SAMHSA

Opioid Overdose Prevention TOOLKIT:

Facts for Community Members
Five Essential Steps for First Responders
Information for Prescribers
Safety Advice for Patients & Family Members
Recovering From Opioid Overdose
Acknowledgments
This publication was prepared for the Substance Abuse and Mental Health Services Administration (SAMHSA) by the Association of State and Territorial Health Officials, in cooperation with Public Health Research Solutions, under contract number 10-233-00100 with SAMHSA, U.S. Department of Health and Human Services (HHS). LCDR Brandon Johnson, M.B.A., served as the Government Project Officer.

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Recommended Citation

Originating Office
Division of Pharmacologic Therapies, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Rockville, MD 20857. HHS Publication No. (SMA) 16-4742. First printed 2013. Revised 2014, 2016.
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FACTS FOR COMMUNITY MEMBERS

SCOPE OF THE PROBLEM

Opioid overdose continues to be a major public health problem in the United States. It has contributed significantly to accidental deaths among those who use or misuse illicit and prescription opioids. In fact, U.S. overdose deaths involving prescription opioid analgesics increased to about 19,000 deaths in 2014, more than three times the number in 2001.1 According to Centers for Disease Control and Prevention (CDC) data, health care providers wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills.3-4

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 can also 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.

Opioid overdose can occur when a patient deliberately misuses a prescription opioid or an illicit drug such as heroin. It can also occur when a patient takes an opioid as directed, but the prescriber miscalculated the opioid dose or an error was made by the dispensing pharmacist or the patient misunderstood the directions for use.

Also at risk are individuals who misuse opioids and combine them with sedative hypnotic agents resulting in sedation and respiratory depression.5,6

WHO IS AT RISK? Anyone who uses opioids for long-term management of chronic cancer or non-cancer pain is at risk for opioid overdose, as are persons who use heroin.7 Others at risk include persons who are:

- Receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed substance use disorder, or non-medical use of prescription or illicit opioids.
- Completing mandatory opioid detoxification or abstinent for a period of time (and presumably with reduced opioid tolerance and high risk of relapse to opioid use).
- Recently released from incarceration and who have a history of opioid use disorder (and presumably have reduced opioid tolerance and high risk of relapse to opioid use).

Tolerance develops when someone uses an opioid drug regularly, so that their body becomes accustomed to the drug and needs a larger or more frequent dose to continue to experience the same effect.

Loss of tolerance occurs when someone stops taking an opioid after long-term use. When someone loses tolerance and then takes the opioid drug again, they can experience serious adverse effects, including overdose, even if they take an amount that caused them no problem in the past.
STRATEGIES TO PREVENT OVERDOSE DEATHS

STRATEGY 1: Encourage providers, persons at high risk, family members, and others to learn how to prevent and manage opioid overdose. Providers should be encouraged to keep their knowledge current about evidence-based practices for the use of opioid analgesics to manage pain, as well as specific steps to prevent and manage opioid overdose.

Federally funded Continuing Medical Education courses are available to providers at no charge at http://www.OpioidPrescribing.com (a series of courses funded by the Substance Abuse and Mental Health Services Administration [SAMHSA]).

Helpful information for laypersons on how to prevent and manage overdose is available from Project Lazarus at http://www.projectlazarus.org or from the Massachusetts Health Promotion Clearinghouse at http://www.maclearinghouse.org.

STRATEGY 2: Ensure access to treatment for individuals who are misusing or addicted to opioids or who have other substance use disorders. Effective treatment of substance use disorders can reduce the risk of overdose and help overdose survivors attain a healthier life. Medication-assisted treatment, as well as counseling and other supportive services, can be obtained at SAMHSA-certified and Drug Enforcement Administration (DEA)-registered opioid treatment programs (OTPs), as well as from physicians who are trained to provide care in office-based settings with medications such as buprenorphine and naltrexone.

Information on treatment services available in or near your community can be obtained from your state health department, your state alcohol and drug agency, or SAMHSA (see page 4).

STRATEGY 3: Ensure ready access to naloxone. 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.7

On the other hand, naloxone is not effective in treating overdoses of benzodiazepines (such as Valium®, Xanax®, or Klonopin®), barbiturates (Seconal® or Fiorinal®), clonidine, Elavil®, GHB, ketamine, or synthetics. It is also not effective in overdoses with stimulants, such as cocaine and amphetamines (including methamphetamine and Ecstasy). However, if opioids are taken in combination with other sedatives or stimulants, naloxone may be helpful.

Naloxone injection has been approved by the United States Food and Drug Administration (FDA) and used for more than 40 years by emergency medical services (EMS) personnel to reverse opioid overdose and resuscitate persons who otherwise might have died in the absence of treatment.8
Naloxone does not have the potential for abuse. It reverses the effects of opioid overdose. Injectable naloxone is relatively inexpensive. It typically is supplied as a kit with two syringes. These kits require training on how to administer naloxone using a syringe. The FDA has also approved an intranasal naloxone product, called Narcan® Nasal Spray, and a naloxone auto-injector, called Evzio®. The intranasal spray is a pre-filled, needle-free device that requires no assembly. The auto-injector can deliver a dose of naloxone through clothing, if necessary, when placed on the outer thigh.

Prior to 2012, just six states had any laws that expanded access to naloxone or limited criminal liability. Today, 42 states and the District of Columbia have statutes that provide criminal liability protections to laypersons or first responders who administer naloxone. Thirty-nine states and the District of Columbia have statutes that provide civil liability protections to laypersons or first responders who administer naloxone. Thirty-eight states have statutes that offer criminal liability protections for prescribing or distributing naloxone. Thirty-three states have statutes that offer civil liability protections for prescribing or distributing naloxone. And 42 states have statutes that allow naloxone distribution to third parties or first responders via direct prescription or standing order. To find states that have adopted relevant laws, visit the White House website at www.whitehouse.gov/sites/default/files/ondcp/Blog/naloxonecirclechart_january2016.pdf.

