



Law Enforcement Agencies Seeking to Obtain Naloxone Hydrochloride (Narcan®)

Updated 10-4-2016

Per Ohio Revised Code Section 2925.61(D) a peace officer employed by a law enforcement agency is not subject to administrative action or criminal prosecution *if the peace officer, acting in good faith, obtains naloxone from the peace officer's law enforcement agency and administers the naloxone to an individual who is apparently experiencing an opioid-related overdose.*

Per Ohio Revised Code Section 4729.51, as enacted by, a law enforcement agency is not subject to licensure as a terminal distributor of dangerous drugs for the *sole purpose* of possessing naloxone. This recent change permits law enforcement agencies to purchase naloxone from wholesalers or other terminal distributors without a license by the State of Ohio Board of Pharmacy.

Please be advised that locations that operate correctional institutions and police dog trainers are still required to obtain a terminal distributor of dangerous drugs (TDDD) license. The agencies that have these existing TDDD licenses from the Board MAY have to submit additional documentation to the Board (see FAQ 3) to purchase and store naloxone.

While you may not be required to obtain licensure to purchase naloxone, the State of Ohio Board of Pharmacy strongly recommends the implementation of the following safeguards to ensure the safe use of naloxone in the event of an opioid overdose:

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 68 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 particulate matter in the naloxone solution.

In order to keep track of expiration dates, law enforcement agencies should keep careful records of when and to whom the medication was dispensed.

TRAINING

The State of Ohio Board of Pharmacy strongly encourages regular trainings on the administration of naloxone in the event of an apparent opioid overdose. These training should consist of the following standard overdose response components:

- Recognizing the signs and symptoms of overdose
- Distinguishing between different types of overdose
- Performing rescue breathing



- Administering intranasal naloxone
- Follow-up care

Such trainings can be conducted by your local EMS agency, emergency department personnel or a local Project DAWN (Deaths Avoided with Naloxone) staff member. A list of the local Project DAWN sites can be accessed here: <http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>

The Attorney General has also developed an eOPOTA naloxone training video for law enforcement is accessible to officers via the Ohio Law Enforcement Gateway (OHLEG): <https://www.ohleg.org/>

In addition, the Ohio Department of Health has a number of training resources available on its web site: <http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>

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 law enforcement in the event of a suspected overdose?

There are no restrictions on the formulations of naloxone that can be used by law enforcement. The following are common methods of administering naloxone in the event of an overdose:

i) Intranasal naloxone (Naloxone Nasal Spray):

- *Naloxone 4mg/.1mL FDA approved nasal spray device, 2 doses per unit – NDC No. 69547-353-02*



ii) Using a device manufactured for the intranasal administration of liquid drugs (i.e. a nasal spray)

In order to administer naloxone via a nasal spray, a law enforcement agency will need to obtain the following:

- *Luer-Jet™ Luer-Lock Prefilled Syringe (2 mg / 2 mL of naloxone) – NDC#: 76329-3369*

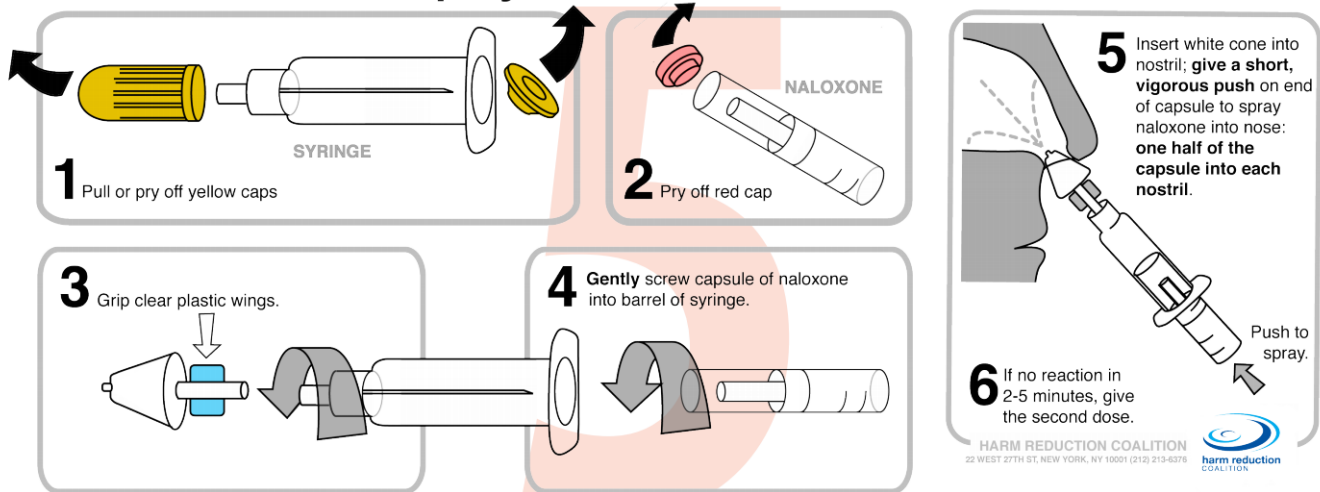


- *MAD300 Nasal Atomization Device: This device can be ordered from a number of medical supply companies without a prescription (it is NOT normally stocked at a local pharmacy).*



