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THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Health

DIVISION OF PUBLIC HEALTH
Director's Office

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July 10, 2024

STATEWIDE MEDICAL STANDING ORDER TO DISTRIBUTE, DISPENSE, AND ADMINISTER an FDA APPROVED OPIOID OVERDOSE NASAL SPRAY

Always activate emergency medical response in suspected opioid overdose including calling 911.
If you are trained in Basic Life Support (BLS)/CPR, administer per guidelines at any time.
Other medical emergencies may exhibit similar signs and symptoms as opioid overdose.
Anticipate life-threatening symptoms of an opioid overdose to recur when naloxone wears off.
Support victim until medical help arrives. Naloxone does not replace professional medical attention.

ISSUANCE

Under the authority of AS 17.20.085, this standing order authorizes any approved Department of Health Project HOPE Overdose Response Program (ORP) to maintain supplies of FDA-approved opioid overdose nasal sprays for the purpose of distributing/administering to a person at risk of experiencing an opioid overdose or a family member, friend, caregiver, or other person in a position to administer the FDA-approved opioid overdose drug to a person at risk of experiencing an opioid overdose.

To become an approved Department of Health Project HOPE authorized Overdose Response Program (ORP), an entity must complete the following steps:

- Complete the ORP application form.
- Review and sign the Project HOPE ORP terms and conditions form.
- Submit the ORP application and terms and conditions to ProjectHOPE@alaska.gov
- Receive ORP training-the-trainer education delivered by a Project HOPE coordinator or designee.

All Department of Health Project HOPE Overdose Response Program (ORP) forms are located at https://dhss.alaska.gov/osmap/Pages/hope.aspx link

TREATMENT

The following drug regimens are approved to reverse an opioid overdose:

- Any FDA-approved opioid reversal nasal spray

https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone link

ORDER TO DISPENSE

Upon satisfactory assessment that the person to receive naloxone

- is a person at risk of experiencing an opioid overdose or a family member, friend, caregiver, or other person in a position to administer an opioid reversal agent to a person at risk of experiencing an opioid overdose; and
- has received education on recognizing the signs and symptoms of an opioid overdose and the proper emergency use and administration of naloxone nasal spray;

The ORP shall dispense:

- FDA-approved opioid overdose nasal spray with instructions for proper use and administration

Items to consider for distribution with naloxone nasal spray:

- Instructions on recognizing the signs and symptoms of an opioid overdose
- Personal protective equipment such as CPR barrier patient face shield with 3M filtrate hydrophobic, nitrile sterile single gloves x2, etc.

The authorized ORP logs all distributed naloxone nasal spray administrations and overdose rescues on a distribution tracker and report-back form approved by the State of Alaska Department of Health.

DIRECTION FOR ADMINISTRATION

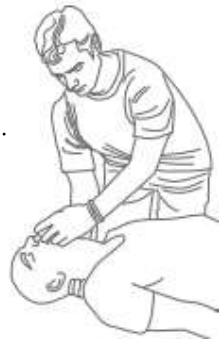
Administer an FDA-approved opioid overdose nasal spray to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:

Step 1: Activate emergency medical response

- Call 911
- Call for nearby help including retrieval of AED
- Initiate BLS/CPR if you are trained

Step 2: Check for heroin/opioid overdose signs

- If any of these signs are present, continue to Step 3:
  - Failure to respond when spoken to
  - Failure to wake up when prompted
  - Slow, interrupted, or no breathing
  - Tiny pupils (the center part of the eye)

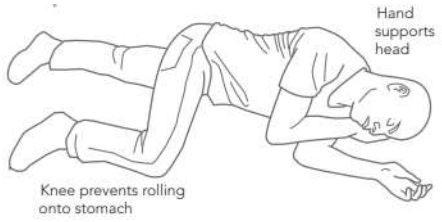


Step 3: Administer dose of the opioid overdose nasal spray

- Remove the opioid overdose nasal spray from package. Each sprayer contains one dose.
- Follow these steps:
  - Tum person on their back
  - Tilt their head back slightly
  - Support their neck with your hand
  - Insert the tip of the nozzle into either of the nostrils
  - Press the plunger firmly to deliver dose

Step 4: Evaluate person's condition

- Continue BLS/CPR if you are trained (check pulse, respirations, etc. and continue BLS/CPR per guidelines).
- Naloxone gives time to get help, but the person is still in danger until they get emergency medical help.
- Move the person onto their side (recovery position)
  - Use hands to support the head
  - Top knee bent forward at a right angle prevents person from rolling onto stomach



- Watch closely for a response
- Give them a second dose in the other nostril if they do not respond in 2 to 3 minutes by:
  - Waking up
  - Responding to voice or touch
  - Breathing normally
- Naloxone nasal spray can be given every 2 to 3 minutes, if available
- Stay with the person until emergency medical responders arrive.