**STRATEGY 4: Encourage the public to call 911.** An individual who is experiencing opioid overdose needs immediate medical attention. An essential first step is to get help from someone with medical expertise as quickly as possible. Therefore, members of the public should be encouraged to call 911. All they have to say is “Someone is not breathing” and give a clear address and location. Thirty-two states and the District of Columbia have “Good Samaritan” statutes that prevent arrest, charge, or prosecution for possession of a controlled substance or paraphernalia if emergency assistance is sought for someone who is experiencing an opioid-induced overdose.

**STRATEGY 5: Encourage prescribers to use state Prescription Drug Monitoring Programs.** State Prescription Drug Monitoring Programs (PDMPs) have emerged as a key strategy for addressing the misuse of prescription opioids and thus preventing opioid overdoses and deaths. Specifically, prescribers can check their state’s PDMP database to determine whether a patient is filling the prescriptions provided and/or obtaining prescriptions for the same or a similar drug from multiple prescribers.

While nearly all states now have operational PDMPs, the programs differ from state to state in terms of the exact information collected, how soon that information is available to prescribers, and who may access the data. Therefore, information about the program in a particular state is best obtained directly from the state PDMP or from the board of medicine or pharmacy.
RESOURCES FOR COMMUNITIES

Resources that may be useful to local communities and organizations are found at:

**Substance Abuse and Mental Health Services Administration (SAMHSA)**
- National Helpline: 1-800-662-HELP (4357) or 1-800-487-4889 (TDD — for hearing impaired)
- Behavioral Health Treatment Locator: https://findtreatment.samhsa.gov to search by address, city, or zip code
- State Substance Abuse Agencies: https://findtreatment.samhsa.gov/TreatmentLocator/faces/about.jspx
- Center for Behavioral Health Statistics and Quality (CBHSQ): http://www.samhsa.gov/data
- SAMHSA Publications: http://store.samhsa.gov 1-877-SAMHSA (1-877-726-4727)

**Centers for Disease Control and Prevention (CDC)**
http://www.cdc.gov/drugoverdose/epidemic
http://www.cdc.gov/homeandrecreationalsafety/poisoning

**White House Office of National Drug Control Policy (ONDCP)**
State and Local Information: http://www.whitehouse.gov/ondcp/state-map

**Association of State and Territorial Health Officials (ASTHO)**

**National Association of State Alcohol and Drug Abuse Directors (NASADAD)**

**American Association for the Treatment of Opioid Dependence (AATOD)**
FIVE ESSENTIAL STEPS FOR FIRST RESPONDERS

O

verdose is common among persons who use illicit opioids such as heroin and among those who misuse medications prescribed for pain, such as oxycodone, hydrocodone, and morphine. The incidence of opioid overdose is rising nationwide. In 2014, 28,647 of drug overdose deaths involved some type of opioid, including heroin. U.S. overdose deaths involving prescription opioid analgesics increased to about 19,000 deaths in 2014 more than three times the number in 2001.

To address the problem, emergency medical personnel, health care professionals, and patients increasingly are being trained in the use of the opioid antagonist naloxone hydrochloride (naloxone), which is the treatment of choice to reverse the potentially fatal respiratory depression caused by opioid overdose. (Note that naloxone has no effect on non-opioid overdoses, such as those involving cocaine, benzodiazepines, or alcohol.)

The steps outlined below are recommended to reduce the number of deaths resulting from opioid overdoses

STEP 1: CALL FOR HELP (DIAL 911)
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, so if no emergency medical services (EMS) or other trained personnel are on the scene, dial 911 immediately. All you have to say is “Someone is not breathing.” Be sure to give a clear address and/or description of your location.

STEP 2: CHECK FOR SIGNS OF OPIOID OVERDOSE
Signs of OVERDOSE, which often results in death if not treated, include:

- Extreme sleepiness, inability to awaken verbally or upon stern rub.
- Breathing problems that 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 stern 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.
- Difficulty waking the person from sleep.

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 such a sound almost always is a sign that the individual is near death.
STEP 3: SUPPORT THE PERSON’S BREATHING

Ventilatory support is an important intervention and may be life-saving on its own. Patients should be ventilated with oxygen prior to administration of naloxone. In situations where oxygen is not available, rescue breathing can be very effective in supporting respiration. Rescue breathing for adults involves the following steps:

- Be sure the person’s airway is clear (check that nothing inside the person’s mouth or throat is blocking the airway).
- Place one hand on the person’s chin, tilt the head back and pinch the nose closed.
- Place your mouth over the person’s mouth to make a seal and give 2 slow breaths.
- The person’s chest should rise (but not the stomach).
- Follow up with one breath every 5 seconds.

STEP 4: ADMINISTER NALOXONE

Any patient who presents with signs of opioid overdose, or when this is suspected, should be administered naloxone. Naloxone injection is approved by the FDA and has been used for decades by EMS personnel to reverse opioid overdose and resuscitate individuals who have overdosed on opioids.

Naloxone can be given by intranasal spray, intramuscular (into the muscle), subcutaneous (under the skin), or intravenous injection. The most rapid onset of action is achieved by intravenous administration, which is recommended in emergency situations. The dose should be titrated to the smallest effective dose that maintains spontaneous normal respiratory drive.

Opioid-naive patients may be given starting doses of up to 2 mg without concern for triggering withdrawal symptoms depending on the route of administration.

The intramuscular route of administration for naloxone may be suitable for patients with suspected opioid use disorder because it provides a slower onset of action and a prolonged duration of effect, which may minimize rapid onset of withdrawal symptoms.

