

Kentucky Department for Public Health

Clinical Protocol for Stock Naloxone (OPIOID ANTAGONIST) Emergency Use in the School Setting Medically Approved Guideline for Stock Over-the-Counter Naloxone Emergency Use in the School Setting

Background

KRS 217.186 Definition -- Provider prescribing or dispensing opioid antagonist -- states that the board of each local public school district and the governing body of each private and parochial school or school district may permit a school to keep naloxone on the premises and regulate the administration of naloxone to any individual suffering from an apparent opiate-related overdose. As used in this document, "opioid antagonist" means naloxone or any other United States Food and Drug Administration-approved drug designed to reverse the effects of an opioid overdose includes:

- The Kentucky Department for Public health (KDPH) shall develop clinical protocols (medically approved guidelines) to address supplies of naloxone including over-the-counter nasal spray kept by the schools.
- A person or agency, including a school employee authorized to administer medication under <u>KRS 156.502</u> may:
 - o Receive a prescription for the drug naloxone.
 - o Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
 - o Administer naloxone to an individual suffering from an apparent opioid-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 an opioid antagonist, naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression, which 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 overdose. 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. There are many formulations of naloxone. The FDA has approved over the counter (OTC), Naloxone ReVive 3 milligram (mg) and Naloxone Narcan generic 4 milligram (mg) single use nasal spray. Other formulations of naloxone will remain available as prescription products.
- Naloxone may 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 Opioid antagonist dispensing. This administrative regulation establishes the minimum
 requirements for the pharmacist to be able to dispense an opioid antagonist pursuant to a physicianapproved protocol. Naloxone is not a substitute for emergency medical care. Repeating dosing may be
 necessary. Use as directed.
- 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.



KRS 314.021 Policy states that "all individuals licensed or privileged under provisions of this chapter and administrative regulations of the board shall be responsible and accountable for making decisions that are based upon the individuals' educational preparation and experience and shall practice with reasonable skill and safety".

Over-the-Counter Naloxone Nasal Spray:

The Kentucky Board of Nursing KBN AOS #16 Scope of Nursing Practice in the Recommendation and Administration of Over the Counter (OTC) Medications states:

- When a nurse, as an employee or volunteer of a healthcare delivery system, provides nonprescription medication to an individual, the nurse should do so based on an order from a qualified healthcare provider or medically approved guidelines to supply the non- prescription medication.
- An educationally prepared and clinically competent nurse, as an individual who is acting
 outside a health delivery system, may choose to recommend or administer a nonprescription drug (in a pre-labeled, pre-packaged form) to a person whose condition
 warrants it based on nursing assessment.
- Nurses who make delegatory decisions regarding the performance of acts/tasks by others are governed by 201 KAR 20:400 Delegation of nursing tasks.

WHAT ARE OPIOIDS?

- Opioids are drugs that alter the body's perception of pain. These drugs are among our most important tools for treating chronic and acute pain. 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 can also trigger other systems of the body, such as those responsible for regulating mood, breathing, and blood pressure
- Opioids work in the same part of the brain that controls breathing. Overloading the brain with too many opioids can slow down or shut down breathing and lead to death.

Common opioids Include:

GENERIC	Brand Name
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail,
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
DiacetyImorphine	Herion
Fenta nyl	Duragesic, Actiq
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Hydromorphone	Dilaudid
Meperidine	Demerol
Methadone	Dolophine, Methadose
Morphine	MSContin, Kadian, Embeda, Avinza
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Oxymorphone	Opana



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.

- Using again after taking a break, a person who has recently gone through opioid withdrawal has
 decreased opioid tolerance and can overdose very easily.
 - > This applies especially to people who have recently been in treatment, recovery, or have been incarcerated.
- 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 unregulated drugs.
- Accidental exposure and unintentional opioid use
 - > Includes members of a patient's household who may discover and use the prescribed opioid inappropriately.
 - Unregulated fentanyl may be found in drugs such as cocaine, meth, or in counterfeit pills.
- 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 in how to recognize the signs and symptoms of an opioid overdose requiring the use of 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 tactile stimulation)
- Slow (less than 5 breaths per minute), shallow respirations in drowsy or a patient that cannot be awakened
- Snoring or gurgling sounds (due to partial upper airway obstruction)
- Cyanosis of the lips/fingernails
- Extremely small "pinpoint" pupils
- Slow heart rate and/or low blood pressure

