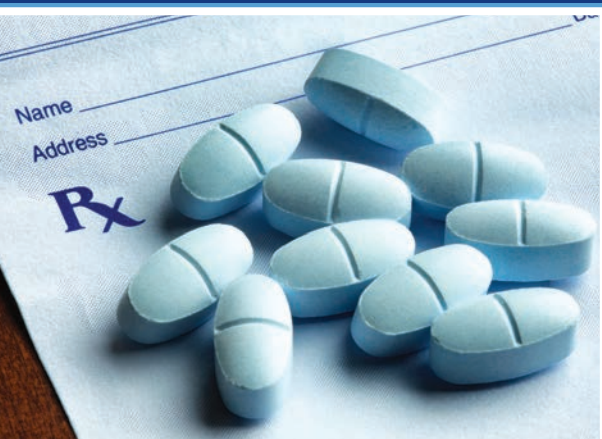


Opioid Safety: Focus on Furnishing Naloxone

A GUIDE FOR PENNSYLVANIA HEALTH CARE PROVIDERS



Purpose of this guide

Health care providers are uniquely poised to engage in efforts to reduce opioid misuse and opioid related overdose. They are often in the difficult position of distinguishing between patients in dire need of pain relief and patients struggling with addiction to opioids.

Health care providers can effectively address and significantly impact our current epidemic of opioid misuse and overdose because they are trusted, knowledgeable, and accessible members of our communities.



Dear Pharmacist,

RE: The Standing Order Prescription for Naloxone for Eligible Persons under Act 139 of 2014.

This letter is to inform you of the Standing Order prescription signed by Dr. Rachel Levine on October 28, 2015 and reauthorized on April 18, 2018. The Standing Order is intended to ensure that all persons who are permitted under Act 139 to receive Naloxone are able to access and effectively use the medication. Naloxone is a safe and effective medication that counters opiate overdoses and restores breathing by blocking the effects of opioids on the brain.

Act 139 was enacted by the General Assembly in response to the current opioid overdose crisis in the Commonwealth. Under Act 139, authorized medical professionals are permitted to dispense, prescribe or distribute Naloxone to anyone at risk of experiencing an opioid-related overdose, as well as to family members, friends or any other person who may be in a position to assist such a person. Thus, the Act specifically permits the writing and filling of both direct and third-party prescriptions for Naloxone.

Further details about Act 139 may be found at the following websites:

www.ddap.pa.gov

www.health.pa.gov

<http://www.legis.state.pa.us>

A person's lack of immediate access to their own primary care physician, or other medical provider should not prevent them from being able to access the life-saving medication, Naloxone. The Standing Order is an authorized prescription for Naloxone that allows a pharmacy to dispense Naloxone in intra-nasal and auto-injector forms to individuals. The standing order has been updated to include the new intra-nasal preparation by Adapt Pharma, NARCAN Nasal Spray 4mg and the auto-injector form, EVZIO®. It does not permit intra-muscular (IM) syringes to be dispensed, although pharmacists may certainly dispense Naloxone in IM form under separate prescriptions written by other health care providers. The Standing Order can be reviewed in full by visiting www.health.pa.gov.

Insurance companies vary in how they cover naloxone and other drugs used to treat an opioid overdose. Fee-for-Service Medicaid and the medical assistance managed care organizations will pay for naloxone dispensed under the Standing Order.

The Standing Order strongly advises any person obtaining Naloxone to complete a training program, and provides links to approved programs. We ask and encourage pharmacists to take the opportunity to fully and appropriately educate Eligible Persons obtaining Naloxone in accordance with

the Standing Order and review with the patient the written materials which come with the drug. Our mutual goal is to ensure that individuals have the information they need to save lives.

The Department of Health and the Department of Drug and Alcohol Programs appreciate your support of this effort and look forward to working with you further to ensure that each and every person in the Commonwealth who can benefit from Naloxone can access it and have the ability to use it effectively. If you have further questions regarding the Standing Order, please visit the links above. On behalf of all Pennsylvanians, we ask for your support in this effort to eradicate death from opiate overdoses, and we thank you for the work you do every day to improve the health and lives of your fellow citizen.

Sincerely,

Handwritten signature of Rachel L Levine, MD, consisting of stylized cursive letters 'RL' followed by '22' and 'MD'.

Rachel L Levine, MD
Secretary
Department of Health

Handwritten signature of Jennifer S Smith in cursive script.

Jennifer S Smith
Secretary
Department of Drug and Alcohol Programs

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Epidemiologic trends in opioid use and overdose

»» Since 1999, sales of prescription opioids in the U.S. have **quadrupled**.¹



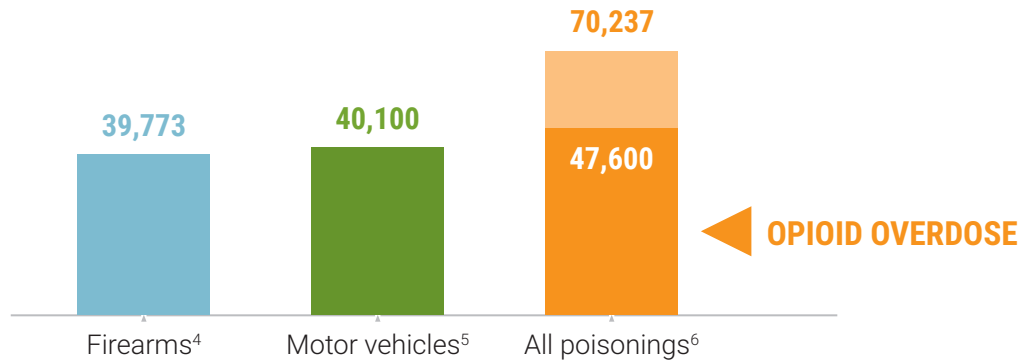
»» In 2014, **10.3 million persons** reported using prescription opioids non-medically.²

»» **71% of people who abuse prescription opioids get them from a friend or relative**.³

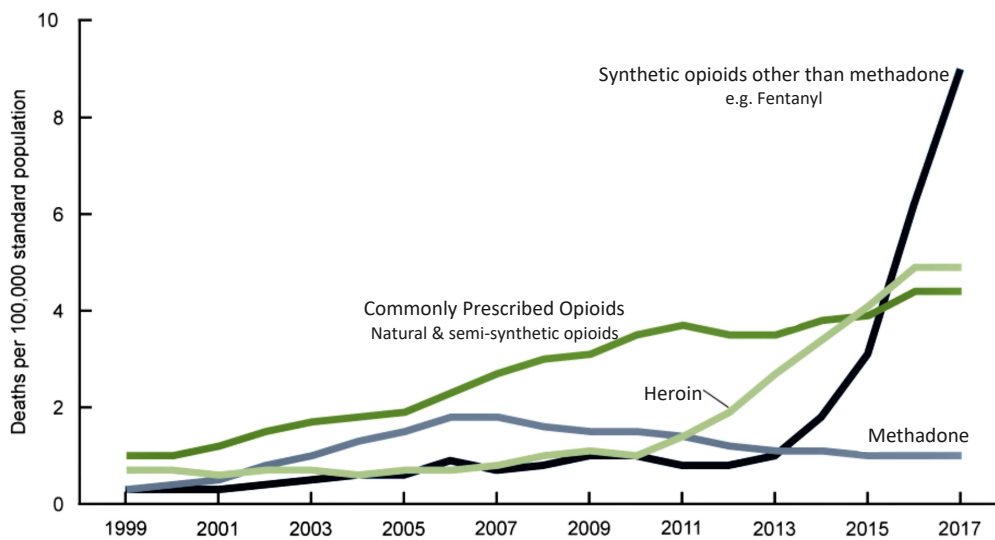


Overdose deaths

INJURY-RELATED DEATH IN THE U.S.