DURATION OF EFFECT. The duration of effect of naloxone is 20 to 90 minutes depending on dose and route of administration, and overdose symptoms. The goal of naloxone therapy should be to restore adequate spontaneous breathing, but not necessarily complete arousal.

More than one dose of naloxone may be needed to revive someone who is overdosing. Patients who have taken longer-acting opioids may require further intravenous bolus doses or an infusion of naloxone.

Comfort the person being treated, as withdrawal triggered by naloxone can feel unpleasant. As a result, some persons become agitated or combative when this happens and need help to remain calm.

SAFETY OF NALOXONE.
The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect. When given to individuals who are not opioid-intoxicated or opioid-dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in tolerant patients may be unpleasant, it is not life-threatening.

Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women. The FDA has approved injectable naloxone, intranasal naloxone (called Narcan® Nasal Spray), and a naloxone auto-injector (called Evzio®). The currently available naloxone kits that include a syringe and naloxone ampules or vials or a prefilled naloxone
syringe and a mucosal atomizer device to enable intranasal delivery require the user to be trained on how to assemble all of the materials and administer the naloxone to the victim. The Narcan Nasal Spray is a pre-filled, needle-free device that requires no assembly, which can deliver a single dose into one nostril. The Evzio auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular) or under the skin (subcutaneous). Once turned on, the device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators. Both Narcan Nasal Spray and Evzio are packaged in a carton containing two doses, to allow for repeat dosing if needed.

**STEP 5: MONITOR THE PERSON’S RESPONSE**

All patients should be monitored for recurrence of signs and symptoms of opioid toxicity for at least 4 hours from the last dose of naloxone or discontinuation of the naloxone infusion. Patients who have overdoses on long-acting opioids should have more prolonged monitoring.²,¹⁰

Most patients respond by returning to spontaneous breathing. The response generally occurs within 3 to 5 minutes of naloxone administration. (Continue rescue breathing while waiting for the naloxone to take effect.)²,⁵,¹⁰

Naloxone will continue to work for 30 to 90 minutes, but after that time, overdose symptoms may return.¹⁷,¹⁸ Therefore, it is essential to get the person to an emergency department or other source of medical care as quickly as possible, even if he or she revives after the initial dose of naloxone and seems to feel better.

**SIGNS OF OPIOID WITHDRAWAL.** The signs and symptoms of opioid withdrawal in an individual who is physically dependent on opioids may include, but are not limited to, the following: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In the neonate, opioid withdrawal may also include convulsions, excessive crying, and hyperactive reflexes.¹⁷

**NALOXONE NON-RESPONDERS.** If a patient does not respond to naloxone, an alternative explanation for the clinical symptoms should be considered. The most likely explanation is that the person is not overdosing on an opioid but rather some other substance or may even be experiencing a non-overdose medical emergency. A possible explanation to consider is that the individual has overdosed on buprenorphine, a long-acting opioid partial agonist. Because buprenorphine has a higher affinity for the opioid receptors than do other opioids, naloxone may not be effective at reversing the effects of buprenorphine-induced opioid overdose.¹⁸

In all cases, support of ventilation, oxygenation, and blood pressure should be sufficient to prevent the complications of opioid overdose and should be given priority if the response to naloxone is not prompt.
SUMMARY
Do’s and Don’ts in Responding to Opioid Overdose
- DO support the person’s breathing by administering oxygen or performing rescue breathing.
- DO administer naloxone.
- DO put the person in the “recovery position” on the side, if he or she is breathing independently.
- DO stay with the person and keep him/her warm.
- DON’T slap or try to forcefully stimulate the person—it will only cause further injury. If you are unable to wake the person by shouting, rubbing your knuckles on the sternum (center of the chest or rib cage), or light pinching, he or she may be unconscious.
- DON’T put the person into a cold bath or shower. This increases the risk of falling, drowning, or going into shock.
- DON’T inject the person with any substance (saltwater, milk, “speed,” heroin, etc.). The only safe and appropriate treatment is naloxone.
- DON’T try to make the person vomit drugs that he or she may have swallowed. Choking or inhaling vomit into the lungs can cause a fatal injury.

NOTE: All naloxone products have an expiration date, so it is important to check the expiration date and obtain replacement naloxone as needed.
Opioid overdose is a major public health problem. In 2014, 28,647 of drug overdose deaths involved some type of opioid, including heroin. Overdose involves both men and women of all ages, ethnicities, and demographic and economic characteristics, and involves both illicit opioids such as heroin and, increasingly, prescription opioid analgesics such as oxycodone, hydrocodone, fentanyl, and methadone.

Physicians and other health care providers can make a major contribution toward reducing the toll of opioid overdose through the care they take in prescribing opioid analgesics and monitoring patients’ response, as well as through their acuity in identifying and effectively addressing opioid overdose. Federally funded Continuing Medical Education (CME) courses are available at no charge at http://www.OpioidPrescribing.com (a series of courses funded by the Substance Abuse and Mental Health Services Administration [SAMHSA])

OPIOID OVERDOSE

The risk of opioid overdose can be minimized through adherence to the following clinical practices, which are supported by a considerable body of evidence.

ASSESS THE PATIENT.

Obtaining a history of the patient’s past use of drugs (either illicit drugs or prescribed medications with misuse potential) is an essential first step in appropriate prescribing. Such a history should include very specific questions. For example:

- “In the past 6 months, have you taken any medications to help you calm down, keep from getting nervous or upset, raise your spirits, make you feel better, and the like?”
- “Have you been taking any medications to help you sleep? Have you been using alcohol for this purpose?”
- “Have you ever taken a medication to help you with a drug or alcohol problem?”
- “Have you ever taken a medication for a nervous stomach?”
- “Have you taken a medication to give you more energy or to cut down on your appetite?”
- “Have you ever been treated for a possible or suspected opioid overdose?”