SIGNS OF OVERMEDICATION (may progress to overdose)

- Unusual sleepiness
- Drowsiness or difficulty staying awake with loud verbal stimulus or tactile stimulation
- Mental confusion
- Slurred speech
- Intoxicated behavior
- Slow or shallow respirations
- Extremely small "pinpoint" pupils, although normal size pupils DO NOT exclude opioid overdose
- Slow heart rate
- Low blood pressure

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 aggressive yelling, or tactical stimulation,

- **➤** ACT PROMPTLY!!
- > CALL FOR HELP
- CHECK FOR BREATHING
- > HAVE SOMEONE CALL 911 IMMEDIATELY
- > GET THE NALOXONE

RESPONDING TO AN OPIOID OVERDOSE

ACT FAST!! Always go with 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.

Suspected opioid poisoning.

- Check for responsiveness.
- Shout for help nearby.
- Activate the emergency response system (call 911).
- Get naloxone and an AED if available.

If the person is breathing normally, you can **prevent deterioration** by:

- Tap and shout.
- Reposition.
- Consider naloxone.
- · Continue until EMS arrives.



If the person is NOT breathing normally (gasping, or shallow, infrequent breathing) but has a pulse felt within 10 seconds:

- Provide rescue breathing, one breath every 6 seconds. Apply a rescue breathing barrier mask, if available.
- Check pulse every 2 minutes, if there is no pulse, start CPR.
- If possible opioid overdose, administer naloxone per protocol.

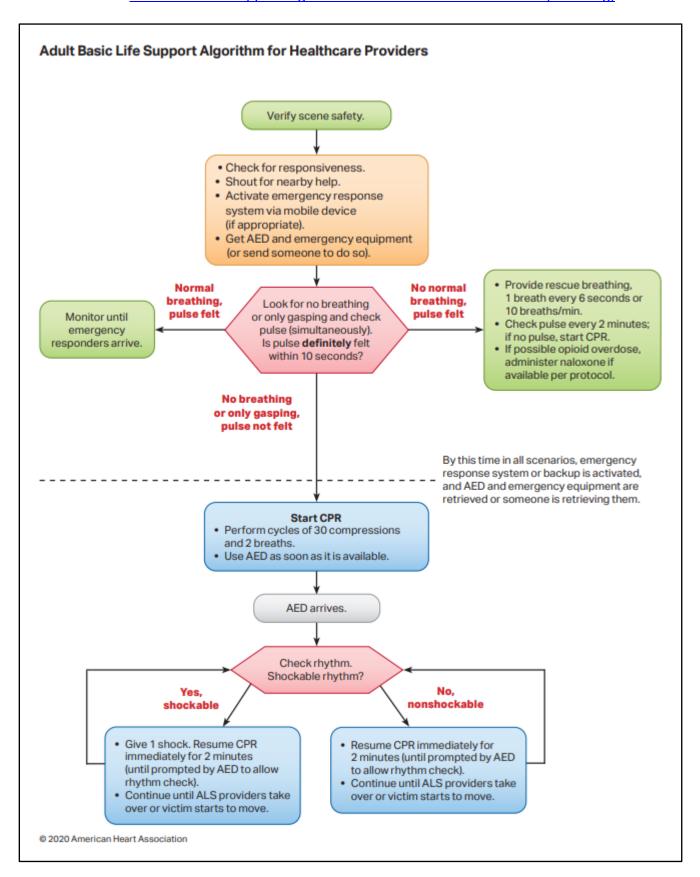
If no breathing or only gasping, and no pulse felt:

- Start CPR
- Perform cycles of 30 compressions and 2 breaths.
- Use an AED as soon as it is available.
- Resume CPR until prompted by AED to allow rhythm check and continue until EMS arrives or victim starts to move.
- Note: For adult and adolescent victims, responders should perform compressions and rescue breaths for opioid associated emergencies if they are trained and perform Hands-Only CPR if not trained to perform rescue breaths. For infants and children, CPR should include compressions with rescue breaths.

