# KENTUCKY DEPARTMENT FOR PUBLIC HEALTH CLINICAL PROTOCOL FOR NALOXONE (OPIOID ANTAGONIST) IN THE SCHOOL SETTING



### **Background**

KRS 217.186 <u>statute.aspx (ky.gov)</u> makes provisions for individuals with life-threatening symptoms of opioid overdose to have access to naloxone by the board of each local public school district and the governing body of each private or parochial school or school district that chooses to keep naloxone on the premises and regulate its administration. KRS 217.186 includes:

- 1. A person or agency, including a school employee authorized to administer medication under <a href="KRS">KRS</a> <a href="156.502">156.502</a> may:
  - a) Receive a prescription for the drug naloxone.
  - b) Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
  - c) Administer naloxone to an individual suffering from an apparent opiate-related overdose.
- A person acting in good faith who administers naloxone received under KRS 217.186 shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.
  - Opioid overdose-related deaths can be prevented when naloxone is administered in a timely manner. As a narcotic antagonist, naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression that usually is the cause of overdose deaths. During the period of time when an overdose can become fatal, respiratory depression can be reversed by giving the individual naloxone. Naloxone should be administered promptly at the first sign of opioid overdoses. It is safer to administer naloxone than to delay treatment for opioid overdose.
  - Each school is encouraged to ensure ready access to naloxone and keep it in a minimum of two (2) locations in the school so that it may be administered to any individual believed to be having a life-threatening opioid overdose.
  - Schools electing to keep naloxone shall maintain the drug in a secure, accessible, but unlocked location. Naloxone may only be purchased with a prescription from a medical provider or pharmacist who has met the requirements and received certification from the Board of Pharmacy, in accordance with 201 KAR 2:360. statute.aspx (ky.gov)
  - Each school electing to keep naloxone shall implement policies and procedures for managing opioid overdose, developed, and approved by the local school board.
  - Administration of appropriate CPR measures may be needed if the individual does not have respirations or a heartbeat.

#### WHAT ARE OPIOIDS?

Opioids include illegal drugs such as heroin, as well as prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone (OxyContin®, Percodan®, Percocet®), hydrocodone (Vicodin®, Lortab®, Norco®), fentanyl (Duragesic®, Fentora®), hydromorphone (Dilaudid®, Exalgo®), and buprenorphine (Subutex®, Suboxone®). Opioids work by binding to specific receptors in the brain, spinal cord and gastrointestinal tract. In doing so, they minimize the body's perception of pain. However, stimulating the opioid receptors or "reward centers" in the brain also can trigger other systems of the body, such as those responsible for regulating mood, breathing and blood pressure.

### **HOW DOES OVERDOSE OCCUR?**

A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis) and overdose, in which breathing and heartbeat slow or even stop.

Since the onset and severity of an opioid overdose is difficult to predict, the overdose may rapidly progress to respiratory depression. In some instances, signs and symptoms of an opioid overdose may appear as an individual experiencing extreme sleepiness or having breathing difficulties. *Naloxone* should be administered promptly at the first sign of an opioid overdose.

### WHO MAY BE AT RISK

The following clinical factors may increase a patient's risk for overdose when taking an opioid

- Anyone who uses opioids for long-term management of chronic cancer or non-cancer pain is at risk for opioid overdose
- Substance abuse, dependence and/or addiction, as are persons who use heroin
- Accidental exposure and unintentional opioid misuse
  - Includes members of a patient's household who may discover and use the prescribed opioid inappropriately
- A morphine-equivalent dose (MED) ≥20 mg per day
- Switching to another opioid
- Chronic pulmonary disease
- Sleep apnea
- Asthma
- Chronic kidney and/or liver impairment
- Use of CNS depressants, including benzodiazepines and alcohol
- Use of certain medications for depression, including monoamine oxidase inhibitors (MAOIs)

### SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

All school staff, including those in extracurricular programs, should be trained on how to recognize the signs and symptoms of an opioid overdose requiring the use of a naloxone. Symptoms of an opioid overdose requiring the use of naloxone may include but are not limited to the following: extreme sleepiness (inability to awaken verbally or upon sternal rub); breathing problems which can range from slow to shallow breathing in a patient that cannot be awakened; fingernails or lips turning blue/purple; extremely small "pinpoint" pupils; slow heartbeat and/or low blood pressure. Signs of overmedication which may progress to overdose include unusual sleepiness; drowsiness; or difficulty staying awake despite loud verbal stimulus or vigorous sternal rub; mental confusion; slurred speech; intoxicated behavior; slow or shallow breathing; extremely small "pinpoint" pupils, although normal size pupils do not exclude opioid overdose; slow heartbeat; low blood pressure; and difficulty waking the person from sleep.