The patient history should also include questions about use of alcohol and over-the-counter (OTC) preparations. For example, the ingredients in many common cold preparations include alcohol and other central nervous system (CNS) depressants, so these products should not be used in combination with opioid analgesics.

Positive answers to any of these questions warrant further investigation.

TAKE SPECIAL PRECAUTIONS WITH NEW PATIENTS.

Many experts recommend that additional precautions be taken in prescribing opioid analgesics for new patients. These might involve the following:

1. Assessment: In addition to doing the patient history and examination, the physician should determine who has been caring for the patient in the past, what medications have been prescribed and for what indications, what substances (including alcohol, illicit drugs, and OTC products) the patient has reported using, and when and what amount was last used and by what route. Medical records should be obtained (with the patient’s consent).

2. Emergencies: In emergency situations, the physician should prescribe the smallest possible quantity, typically not exceeding 3 days’ supply, and arrange for a

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In addition, consider prescribing naloxone to help mitigate risk associated with these emergent situations. At a minimum, the patient’s identity should be verified by asking for proper identification.

3. **Non-emergencies:** In non-emergency situations, only enough of an opioid analgesic should be prescribed to meet the patient’s needs until the next appointment. The patient should be directed to return to the office for additional prescriptions, as telephone orders do not allow the physician to reassess the patient’s continued need for the medication.

**STATE PRESCRIPTION DRUG MONITORING PROGRAMS.** State Prescription Drug Monitoring Programs (PDMPs) have emerged as a key strategy for addressing the misuse of prescription opioids and thus preventing opioid overdoses and deaths. Specifically, prescribers can check their state’s PDMP database to determine whether a patient is filling the prescriptions provided and/or obtaining prescriptions for the same or similar drugs from multiple physicians.

While nearly all states now have operational PDMPs, the programs differ from state to state in terms of the exact information collected, how soon that information is available to physicians, and who may access the data. Therefore, information about the program in a particular state is best obtained directly from the PDMP or from the state board of medicine or pharmacy.

**SELECT AN APPROPRIATE MEDICATION.** Rational drug therapy demands that the efficacy and safety of all potentially useful medications be reviewed for their relevance to the patient’s disease or disorder.2,22

Even when sound medical indications have been established, physicians typically consider three additional factors before deciding to prescribe an opioid analgesic2,22:

1. The **severity of symptoms**, in terms of the patient’s ability to accommodate them. Relief of symptoms is a legitimate goal of medical practice, but using opioid analgesics requires caution.

2. The patient’s **reliability in taking medications**, noted through observation and careful history-taking. The physician should assess a patient’s history of and risk factors for substance use disorders before prescribing any psychoactive drug and weigh the benefits against the risks. The likely development of physical dependence in patients on long-term opioid therapy should be monitored through periodic checkups.

3. The **dependence-producing potential of the medication.** The physician should consider whether a product with less potential for misuse, or even a non-drug therapy, would provide equivalent benefits. Patients should be warned about possible adverse effects caused by interactions between opioids and other medications or substances, including alcohol. At the time a drug is prescribed, patients should be informed that it is illegal to sell, give away, or otherwise share their medication with others.
including family members. The patient’s obligation extends to keeping the medication in a locked cabinet or otherwise restricting access to it and to safely disposing of any unused supply (visit http://www.fda.gov/ForConsumers/Consumer-Updates/ucm101653.htm for advice from the United States Food and Drug Administration (FDA) on how to safely dispose of unused medications).

**EDUCATE THE PATIENT AND OBTAIN INFORMED CONSENT.** Obtaining informed consent involves informing the patient about the risks and benefits of the proposed therapy and of the ethical and legal obligations such therapy imposes on both physician and patient. Such informed consent can serve multiple purposes: (1) it provides the patient with information about the risks and benefits of opioid therapy; (2) it fosters adherence to the treatment plan; it limits the potential for inadvertent drug misuse; and (4) it improves the efficacy of the treatment program.

Patient education and informed consent should specifically address the potential for physical dependence and cognitive impairment as side effects of opioid analgesics. Other issues that should be addressed in the informed consent or treatment agreement include the following:

- The agreement instructs the patient to stop taking all other pain medications, unless explicitly told to continue by the physician. Such a statement reinforces the need to adhere to a single treatment regimen.
- The patient agrees to obtain the prescribed medication from only one physician and, if possible, from one designated pharmacy.
- The patient agrees to take the medication only as prescribed (for some patients, it may be possible to offer latitude to adjust the dose as symptoms dictate).
- The agreement makes it clear that the patient is responsible for safeguarding the written prescription and the supply of medications, and arranging refills during regular office hours. This responsibility includes planning ahead so as not to run out of medication during weekends or vacation.
- The agreement specifies the consequences for failing to adhere to the treatment plan, which may include discontinuation of opioid therapy if the patient’s actions compromise his or her safety.

Both patient and physician should sign the informed consent agreement, and a copy should be placed in the patient’s medical record. It also is helpful to give the patient a copy of the agreement to carry with him or her, to document the source and reason for any controlled drugs in his or her possession.

Some physicians provide a laminated card that identifies the individual as a patient of their practice. This is helpful to other physicians who may see the patient and in the event the patient is seen in an emergency department.

