing an opioid overdose, call 911!
2. Remain with the person until first responders arrive. Act 139 provides that you will not be arrested or charged with parole violations or drug offenses if you call 911, provide all necessary information and remain with the person in distress.
3. Become familiar with how to use Naloxone before someone needs it, through the pharmacist, your medical provider, or online training.
4. If you have questions about the proper use of Naloxone, ask the pharmacist, contact your health care provider, or go to the DOH website at <http://bit.ly/OpioidsinPA>

This Standing Order will automatically expire on the date that the physician whose signature appears below has ceased serving as an employee of the Pennsylvania Department of Health. This Standing Order will be reviewed, and may be updated, if there is relevant new science about Naloxone administration, or at least in 4 years.



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Deputy Secretary Signature and License Number

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This Standing Order may be revised or withdrawn at any time.

NALOXONE STANDING ORDER DOH-001-2023

Naloxone Prescription for Overdose Prevention

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

I. PURPOSE

This Standing Order is intended to ensure that residents of the Commonwealth of Pennsylvania who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose (Eligible Persons), are able to obtain Naloxone. Unless otherwise expressly permitted herein, this Standing Order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Such organizations should utilize the medical professionals with whom they have a relationship to write prescriptions specific to personnel who would be expected to administer Naloxone and would be wise to ensure that all such personnel are appropriately trained in the administration of Naloxone.

II. AUTHORITY

This Standing Order is issued pursuant to Act 139 of 2014 (Act 139) (amending The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 et seq.)), which permits health care professionals otherwise authorized to prescribe Naloxone to prescribe it via standing order to Eligible Persons.

III. AUTHORIZATION

This Standing Order may be used by Eligible Persons as a prescription or third-party prescription to obtain Naloxone from a pharmacy in the event that they are unable to obtain Naloxone or a prescription for Naloxone from their regular health care providers or another source. This Standing Order is authorization for pharmacists to dispense Naloxone and devices for its administration SOLELY in the forms prescribed herein.¹

This Standing Order may also be used by community-based organizations (CBOS) that are in a position to assist a person at risk of experiencing an opioid-related overdose, to obtain Naloxone and provide it to individuals at risk of experiencing an opioid-opioid related overdose, their family members and friends, or other persons in a position to assist a person at risk of experiencing and opioid-related overdose. CBOs may provide the Naloxone in person or via the mail. This authorization is in no way intended to establish an agency relationship between CBOs operating under this standing order and the Department of Health (DOH).

¹ Or their FDA-authorized generic equivalents.

IV. TRAINING AND INSTRUCTIONAL MATERIALS

Prior to obtaining Naloxone under this Standing Order, Eligible Persons are strongly advised to complete a training program approved by the Pennsylvania Department of Health (DOH) in consultation with the Pennsylvania Department of Drug and Alcohol Programs (DDAP), such as the one found online at Train PA's website (<https://www.train.org/pa/admin/course/1085469/>) and obtain a certificate of completion. Act 139 does not require training; however, training is necessary in order to ensure that Eligible Persons are protected from legal liability to the extent that Act 139 provides that the receipt of DOH/DDAP-approved training and instructional materials and prompt seeking of additional medical assistance creates a rebuttable presumption that an Eligible Person acted with reasonable care in administering Naloxone.

V. SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

1. A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
2. Unresponsive or unconscious individuals.
3. Not breathing or slow/shallow respirations
4. Snoring or gurgling sounds (due to partial upper airway obstruction).
5. Blue lips and/or nail beds.
6. Pinpoint pupils.
7. Clammy skin.
8. 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

Eligible Persons should be aware of the following information when dealing with a person who it is suspected is experiencing an opioid overdose event:

- 1. Call 911 for EMS to be dispatched.**
2. In cardiac arrest or pulseless patients: Call 911 for EMS and start CPR if able and trained to do so. In cardiac arrest, CPR is the most important treatment, and any attempt to administer Naloxone should not interrupt chest compressions and rescue breathing.

3. Naloxone should only be given to someone suspected of opioid overdose as noted in the signs and symptoms listed in Section V above.
4. In respiratory arrest or a non-breathing patient: If able to do rescue breathing, rescue breathing takes priority over Naloxone administration. Administer Naloxone if possible while doing rescue breathing.
5. Administration of Naloxone (only give to someone with suspected opioid overdose based on signs and symptoms listed in Section V above).

A. INTRA-NASAL NALOXONE

Eligible Persons should be provided with the following:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration 1 mg/mL).
- b. Two mucosal atomization devices.
- c. Patient information pamphlet containing dosage and administration instructions.

2. NARCAN Nasal Spray

- a. Carton containing two blister packages each with single 4 mg dose of naloxone in a 0.1 mL intranasal spray.
- b. Package insert containing dosage and administration instructions.

