

Guidance Document

Updated: November 13, 2014

REQUIREMENTS:

First Responder Agencies Seeking to Obtain Naloxone Hydrochloride

Per Act 139 of 2014, [PA SB 1164](#), which amended the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, a first responder organization) seeking to obtain, carry, and administer naloxone in the event of an opioid overdose must first enter into a written agreement with an Emergency Medical Services (EMS) agency. For purposes of this Guidance Document, a first responder organization is a law enforcement or firefighter agency that is not licensed by the Department of Health as an EMS agency. This written agreement is valid only under the consent of the EMS Medical Director or another physician. The consented written agreement must also include the following:

HOW the first responder agency will obtain the supply of naloxone, i.e., direct prescription or by standing order.

***A standing order** is a prescription written by the EMS medical director or another physician, allowing for a specific number of naloxone units with the ability to refill the medication when supplies have depleted or units have expired. As part of a first responder agency's naloxone protocol, standing orders will specify the route of administration, dosage, when to administer and under which circumstances a second dose of naloxone is necessary. Standing orders would need to be renewed at least annually. A standing order cannot be written for an individual, i.e., family member or loved one.*

WHO will be prescribing naloxone to your agency.

WHAT method or route of administration will be prescribed and used by the agency.

WHERE the medication will be obtained (such as a local pharmacy name, address) and with whom it will be stored after the supply is obtained. (For example, EMS can hold a surplus supply of naloxone until replenishment is needed OR your agency can store, manage, and replenish the entire supply, according to language in the standing order)

RECOMMENDATIONS:

It is strongly recommended that the following safeguards are implemented to ensure the safe use of naloxone in the event of an opioid overdose.

THE DEPARTMENTS STRONGLY RECOMMEND THE AGREEMENT INCLUDE THE UNDERSTANDING THAT PROMPT MEDICAL ASSISTANCE WILL BE SUMMONED AT THE SCENE OF AN OVERDOSE AND ONLY THOSE AUTHORIZED BY HAVING COMPLETED A PENNSYLVANIA DEPARTMENT OF HEALTH APPROVED ONLINE NALOXONE TRAINING MAY ADMINISTER THE MEDICATION. Under Act 139, these conditions, when met, create a rebuttable presumption that the first responder acted with reasonable care in administering naloxone, which is important regarding the first responder's immunity protection. NOTE: First responders must be trained on the specific method of naloxone administration to be used by the agency. Trainings and support materials are available on all methods at (DOH/DDAP webpage).

STORAGE AND TEMPERATURE CONTROL

Naloxone should be stored at room temperature and away from light. According to the manufacturer, the drug must be kept out of direct light and at room temperature (between 59 and 77 degrees Fahrenheit). Please be aware that it should not be left in a car for extended periods of time and should not be subjected to extreme heat or cold (it will freeze) as it may impact the effectiveness of the medication.

SHELF LIFE

The shelf life of naloxone is approximately two years. All doses should be checked periodically to ensure that the naloxone is not adulterated. A dose of naloxone is considered adulterated when:

- a. It is beyond the manufacturer's or distributor's expiration date; and/or
- b. There are signs of discoloration or particles in the naloxone solution.

In order to keep track of expiration dates, first responder agencies should keep careful records of each dose, including but not limited to, when and whom the medication was dispensed.

ADDITIONAL RECOMMENDATIONS

Although not mandated, it is strongly recommended that in-house policies and protocols are in place regarding the appropriate use of naloxone, steps to be taken upon administration; follow-up care protocols, proper disposal of used, expired, or adulterated units, and proper reporting procedures. This is further defined in the example policy attached.

TRAINING

Any first responder administering naloxone must first be trained on its use. Act 139 recognizes only those trainings which are officially approved by the Pennsylvania Department of Health. The trainings will consist of the following components:

- Understanding Opioid addiction, who it effects and how it effects them
- Recognizing the signs and symptoms of overdose

- Distinguishing between different types of overdose
- Performing rescue techniques
- Understanding the mechanism of action of naloxone
- Administration of naloxone
- Promptly seeking medical attention

FREQUENTLY ASKED QUESTIONS

1) What is naloxone?

Naloxone (also known as Narcan) is a medication that can reverse an overdose that is caused by an opioid drug (i.e. prescription pain medication or heroin). When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing within two to eight minutes. Naloxone has been used safely by emergency medical professionals for more than 40 years and has only one function: to reverse the effects of opioids on the brain and respiratory system in order to prevent death. Naloxone has no potential for abuse.

2) What type of naloxone can be administered by first responders in the event of a suspected overdose?

Commonly used methods by which naloxone is administered are intranasal, auto-injector, and intramuscular.

In order to administer naloxone nasal spray, a first responder agency will need to obtain the following:

- 2mg/2mL of naloxone (prefilled syringe). Make sure it will be made available at the pharmacy stated on the standing order and/or agreement.



Nasal Atomization Device (**sold separately**). Although this attachment is not normally stocked, your local pharmacy may assist in ordering. Atomizer can also be ordered from a number of medical supply companies without a prescription. [Link to assembly instructions here](#)

Using an auto-injector in a manufactured dosage form (similar to an epi-pen)

On April 3, 2014, the U.S. Food and Drug Administration approved the first naloxone auto-injector which can be used intramuscularly (IN) or just below the skin of the thigh area. This form of administration requires no assembly and provides real time instruction. To read more about this product please visit:

<http://evzio.com/patient/about-evzio/what-is-evzio.php>



Dimensions
3 3/8" high
2" wide
5/8" thick



About the height and
width of a credit card



About the thickness
of a smartphone

Intramuscular administration



3) After I obtain a prescription, where can I go to purchase the naloxone?

Whatever form or route of naloxone administration prescribed to you, there are a few ways to obtain the medication and its associated attachments. First, check with your local pharmacies to see if they have the medication and other necessary equipment in store. If the products you need are not available and time permits, ask your pharmacy if they will assist in ordering. EMS medical supply companies can also be a great way of obtaining supplies of naloxone. Some companies make kits available with all necessary pieces. Most of these companies can be found online.

4) Where do I find an approved online training?

Please visit the Pennsylvania Department of Health or the Department of Drug and Alcohol Programs websites for approved training venues and supportive information.

5) How does someone who administers naloxone qualify for the statutory immunity as described in ACT 139?

1. Prior to administering naloxone, the person must act in good faith, with reasonable care, and under the belief that the individual was indeed suffering from an opioid-related drug overdose.
2. The person must have completed an approved training prior to administering naloxone to a victim of overdose. Please visit www.givenaloxone.org for available trainings.
3. In the event of an overdose, in conjunction with administering the naloxone, the individual must promptly seek medical assistance.

6) How can first responders encourage overdose survivors to seek the treatment they need?

Inform victims that help is available and recovery is attainable. It is suggested that first responders who administer naloxone have contact information for their county's drug and alcohol office on hand. This information can be found at http://www.ddap.pa.gov/portal/server.pt/community/need_help_now_/20933. Also encourage the individual to discuss substance abuse treatment with the emergency department healthcare staff.