**EXECUTE THE PRESCRIPTION ORDER.** Careful execution of the prescription order can prevent manipulation by the patient or others intent on obtaining opioids for non-medical purposes. For example, federal law requires that prescription orders for controlled substances be signed and dated on the day they are issued. Also under federal law, every prescription or der must include at least the following information:

- Name and address of the patient
- Name, address, and DEA registration number of the physician

For a general patient counseling document on opioid analgesics, available in English or Spanish, please visit: http://www.er-la-opioidrems.com/lwgUI/remis/pcd.action

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3 An important source of patient information is the FDA package insert. The medication guides that accompany all extended-release or long-acting as well as oral solution opioids should be reviewed as part of the FDA Risk Evaluation and Management Strategy (REMS). For links to medication guides, please visit http://www.er-la-opioidrems.com/lwgUI/remis/products.action.
INFORMATION FOR PRESCRIBERS

- Signature of the physician
- Name and quantity of the drug prescribed
- Directions for use
- Refill information
- Effective date if other than the date on which the prescription was written

Many states impose additional requirements, which the physician can determine by consulting the state medical licensing board. In addition, there are special federal requirements for drugs in different schedules of the federal Controlled Substances Act (CSA), particularly those in Schedule II, where many opioid analgesics are classified.

Blank prescription pads as well as information such as the names of physicians who recently retired, left the state, or died all can be used to forge prescriptions. Therefore, it is a sound practice to store blank prescriptions in a secure place rather than leaving them in examining rooms.

NOTE: The physician should immediately report the theft or loss of prescription blanks to the nearest field office of the federal Drug Enforcement Administration and to the state board of medicine or pharmacy.

MONITOR THE PATIENT’S RESPONSE TO TREATMENT.
Proper prescription practices do not end when the patient receives a prescription. Plans to monitor for drug efficacy and safety, compliance, and potential development of tolerance must be documented and clearly communicated to the patient.²

Subjective symptoms are important in monitoring, as are objective clinical signs (such as body weight, pulse rate, temperature, blood pressure, and levels of drug metabolites in the bloodstream). These can serve as early signs of therapeutic failure or unacceptable adverse drug reactions that require modification of the treatment plan.

Asking the patient to keep a log of signs and symptoms gives him or her a sense of participation in the treatment program and facilitates the physician’s review of therapeutic progress and adverse events.

Simply recognizing the potential for non-adherence, especially during prolonged treatment, is a significant step toward improving medication use.²⁵ Steps such as simplifying the drug regimen and offering patient education also improve adherence, as do phone calls to patients, home visits by nursing personnel, convenient packaging of medication, and periodic urine testing for the prescribed opioid as well as any other respiratory depressant.

Finally, the physician should convey to the patient through attitude and manner that any medication, no matter how helpful, is only part of an overall treatment plan.

When the physician is concerned about the behavior or clinical progress (or lack thereof) of a patient being treated with an opioid analgesic, it usually is advisable to seek a consultation with an expert in the disorder for which the patient is being treated and an expert in addiction. Physicians place themselves at risk if they continue to prescribe opioids in the absence of such consultations.²²

CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT’S INITIAL OPIOID PRESCRIPTION. Naloxone competes with opioid receptors and is the antidote to acute opioid toxicity. With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from being prescribed (1) a naloxone kit containing naloxone, syringes, and needles; (2) Narcan® Nasal Spray, which delivers a single dose of naloxone into one nostril via a pre-filled intranasal spray; or (3)
Evzio®, which delivers a single dose of naloxone to the outer thigh via a hand-held auto-injector. 

Patients who are candidates for such kits include those who are:
- Taking high doses of opioids for long-term management of chronic malignant or non-malignant pain.
- Receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance use disorder or non-medical use of prescription or illicit opioids.
- On certain opioid preparations that may increase risk for opioid overdose such as extended release/long-acting preparations.
- Completing mandatory opioid detoxification or abstinence programs.
- Recently released from incarceration and with a history of opioid use disorder (and presumably with reduced opioid tolerance and high risk of relapse to opioid use).

It may also be advisable to suggest that the at-risk patient create an “overdose plan” to share with friends, partners, and/or caregivers. Such a plan would contain information on the signs of overdose and how to administer naloxone or otherwise provide emergency care (as by calling 911).

DECIDE WHETHER AND WHEN TO END OPIOID THERAPY. Certain situations may warrant immediate cessation of prescribing. These generally occur when out-of-control behaviors indicate that continued prescribing is unsafe or causing harm to the patient. Examples include altering or selling prescriptions, accidental or intentional overdose, multiple episodes of running out early (due to excessive use), doctor shopping, or engaging in threatening behavior.

When such events arise, it is important to separate the patient as a person from the behaviors caused by the disease of addiction, as by demonstrating a positive regard for the person but no tolerance for the aberrant behaviors.

In such a situation, the essential steps are to (1) stop prescribing, (2) tell the patient that continued prescribing is not clinically supportable (and thus not possible), (3) urge the patient to accept a referral for assessment by an addiction specialist, (4) educate the patient about signs and symptoms of spontaneous withdrawal and urge the patient to go to the emergency department if withdrawal symptoms occur, (5) retrain on the risks and the signs of opioid overdose and on the use of naloxone and consider prescribing naloxone if deemed appropriate, and (6) assure the patient that he or she will continue to receive care for the presenting symptoms or condition.

Identification of a patient who is misusing a prescribed opioid presents a major therapeutic opportunity. The physician should have a plan for managing such a patient, typically involving work with the patient and the patient’s family, referral to an addiction expert for assessment and placement in a formal addiction treatment program, long-term participation in a 12-Step mutual-help program such as Narcotics Anonymous, and follow-up of any associated medical or psychiatric comorbidities.

Providing training on use of naloxone and prescribing a naloxone kit or FDA-approved naloxone should be considered.