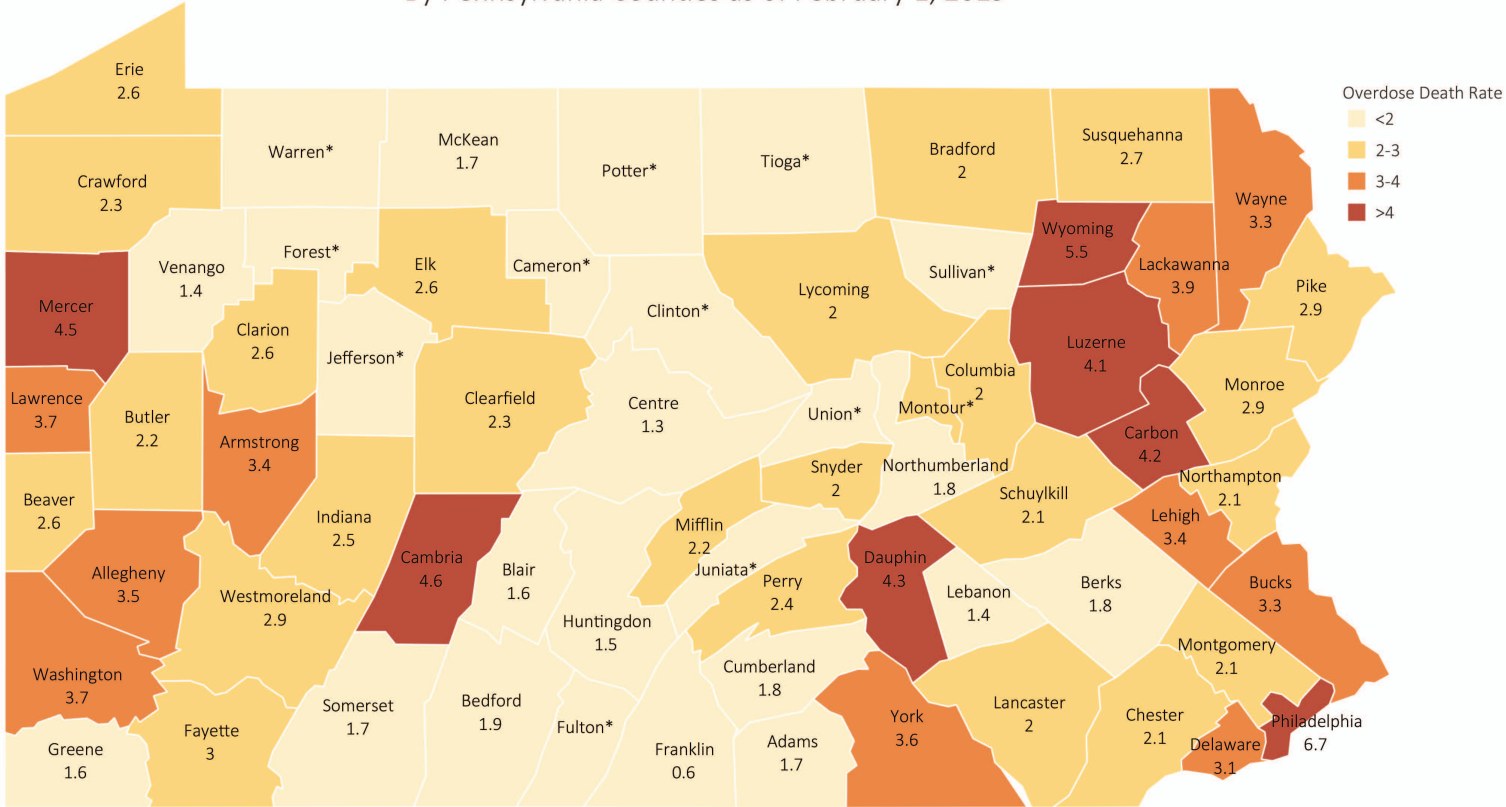
DRUG OVERDOSE DEATH RATES CONTINUE TO INCREASE IN THE U.S.⁷



130
AMERICANS die every day from an opioid overdose (that includes prescription opioids and heroin)⁸

Drug overdose deaths in Pennsylvania

Provisional 2018 Drug Overdose Deaths per 10,000 Residents By Pennsylvania Counties as of February 1, 2019



- These data were supplied by the Bureau of Health Statistics and Registries, Harrisburg, Pennsylvania. The Bureau of Health Statistics and Registries specifically disclaims responsibility for any analyses, interpretations or conclusions.
- Drug overdose deaths are identified using ICD-10 underlying cause-of-death codes: X40-X44, X49, X60-X64, X85, and Y10-Y14.
- Please note that finalized death certificates for overdoses deaths are often delayed by at least 3 months.
- County is location of death.
- *Data is suppressed for counties with an OD Death Count below 6.

The role of health care practitioners and pharmacists in opioid safety



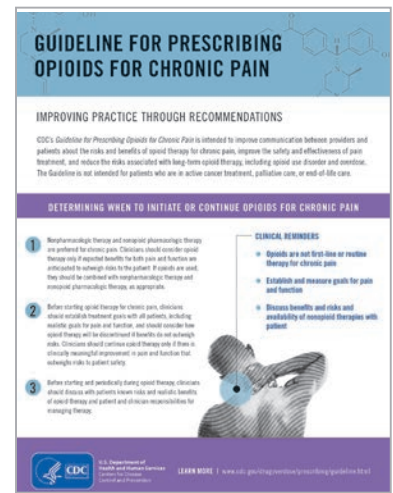
It is clear we are amid an epidemic.

To halt the epidemic, new cases of opioid addiction must be prevented and access to treatment for those who have already developed a substance use disorder must be expanded.



