

Kentucky Department for Public Health (KDPH) CLINICAL PROTOCOL FOR NALOXONE (OPIOID ANTAGONIST) USE IN THE SCHOOL SETTING MEDICALLY APPROVED GUIDELINE FOR OVER-THE-COUNTER 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.

KRS 217.186 includes:

- ➤ KDPH shall develop clinical protocols (medically approved guidelines) to address supplies of naloxone including over-the-counter Naloxone Nasal Spray kept by the schools.
- A person or agency, including a school employee authorized to administer medication under KRS 156.502 may:
 - Receive a prescription for the drug naloxone.
 - Possess naloxone pursuant to this subsection and any equipment needed for its administration; and
 - 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 lifethreatening 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 <u>201 KAR 2:360</u>
 Opioid antagonist dispensing. This administrative regulation establishes the minimum requirements for the
 pharmacist to be able to dispense an opioid antagonist pursuant to a physician-approved protocol. Naloxone
 is not a substitute for emergency medical care. Repeat 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
Fentanyl	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, very difficult or unable to wake up.
- Inability to talk.
- Slow heartbeat and or low blood pressure.
- Small pinpoint pupils.
- Slow breathing with respiratory rate less than 10 times per minute.
- Shallow breathing and/or making snoring, gurgling, or rattling sounds.
- Pale skin, cool and clammy to the touch.
- Fingernails or lips may be grey, blue, or purple.



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

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

If the person is breathing normally prevent deterioration by:

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

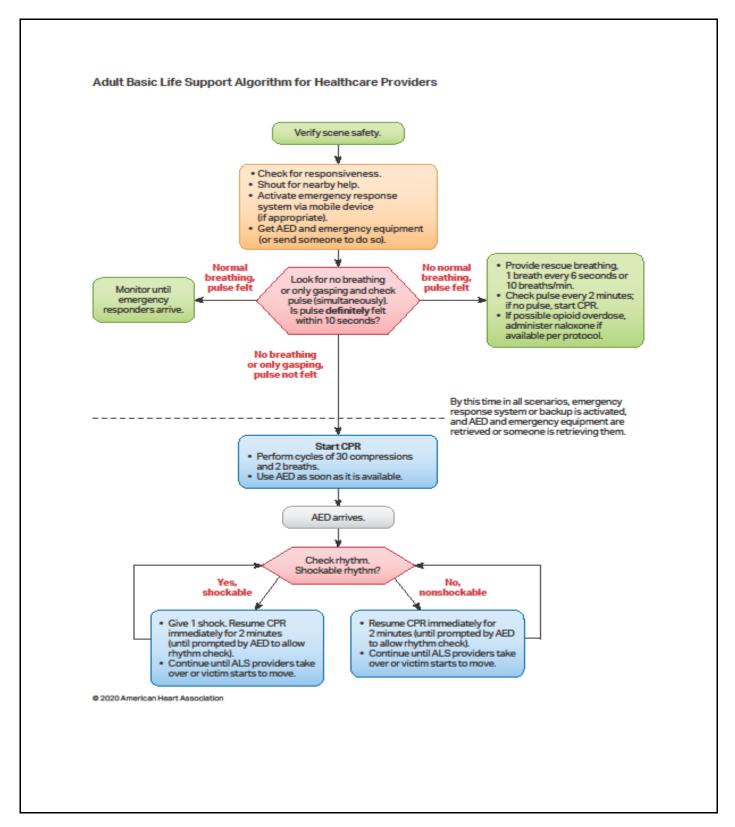
If the person is NOT breathing normally (gasping, or shallow, infrequent breathing) but has a pulse felt within 10 seconds:

- Provide rescue breathing, one breath every 6 seconds. Apply a rescue breathing barrier mask, if available.
- Check pulse every 2 minutes, if 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..





Basic Adult Life Support Algorithm for Healthcare Providers2020 (heart.org)



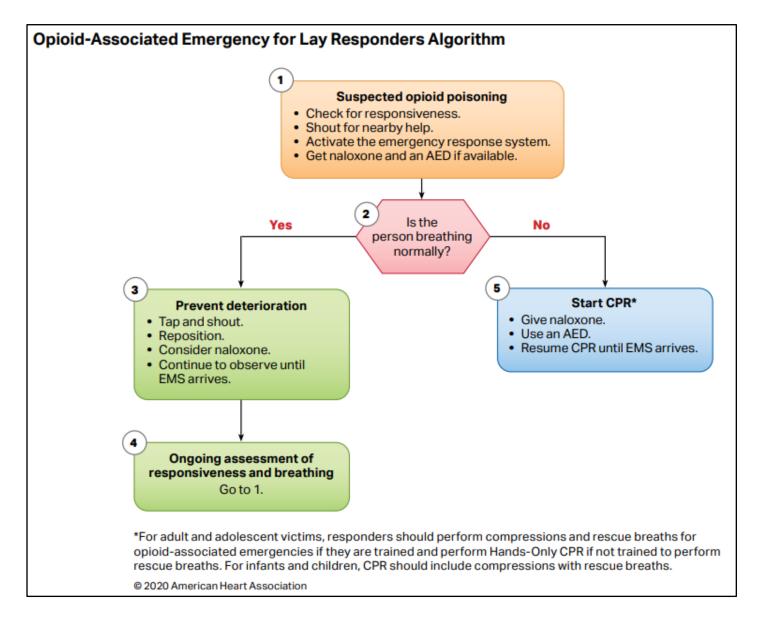
Note: For adult and adolescent victims, responders should perform compressions and rescue breaths for opioid associated emergencies if they are trained and perform Hands-Only CPR if not trained to perform rescue breaths. For infants and children, CPR should include compressions with rescue breaths.

