pennsylvania
DEPARTMENT OF HEALTH

STANDING ORDER DOH-002-2015
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 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. This 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 order is authorization for pharmacists to dispense Naloxone and devices for its administration SOLELY in the forms prescribed herein.

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 on line at http://www.getnaloxonenow.org/online_training.html or at the DOH website at http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/A-D/Pages/Act-139-of-2014.aspx#.VTfP2WTD-Uk 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

A. A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
B. Unresponsive or unconscious individuals.
C. Not breathing or slow/shallow respirations
D. Snoring or gurgling sounds (due to partial upper airway obstruction).
E. Blue lips and/or nail beds.
F. Pinpoint pupils.
G. Clammy skin.
H. 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, BY WAY OF A MUCOSAL ATOMIZER DEVICE (MAD)

1. Eligible Persons should be provided with the following:
   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 with overdose prevention information and step-by-step instructions for overdose responses and naloxone administration.

2. Instructions for use:

   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 (1ml) of the Naloxone in one nostril and the other half (1ml) 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. 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.
   h. If patient does not awaken after 4 minutes, administer second dose of Naloxone (if available) (1mL) briskly in one nostril and the other half (1mL) briskly in the other nostril.

B. INTRA-MUSCULAR NALOXONE, BY WAY OF AUTO-INJECTOR

1. Eligible Persons should be provided with the following:
   a. Two EVZIO (naloxone hydrochloride injection, USP) 0.4 mg auto-injectors

b. A single Trainer for EVZIO
c. Patient instructions

2. Currently the only available auto injector comes with automated voice instructions (EVZIO®) and has a speaker that provides voice instructions to help guide you through each step of the injection.
    a. Follow automated voice instructions.
3. If the auto-injection device does not come with automated voice instruction or the automated voice instruction is otherwise disabled, follow below. The auto-injection device should still work even if the automated voice instructions do not.
    a. Prepare device
        i. For EVZIO®
            1. Pull off the **Red** safety guard. **Note:** The **Red** safety guard is made to fit tightly. **Pull firmly to remove.** To reduce the chance of an accidental injection, do not touch the **Black** base of the auto-injector, which is where the needle comes out.
    b. Hold injector with a fisted hand if possible and press firmly against outer thigh, until you hear a click or hiss. EVZIO® can be used through clothing. One auto injector delivers 0.4 mg naloxone.
    c. Continue to hold pressure for a full 10 seconds to ensure full delivery of medication. Note: The needle will inject and then retract back up into the EVZIO® auto-injector and is not visible after use. Do not look for the needle as this will put you at risk for needle stick injury.
    d. Continue to monitor breathing and pulse. If not breathing, give rescue breathing. If no pulse, start CPR.
    e. If no response in 3-5 minutes, repeat the above instruction with a new auto-injection device.
    f. Remain with the person, monitor and support breathing until he or she is under the care of a medical professional, such as a physician, nurse, or EMS.

C. REFILLS

Refills may be obtained as needed under this standing order.

VII. CONTRAINDICATIONS

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,

XI. 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://www.portal.health.state.pa.us/portal/server.pt/community/emergency_medical_services/14138/act_139_-_naloxone/1938552**

XII. REVIEW

This standing order will automatically expire on the date that the physician whose signature appears below has ceased being Physician General or until a health care professional otherwise authorized to prescribe Naloxone to the Eligible Person does so as authorized under Act 139-2014, whichever occurs first. 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.

MD050119-L

Physician General's Signature and License Number

10/28/15

Effective Date

Dr. Rachel Levine

Physician General's Name (Print)

This standing order may be revised or withdrawn at any time.