The following provides an overview of how to assemble the nasal spray:

How to Give Nasal Spray Naloxone



ii) Using an autoinjector 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. To read more about this product please visit:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm>

- Naloxone 0.4 mg/0.4 ml - NDC No. 60842-030-01

iii) Intramuscular injection using a syringe

- Naloxone 0.4 mg/ml single dose vial, 2 vials
- NDC No. 00409-1215-01
- Syringe 3 ml 25G x1 inch No. 2

For more information on administering naloxone intramuscularly, please visit:

www.pharmacy.ohio.gov/naloxone and review the diagrams found in the *Patient Counseling Brochure*.

3) I already have a TDDD license for my agency? What do I need to do to obtain naloxone?

If you have an unlimited category II or category III TDDD license you are not required to do anything to order naloxone.

If your agency has a limited TDDD category II or III license, you will need to update your drug list to reflect the addition of naloxone. The new drug list must contain the following information:

- a) the brand name (Narcan®)
- b) the generic name (Naloxone)
- c) strength to be stocked (Naloxone 2 mg / 2 mL)
- d) dosage form (*intranasal solution*)

You can update your drug list by visiting: <http://www.pharmacy.ohio.gov/Licensing/DrugList.aspx>

BE ADVISED: Each time you revise your drug list you must upload your **ENTIRE** list. Previous versions of your drug list will not be displayed on the website; they will be replaced with your most current submissions once approved.

To check to see if your agency has a terminal distributor of dangerous drugs, please visit:

www.pharmacy.ohio.gov/licenselookup

4) I want to order naloxone for my agency, where do I purchase it?

Naloxone can be obtained by three methods.

Wholesale Purchase: A law enforcement agency is permitted to order the drug from a wholesaler that is licensed by the State of Ohio Board of Pharmacy. To verify a wholesale drug distributor is licensed in Ohio, visit: www.pharmacy.ohio.gov/licenselookup

Wholesale Purchase from a Pharmacy: The State of Ohio Board of Pharmacy permits a pharmacy licensed as a terminal distributor dangerous drugs to conduct an occasional sale of drugs at wholesale. **There are no restrictions on the amount that can be provided by a pharmacy to a law enforcement agency pursuant to rule 4729-9-10.**

The Ohio Department of Mental Health and Addiction Services operates Ohio Pharmacy Services, which sells naloxone kits to local governments, including law enforcement. To contact Ohio Pharmacy Services, please call: 614-752-0158.

Wholesale Purchase from a Local Health Department: The State of Ohio Board of Pharmacy also permits a health department licensed as a terminal distributor dangerous drugs to provide naloxone at wholesale to a law enforcement agency. Please be advised that the terminal distributor must properly document the transaction (even if the health department is donating the naloxone). **There are no restrictions on the amount that can be provided by a health department to a law enforcement agency.**

The State of Ohio Board of Pharmacy strongly supports efforts to reduce opioid overdose death through expanded use of naloxone. If you have any questions regarding the purchase, storage or use of naloxone, please call us at 614-466-4143 or email us by visiting <http://www.pharmacy.ohio.gov/Contact.aspx> and we will do everything we can to assist you.

5) Is there any financial assistance available for paying for the medication?

On March 2, 2015, Ohio Attorney General Mike DeWine and Amphastar Pharmaceuticals, Inc. entered into an agreement where the drug manufacturer has agreed to provide a \$6 rebate for each Amphastar naloxone syringe purchased by certain Ohio public entities for the next year. A copy of that agreement can be found at www.OhioAttorneyGeneral.gov/AmphastarRebateAgreement. As part of the agreement, the Ohio Attorney General has agreed to process all of the rebate requests. For more information about the rebate, please visit: <http://www.ohioattorneygeneral.gov/naloxonerebate>

The Ohio Mental Health and Addiction Services (OhioMHAS) is committing up to \$500,000 in each state fiscal year to enhance access to naloxone in every Ohio county. Funds allocated to the department will be used to purchase naloxone, including complete Project DAWN Kits (Death Avoidance With Naloxone), for distribution to county health departments to dispense to local law enforcement, emergency personnel and first responders (as required by House Bill 64). For more information, please visit: <http://mha.ohio.gov/Default.aspx?tabid=817>