The steps for rescue breathing are:

- 1. Kneel beside the person. Place the person on their back on a firm, flat surface.
- 2. Open the airway to a past-neutral position using the head-tilt/chin-lift technique.
- 3. Pinch the nose shut, take a normal breath, and make complete seal over the person's mouth with your mouth.
- 4. Ensure each breath lasts about 1 second and makes the chest rise; allow air to exit before giving the next breath.
- 5. Breathe again every 5 seconds until the patient is breathing on their own, or EMS arrives and takes over.

Note: If the 1st breath does not cause the chest to rise, retilt the head and ensure a proper seal before giving the second breath. If the 2nd breath does not make the chest rise, an object may be blocking the airway.





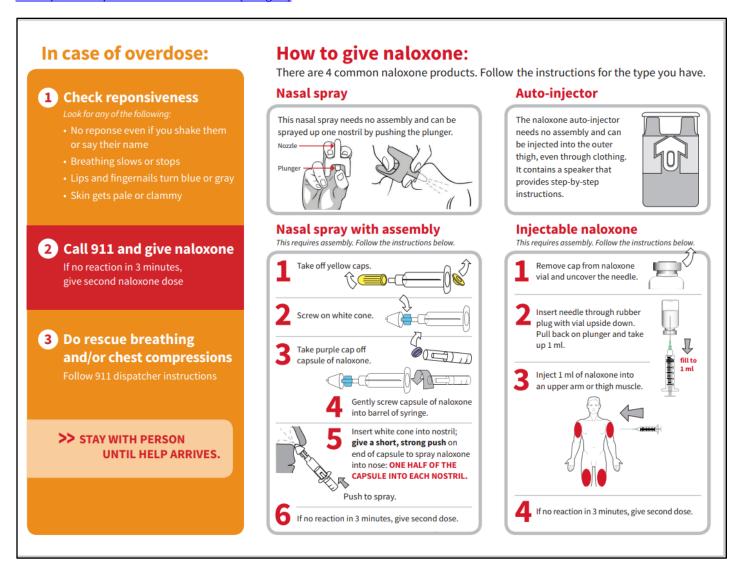
Algorithm Opioid Lay Responder 2006 (heart.org)

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)



Naloxone-How to Use Poster 2016.pdf (prescribetoprevent.org)

How to Use Naloxone-4 common methods-AMA 2021 (YouTube Video 2:40 min)

How to Use Naloxone Nasal Spray-CDC (YouTube 0:30 sec)

How to Use Injectable Naloxone-CDC (YouTube 0:30 sec)



Most patients respond by returning to spontaneous breathing with minimal withdrawal symptoms. The response generally occurs within 2 to 3 minutes after naloxone administration. Rescue breathing should continue while waiting for the naloxone to take effect. Wait at least 2 minutes for a response before giving another dose.

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.**

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. 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.

3. STAY WITH THE PERSON AND MONITOR 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.



4. REPEAT NALOXONE ADMINISTRATION IF SYMPTOMS CONTINUE.

- If the person is not effectively breathing 2-3 minutes after the first dose, administer a second dose in the other nostril.
- Resume rescue breathing and continue giving naloxone every 2-3 minutes until:
 - Effective breathing resumes,
 - EMS arrives,
 - No more naloxone is available.



5. 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.

NALOXONE

Naloxone comes in two FDA-approved forms: injectable and intranasal, some of which come in an over-the-counter prepackaged nasal spray. No matter what dosage form you use, it's important to understand how and when to use naloxone. You should also read the product instructions and check the expiration date.

- 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 the muscle, although it also may be administered into a vein or under the skin.
- Prepackaged Nasal Spray is a prefilled device that spray medication into the nose 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 with Therapeutic Equivalence Evaluations (fda.gov)</u>

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 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 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.
- 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.
- There is also a commercially available prefilled syringe and needle.