Make a positive impact

- **Ensure the appropriate use of opioids.** Be well-versed in pain management and work with prescribers and patients to appropriately manage pain.
- **Read the PA Prescribing Guidelines and PA Dispensing Guidelines:** [tinyurl.com/yaffl2sw](https://www.tinyurl.com/yaffl2sw)
- **Read the CDC Guideline for Prescribing Opioids for Chronic Pain,** which addresses how to optimally manage pain while preventing opioid use disorder (dependence, addiction, abuse) and overdose. The guideline was developed to:
 - Improve communication between providers and patients about risks and benefits of opioids
 - Improve safety and effectiveness of pain treatment
 - Reduce risks associated with long-term opioid therapy, including opioid use disorder and overdose
- **Recognize legitimate uses for opioids,** including short-term treatment of acute pain, cancer pain, or end-of-life care.
- **Limit access to opioids for illegitimate use.** For red flags, refer to Pennsylvania's Prescription Drug Monitoring Program (PDMP).
- **Assess for risk of an opioid use disorder** with a simple question such as: "How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?"
- **Become aware of treatment resources** in your community and refer patients for medication-assisted treatment (MAT) with methadone or buprenorphine. For more information, please visit [pa.gov/guides/opioid-epidemic](https://www.pa.gov/guides/opioid-epidemic).
- **Provide opportunities for drug destruction and take-back** for individuals in the community to dispose of controlled substances safely: [tinyurl.com/y85jrj8u](https://www.tinyurl.com/y85jrj8u)
- **Educate individuals at risk for overdose** about, and expand access to, life-saving naloxone.



Access the CDC Guideline for Prescribing Opioids for Chronic Pain: [tinyurl.com/kdy59jc](https://www.tinyurl.com/kdy59jc)





Evaluate opioid prescriptions

Validity:

- Has prescription been forged or altered?
- Has prescriber's DEA number been verified?
- Is prescription within the prescriber's scope of practice?
- Has patient's identity been verified?
- Has PA PDMP been checked?



Appropriateness:

- Is opioid indicated for patient's pain?
- Have other agents been tried?
- Is current regimen meeting treatment goals?
- Can opioids be reduced to a lower dosage or discontinued?

Safety:

- Are there any medications that may interact (e.g., benzodiazepines)?
- Is patient using alcohol or illicit substances?



Look for red flags

Look for signs of opioid use disorder or diversion of prescription opioids. PA PDMP will help identify some of these red flags.

- Forged prescriptions presented with unusual wording or abbreviations, absence of typical abbreviations, overly meticulous writing, or an unusual signature
- Altered prescriptions presented with multiple colors, ink types, or handwriting styles on one prescription
- Patients or prescriptions originating from outside the local geographic area
- Prescribers practicing outside their scope of practice
- Prescriptions for high dosages or high quantities
- Patients appearing intoxicated
- Patients who pay with cash only
- Patients who ask for early refills
- Patients with multiple prescribers or multiple pharmacies



If prescription opioid misuse is suspected:

- A pharmacist should contact the prescriber to obtain more information. If a pharmacist cannot determine validity of a prescription, the prescription should be refused until validity can be determined.

In case of fraudulent or theft situations:

- Call the Pennsylvania State Board of Pharmacy to report the dispenser at 717-783-7156.
- Anonymously text the Pennsylvania Office of Attorney General to submit tips about suspicious activity by texting PADRUGS + YOUR TIP to 847411.
- Report illegal prescription drug sales or suspicious internet pharmacies by calling 877-RxAbuse (877-792-2873). This number is a Drug Enforcement Administration tip line.
- Report suspicious activity involving prescription medications with the Pennsylvania Prescription Drug Diversion: Suspicious Activity Report found here: <https://www.attorneygeneral.gov/rx/>



Assess for risk of overdose

Patients at highest risk of overdose include:

- Those who have had a prior overdose
- Those taking higher doses of opioids (≥ 50 morphine milligram equivalents or MME/day; resource for calculating MME: tinyurl.com/lvfdksv)
- Those who use opioids while they are alone (not at greater risk for overdose, but at greater risk for fatal overdose)
- Those with reduced tolerance, e.g., period of abstinence (including incarceration or rehab) or a change in dose
- Those using other substances concomitantly, particularly alcohol, benzodiazepines, or cocaine
- Those with chronic medical illnesses that impact lung, liver, and kidney functions





How to talk about opioids

Communicating with patients

General tips:

- Be empathic. Don't be judgmental.
- Ask open-ended questions.
- Use active listening techniques.
- Use clear words. Avoid technical verbiage.
- The approach should be “risky medicines” not “risky patients.”
- The term “overdose” carries stigma especially to prescription opioid users. Use terms such as “toxicity,” “bad reaction,” and “antidote.”
- Direct patients to additional resources.



Questions you might ask to engage patients:

- What medications are you currently taking?
- What pain medications have you taken and how have they worked for you?
- How well is your medication working to relieve your pain?
- What other ways do you have to help manage your pain?
- Are you experiencing any side effects from your medications?
- Do you know which medications you should avoid taking with your opioid medication?
- Do you have any questions for me about any of your medications?

Provide education about:

- Pain management
- Proper use of opioids, including dosing and refill expectations
- Avoiding alcohol, benzodiazepines, and other CNS depressants when taking opioids
- Safe and secure storage which restricts access to others, and safe disposal of unused medication
- Opioid use disorder (provide resources and referral to treatment)
- Risks and signs of opioid overdose (provide resource such as “Opioid safety and how to use naloxone” trifold)
- Use of naloxone to reverse overdose



How to talk about opioids *(continued)*

Communicating with prescribers

When to call prescribers:

- Fraudulent prescription presented
- Patient appears intoxicated
- PA PDMP elicits concern (e.g. multiple prescribers)
- Patient taking other CNS depressants (e.g., benzodiazepines)
- Patient presenting early for refill

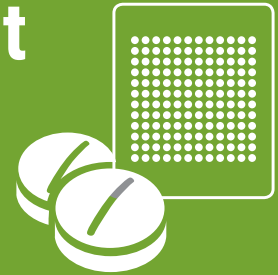


Benefits of communicating with prescribers:

- Collaborate with prescribers to optimize pain management for patients.
- Reduce potential for misuse or diversion by communicating about any red flags.
- Reduce potential for overdose by discussing concerns about concurrent medication or substance use.
- Provide recommendations to prescribers when medication assisted treatment (MAT) for opioid use disorder is indicated.
- Identify prescribers in your community who are pain management specialists.
- Identify prescribers in your community who provide MAT.



Treating opioid use disorder: medication-assisted treatment



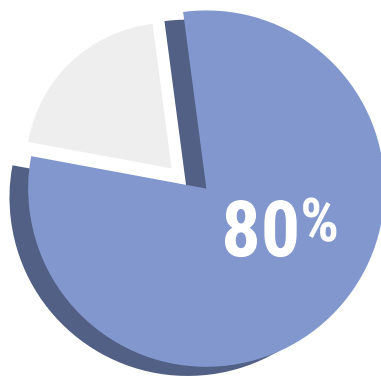
Use of medication-assisted treatment (MAT) has been shown to increase recovery rates, decrease overdose deaths, decrease criminal activity, and lower the risk of infections such as HIV and hepatitis C.