In all cases, patients should be given the benefit of the physician’s concern and attention. It is important to remember that even drug-seeking patients often have

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4 For further information about Evzio® visit http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
very real medical problems that demand and deserve the same high-quality medical care offered to any patient.2,22

TREATING OPIOID OVERDOSE

In the time it takes for an overdose to become fatal, it is possible to reverse the respiratory depression and other effects of opioids through respiratory support and administration of the opioid antagonist naloxone.17 Naloxone is approved by the FDA and has been used for decades to reverse overdose and resuscitate individuals who have overdosed on opioids. The routes of administration for naloxone are intravenous, intranasal, intramuscular, and subcutaneous.

The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect.6,17 If given to individuals who are not opioid-intoxicated or opioid-dependent, naloxone produces no clinical effects, even at high doses. Moreover, while rapid opioid withdrawal in tolerant patients may be unpleasant, it is not typically life-threatening.

Naloxone should be part of an overall approach to known or suspected opioid overdose that incorporates the steps below.

RECOGNIZE THE SIGNS OF OVERDOSE. An opioid overdose requires rapid diagnosis. The most common signs of overdose include2:

- Extreme sleepiness, inability to awaken verbally or upon sternal rub.
- Breathing problems that can range from slow to shallow breathing in a patient who 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, include2:

- 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.
- Pinpoint (small) pupils; normal size pupils does not exclude opioid overdose.
- Slow heartbeat, low blood pressure.
- Difficulty waking the person from sleep.

Because opioids depress respiratory function and breathing, one telltale sign of an individual in a critical medical state is the “death rattle.” This is an exhaled breath with a very distinct, labored sound coming from the throat. It indicates that emergency resuscitation is needed immediately.26

SUPPORT RESPIRATION. Supporting respiration is the single most important intervention for opioid overdose and may be lifesaving on its own. Ideally, individuals who are experiencing opioid overdose should be ventilated with oxygen before naloxone is administered to reduce the risk of acute lung injury.2,6 In situations where oxygen is not available, rescue breathing can be very effective in supporting respiration until naloxone becomes available.27 Rescue breathing involves the following steps:

- Verify that the airway is clear.
- With one hand on the patient’s chin, tilt the head back and pinch the nose closed.
- Place your mouth over the patient’s mouth to make a seal and give 2 slow breaths (the patient’s chest should rise, but not the stomach).
- Follow up with 1 breath every 5 seconds.

ADMINISTER NALOXONE. Naloxone competitively binds opioid receptors and is the antagonist of choice for the reversal of acute opioid toxicity. Any patient who presents with signs of opioid overdose, or when
this is suspected, should be administered naloxone.\textsuperscript{9} Naloxone can be given intranasally intramuscularly, subcutaneously, or by intravenous injection.\textsuperscript{9,17,16}

**PREGNANT PATIENTS.** Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women.\textsuperscript{9}

**MONITOR THE PATIENT’S RESPONSE.** Patients should be monitored for re-emergence of signs and symptoms of opioid toxicity for at least 4 hours following the last dose of naloxone (however, patients who have overdosed on long-acting opioids require more prolonged monitoring).\textsuperscript{6}

Most patients respond to naloxone by returning to spontaneous breathing, with mild withdrawal symptoms.\textsuperscript{6} The response generally occurs within 3 to 5 minutes of naloxone administration. (Continue rescue breathing while waiting for the naloxone to take effect.)

The duration of effect of naloxone is 20 to 90 minutes depending on dose and route of administration. Patients should be observed after that time for re-emergence of overdose symptoms. The goal of naloxone therapy should be restoration of adequate spontaneous breathing, but not necessarily complete arousal.\textsuperscript{18,19}

More than one dose of naloxone may be required to revive the patient. Those who have taken longer-acting opioids or opioid partial agonists may require further doses or may require further intravenous bolus doses or an infusion of naloxone.\textsuperscript{22} Therefore, it is essential to get the person to an emergency department or other source of acute care as quickly as possible, even if he or she revives after the initial dose of naloxone and seems to feel better.

**SIGNS OF OPIOID WITHDRAWAL.** Withdrawal triggered by naloxone can feel unpleasant. As a result, some persons become agitated or combative when this happens and need help to remain calm.

The signs and symptoms of opioid withdrawal in an individual who is physically dependent on opioids may include (but are not limited to) the following: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.\textsuperscript{17} Withdrawal syndromes may be precipitated by as little as 0.05 to 0.2 mg intravenous naloxone in a patient taking 24 mg per day of methadone.

In neonates, opioid withdrawal may also produce convulsions, excessive crying, and hyperactive reflexes.\textsuperscript{17} Additionally, in neonates, opiate withdrawal may be life-threatening if not recognized and properly treated.

**NALOXONE NON-RESPONDERS.** If a patient does not respond to naloxone, an alternative explanation for the clinical symptoms should be considered. The most likely explanation is that the person is not overdosing on an opioid but rather some other substance or may even be experiencing a non-overdose medical emergency. Another possible explanation to consider is that the individual has overdosed on buprenorphine, a long-acting opioid partial agonist. Because buprenorphine has a higher affinity for the opioid receptors than do other opioids, naloxone may not be effective at reversing the effects of buprenorphine-induced opioid overdose\textsuperscript{5}.

In all cases, support of ventilation, oxygenation, and blood pressure should be sufficient to prevent the complications of opioid overdose and should be given the highest priority if the patient’s response to naloxone is not prompt.

**NOTE:** All naloxone products have an expiration date. It is important to check the expiration date and obtain replacement naloxone as needed.
LEGAL AND LIABILITY CONSIDERATIONS

Health care professionals who are concerned about legal risks associated with prescribing naloxone may be reassured by the fact that prescribing naloxone to manage opioid overdose is consistent with the drug’s FDA-approved indication, resulting in no increased liability so long as the prescriber adheres to general rules of professional conduct. Many state laws and regulations now permit physicians to prescribe naloxone to a third party, such as a caregiver. More information on state policies is available at http://www.prescribetoprevent.org or from individual state medical boards.