SIGNATURE

Robert T. Lawrence, MD
Alaska State Chief Medical Officer

11/01/2024
Date

STANDING ORDER OF THE STATE HEALTH OFFICER
OPIOID REVERSAL AGENT DISTRIBUTION FOR OVERDOSE PREVENTION

Naloxone Hydrochloride (naloxone) and nalmefene* are opioid antagonists indicated for the reversal of an opioid overdose, whether from legally prescribed opioids or from illegal opioids such as heroin or illegally produced fentanyl, in the setting of respiratory depression or unresponsiveness. Naloxone may be delivered intranasally with a mucosal atomizer device, intranasally with a nasal spray, or intramuscularly with a needle; and nalmefene is delivered intranasally with a nasal spray.

*Nalmefene is approved for persons 12 years of age and older.

I. PURPOSE

This Standing Order is intended to ensure that opioid reversal agents are readily obtainable by any person who is:

A. An individual at risk of experiencing an opioid-related overdose.

B. A family member, friend, or other individual, including law enforcement, fire department, rescue squad, and volunteer fire department personnel, who is in a position to assist a person at risk of experiencing an opioid-related overdose.

II. AUTHORITY

This Standing Order is issued pursuant to Act 2016-307, which authorizes the State Health Officer to prescribe opioid reversal agents via standing order.

III. AUTHORIZATION

This Standing Order may be used as a prescription to obtain an opioid reversal agent from a pharmacy in the event there is an inability to obtain an opioid reversal agent or a prescription for an opioid reversal agent from an eligible person's regular healthcare provider or another source. This order is authorization for pharmacists to dispense the opioid reversal and devices for its administration solely in the forms prescribed herein.

IV. ORDER TO DISPENSE

Upon receipt of written communication that provides a factual basis for a reasonable conclusion that the person to receive the opioid reversal is an eligible person, **and** upon receipt of basic instruction and information on how to recognize and respond to a possible opioid overdose and

how to administer the opioid reversal agent, dispense one opioid reversal agent kit (*refer further to Protocol, Pharmacist Actions set out on page 5*). Opioid reversal agent kits may be dispensed in bulk quantities to law enforcement agencies, fire departments, rescue squads, and volunteer fire departments.

Pharmacists should use clinical judgment to determine preferred formulation. Unlimited refills are authorized.

A. Intranasal naloxone with atomizer kits must contain a minimum of the following:

- Two 2-mL Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2 mg/2 mL).
- Two mucosal atomization devices.
- Step-by-step instructions for administration of intranasal naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.

B. Intranasal naloxone spray kits must contain a minimum of the following:

- One package of two doses of naloxone nasal spray.
- Step-by-step instructions for administration of intranasal naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.

C. Intranasal nalmefene spray kits must contain a minimum of the following:

- One package of two doses of nalmefene nasal spray.
- Step-by-step instructions for administration of intranasal nalmefene including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.

D. Intramuscular naloxone kits must contain a minimum of the following:

- Two single-use 1 mL vials of naloxone hydrochloride.
- Two intramuscular needles with syringes.
- Step-by-step instructions for administration of intramuscular naloxone including a possible second dose, along with basic instructions on calling 911, providing rescue breathing, and monitoring the overdose victim until professional help arrives.

V. APPROPRIATE USE AND DIRECTIONS

A. Call 911 as soon as possible for a person suspected of an overdose with respiratory depression or unresponsiveness and initiate rescue breathing.