It is important to note that not <u>all</u> signs and symptoms may be present during an opioid overdose. If the individual is not responsive to shaking, yelling, or vigorously rubbing their sternum, **ACT PROMPTLY!!** 

- > CALL FOR HELP!
- CHECK FOR BREATHING!
- > CALL 911 IMMEDIATELY!
- **➢** GET THE NALOXONE!

### Differentiating between overdose and an opioid high

Sometimes it is difficult to tell if someone is overdosing or if they are just really high. The table below offers clues on how a responder might be able to tell the difference.

REALLY HIGH OVERDOSE	REALLY HIGH	OVERDOSE
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Muscles become relaxed	Pale, clammy skin
Speech is slowed/slurred	Very infrequent or no breathing
Sleepy looking	Deep snoring or gurgling (death rattle)
Responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc)	Not responsive to stimuli (such as shaking, yelling, vigorous sternal rub, etc)
Normal heartbeat/pulse	Slow heartbeat/pulse
Normal skin tone/color	Blue lips and/ or fingertips

Because opioids depress respiratory function and breathing, one telltale sign of a person in a critical medical state is the "death rattle." If a person emits a "death rattle" an exhaled breath with a very distinct, labored sound coming from the throat, emergency resuscitation will be necessary immediately, as it almost always is a sign that the individual is near death.

### **RESPONDING TO AN OPIOID OVERDOSE**

### IF YOU SUSPECT AN OVERDOSE

**ACT PROMPTLY!!** Always go a distressed individual. Never send the individual to the health room/school nurse alone or leave them alone. Do not move an individual who is in severe distress.

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the patient as soon as possible, **CALL 911 immediately** to activate emergency medical services (EMS).

### 1. CALL 911 immediately

If you suspect an opioid overdose or if someone is showing signs of respiratory distress (infrequent or no breathing, deep snoring, or gurgling), call 911 or direct someone to call 911 to request immediate medical assistance. Advise the 911 operator that an opioid overdose is suspected, and that naloxone has been given or is being given.

### 2. PROVIDE RESCUE BREATHING if necessary

For a person who is *not breathing* or who is unresponsive with shallow, infrequent breathing, rescue breathing is the quickest way to get oxygen to the brain and is an important step in preventing an overdose death.

### Steps for rescue breathing are:

- a) Place the person on his or her back and pinch their nose.
- b) Open the person's airway by tilting the chin up and gently pushing down on the forehead. Look into the mouth to see if there is anything blocking the airway. If so, remove it.
- c) Create an airtight mouth to mouth seal on the victim's mouth.
- d) Take a regular (not deep) breath and give a breath over 1 second.



- e) Blow enough air into the lungs to make the chest rise. If the chest is not rising, tilt the head back more and try again.
- f) Give a second rescue breath over 1 second.
- g) Breathe again every 5 seconds until the patient is breathing on their own, or EMS arrive and take over.

### 3. ADMINISTER NALOXONE

There are multiple routes of administration for FDA approved naloxone: intramuscular, subcutaneous, intranasal, and intravenous. Schools may choose to use administration method that best suit their needs. Current drug products approved by the FDA may be found here: <a href="Orange Book: Approved Drug Products">Orange Book: Approved Drug Products</a> with Therapeutic Equivalence Evaluations (fda.gov)

Most patients respond by returning to spontaneous breathing, with minimal withdrawal symptoms. The response generally occurs within 3 to 5 minutes of naloxone administration. Rescue breathing should continue while waiting for the naloxone to take effect.