CLAIMS CODING AND BILLING

Most private health insurance plans, Medicare, and Medicaid cover naloxone for the treatment of opioid overdose, but policies vary by state. The cost of take-home naloxone should not be a prohibitive factor. Not all community pharmacies stock naloxone routinely, but they can always order it. If you are caring for a large population of patients who are likely to benefit from naloxone, you may wish to notify the pharmacy when you implement naloxone prescribing as a routine practice.

The codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be used to bill time for counseling a patient about how to recognize overdose and how to administer naloxone. Billing codes for SBIRT are as follows:

- Commercial Insurance: CPT 99408 (15 to 30 minutes)
- Medicare: G0396 (15 to 30 minutes)
- Medicaid: H0050 (per 15 minutes)

For counseling and instruction on the safe use of opioids, including the use of naloxone outside of the context of SBIRT services, the provider should document the time spent in medication education and use the E&M code that accurately captures the time and complexity. For example, for new patients deemed appropriate for opioid pharmacotherapy and when a substantial and appropriate amount of additional time is used to provide a separate service such as behavioral counseling (e.g., opioid overdose risk assessment and naloxone administration training), consider using modifier–25 in addition to the E&M code.

In addition, when using an evidence-based opioid use disorder or overdose risk factor assessment tool/screening instrument, CPT Code 99420 (Administration and interpretation of health risk assessment instrument) can be used for patients with commercial insurance.
RESOURCES FOR PRESCRIBERS

Additional information on prescribing opioids for chronic pain is available at the following websites: http://www.opioidprescribing.com.

Sponsored by the Boston University School of Medicine, with support from SAMHSA, this site presents course modules on various aspects of prescribing opioids for chronic pain. To view the list of courses and to register, go to http://www.opioidprescribing.com/overview. CME credits are available at no charge.

http://pcss-o.org or www.pcssmat.org. Sponsored by the American Academy of Addiction Psychiatry in collaboration with other specialty societies and with support from SAMHSA, the Providers’ Clinical Support System offers multiple resources related to opioid prescribing and the diagnosis and management of opioid use disorder.

http://www.er-la-opioidrems.com/lwgUI/rems/home.action. As required by the FDA under a risk management program for extended-release and long-acting opioid analgesics, this website provides physician training and patient education on the use of such medications.


http://prescribetoprevent.org. Compiled by prescribers, pharmacists, public health workers, lawyers, and researchers working on overdose prevention and naloxone access, this privately funded site provides resources to help health care providers educate their patients to reduce overdose risk and provide naloxone rescue kits to patients.
SAFETY ADVICE FOR PATIENTS & FAMILY MEMBERS

WHAT ARE OPIOIDS?
Opioids include illicit drugs such as heroin and prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl, hydromorphone, and buprenorphine.

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.

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

Opioid overdose can occur when a patient misunderstands the directions for use, accidentally takes an extra dose, or deliberately misuses a prescription opioid or an illicit drug such as heroin.

Also at risk is the person who takes opioid medications prescribed for someone else, as is the individual who combines opioids—prescribed or illicit—with alcohol, certain other medications, and even some over-the-counter products that depress breathing, heart rate, and other functions of the central nervous system.

PREVENTING OVERDOSE
If you are concerned about your own use of opioids, don’t wait! Talk with the health care professional(s) who prescribed the medications for you. If you are concerned about a family member or friend, urge him or her to talk to whoever prescribed the medication.

Effective treatment of opioid use disorder can reduce the risk of overdose and help a person who is misusing or addicted to opioid medications attain a healthier life. An evidence-based practice for treating opioid addiction is the use of United States Food and Drug Administration (FDA)-approved medications, along with counseling and other supportive services. These services are available at SAMHSA-certified and DEA-registered opioid treatment programs (OTPs).

In addition, physicians who are trained to provide treatment for opioid addiction in office-based and other settings with medications such as buprenorphine/naloxone and naltrexone may be available in your community.

IF YOU SUSPECT AN OVERDOSE
An opioid overdose requires immediate medical attention. An essential first step is to get help from someone with medical expertise as soon as possible. Call 911 immediately if you or someone you know exhibits any of the symptoms listed below. All you have to say: “Someone is unresponsive and not breathing.” Give a clear address and/or description of your location.

Signs of OVERDOSE, which is a life-threatening emergency, include the following:

- The face is extremely pale and/or clammy to the touch.
- The body is limp.
- Fingernails or lips have a blue or purple cast.
- The person is vomiting or making gurgling noises.
- He or she cannot be awakened from sleep or is unable to speak.
- Breathing is very slow or stopped.
- The heartbeat is very slow or stopped.

Signs of OVERMEDICATION, which may progress to overdose, include:

- Unusual sleepiness or drowsiness.
- Mental confusion, slurred speech, or intoxicated behavior.
- Slow or shallow breathing.
- Extremely small “pinpoint” pupils.
- Slow heartbeat or low blood pressure.
- Difficulty in being awakened from sleep.
SAFETY ADVICE FOR PATIENTS & FAMILY MEMBERS

WHAT IS NALOXONE?

Naloxone is an antidote to opioid overdose. It is an opioid antagonist that is used to reverse the effects of opioids. Naloxone works by blocking opiate receptor sites. It is not effective in treating overdoses of benzodiazepines (such as Valium®, Xanax®, or Klonopin®), barbiturates (Seconal® or Fiorinal®), clonidine, Elavil®, GHB, or ketamine. It is also not effective in treating overdoses of stimulants such as cocaine and amphetamines (including methamphetamine and Ecstasy). However, if opioids are taken in combination with other sedatives or stimulants, naloxone may be helpful.