B. Administer the opioid reversal agent as follows (pharmacist to indicate to the client which instructions to follow based upon the form of an opioid reversal agent being dispensed):

1. Intranasal naloxone with syringe and atomizer:

- Pop off two-colored caps from the delivery syringe and one from the naloxone vial.
- Screw the naloxone vial gently into the delivery syringe.
- Screw the mucosal atomizer device onto the tip of the syringe.
- Spray half (1 mL) of the naloxone in one nostril and the other half (1 mL) in the other nostril.
- Repeat if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

2. Intranasal naloxone in nasal spray device:

- Deliver one spray into one nostril (do not "prime" or test the spray device before spraying it into the nostril, as this will waste the medicine).
- Repeat with the second nasal spray device in the opposite nostril if there is no response after 2-3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

3. Intranasal nalmefene in nasal spray device:

- Deliver one spray into one nostril (do not "prime" or test the spray device before spraying it into the nostril, as this will waste the medicine).
- Repeat with the second nasal spray device in the opposite nostril if there is no response after 2-5 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

4. Intramuscular naloxone with syringe and needle:

- Uncap the naloxone vial and uncap the needle on the syringe.
- Insert the needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 mL of naloxone liquid, and withdraw the needle.
- Insert the needle into the muscle of the upper arm or thigh of the victim, through the clothing if needed, and push the plunger to inject all of the naloxone.
- Repeat the injection with second 1 mL vial of naloxone if there is no response after 3 minutes, or if the victim relapses back into respiratory depression or unresponsiveness before emergency assistance arrives.

C. Continue to monitor respiration and responsiveness of the victim, and continue to provide rescue breathing as necessary until emergency assistance arrives.

VI. CONTRAINDICATIONS

Do not administer an opioid reversal agent to a person with known hypersensitivity to the product or to any of the other ingredients listed in the packaging insert for the product.

VII. PRECAUTIONS

Respiratory depression due to other drugs. Opioid reversal agents are not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and call 911.

VIII. ADVERSE REACTIONS

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, increased blood pressure, shaking, shivering, seizures, and hot flashes.

IX. EXPIRATION AND REVIEW

This Standing Order will be reviewed, and may be updated, if there is relevant new science about the administration of an opioid reversal agent and will be posted at http://www.alabamapublichealth.gov, search Opioid Reversal Agents.

Scott Harris, M.D., M.P.H.
State Health Officer
NPI Number: 1992713408
License Number: MD.16614

9/21/2023
Date

PROTOCOL FOR NALOXONE STANDING ORDER

I. INDICATIONS AND USAGE

Opioid reversal agents are indicated for the complete or partial reversal of opioid overdose induced by natural or synthetic opioids, and evidenced by respiratory depression or unresponsiveness.

II. ASSESSMENT

A. There is a factual basis for a reasonable conclusion that the individual to receive the opioid reversal agent is an individual at risk of experiencing an opioid-related overdose, or is a family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose.

B. The individual to whom the opioid reversal agent is dispensed is able to understand the essential components of overdose recognition and response and opioid reversal agent administration.

C. The person to potentially be administered the opioid reversal agent, if known, does not have a history of known serious adverse reaction to the medication. Note that opioid withdrawal symptoms, including body aches, abdominal cramps, diarrhea, nausea or vomiting, increased heart rate, restlessness or irritability, shivering or trembling, can be expected with reversal of an opioid overdose, and should not be equated with a serious adverse reaction to the opioid reversal agent.

III. PHARMACIST ACTIONS

A. Provide basic instruction on recognition of opioid overdose, calling 911, rescue breathing, and administration of the opioid reversal agent as described in the Standing Order.

B. Dispense the opioid reversal agent kit and explain contents to the individual.

C. Counseling: Offer information on risk factors for opioid overdose, overdose prevention measures, risk and recognition of addiction, and resources for mental health and addiction treatment services.

D. Have client complete and sign Client Form (page 6) attesting to need for the opioid reversal agent , receipt of instructions, and offer of counseling. If bulk dispensing to a law enforcement agency, fire department, rescue squad, or volunteer fire department, have the agency representative complete and sign the Agency Form (page 7).

E. Keep a record of all clients who have received the opioid reversal agent via this Standing Order.

Scott Harris, M.D., M.P.H.
State Health Officer
NPI Number: 1992713408
License Number: MD.16614

9/21/2023
Date

OPIOID REVERSAL AGENT CLIENT FORM

1. Check one:

   a) ___ I am an individual at risk of experiencing an opioid-related overdose.

   b) ___ I am a family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose.