Give Rescue Breaths! A person who has overdosed may wake up after naloxone 1. Place them on their back. Make sure nothing is their mouth. administration 2. Apply a barrier mask, if available. Tilt their head back, lift or they may remain their chin and pinch their nose closed. This opens the airway. unconscious. 3. Give one breath slowly, watching to see their chest rise. 4. Continue giving one breath every five seconds. If someone who received naloxone 5. If they start to gurgle or breathe on their own, stop and roll is breathing them onto their side in recovery position. slowly, shallowly or not at all, rescue breathing **Steps 1 - 2 Steps 3 - 4** Step 5 is essential. laloxone



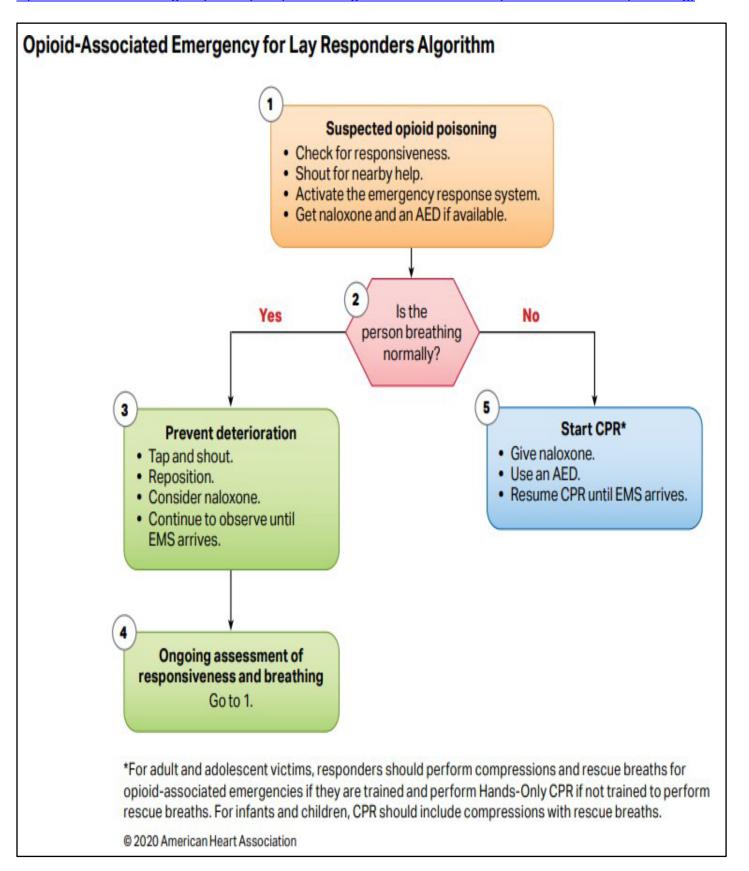
Basic Adult Life Support Algorithm for Healthcare Providers 2020 (heart.org)





Algorithm Opioid Lay Responder 2006 (heart.org)

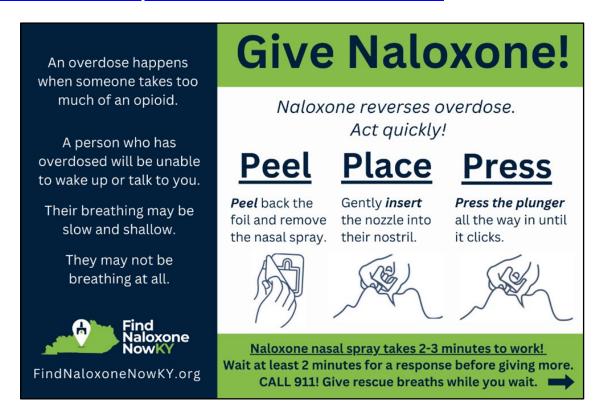
Opioid-Associated Emergency for Lay Responders Algorithm-Written description of illustration (heart.org)