Overview

Medication-assisted treatment (MAT) is the use of medications such as buprenorphine, methadone, and extended release naltrexone, often in combination with counseling and behavioral therapies, to treat opioid use disorder.

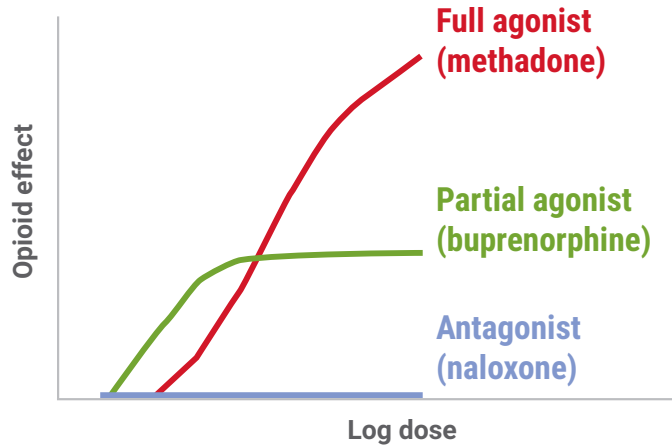
- Barriers to MAT include stigma of addiction (substance use disorder), not recognizing opioid use disorder, a lack of awareness of treatments available, lack of physician training, and limited access to treatments and treatment providers.
- For more information and a detailed resource on MAT, please visit the Substance Abuse and Mental Health Services Administration (SAMHSA) MAT webpage: <https://www.samhsa.gov/medication-assisted-treatment>



Nearly 80% of those with an opioid use disorder don't receive treatment.⁹



Buprenorphine



BUPRENORPHINE

- A partial opioid agonist
- Typically lasts 36 hours
- Has very high affinity, blocking effects of heroin or other opioids

Formulations

STANDARD FOR OPIOID USE DISORDER:

- Coformulated buprenorphine/naloxone SL tab
- Coformulated buprenorphine/naloxone SL and buccal film



IF PATIENT DOES NOT TOLERATE/CANNOT ACCESS COFORMULATED PRODUCTS:

- Monoformulated buprenorphine SL tablets



LONG ACTING BUPRENORPHINE PRODUCTS:

- Monoformulated buprenorphine subdermal implant
- Monoformulated buprenorphine extended release monthly injection





Buprenorphine *(continued)*

FOR OPIOID USE DISORDER:

- No prior authorization necessary for PA Medicaid
- Medication is generally administered sublingually and daily
- Medication is generally administered sublingually and daily, but long-acting injectable formulations are also available and may be beneficial due to increased compliance

Clinical pearls

- “Ceiling effect” due to partial agonism; lower potential for misuse, diversion, respiratory depression, and overdose than other opioids
- Co-formulation products are not appropriate for use in opioid overdose; naloxone is added to reduce potential for diversion or injection
- Combination product favored except in pregnant women
- Generally prescribed in very limited quantities to ensure close follow up, particularly early in treatment; opportunities for pharmacist to actively assist patients in treatment for opioid use disorder



Buprenorphine *(continued)*

Patient counseling tips

- Sublingual tablets or film should be kept under tongue and buccal film should be placed on the inside of cheek until completely dissolved. Due to low oral bioavailability, swallowing will result in reduced effect and may induce withdrawal symptoms.
- Tablets, sublingual film, and buccal film are not equivalent; some patients may require a change in dose when transitioning from one product to another.
- Avoid combining with other CNS depressants, such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medication assisted treatment should not be withheld from patients taking other CNS depressants and buprenorphine may be a safer option than methadone.
- Store in a safe and secure location to prevent accidental ingestion by others.



Methadone

Clinical pearls

- Full opioid agonist
- Methadone for pain prescribed then dispensed by pharmacies, but methadone for opioid use disorder only dispensed through opioid treatment programs
- Long half life (up to 59 hours), may accumulate
- QT prolongation and increased risk for serious arrhythmias
- Potential for drug interactions
- Respiratory depression and overdose risk
- Methadone dispensed from narcotic treatment programs not reported to PA PDMP (prescriptions dispensed at pharmacies reported)

Patient counseling tips

- **Many medications may interact with methadone;** check with physician or pharmacist anytime you start or stop a new medicine.
- **Report excessive sedation, shallow breathing, or dizziness** to physician.
- **Avoid combining with other CNS depressants,** such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medication assisted treatment should not be withheld from patients taking other CNS depressants.



Extended release naltrexone

Clinical pearls

- Opioid antagonist; blocks euphoric effects of opioid agonists
- No addiction potential; not a controlled substance; may be prescribed by any prescriber
- More effective than oral naltrexone for opioid use disorder but less favored by patients compared to buprenorphine or methadone
- Withdrawal may be precipitated if agonists (full or partial) are on board; must be 7-10 days without other opioids before starting naltrexone (up to 14 days after discontinuing long-acting opioids such as buprenorphine or methadone)
- Increased risk for overdose during washout period prior to starting treatment, or during treatment if large amounts of opioids used to overcome naltrexone's opioid blockade
- Increased risk of overdose with relapse after extended release naltrexone discontinuation due to loss of tolerance
- Improved adherence with monthly dosing

Patient counseling tips

- Because a patient's tolerance to opioids may be reduced, the patient's risk for overdose is increased during the waiting period to initiate naltrexone and after stopping naltrexone.



Additional medical care for patients with opioid use disorder

Due to increased risk for various complications, patients with an opioid use disorder should also be considered for:



Screening for infections such as HIV, hepatitis B, hepatitis C, sexually-transmitted infections and tuberculosis (at least annually for most patients)



Vaccinations such as hepatitis A, hepatitis B, tetanus-diphtheria- pertussis, influenza and pneumococcus



Aggressive management of cardiac risk factors, particularly for people who also use stimulants or tobacco, including blood pressure and lipid control, as well as smoking cessation



Treatment of other comorbid substance use disorders, including tobacco and alcohol use disorders



Treatment of comorbid psychiatric disorders



Recommendation of clean injection equipment for the prevention of infectious diseases



Lay terminology for syringes/needles

Some patients may not know the standard terminology for the syringe/needle they want to purchase and will need to ask the pharmacy staff to assist them by showing which are available for purchase. Below is an overview of syringes/needles that customers may seek to purchase and the associated slang terms.