Write in this box the facts that support the statement checked above (this information will be kept confidential, but it is needed to verify your need for an opioid reversal agent):

2. ___ I have received information on how to recognize and respond to a possible opioid overdose.

3. ___ I have received basic instructions on how to administer the opioid reversal agent.

4. ___ I have been offered information/counseling on risk factors for opioid overdose, overdose prevention measures, risk and recognition of addiction, and resources for mental health and addiction treatment services.

I understand that I may administer an opioid reversal agent to another individual if I have a good faith belief that the individual is experiencing an opioid-related overdose, and if I exercise reasonable care in administering the opioid reversal agent.

Signature: _____ Date Signed: _____

Print Name: _____ Date of Birth: _____

OPIOID REVERSAL AGENT AGENCY FORM

1. ___ I am a representative of an agency that responds to emergencies involving individuals who may be at risk of experiencing an opioid-related overdose or to emergencies that may place the first responder at risk for exposure to opioids.

Name of Agency: _____

Write in this box the facts that support the statement checked above (this information will be kept confidential, but it is needed to verify your need for an opioid reversal agent):

2. ___ I have received information on how to recognize and respond to a possible opioid overdose.

3. ___ I have received basic instructions on how to administer the opioid reversal agent.

4. ___ I will ensure that all persons within my agency who have access or who may at some time administer the opioid reversal agent are trained.

Signature: _____ Date Signed: _____

Print Name: _____ Date of Birth: _____

Arkansas Opioid Antagonist Protocol

Opioid antagonists are medications that reverse or block the effects of opioid analgesics. Timely administration of an opioid reversal agent (opioid antagonist) in the event of an opioid overdose can stop the potentially fatal respiratory depression that is linked with an opioid overdose. Factors that increase risk for an opioid overdose include a history of overdose or substance use disorder, opioid dosages ≥50 MME per day, and concurrent use of benzodiazepines, muscle relaxants or other similar drugs, all of which are indications for prescribing naloxone that providers should consider.

Purpose

The purpose of this standing order is to reduce the morbidity and mortality of opioid overdoses in Arkansas by allowing Arkansas-licensed pharmacists to initiate therapy including ordering, dispensing and/or administering opioid antagonists, along with any necessary supplies for administration, to eligible persons who are at risk of experiencing an opioid-related overdose, or who are family members, friends, or others who are in a position to assist a person at risk of experiencing an opioid-related overdose.

Authority and Eligibility

This standing order is issued pursuant to (Arkansas Code § 17-92- 101(18)) to authorize licensed pharmacists in Arkansas to order, dispense and/or administer naloxone according to the provisions of Arkansas Code § 17-92-101(18) and the requirements of this standing order.

In addition to naloxone, Pursuant to Arkansas Code § 20-13-1804:
(a) A healthcare professional acting in good faith may directly or by standing order prescribe, dispense, and supply an opioid antagonist to:

(1) A person at risk of experiencing an opioid-related drug overdose;
(2) A family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose;
(3) An individual who is employed or contracted by a public or private organization, including without limitation:
  (A) A state, municipal, or county entity;
  (B) A hospital or clinic;
  (C) A law enforcement agency;
  (D) A harm reduction organization;
  (E) A shelter or homeless services organization;
  (F) An educational institution;
  (G) A building manager; or
  (H) A pain management center;
(4) An emergency medical services technician;
(5) A first responder;
(6) A law enforcement officer; or
(7) An employee of the State Crime Laboratory.

Additional Guidelines

Contraindications:
Do not administer an opioid antagonist if there is a known hypersensitivity to the medication or any of its components.