1. ADMINISTER NALOXONE

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



- 1. Remove blister packs from carton.
- 2. Peel back the foil on one blister pack.
- 3. Remove the nasal spray device from the blister pack.
- 4. Hold the nasal spray device with index and middle finger on either side of the nozzle. Be careful not to press the plunger yet.
- 5. Insert the nasal spray device into a nostril. The index and middle fingers should be touching the bottom of the nostril.
- 6. Press the plunger all the way in until it clicks.
- 7. Remove the nasal spray device from the nostril.
- 8. Assure that 911 has been called.
- 9. Begin rescue breathing.
- 10. Repeat every 2-3 minutes until the person begins breathing effectively or EMS arrives. Follow each dose with rescue breathing. If the person begins to breathe effectively, wake up, or vomit, place the person on his/her side in the recovery position. Allow space between you and the individual to protect yourself.

DIRECT SOMEONE TO CALL AND NOTIFY THE FRONT OFFICE AND THE SCHOOL NURSE



Following naloxone administration, assure that 911 has been called and that EMS has been activated.

Stay with the person and monitor and intervene for respiratory distress.

If there is no breathing or breathing continues to be slow (less than 5 breaths/minute) or shallow, continue to administer doses of naloxone every 2-3 minutes. Between doses, continue to perform rescue breathing while waiting for the return of an effective breathing pattern or the arrival of EMS. If they are breathing effectively on their own, place them in the recovery position, on their side and support the body with one bent knee with the face turned to the side.

Repeat naloxone administration if overdose symptoms are present again.

The duration of action of most opioids may 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.

A person may remain unconscious if non-opioid drugs have been taken or if they have experienced another medical emergency such as:

- Traumatic brain Injury
- Stroke
- Diabetes
- Infection
- Heart attack
- Seizures

2. DOCUMENT

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 the school incident report.
- Replace naloxone in-stock medication as appropriate as soon as possible.

Following naloxone administration, assure that 911 has been called and that EMS has been activated.

Stay with the person and monitor and intervene for respiratory distress.



NALOXONE

Naloxone Hydrochloride Nasal Spray: 4mg / 0.1mL in carton containing two blister packages each with a single nasal spray.

- Adults: 1 spray (4mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each devise contains a single dose. Follow each dose with rescue breathing.
- <u>Infants, Children & Adolescents</u>: 1 spray (4 mg) intranasally; repeat every 2-3 minutes alternating nostrils until desired response, breathing returns or EMS arrives. Each device contains a single dose.

Follow each dose with rescue breathing.

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

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

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. Prolonged respiratory depression may result in damage to the central
 nervous system or death. Do not delay life-saving interventions.
- Make sure someone calls 911 to activate EMS as soon as an emergency is identified. Assure 911 has been called immediately after administering the first dose of naloxone.

HOW NALOXONE IS SUPPLIED

- The intranasal formulation can be dispensed as a commercially available product or a kit that requires assembly.
- The commercially produced naloxone nasal spray may be preferred by patients and caregivers due to cost and ease of assembly/administration.
- Naloxone can be supplied as an intramuscular (IM) injection into a person's muscle, typically the butt, shoulder, or thigh, or as an intranasal (IN) spray, a device that sprays the medication into the person's nose. Both formulations are effective. There are two primary ways naloxone can be administered.
 Different FDA-approved naloxone products are available in different doses.
- There is also a commercially available prefilled syringe and needle



STORAGE AND HANDLING OF NALOXONE

- Store naloxone at controlled room temperature 15°C to 25°C (59°F to 77°F) and in a dark area.
- The naloxone should be checked monthly to ensure proper storage, expiration date, and medication stability. Expired naloxone or those with discolored solution or solid particles should not be used. Discard in a sharps container.
- School staff should be familiar with the type of naloxone maintained by their agency and its
 use.
- School staff should <u>refer to the package insert for the naloxone used in their facility and store</u> naloxone hydrochloride according to the individual manufacturer's direction.