SLANG TERM	USE	TECHNICAL INFORMATION
“Super Shorts”	Used for surface veins	Comes in two volumes: <ul style="list-style-type: none"> • 31 gauge, 5/16 inch needle, 1 cc barrel • 31 gauge, 5/16 inch needle, 1/2 cc barrel
“Micros” (“Fulls”)	Used for small veins, including those in the hands and feet	29 gauge, 1/2 inch needle, 1 cc barrel
“Micros” (“Halves”)	Same as above but holds half the volume	29 gauge, 1/2 inch needle, 1/2 cc barrel
“Shorts”	The standard syringe	28 gauge, 1/2 inch needle, 1 cc barrel
“Halves” (“50s”)	Same as above but holds half the volume	28 gauge, 1/2 inch needle, 1/2 cc barrel
“Longs”	Used for deep or scarred veins	27 gauge, 5/8 inch needle, 1 cc barrel
“Muscle”	Used for injecting into muscle	Comes in two lengths and two gauges: <ul style="list-style-type: none"> • 25 gauge, 1 inch needle, 3 cc barrel • 23 gauge, 1-1/2 inch needle, 3 cc barrel

Adapted with permission from Project Inform: projectinform.org/pdf/CAsyringesFACTSHEET.pdf

Providing access to naloxone



Naloxone saves lives

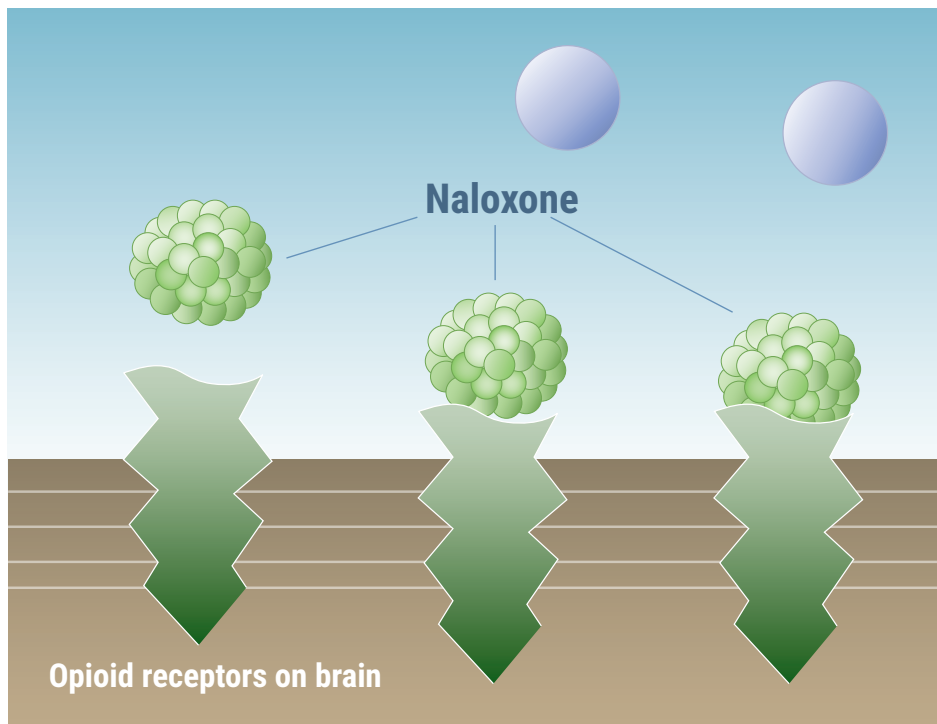
In Pennsylvania, a health care professional authorized to prescribe or dispense Naloxone can provide it to the Eligible Person under Act **139-2014**: [tinyurl.com/yacp5kg3](https://www.tinyurl.com/yacp5kg3)



Naloxone

NALOXONE MECHANISM OF ACTION

- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids
- Naloxone is not a controlled substance and doesn't get people "high"
- Lasts 30-90 minutes
- Can be administered by laypeople
- Virtually no side effects or effects in the absence of opioids
- Should still be given if overdose is due to combination of opioids and other drugs





State law encourages naloxone prescribing

Naloxone is NOT a controlled substance. Any licensed healthcare provider can prescribe naloxone. David's Law - PA Act 139 of 2014 provides additional protections to encourage naloxone prescribing and distribution.



PROVIDER AND PATIENT INFORMATION

- Providers are encouraged to prescribe naloxone to patients receiving a chronic opioid prescription.
- Naloxone prescriptions also can be written directly to third party individuals (caregivers, family members, friends, etc.) who are in a position to witness and assist a person at risk of an opioid overdose.
- A licensed healthcare prescriber can issue a standing order for the dispensing of naloxone by healthcare or community workers to individuals at risk of experiencing or witnessing an overdose.
- Members of the community, family members, friends, and bystanders may be prescribed naloxone and can lawfully administer the drug to someone who is experiencing an overdose.

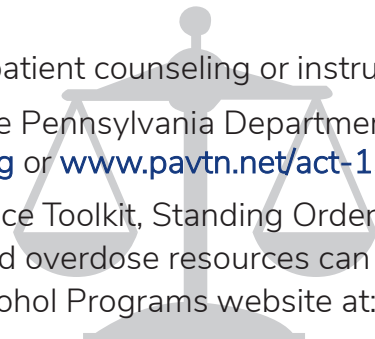
Additional resources for prescribers can be found at www.prescribetoprevent.org. Individuals are encouraged to complete overdose awareness and naloxone administration training at: www.getnaloxonenow.org or www.pavtn.net/act-139-training. Completion of this training is not a requirement to prescribe naloxone to an individual. However, it will prepare them to respond appropriately to an opioid related overdose event.

GOOD SAMARITAN PROTECTION (David's Law - PA Act 139)

- Through the Good Samaritan provision of Act 139, witnesses of an overdose who seek medical help are provided legal protection from arrest and prosecution for minor drug and alcohol violations.

COUNSELING

- Instruct patients to administer if non-responsive from opioid use and how to assemble for administration.
- Include family/caregivers in patient counseling or instruct patients to train others.
- Free training approved by the Pennsylvania Department of Health can be accessed online at: www.getnaloxonenow.org or www.pavtn.net/act-139-training.
- A Friends and Family Guidance Toolkit, Standing Order (which serves as a prescription) for naloxone, and other opioid overdose resources can also be found at the Pennsylvania Department of Drug and Alcohol Programs website at: www.ddap.pa.gov.





Identifying patients for naloxone

- Patients who have previously experienced opioid intoxication or overdose
- Patients with recent period of opioid abstinence and reinitiation of opioid
- Patients on long-term opioid therapy, on high dose opioids (≥ 50 morphine milligram equivalents/day), or those with recent increase in dosage
- Patients with a history of nonmedical use of opioids or other substance use disorder (including, but not limited to, alcohol, marijuana, cocaine, methamphetamines)
- Patients on long-acting opioids (e.g., methadone, fentanyl patch) or on regimens of multiple opioids
- Patients on concurrent benzodiazepine or other CNS depressant
- Patients requesting access to naloxone
- Family members or friends of any patient meeting above criteria or anyone at risk of witnessing an overdose (as third party prescribing or furnishing)





Pharmacy access

All pharmacies can fill naloxone prescriptions, but naloxone is new for many pharmacists so some may not know how. If a pharmacist is unsure how to fill a naloxone prescription, the information outlined on this page may be helpful.