Product Availability:
An Arkansas Licensed Pharmacist may prescribe, dispense and supply any fast-acting Opioid Antagonist such as naloxone and nalmefene products that are FDA approved and commercially available to qualifying patients to be used according to manufacturer instructions.
Common examples of opioid antagonists include but are not limited to:
Naloxone in various forms: nasal spray, solution, autoinjector
Nalmefene nasal spray

Warnings/Precautions:

1. Abrupt reversal of opioid effects in a person with a physical dependence on opioids can cause acute withdrawal symptoms such as, but not limited to, the following: nausea/vomiting, diarrhea, fever, body aches, sweating, sneezing, yawning, shivering/trembling, irritability, chills, anxiety, combativeness/disorientation .
2. Abruptly reversing the effects of opioids could result in a pain crisis due to neutralization of the analgesic effects of the opioid.
3. Opioid antagonists should be used with caution in patients with a history of seizures and/or cardiovascular disease.
4. Opioid antagonists will have no effect on respiratory depression caused from non-opioid substances.
5. Whenever an opioid antagonist is administered to reverse a potential opioid overdose, medical follow- up is needed as overdose reversal effects may wear off quickly resulting in the need for further medical care. Opioid antagonists should be considered a temporary overdose reversal agent with the potential need for multiple doses under acute medical care.

If you do not have a primary care provider you should consult a provider of your choice.

Protocol Approved by the Arkansas State Medical Board and the Arkansas State Board of Pharmacy. The prescriber of record for any pharmacy related paperwork may be listed as Dr. Bala Simon with ADH or the deciding pharmacist so that any questions back on this would be directed to the pharmacy and pharmacist using this protocol.

ARIZONA DEPARTMENT
OF HEALTH SERVICES

STANDING ORDERS FOR NALOXONE

This standing order is issued by Dr. Lisa Villarroel, MD MPH (NPI #1598085896), Chief Medical Officer of Public Health Services at the Arizona Department of Health Services. The standing order authorizes any Arizona-licensed pharmacist to dispense naloxone to any individual in accordance with the conditions of this order.

One of the following naloxone products can be dispensed to eligible persons based on product availability and preference.

☐	**For intranasal administration** Dispense: NARCAN™ 4mg/0.1mL nasal spray Sig: For suspected opioid overdose, administer a single spray of Narcan in one nostril. Repeat after 3 minutes if no or minimal response. Refills: PRN x 1 year
☐	**For intramuscular injection** Disp: 0.4mg/mL in 1mL single dose vials. Include one 3cc, 23g, 1" syringe per dose dispensed. Sig: For suspected opioid overdose, inject 1mL IM in shoulder or thigh, PRN opioid overdose. Repeat after 3 minutes if no or minimal response. Refills: PRN x 1 year
☐	**Other FDA approved medication for the reversal of opioid overdose** Refills: PRN x 1 year

Lisa Villarroel, MD MPH, Chief Medical Officer of Public Health Services, ADHS
Signed 8/23/23, expires 8/22/24

GEORGIA DEPARTMENT OF PUBLIC HEALTH

Kathleen E. Toomey, M.D., M.P.H., Commissioner / Brian Kemp, Governor

200 Piedmont Avenue, SE
Atlanta, Georgia 30334

dph.ga.gov

STANDING ORDER FOR PRESCRIPTION OF NALOXONE FOR OVERDOSE PREVENTION

I. Authority.

This Standing Order is issued pursuant to authority vested in me as the Commissioner of Public Health and State Health Officer, acting under Georgia Code Sections 31-1-10(b)(2), 31-2A-2(b), 31-2A-4, and 16-13-71(b)(635) and (c)(14.25).

II. Purpose.

The purpose of this Standing Order is to facilitate the widest possible availability of naloxone among the residents of this State, to ensure that family members, friends, co-workers, first responders, schools, pain management clinics, harm reduction organizations, and any other persons or entities ("Eligible Persons or Entities") are in a position to provide assistance to a person experiencing an opioid-related overdose through the timely administration of the opioid antagonist naloxone.

III. Authorization.

This Standing Order may be used by Eligible Persons or Entities as a prescription to obtain naloxone from a licensed Pharmacy. This Standing Order is authorization for a Pharmacy to dispense naloxone in any of the forms shown on the attached Exhibit A. Prior to obtaining naloxone under this Standing Order, Eligible Persons and Entities are strongly advised to complete a training program in the administration of opioid antagonists, such as the course available from the Georgia Department of Public Health through this portal:

https://dph.georgia.gov/approved-training

Eligible Persons and Entities are further advised to become familiar with the following **Signs and Symptoms of Opioid Overdose** and the appropriate use of naloxone as directed by the manufacturer and the pharmacist.

IV. Signs and Symptoms of Opioid Overdose.

It is crucial to call 911 immediately upon discovering a possible case of opioid overdose or any medical emergency.