NALOXONE RESOURCES

KDPH:

- Harm Reduction Program Cabinet for Health and Family Services (ky.gov)
 - o Harm Reduction: Outreach Services
 - You Can Reverse Overdose: Naloxone and Rescue Breathing YouTube 4:15
 - o <u>KDPH EHP From Crisis to Care: Overdose Interventions for First Responders ID: 1121200 Kentucky</u> TRAIN an affiliate of the TRAIN Learning Network powered by the Public Health Foundation
 - o <u>Fentanyl and Xylazine Test Strips</u>
- Find Naloxone Now Kentucky
 - o What are Opioids? FINDNALOXONE
 - o What is Naloxone? FINDNALOXONE
 - o How Do I Use Naloxone? FINDNALOXONE
 - Nasal Spray Generic Opioid Overdose Recognition and Response
 - KLOXXADO® (naloxone HCl) Nasal Spray
 - NARCAN® Nasal Spray
 - Rivive Harm Reduction Therapeutics
 - IM Generic Opioid Overdose Recognition and Response
 - ZIMHI® for Opioid Overdose Emergency Rescue
 - Opioid Overdose Prevention FINDNALOXONE

CDC:

- Lifesaving Naloxone | Stop Overdose | CDC
- Naloxone Toolkit | Overdose Prevention | CDC
- Reverse Opioid Overdose to Prevent Death | Overdose Prevention | CDC
- Naloxone Frequently Asked Questions | Stop Overdose | CDC

FDA:

- FDA Approves First Over-the-Counter Naloxone Nasal Spray | FDA
- OTC Naloxone.pdf (kphanet.org)
- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)

NIH:

Naloxone Drug Facts | National Institute on Drug Abuse (NIDA) (nih.gov)

MedlinePlus:

• Naloxone Nasal Spray: MedlinePlus Drug Information

FREE Naloxone in Kentucky:

- Find Naloxone Now Kentucky (Naloxone locator and map)
- Next Distro: Free Naloxone Access for Impacted Communities NEXT Distro
- Kentucky NEXT Distro



REFERENCES AND RESOURCES

American Heart Association

- Part 3: Adult Basic and Advanced Life Support | American Heart Association CPR & First Aid
- Opioid Education | American Heart Association CPR & First Aid

American Red Cross

• How to Perform CPR | Red Cross

Center for Disease Control (CDC)

- Drug Overdose | Injury Center | CDC
- Fentanyl: Emergency Responders at Risk | Substance Use | CDC
- Fentanyl Safety Recommendations for First Responders

Kentucky Board of Nursing (KBN)

- Overview KBN (ky.gov)
- Advisory Opinion Statements

Kentucky Department of Education (KDE)

Medication Administration Training Program - Kentucky Department of Education

Kentucky Department for Public Health (KDPH)

- Kentucky Department for Public Health HARM REDUCTION PROGRAM
- Find Naloxone Now Kentucky FINDNALOXONE

National Association of School Nurses

- <u>Drugs of Abuse National Association of School Nurses (nasn.org)</u>
- Naloxone in the School Setting National Association of School Nurses

National Harm Reduction Coalition

Overdose Prevention Resources | National Harm Reduction Coalition

National Institute on Drug Abuse (NIDA)

- Commonly Used Drugs Charts | National Institute on Drug Abuse (NIDA) (nih.gov)
- Opioids | National Institute on Drug Abuse (NIDA)

Readiness and Emergency Management for Schools (REMS)

- Readiness and Emergency Management for Schools Technical Assistance Center (ed.gov)
- Fact Sheet Preparing for Opioid-Related Emergencies for K-12 Schools
- Naloxone Saves Lives in Opioid Overdose | National Institute on Drug Abuse (video 5:39 min)

Substance Abuse and Mental Health Services Administration (SAMHSA)

- SAMHSA Overdose Prevention and Response Toolkit (Revised 2024)
- Preventing, Recognizing, and Treating Opioid Overdose | SAMHSA
- Evidence-Based Resources About Opioid Overdose | SAMHSA
- Substance Misuse Prevention for Young Adults | SAMHSA Publications and Digital Products
- <u>Talk. They Hear You: What Educators Can Do to Help Prevent Underage Drinking and Other Drug Use</u> Fact Sheet | SAMHSA Publications and Digital Products

U.S. Department of Health and Human Services (HHS)

- National Opioids Crisis: Help and Resources | HHS.gov
- U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose | HHS.gov