STORAGE AND HANDLING OF NALOXONE

- Store naloxone in an easily accessible place in the original package at room temperature.
- Avoid light exposure.
- When stored under appropriate conditions, the shelf life of naloxone is 36-48 months for a nasal spray and 18-24 months for injectables.
- If stored properly, naloxone should be effective until at least the expiration date on the packaging.
- Monitor the expiration date on naloxone and replace it before it expires.
- When there are no other alternatives, expired naloxone can be administered but may not be as effective.

NALOXONE RESOURCES

KDPH:

- Harm Reduction Program Cabinet for Health and Family Services (ky.gov)
 - Overdose Recognition and Response
- Find Naloxone Now Kentucky
 - What is Naloxone?
 - ➤ How Do I Use Naloxone?
 - Guide to Using Generic Intramuscular Naloxone Injection
 - Guide to Using Generic Naloxone Nasal Spray
 - Guide to Using Kloxxado® Nasal Spray
 - Guide to Using Narcan® Nasal Spray
 - ➤ Guide to Using RiVive[™] Nasal Spray
 - ➤ Guide to Using Zimhi® Intramuscular Injection

CDC:

- Lifesaving Naloxone (cdc.gov)
 - o Fact Sheets | Naloxone | Opioids (cdc.gov)
 - o REVERSING OPIOID OVERDOSES WITH LIFESAVING NALOXONE (cdc.gov)
- Frequently Asked Questions about Naloxone (cdc.gov)

FDA:

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

SAMHSA:

- What is Naloxone? | SAMHSA
- Non-prescription ("Over the Counter") Naloxone Frequently Asked Questions | SAMHSA

NIH:

- Naloxone Drug Facts | National Institute on Drug Abuse (NIDA) (nih.gov)
 - ➤ Naloxone Nasal Spray: MedlinePlus Drug Information

FREE Naloxone in Kentucky:

- <u>Find Naloxone Now Kentucky</u> (Naloxone locator and map)
 - o Naloxone Agency Request (schools should use for large quantities)
- Next Distro: Free Naloxone Access for Impacted Communities NEXT Distro
 - Kentucky NEXT Distro



SAVE A LIFE. GET NALOXONE.

Naloxone stops an overdose caused by opioid pain medication, methadone or heroin.

People at risk for overdose and their family and friends can learn to spot an overdose and respond to save a life.

To get naloxone, present this card to the pharmacy staff.



DIRECTIONS: Spray 1 mL (half of the syringe) into each nostril.

NO BRAND NAME/GENERIC COST: \$-\$\$



SINGLE-STEP NASAL SPRAY DIRECTIONS: Spray full

dose into one nostril.

BRAND NAME: Narcan
COST: \$\$\$



INJECTION

DIRECTIONS: Inject 1 mL in shoulder or thigh.

NO BRAND NAME/GENERIC COST: \$-\$\$



AUTO-INJECTOR

DIRECTIONS: Use as directed by voice-prompt. Press black side firmly on outer thigh.

BRAND NAME: Evzio

COST: \$\$\$\$

Coupons available, see evzio.com for more info

FOR ALL PRODUCTS, repeat naloxone administration after 2-3 minutes if there is no response.

Most insurance will cover at least one of these options, or you can pay cash. All products contain at least two doses

For more on opioid safety, videos on how to use naloxone, or to get help for addiction, go to PrescribetoPrevent.org

PREVENT & PROTECT

Used with permission from Boston Medical Center

Prevent & Protect - Save a Life, Get Naloxone - Opioid Safety and Overdose Prevention Information (prevent-protect.org)



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

American Red Cross

• CPR Steps | Perform CPR | Red Cross

Center for Disease Control (CDC)

- <u>Drug Overdose | Injury Center | CDC</u>
- Fentanyl: Emergency Responders at Risk | NIOSH | CDC
- Fentanyl Safety Recommendations for First Responders (ojp.gov)

Kentucky Board of Nursing (KBN)

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

Kentucky Department of Education (KDE)

 KDE Medication Administration Training Manual for Non-Licensed School Personnel, Chapter 3, Emergency Medications 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.ky.gov

National Association of School Nurses

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

National Harm Reduction Coalition

Overdose Prevention Resources | National Harm Reduction Coalition

This Harm Reduction Coalition (HRC) manual outlines the process of developing an Overdose Prevention and Education Program that may involve a take-home naloxone component.

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) (nih.gov)

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 and Institutions of Higher Education
- How Naloxone Saves Lives in Opioid Overdose | National Institute on Drug Abuse (NIDA) (nih.gov) (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

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

- <u>National Opioids Crisis: Help and Resources | HHS.gov</u>- Increased prescription of opioid medications like oxycodone and hydrocodone led to widespread misuse of both prescription and non- prescription opioids. Prevention, treatment, and recovery information is available here to help health professionals and families combat the epidemic.
- U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose | HHS.gov