The following are signs and symptoms of an opioid overdose:

- The victim has a history of use of narcotics or opioids (either in prescription drug form or illegal drugs, such as heroin).
- Fentanyl patches or needle punctures in the skin.
- The presence of nearby drug paraphernalia such as needles or rubber tubing.
- The victim is unresponsive or unconscious.
- Breathing is slow, or shallow, or not present.
- Snoring or gurgling sounds from the throat due to partial upper airway obstruction.
- Lips and/or nail beds are blue.
- Pinpoint pupils.
- Skin is clammy to the touch.

Note that these symptoms may also indicate other health conditions. Administering an opioid antagonist in such cases generally does not cause harm. If the victim has no discernable pulse, they require immediate CPR. It is important to note that the effects of opioid antagonists are temporary, and overdose symptoms may return. Furthermore, **it is crucial to call 911 immediately if someone is found unconscious and not breathing.**

I. Duration.

This Standing Order shall remain in effect until revoked by me or my successor in office.

This 4 day of December, 2024.

Kathleen E. Toomey, MD, M.P.H.
Commissioner
Georgia Department of Public Health

NPI No. 1407293889
DEA No. AT8967424

Exhibit A
STANDING ORDER FOR PRESCRIPTION OF OPIOID ANTAGONIST FOR OVERDOSE PREVENTION

(Substitution of Pharmaceutically Equivalent Product Allowed)

Considerations for selecting product:	•Treatment decisions may include but are not limited to the following: required administration technique, dosage, potency, elimination half-life, shelf-life, and affordability of medication. •Intranasal products may be easier for people who have no formal training, while injectable products may be preferable for those with experience administering medication with a needle. •A report from the US Centers for Disease Control and Prevention showed that administering an 8 mg dose of intranasal naloxone does not increase the odds of surviving an opioid overdose; a higher dose may result in a greater risk for onset of opioid withdrawal symptoms. https://www.cdc.gov/mmwr/volumes/73/wr/mm7305a4.htm

OPIOID ANTAGONIST	Route	Strength	Quantity	Additional Administration Supplies Required	Sig. (For suspected opioid overdose)	Supplied (other package sizes acceptable)
Naloxone Pre-filled needleless syringe	Nasal	1 mg/mL (2mL)	•This standing order does not require a minimum or a maximum quantity to be dispensed. • It is recommended the patient have at least 2 doses on hand.	(1) Teleflex mucosal atomizer devices (MAD-300) per pre-filled needleless syringe	Spray 1mL- (1/2 syringe) into each nostril via intranasal mucosal atomization device. Call 911 and seek immediate medical attention. May repeat dose in 3 to 5 minutes if no or minimal response.	Box of 10 or 24 Luer-Lock prefilled syringes
Naloxone Pre-filled syringe	IM or SC	5 mg/0.5 mL			Administer the single dose, prefilled syringe intramuscularly or subcutaneously into the outer thigh, through clothing if necessary. Call 911. If minimal or no response, may repeat using a new device every 2-3 minutes for continued or recurrent respiratory depression until EMS arrives.	Case containing one 5 mg/0.5 mL single-dose, prefilled syringe or carton of 2 cases, each of which contain one 5 mg/0.5 mL single-dose, pre-filled syringe.
Naloxone Intranasal Liquid	Nasal	3 mg/0.1 mL OR 4 mg/0.1 mL OR 4 mg/0.25 mL OR 8 mg/0.1 mL			Administer a single spray in one nostril upon signs of opioid overdose. Call 911. If minimal or no response, may repeat in alternating nostrils using a new nasal spray with each dose every 2-3 minutes for continued or recurrent respiratory depression until EMS arrives.	2 EA BOX
Naloxone Injection Solution	IM	0.4 mg/mL (1 mL)		(1) 3mL syringes w/ 21-25 gauge 1-1.5 inch needles per dose	Inject 1 mL in outer thigh. Call 911 and seek immediate medical attention. If minimal or no response, may repeat dose every 2-3 minutes for continued or recurrent respiratory depression until EMS arrives.	Box of 10 or 25 single-dose vials (1 mL)
Naloxone Injection Solution	IM	0.4 mg/mL (10 mL)		(1)multidose (MDV)- 10mL vial (2-10) 3mL syringes w/ 21-25 gauge 1-1.5 inch needles per MDV *IMPORTANT: Due to anticipated absence of aseptic technique, a new vial should be used for separate events.*	Inject 1 mL in outer thigh. Call 911 and seek immediate medical attention. If minimal or no response, may repeat dose every 2-3 minutes for continued or recurrent respiratory depression until EMS arrives. The vial should be discarded after the event.	1 MDV or case containing 25 multidose vials (10 mL)
Nalmefene	Nasal	2.7mg/0.1mL			Administer a single spray in one nostril upon signs of opioid overdose. Call 911. If minimal or no response, may repeat in alternating nostrils using a new nasal spray with each dose every 2-3 minutes for continued or recurrent respiratory depression until EMS arrives.	2 EA BOX