Pennsylvania has a standing order in place for naloxone. A standing order is a pre-written medication order and specific instructions laid out by a physician. Standing orders allow pharmacies to dispense medication, rather than needing a separate prescription written out to each individual by his/her personal physician for the medication. A copy of the standing order can be found on the Department of Drug and Alcohol website at: www.ddap.pa.gov.

In some instances, insurance may not pay for a prescription that is not written for/issued to a specific individual by name or intended for use by their insured. In this instance, it may still be helpful to acquire a prescription written by a healthcare provider to a particular person.

ORDERING:

- Intranasal (FDA Approved): NDC#69547-353-02
- MAD (atomizer) nasal devices produced by Teleflex*
- Auto-injector: NDC#60842-051-01
- Injectable: Hospira NDC#00409-1215-01; Mylan DC#0409-1215-01

BILLING:

- Naloxone is covered by Medicaid, Medicare and many other private insurance plans.
- The MAD does not have an NDC, therefore cannot be billed through usual pharmacy billing routes. Pharmacies may be willing to cover the cost of the MAD or patients may be requested to pay for the cost of the MAD, which is around \$5 per atomizer.

SIDE EFFECTS: Anxiety, sweating, nausea/vomiting or shaking. Talk to your doctor if these occur. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.



Educate patients and caregivers about preventing overdose



How to counsel patients and caregivers

- Only take medicine prescribed to you.
- Don't take more than prescribed; call your doctor if pain not controlled.
- Don't mix with alcohol or sleeping pills.
- Don't use alone; don't use opioids from an unknown source.
- Abstinence lowers tolerance; take less upon restart.
- Store in a secure place.
- Dispose of unused medications.
- Teach your family and friends how to respond to an overdose and how to use naloxone.
- If you are having difficulty taking opioids safely, I can refer you to help.





How to respond to an overdose

1 Recognize the signs of an overdose

- Slow or shallow breathing; gasping for air while sleeping; pale, clammy, or bluish skin or fingernails; slowed heartbeat; low blood pressure; won't wake up or respond (rub knuckles on sternum)

2 Call 911 and give naloxone

- Administer dose per instructions in patient education guides provided with naloxone products, or view educational videos online: prescribetoprevent.org/patient-education/videos.
- Assess response; give repeat dose if no or minimal response in 2-3 minutes.
- Lay the person on his or her side to prevent choking.
- Quick response improves survival.
- Say “Someone is unresponsive and not breathing.” Give clear address and location.

3 Follow 911 dispatcher instructions

- Clear airway, give rescue breaths if not breathing and/or chest compressions.
- With victim laying flat on back, put one hand on chin, tilt head back, pinch nose closed, make seal over mouth, and breathe 1 breath every 5 seconds. Chest should rise, not stomach.

4 Stay until help arrives—naloxone effects last 30-90 minutes

- Patient can go back into overdose if long-acting opioids were taken (e.g., fentanyl patch, methadone, extended release formulations of morphine or oxycodone).
- Following up naloxone administration with medical care is important.



Naloxone formulations

These devices are designed for lay use. Manufacturers provide written patient education.

INTRANASAL (NARCAN)

- Naloxone 4mg (two pack, NDC: 69547-353-02)
- Dispense #1
- SIG: Use as needed for suspected opioid overdose. Spray into one nostril upon signs of opioid overdose. Repeat into other nostril with a new spray after 2-3 minutes if no or minimal response.
- Call 911.
- Repeat in each nostril after 2-3 minutes if no response until help arrives.



AUTO-INJECTOR (EVZIO)

- Naloxone auto-injector 2mg (two pack, NDC: 60842-051-01)
- Dispense #1
- SIG: Use as needed for suspected opioid overdose. Inject IM into outer thigh, depress and hold for 5 seconds, as directed by voice prompt system upon signs of opioid overdose. Repeat with second device in 2-3 minutes if no or minimal response. Call 911.



Note: Evzio 0.4 mg auto-injector no longer manufactured.

- Inform patients to alert others about naloxone, how to use it and where it's kept, as it is generally not self-administered.
- Shelf life is 12-24 months; store at room temperature.
- Side effects include risk for withdrawal, anxiety, sweating, nausea/vomiting, or shaking.



Naloxone formulations *(continued)*

If the devices on the previous page are not available, dispense the injectable formulation and provide thorough education on assembly and use.

INJECTABLE

- Naloxone 0.4mg/ml 1ml single dose vial (NDC: Hospira 0409-1215-01; Mylan 67457-292-00)
 - Dispense #2
 - SIG: Use as needed for suspected opioid overdose. Inject 1 ml IM in shoulder or thigh upon signs of opioid overdose. Repeat after 2-3 minutes if no or minimal response. Call 911.
- 3ml syringe with 25g 1" needle
 - Dispense #2
 - Use as directed for naloxone administration.



Clinical pearls

- Can use 3ml syringe with 23-35 gauge 1-1.5 inch needles
- All components available at community pharmacies
- Third party reimbursement possible
- Some patients may not be comfortable with needles

FORMULATIONS NOT APPROPRIATE FOR PHARMACIST FURNISHING

DO NOT furnish these for take-home reversal of an opioid overdose:



- Buprenorphine/naloxone tablets or films (naloxone added as abuse deterrent)
- Naloxone Carpuject Luer Lock Glass Syringe (requires injector, difficult to assemble, not appropriate for layperson use)
- Min-I-Jet Fixed Needle Syringe (not appropriate for layperson use)



Frequently asked questions

Does insurance cover naloxone?

Insurance companies, including those who administer plans for self-funding health care coverage, vary in how they cover naloxone and other drugs used to treat an opioid overdose. Prior to having a naloxone prescription filled by a pharmacy, consumers are encouraged to check with their insurance carriers or health care benefits providers to find out whether naloxone is a covered benefit under their policy, and, if so, what form of naloxone is covered, as well as any cost-sharing amounts that may apply under their policy.

Will Fee-for-Service and the managed care organizations (MCOs) pay for naloxone dispensed under the standing order for Medical Assistance recipients?

Yes.

Will Fee-for-Service Medicaid and the Medicaid managed care organizations (MCOs) pay for naloxone dispensed under the standing order for Medical Assistance recipients?

Yes, per 55 Pa. Code, Chapter 1121 – Pharmaceutical Services - §1121.52, pharmacists can treat the standing order as a verbal order for Medical Assistance recipients.

Can a person other than the eligible Medical Assistance recipient (friend or family member) obtain the naloxone at the pharmacy on the recipient's behalf? Will the Medical Assistance Program make payment?