Naloxone will continue to work for as long as 30 to 90 minutes, but after that time, overdose symptoms may return. **ASSURE 911 HAS BEEN CALLED** and that EMS was activated. If no one has yet called 911, **IMMEDIATELY CALL 911.** 

### 4. DIRECT SOMEONE TO CALL AND NOTIFY THE FRONT OFFICE AND THE SCHOOL NURSE

### If the individual is breathing on their own, place them in the recovery position

After giving naloxone, stay with the individual. If they are breathing on their own, to decrease the individual's chance of choking on their vomit, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

## 5. <u>STAY WITH THE PERSON AND MONITOR</u> FOR RESPIRATORY DISTRESS.

### Provide rescue breathing as necessary.

It is necessary to seek immediate emergency medical assistance (911) after delivering the first dose of naloxone, keep the patient under continued surveillance, and repeat doses of naloxone as necessary.







### How to give naloxone:

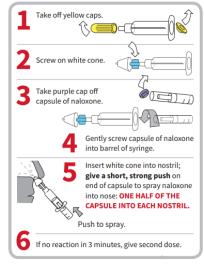
There are 4 common naloxone products. Follow the instructions for the type you have.

### **Nasal spray**



### Nasal spray with assembly

This requires assembly. Follow the instructions below.



### **Auto-injector**

The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



### Injectable naloxone

This requires assembly. Follow the instructions below.

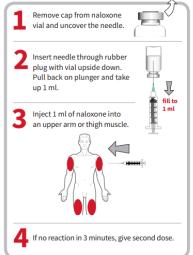


Image by Harm Reduction Coalition.

http://harmreduction.org/issues/overdose prevention/tools-best-practices/od-kit materials/. Updated October 2014

Images in Public Domain.

NaloxonePatientFlyer SFDPH 2016.pdf (prescribetoprevent.org)

### 6. REPEAT NALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE.

The duration of action of most opioids is likely to exceed the 30-90 minutes that naloxone will be effective, resulting in a return of respiratory and/or central nervous system depression, even after an initial improvement in symptoms. If the desired response is not obtained after 2 or 3 minutes, another dose of naloxone may be administered if available.

If after 1-2 doses of naloxone there is no breathing or breathing continues to be shallow, lay the person on their back and continue to perform rescue breathing while waiting for the naloxone to take effect, they breathe for themselves, or EMS arrives.

<u>DOCUMENT</u> the individual's name, date, time and route the naloxone was administered and give this information to EMS, so that the information will accompany the individual to the hospital's emergency department.

Document the incident and complete school incident report.

Replace naloxone in-stock medication as appropriate as soon as possible.

### **NALOXONE**

Naloxone comes in two FDA-approved forms: injectable and prepackaged nasal spray. No matter what dosage form you use, it's important to receive training on how and when to use naloxone. You should also read the product instructions and check the expiration date.

- 1. Injectable brands of naloxone are offered by different companies listed in the FDA Orange Book under "naloxone" (look for "injectable"). Typically, the proper dose must be drawn up from a vial. Usually, it is injected with a needle into muscle, although it also may be administered into a vein or under the skin.
- 2. Prepackaged Nasal Spray (generic naloxone, Narcan®, Kloxxado®), is an FDA-approved prefilled, needle-free device that requires no assembly and is sprayed into one nostril while the person lays on their back. This device can also be easier for loved ones and bystanders without formal training to use.

Current drug products approved by the FDA may be found here: <u>Orange Book: Approved Drug Products</u> with Therapeutic Equivalence Evaluations (fda.gov)

### **INDICATIONS AND USAGE**

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Naloxone is intended for immediate administration as emergency therapy in settings where opioids may be present. **Naloxone is not a substitute for emergency medical care.** When in doubt, if an individual is unresponsive and an opioid overdose is suspected, administer naloxone as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. Call 911 to activate EMS immediately after administering the first dose of naloxone.