IMPORTANT SAFETY INFORMATION. Naloxone may cause dizziness, drowsiness, or fainting. These effects may be worse if it is taken with alcohol or certain medicines. For more information, see http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm472923.htm.

REPORT ANY SIDE EFFECTS

Get emergency medical help if you or someone has any signs of an allergic reaction after taking naloxone, such as hives, difficulty breathing, or swelling of your face, lips, tongue, or throat.

Call your doctor or 911 at once if you have a serious side effect such as:
- Chest pain, or fast or irregular heartbeats.
- Dry cough, wheezing, or feeling short of breath.
- Sweating, severe nausea, or vomiting.
- Severe headache, agitation, anxiety, confusion, or ringing in your ears.
- Seizures (convulsions).
- Feeling that you might pass out.
- Slow heart rate, weak pulse, fainting, or slowed breathing.

If you are being treated for opioid use disorder (either an illicit drug like heroin or a medication prescribed for pain), you may experience the following symptoms of opioid withdrawal after taking naloxone:
- Feeling nervous, restless, or irritable.
- Body aches.
- Dizziness or weakness.
- Diarrhea, stomach pain, or mild nausea.
- Fever, chills, or goosebumps.
- Sneezing or runny nose in the absence of a cold.

This is not a complete list of side effects, and others may occur. Talk to your doctor about side effects and how to deal with them.

STORE NALOXONE IN A SAFE PLACE

Naloxone is usually handled and stored by a health care provider. If you are using naloxone at home, store it in a locked cabinet or other space that is out of the reach of children or pets.

SUMMARY: HOW TO AVOID OPIOID OVERDOSE

1. Take medicine only if it has been prescribed to you by your doctor.
2. Do not take more medicine or take it more often than instructed.
3. Call a doctor if your pain gets worse.
4. Never mix pain medicines with alcohol, sleeping pills, or any illicit substance.
5. Store your medicine in a safe place where children or pets cannot reach it.
6. Learn the signs of overdose and how to use naloxone to keep it from becoming fatal.
7. Teach your family and friends how to respond to an overdose.
8. Dispose of unused medication properly.

READ MORE AT http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm472923.htm.
RESOURCES FOR OVERDOSE SURVIVORS AND FAMILY MEMBERS

Survivors of opioid overdose have experienced a life-changing and traumatic event. They have had to deal with the emotional consequences of overdosing, which can involve embarrassment, guilt, anger, and gratitude, all accompanied by the discomfort of opioid withdrawal. Most need the support of family and friends to take the next steps toward recovery.

While many factors can contribute to opioid overdose, it is almost always an accident. Moreover, the underlying problem that led to opioid use—most often pain or substance use disorder—still exists and continues to require attention.

Moreover, the individual who has experienced an overdose is not the only one who has endured a traumatic event. Family members often feel judged or inadequate because they could not prevent the overdose. It is important for family members to work together to help the overdose survivor obtain the help that he or she needs.

FINDING A NETWORK OF SUPPORT

As with any disease, it is not a sign of weakness to admit that a person or a family cannot deal with the trauma of overdose without help. It takes real courage to reach out to others for support and to connect with members of the community to get help.

Health care providers, including those who specialize in treating substance use disorders, can provide structured, therapeutic support and feedback.

If the survivor’s underlying problem is pain, referral to a pain specialist may be in order. If it is addiction, the patient should be referred to an addiction specialist for assessment and treatment, either by a physician specializing in the treatment of opioid addiction, in a residential treatment program, or in a federally certified Opioid Treatment Program (OTP). In each case, counseling can help the individual manage his or her problems in a healthier way. Choosing the path to recovery can be a dynamic and challenging process, but there are ways to help.

In addition to receiving support from family and friends, overdose survivors can access a variety of community-based organizations and institutions, such as:

- Health care and behavioral health providers.
- Peer-to-peer recovery support groups such as Narcotics Anonymous.
- Faith-based organizations.
- Educational institutions.
- Neighborhood groups.
- Government agencies.
- Family and community support programs.
RESOURCES
Information on opioid overdose and helpful advice for overdose survivors and their families can be found at:

**Substance Abuse and Mental Health Services Administration (SAMHSA)**
- National Helpline 1-800-662-HELP (4357) or 1-800-487-4889 (TDD—for hearing impaired)
- Behavioral Health Treatment Services Locator: [https://findtreatment.samhsa.gov](https://findtreatment.samhsa.gov) to search by address, city, or zip code
- State Substance Abuse Agencies: [https://findtreatment.samhsa.gov/TreatmentLocator/faces/about.jspx](https://findtreatment.samhsa.gov/TreatmentLocator/faces/about.jspx)

**Centers for Disease Control and Prevention (CDC):**
[http://www.cdc.gov/drugoverdose/epidemic](http://www.cdc.gov/drugoverdose/epidemic)

**National Institutes of Health (NIH), National Center for Biotechnical Information:**

**Partnership for Drug-Free Kids:**

**Project Lazarus:**
[http://www.projectlazarus.org](http://www.projectlazarus.org)

**Harm Reduction Coalition:**
[http://www.harmreduction.org](http://www.harmreduction.org)

**Overdose Prevention Alliance:**
[http://www.overdosepreventionalliance.org](http://www.overdosepreventionalliance.org)

**Toward the Heart:**
[http://www.towardtheheart.com/naloxne](http://www.towardtheheart.com/naloxne)
REFERENCES


29 SAMHSA’s National Helpline 1-800-662-HELP (4357) or 1-800-487-4889 (TDD for hearing impaired).

30 Behavioral Health Treatment Services Locator: [https://findtreatment.samhsa.gov](https://findtreatment.samhsa.gov) to search by address, city, or zip code.