

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 <https://bit.ly/GetNaloxone>.**

This Standing Order replaces Standing Order DOH-002-2023. 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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Acting Secretary of Health Signature and License Number

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This Standing Order may be revised or withdrawn at any time.

NALOXONE STANDING ORDER DOH-004-2023

Naloxone Prescription for Overdose Prevention

Naloxone Hydrochloride (Naloxone) is a medication indicated for reversal of opioid 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 applies to Commonwealth of Pennsylvania firefighters and law enforcement officers (collectively Eligible Persons) who are providing care with an employer who meets the requirements under section III below. This Standing Order does not apply to Department of Health (Department) certified emergency medical services (EMS) providers or Department-licensed EMS agencies, except as specifically provided herein.

II. DEPARTMENT-CERTIFIED EMS PROVIDERS AND DEPARTMENT-LICENSED EMS AGENCIES

This Standing Order authorizes Department-certified EMS providers or Department-licensed EMS agencies who have responded to an individual experiencing an opioid-related overdose (At-Risk Person), and who are therefore in a position to assist that At-Risk Person, to leave behind naloxone with the At-Risk Person or with family members, friends, or other persons who are in a position to assist the At-Risk Person, along with instructions to follow the Naloxone package insert directions and the guidance provided in Naloxone Standing Order DOH-003-2023 available on the Department's website.

III. 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, and to persons who are in a position to assist an individual at risk of experiencing an opioid-related overdose.¹

IV. WRITTEN AGREEMENT REQUIRED

Prior to obtaining and using Naloxone under this Standing Order, employers of Eligible Persons shall enter into a written agreement with a Department-licensed EMS agency to obtain the supply of Naloxone. Eligible Persons also shall complete a Department approved training program.

¹ This Standing Order is authorization to dispense Naloxone and devices for their administration solely in the forms prescribed herein or their FDA-authorized generic equivalents. This also includes FDA-authorized over-the-counter Naloxone products.

V. 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.

VI. 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.

VII. APPROPRIATE USE AND DIRECTIONS

This Standing Order may be used by Eligible Persons in the event that there is no other protocol, prescription, standing order or guidance for the administration of naloxone. Existing Naloxone protocols, prescriptions, standing orders or guidance for the administration of Naloxone that was created by an Act 139 authorized person for Eligible Persons supersedes this Standing Order.

Upon completion of a Department-approved training program and documentation of training to his or her employer, eligible persons may administer either intra-nasal naloxone or auto-injector naloxone (intra-muscular) (whichever is available) to a person suspected of a drug overdose event as follows:

- 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 VI 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 VI 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. INTRA-MUSCULAR NALOXONE, BY WAY OF 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.

VIII. 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.

IX. 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.

X. 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.

XI. 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.

Most often the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.

XII. DEFINITIONS

A. DRUG OVERDOSE EVENT:

This event is an acute medical condition, including, but not limited to, severe physical illness, coma, mania, hysteria or death, which is the result of consumption or use of one or more controlled substances causing an adverse reaction. A patient's condition shall be deemed to be a drug overdose if a prudent layperson, possessing an average knowledge of medicine and health, would reasonably believe that the condition is in fact a drug overdose and requires immediate medical attention

B. LAW ENFORCEMENT OFFICER:

A person who by virtue of the person's office or public employment is vested by law with a duty to maintain public order or to make arrests for offenses, whether that duty extends to all offenses or is limited to specific offenses, or a person on active State duty under 51 Pa.C.S. § 508 (relating to active duty for emergency).

C. RESCUE BREATHING:

A skill performed for a victim who is not breathing at all, or whose breaths are too slow or irregular to be effective. In rescue breathing, breaths are delivered to the victim by pinching the nose shut and breathing into the victim's mouth. Masks and other barrier devices are available to decrease the risk of disease transmission when giving rescue breaths.

D. CARDIOPULMONARY RESUSCITATION (CPR):

A lifesaving technique that is useful when someone's breathing or heartbeat has stopped. CPR is offered by such organizations as the American Heart Association and the American Red Cross. Rescue breathing is combined with chest compressions to send oxygen-containing blood to the brain and vital organs for a person who is not breathing and whose heart is not beating.