### **HOW NALOXONE IS SUPPLIED**

Naloxone can be supplied as an intramuscular (IM) injection or as an intranasal (IN) spray. Both formulations are effective. The intranasal formulation can be dispensed as a commercially available product or a kit that requires assembly. In many cases, the commercially produced naloxone nasal spray may be preferred by

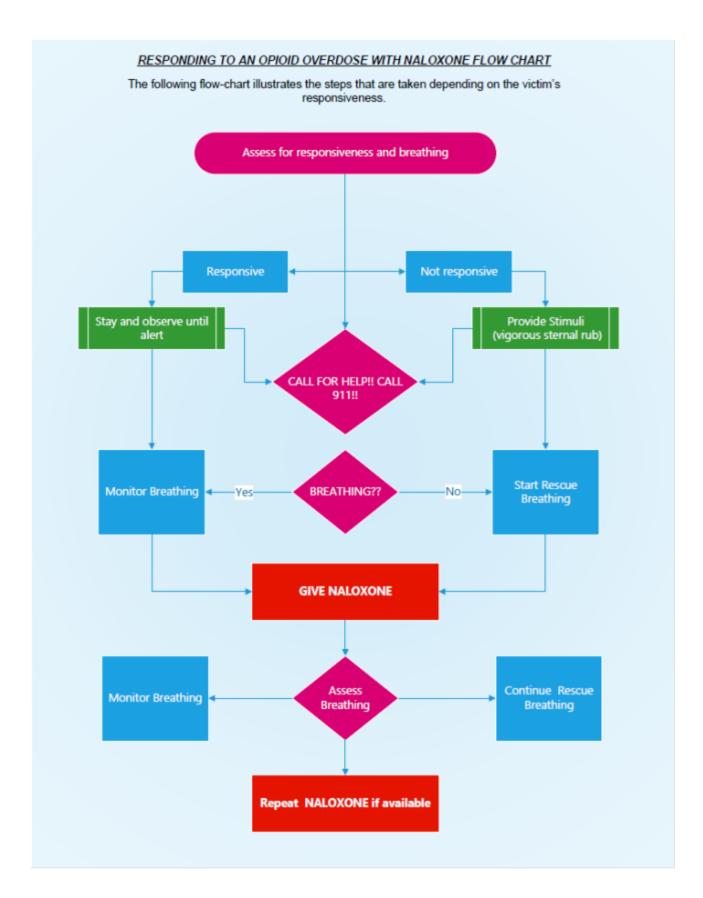
patients and caregivers due to cost and ease of assembly/administration. There is also an IM autoinjector. Pharmacists should note that dosing and administration instructions vary among the formulations.

- 1. Intranasal spray naloxone commercially available as a twin pack with directions for administration included. Each kit should contain: 2 naloxone 2 mg/2 ml prefilled syringes, 2 atomizers, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.
- 2. Injectable intramuscular injection kit should include; 2 naloxone 0.4 mg/ml vials, 2 IM syringes, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

For questions regarding dosage or timing of the brand being used, please see product package insert instructions developed by the manufacturer.

### STORAGE AND HANDLING OF NALOXONE

- Store naloxone in an easily accessible place in the original package at room temperature. Avoid light exposure.
- The shelf life of naloxone is generally 12 to 18 months. If stored properly, naloxone should be effective until at least the expiration date on the packaging.
- Do not insert naloxone into the prefilled syringe until ready to use. Once inserted, it expires within 2 weeks.
- Monitor the expiration date on naloxone and replace before it expires. When there are no other alternatives, expired naloxone can be administered but may not be as effective.



### **REFERENCES AND RESOURCES**

- 1. Lifesaving Naloxone (cdc.gov)
- 2. Frequently Asked Questions about Naloxone (cdc.gov)
- 3. SAMHSA Opioid Overdose Toolkit
- 4. Naloxone Drug Facts | National Institute on Drug Abuse (NIDA) (nih.gov)
- 5. Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA

The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

- 6. Naloxone Access: A Practical Guideline for Pharmacists (2020)
- 7. How to Use Naloxone Nasal Spray (:30) YouTube
- 8. How to Use Injectable Naloxone (:30) YouTube
- 9. Naloxone in the School Setting National Association of School Nurses (nasn.org)
- 10. KDEMedication Administration Training Manual for Non-Licensed School Personnel, Chapter 3, Emergency Medications <u>Medication Administration Training Program Kentucky Department of Education</u>
- 11. Kentucky Department for Public Health HARM REDUCTION PROGRAM
- 12. <u>Naloxone (Nasal Route) Proper Use Mayo</u> Clinic
- 13. <u>NaloxonePatientFlyer\_SFDPH\_2016.pdf</u> (prescribetoprevent.org)
- 14. <u>Learn About Opioid Overdose</u> Stopoverdose.org