Pa. Medical Assistance will make payment for naloxone for the eligible Medical Assistance recipient.

Is prior authorization required by Medical Assistance for any of the naloxone products or supplies?

The Evzio® Auto-Injector is covered by Medical Assistance, but requires prior authorization.



Frequently asked questions *(continued)*

Where can a pharmacy access Medical Assistance billing procedures for naloxone and the nasal actuator?

The Fee-for-Service Program will post information related to billing for naloxone on the DHS Pharmacy Services website. Pharmacies will need to contact each MCO individually to obtain information about billing procedures. <http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/>

Will Medical Assistance copays apply for the naloxone products and nasal actuator?

No, the Medical Assistance copay will not apply.

Is there a limit to the number of times that a Medical Assistance recipient can get naloxone?

No, there is no limit to the number of fills that can be obtained.

How can someone with an addiction to prescription pain medicines, heroin or other drugs get help?

Treatment for drug abuse and addiction is available! You can find out more by calling the county drug and alcohol office where you live. For more information or to get the contact information for your local office, visit: <https://apps.ddap.pa.gov/GetHelpNow/> call 717-783-8200.

While it may be uncomfortable to talk to someone about their substance abuse problem, research shows that it is more likely for an individual to seek help for their problem within 30 days following an overdose if someone talks to them right after the overdose event about going to treatment.

Additional resources

Centers for Disease Control and Prevention (CDC) Clinical Tools: tinyurl.com/ltduw3v

- *Guideline for Prescribing Opioids for Chronic Pain*
- *Pharmacists: On the Front Lines*
- *Tapering Opioids for Chronic Pain*
- *Nonopioid Treatments for Chronic Pain*
- *Assessing Benefits and Harms of Opioid Therapy*
- *Calculating Total Daily Dose of Opioids for Safer Dosage*
- *Prescription Drug Monitoring Programs*
- **Free Opioid Guide App** (calculate total daily opioid dose, clinical guidance, motivational interviewing communication skills): tinyurl.com/kw4jbav
- **Prescription Opioids: What You Need to Know:** One-page patient education fact sheet for patients taking prescription opioids: tinyurl.com/n3ylg6p

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov/medication-assisted-treatment

- Regulations, training resources, and treatment guidelines for medication-assisted treatment (MAT) of opioid use disorder with buprenorphine, methadone, and naltrexone
- Opioid treatment program directory (services locator)

College of Psychiatric and Neurologic Pharmacists (CPNP)

- **Opioid Use Disorders: Interventions for Community Pharmacists:** Guideline to educate community pharmacists on interventions to provide safe access to opioids while protecting communities from consequences of misuse: cpnp.org/guideline/opioid
- **Naloxone Access: A Practical Guide for Pharmacists:** Guideline to educate community pharmacists on increasing access to naloxone: cpnp.org/guideline/naloxone

Additional resources *(continued)*

Prescribe to Prevent: prescribetoprevent.org

- Information on prescribing and dispensing naloxone
- Resources targeted to prescribers and pharmacists
- Excellent resources for patient education including posters and videos
- Resources related to legal and advocacy issues

Pennsylvania Department of Health: health.pa.gov

- Prescribing guidelines for different medical specialties on the safe and effective use of opioids in the treatment of pain: tinyurl.com/yaffl2sw
- Continuing education curriculum for prescribers titled Evidence-Based Prescribing: Tools you can use to fight the opioid epidemic: tinyurl.com/yd2v8ar6

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About this publication

This publication was adapted for use by the Pennsylvania Department of Drug and Alcohol Programs and the Pennsylvania Department of Health with permission from the San Francisco Department of Public Health (SFDPH), California Department of Public Health (CDPH), and Keck Graduate Institute (KGI)

The recommendations contained in this brochure are general and informational only; specific clinical decisions should be made by providers on an individual case basis.



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KEY INFORMATION

1. **If you believe, someone is experiencing an opioid overdose, call 911!**
2. **Remain with the person until first responders arrive. Act 139 provides that you will not be arrested or charged with parole violations or drug offenses if you call 911, provide all necessary information and remain with the person in distress.**
3. **Become familiar with how to use Naloxone before someone needs it, through the pharmacist, your medical provider, or online training.**
4. **If you have questions about the proper use of Naloxone, ask the pharmacist, contact your health care provider, or go to the DOH website at <http://bit.ly/OpioidsinPA>**

This standing order will automatically expire on the date that the physician whose signature appears below has ceased acting as Secretary of Health or until a health care professional otherwise authorized to prescribe Naloxone to the Eligible Person does so as authorized under Act 139-2014, whichever occurs first. This standing order will be reviewed, and may be updated, if there is relevant new science about Naloxone administration, or at least in 4 years.

 MD050119-L

Secretary of Health's Signature and License Number



Effective Date



Secretary of Health Name (Print)

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

STANDING ORDER DOH-002-2018

Naloxone Prescription for Overdose Prevention

Naloxone Hydrochloride (Naloxone) is a medication indicated for reversal of opioid overdose in the event of a drug overdose that is the result of consumption or use of one or more opioid-related drugs causing a drug overdose event.

I. PURPOSE

This standing order is intended to ensure that residents of the Commonwealth of Pennsylvania who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose (Eligible Persons), are able to obtain Naloxone. This order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Such organizations should utilize the medical professionals with whom they have a relationship to write prescriptions specific to personnel who would be expected to administer Naloxone, and would be wise to ensure that all such personnel are appropriately trained in the administration of Naloxone.

II. AUTHORITY

This standing order is issued pursuant to Act 139 of 2014 (Act 139) (amending The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 *et seq.*)), which permits health care professionals otherwise authorized to prescribe Naloxone to prescribe it via standing order to Eligible Persons.

III. AUTHORIZATION

This standing order may be used by Eligible Persons as a prescription or third-party prescription to obtain Naloxone from a pharmacy in the event that they are unable to obtain Naloxone or a prescription for Naloxone from their regular health care providers or another source. This order is authorization for pharmacists to dispense Naloxone and devices for its administration SOLELY in the forms prescribed herein.

IV. TRAINING AND INSTRUCTIONAL MATERIALS

Prior to obtaining Naloxone under this standing order, Eligible Persons are strongly advised to complete a training program approved by the Pennsylvania Department of Health (DOH) in consultation with the Pennsylvania Department of Drug and Alcohol Programs (DDAP), such as the one found on line at www.getnaloxonenow.org or at the DOH website at <http://bit.ly/NaloxoneinPA> and obtain a certificate of completion. Act 139 does not require training; however, training is necessary in order to ensure that Eligible Persons are protected from legal liability to the extent that Act 139 provides that the receipt of DOH/DDAP-approved training

and instructional materials and prompt seeking of additional medical assistance creates a rebuttable presumption that an Eligible Person acted with reasonable care in administering Naloxone.

V. SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

1. A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
2. Unresponsive or unconscious individuals.
3. Not breathing or slow/shallow respirations
4. Snoring or gurgling sounds (due to partial upper airway obstruction).
5. Blue lips and/or nail beds.
6. Pinpoint pupils.
7. Clammy skin.
8. Note that individuals in cardiac arrest from all causes share many symptoms with someone with a narcotic overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue skin/nail beds). If no pulse, these individuals are in cardiac arrest and require CPR.

VI. APPROPRIATE USE AND DIRECTIONS

Eligible Persons should be aware of the following information when dealing with a person who it is suspected is experiencing an opioid overdose event:

1. **Call 911 for EMS to be dispatched.**
2. In cardiac arrest or pulseless patients: Call 911 for EMS and start CPR if able and trained to do so. In cardiac arrest, CPR is the most important treatment, and any attempt to administer Naloxone should not interrupt chest compressions and rescue breathing.
3. Naloxone should only be given to someone suspected of opioid overdose as noted in the signs and symptoms listed in Section V above.
4. In respiratory arrest or a non-breathing patient: If able to do rescue breathing, rescue breathing takes priority over Naloxone administration. Administer Naloxone if possible while doing rescue breathing.
5. Administration of Naloxone (only give to someone with suspected opioid overdose based on signs and symptoms listed in Section V above).

A. INTRA-NASAL NALOXONE

Eligible Persons should be provided with the following:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration 1 mg/mL);
- b. Two mucosal atomization devices
- c. Patient information pamphlet containing dosage and administration instructions.

2. NARCAN Nasal Spray

- a. Carton containing two blister packages each with single 4 mg dose of naloxone in a 0.1 mL intranasal spray
- b. Package insert containing dosage and administration instructions.

Instructions for use:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Pop off two yellow caps from the delivery syringe and one red cap from the naloxone vial.
- b. Screw the Naloxone vial gently into the delivery syringe.
- c. Screw the mucosal atomizer device onto the top of the syringe.
- d. Spray half (1ml) of the Naloxone in one nostril and the other half (1ml) in the other nostril.
- e. Note: Administer the Naloxone in a quick burst to ensure that it is atomized. A slow administration will cause liquid to trickle in without being atomized properly, which will slow delivery to the bloodstream.
- f. Continue to monitor breathing and pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- g. If patient does not awaken after 4 minutes, administer second dose of Naloxone (if available) (1mL) briskly in one nostril and the other half (1mL) briskly in the other nostril.

- h. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.

2. NARCAN Nasal Spray

- a. Lay person on their back to receive a dose of NARCAN Nasal Spray.
- b. Remove NARCAN from the box. Peel back the tab with the circle to open the NARCAN Nasal Spray.
- c. Hold the NARCAN Nasal Spray with your thumb on the bottom of the plunger and first and middle fingers on either side of the nozzle.
- d. Tilt the person's head back and provide support under the neck with your hand. Gently insert tip of nozzle into one nostril until fingers on either side of the nozzle are against the bottom of the person's nose.
- e. Press the plunger firmly to give the dose of NARCAN Nasal Spray.
- f. Remove the NARCAN Nasal Spray from the nostril after giving the dose.
- g. Move the person onto their side after giving NARCAN Nasal Spray.
- h. Remain with the person, monitor breathing/pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- i. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.
- j. Watch the person closely. If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available, until the person responds or emergency medical help is received.

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

Eligible Persons should be provided with the following:

1. Two EVZIO (naloxone hydrochloride injection, USP) 0.4 mg auto-injectors or two 2.0 mg auto-injectors
2. A single Trainer for EVZIO
3. Patient instructions

Instructions for use:

1. Currently the only available auto injector comes with automated voice instructions (EVZIO®) and has a speaker that provides voice instructions to help guide you through each step of the injection.
 - a. Follow automated voice instructions.
2. If the auto-injection device does not come with automated voice instruction or the automated voice instruction is otherwise disabled, follow below. The auto-injection device should still work even if the automated voice instructions do not.
 - a. Prepare device
 - i. For EVZIO®
 1. Pull off the Red safety guard. Note: The Red safety guard is made to fit tightly. Pull firmly to remove. To reduce the chance of an accidental injection, do not touch the Black base of the auto-injector, which is where the needle comes out.
 - b. Hold injector with a fistful hand if possible and press firmly against outer thigh, until you hear a click or hiss. EVZIO® can be used through clothing. One auto injector delivers 0.4 mg or 2.0 mg naloxone.
 - c. Continue to hold pressure for a full 10 seconds to ensure full delivery of medication. Note: The needle will inject and then retract back up into the EVZIO® auto-injector and is not visible after use. Do not look for the needle as this will put you at risk for needle stick injury.
 - d. Continue to monitor breathing and pulse. If not breathing, give rescue breathing. If no pulse, start CPR.
 - e. If no response in 3-5 minutes, repeat the above instruction with a new auto-injection device.
 - f. Remain with the person, monitor and support breathing until he or she is under the care of a medical professional, such as a physician, nurse, or EMS.

C. REFILLS

Refills may be obtained as needed under this standing order.

VII. CONTRADICTIONS

Do not administer Naloxone to a person with known hypersensitivity to Naloxone or to any of the other ingredients contained in the packaging insert for Naloxone.

VIII. PRECAUTIONS

A. DRUG DEPENDENCE

Those who may be chronically taking opioids are more likely to experience adverse reactions from Naloxone. (See adverse reactions under section X below). Additionally, after administration, they may awaken disoriented. Being disoriented can sometimes lead to combative behavior, especially if Naloxone is given by someone unfamiliar.

B. RESPIRATORY DEPRESSION DUE TO OTHER DRUGS

Naloxone is not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and contact 911.

C. PAIN CRISIS

In patients taking an opioid medication for a painful illness such as cancer, administration of Naloxone can cause a pain crisis, which is an intense increase in the experience of pain as the Naloxone neutralizes the pain-relieving effect of the opioid medication. Comfort the patient as much as possible and contact 911 as the patient may need advanced medical treatment to ease the pain crisis.

IX. USE IN PREGNANCY (Teratogenic Effects: Pregnancy Category C)

Based on animal studies, no definitive evidence of birth defects in pregnant or nursing women exists to date. There also have not been adequate studies in humans to make a determination.

X. ADVERSE REACTIONS

A. OPIOID DEPRESSION

Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, abnormal heart beats, fluid development in the lungs and opioid acute withdrawal syndrome (see part B below), increased blood pressure, shaking, shivering, seizures and hot flashes.

B. OPIOID DEPENDENCE

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may cause an acute withdrawal syndrome.

Acute withdrawal syndrome may include, but not be limited to, the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, yawning, weakness,

shivering or trembling, nervousness, or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and fast heart beats.

Most often the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.