3. KLOXXADO Nasal Spray

- a. Carton containing two blister packages each with a single 8 mg dose of naloxone hydrochloride in 0.1 mL.
- b. Package insert containing dosage and administration instructions.

Instructions for use:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Pop off two yellow caps from the delivery syringe and one red cap from the naloxone vial.
- b. Screw the Naloxone vial gently into the delivery syringe.
- c. Screw the mucosal atomizer device onto the top of the syringe.
- d. Spray half (1 ml) of the Naloxone in one nostril and the other half (1 ml) in the other nostril.

- e. Note: Administer the Naloxone in a quick burst to ensure that it is atomized. A slow administration will cause liquid to trickle in without being atomized properly, which will slow delivery to the bloodstream.
- f. Continue to monitor breathing and pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- g. If patient does not awaken after 4 minutes, administer second dose of Naloxone (if available) (1 mL) briskly in one nostril and the other half (1 mL) briskly in the other nostril.
- h. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.

2. NARCAN Nasal Spray

- a. Lay person on their back to receive a dose of NARCAN Nasal Spray.
- b. Remove NARCAN from the box. Peel back the tab with the circle to open the NARCAN Nasal Spray.
- c. Hold the NARCAN Nasal Spray with your thumb on the bottom of the plunger and first and middle fingers on either side of the nozzle.
- d. Tilt the person's head back and provide support under the neck with your hand. Gently insert tip of nozzle into one nostril until fingers on either side of the nozzle are against the bottom of the person's nose.
- e. Press the plunger firmly to give the dose of NARCAN Nasal Spray.
- f. Remove the NARCAN Nasal Spray from the nostril after giving the dose.
- g. Move the person onto their side after giving NARCAN Nasal Spray.
- h. Remain with the person, monitor breathing/pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- i. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.
- j. Watch the person closely. If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available, until the person responds, or emergency medical help is received.

3. KLOXXADO Nasal Spray

- a. Lay the person on their back to receive a dose of KLOXXADO nasal spray.
- b. Remove KLOXXADO nasal spray from the box. Peel back the tab with the black triangle to open the KLOXXADO nasal spray blister.
- c. Hold the KLOXXADO nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. Do not apply pressure until you are ready to give the dose.
- d. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.
- e. Press the plunger firmly to give the dose of KLOXXADO nasal spray.
- f. Remove the KLOXXADO nasal spray from the nostril after giving the dose.
- g. Move the person onto their side after giving KLOXXADO nasal spray.
- h. Get emergency help right away. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.
- i. Watch the person closely. If the person does not respond by waking up, to voice or touch, or start breathing normally, another dose may be given. KLOXXADO may be dosed every 2 to 3 minutes, if available, until the person responds, or emergency medical help is received.

B. NALOXONE VIA AUTO INJECTOR

Eligible Persons should be provided with the following:

1. ZIMHI (naloxone hydrochloride injection)

- a. Case containing one 5 mg/0.5 mL single-dose prefilled syringe or carton containing two cases, each of which contain one 5 mg/0.5 mL single-dose prefilled syringe
- b. Patient instructions

Instructions for use:

1. ZIMHI (naloxone hydrochloride injection)

- a. ZIMHI is intended to be administered by individuals 12 years of age or older
- b. Press needle into outer thigh after twisting off needle cap. Do not touch the plunger until this step is completed.

- c. Push plunger until it clicks and hold for 2 seconds before removing the needle. The correct dose has been given if the plunger has been pushed all the way down and blocks part of the solution window. It is normal for most of the medicine to remain in the syringe after the dose has been injected.
- d. Pull the safety guard down using one hand with fingers behind the needle. Do this right after you give the injection.
- e. Place the used syringe into the blue case, close it, and call 911. Give the used ZIMHI syringe to the healthcare provider for inspection and proper disposal.
- f. If the person is unresponsive after 2 to 3 minutes, give an additional dose of ZIMHI using a new device.

C. INTRAMUSCULAR NALOXONE

Eligible Persons should be provided with the following:

1. Naloxone 0.4mg/mL in 1mL single dose vials
 - a. Quantity to dispense: two single dose vials
2. Include one 3 cc, 23g or 25g, 1-inch or 1 ½-inch syringe per dose
3. Patient Instructions

Instructions for use:

1. Uncap the Naloxone vial and uncap the needle on the syringe.
2. Insert the needle through the rubber membrane on the Naloxone vial, turn the vial upside down, draw up Naloxone liquid, and withdraw the needle.
3. Insert the needle into the muscle of the upper arm or thigh of the person, through the clothing if needed, and push the plunger to inject all of the Naloxone.
4. Repeat the injection with the second vial of Naloxone if there is no response after 3 minutes, or if the person relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

D. REFILLS

Refills may be obtained as needed under this standing order.

VII. CONTRADICTIONS

Do not administer Naloxone to a person with known hypersensitivity to Naloxone or to any of the other ingredients contained in the packaging 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 combative behavior, 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 beats, 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 beats.