Illinois Opioid Overdose Reversal Agent
Standardized Procedure

This updated Opioid Overdose Reversal Agent Standardized Procedure (Procedure) (formerly limited to Naloxone only) outlines for healthcare and other trained personnel how entities, including schools, may become authorized to obtain, dispense, and administer naloxone or nalmefene for the purpose of reversing an opioid overdose This Procedure also presents the educational requirements for obtaining the Illinois Opioid Overdose Reversal Agents Standing Order and the technique for administering these reversal agents.

Introduction

In September 2015, Illinois added Section 85/19.1 to the Illinois Pharmacy Practice Act, 225 ILCS 85/19.1, expanding access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. This statute authorizes personnel trained to dispense and/or administer reversal agents as an opioid antagonist intervention, per the instructions below.

In May 2023, nalmefene was also approved by the FDA as an opioid reversal agent, similar in mechanism to naloxone, and is therefore included in this update.

In January 2024, this Standing Order was expanded to include Illinois schools as a naloxone entity due to the need to have emergency procedures in place should persons exhibits signs of opioid overdose while on school premises. See Illinois School Code, 105 ILCS 5/22-30(e-10), (f), (f-5) and (g).

Pursuant to the Substance Use Disorder Act, 20 ILCS 301/, the Pharmacy Practice Act, and the School Code, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone and nalmefene to persons suspected of drug overdose.

Naloxone Entity

Naloxone Entities may dispense either naloxone or nalmefene, and include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs, as discussed below:

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85) and have knowledge of this Procedure, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists shall report naloxone and nalmefene dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.

- Any non-pharmacy OEND program, except schools, must be registered with the IDHS Division of Substance Use Prevention and Recovery Drug Overdose Prevention Program (DOPP) at https://www.dhs.state.il.us/page.aspx?item=58142.
- This may include law enforcement agencies, drug treatment programs, local health departments, hospitals, or urgent care facilities, or other for-profit or not-for-profit community-based organizations.
- Schools registered with the Illinois State Board of Education (ISBE) and their staff members who have met the educational requirements listed below regarding the administration of reversal agents to persons suspected of potential opioid overdose.

Educational Requirement

Under this standardized procedure, eligible entities must complete training in opioid overdose reversal that includes the following:

- Opioid overdose prevention and recognition
- The need to quickly administer treatment to reduce the risk of severe injury or death
- The techniques for administering naloxone and nalmefene
- Trained individuals must be familiar with the product that they will be administering, including potential responses to administering the medication
- The importance of calling 911 for the care of the overdose victim
- The goal of treatment is to restore normal breathing
- For schools, the training outlined in Section 22-30(h-5) of the Illinois School Code

Signs and Symptoms of Opioid Overdose, include but are not limited to the following:

- Slowed, irregular, or no breathing
- Skin, nails turn blue
- Extreme sleepiness
- Unresponsive to sternal rub or when shaken
- Pinpoint pupils
- Generalized seizures in children not known to have epilepsy

If an individual is suspected of overdosing, an Opioid Overdose Reversal Agent must be administered as quickly as possible, because an overdose may result in death.

Naloxone Hydrochloride

Naloxone is indicated for the reversal of opioid overdose, induced by natural or synthetic opioids, as manifested by respiratory depression or unresponsiveness. **It is safe to give this medication to a child of any age or adult with symptoms of opioid overdose, even if you are not sure if they overdosed on opioids.** It should not be given to anyone known to be allergic to naloxone hydrochloride. It may be delivered to persons subcutaneously or intramuscularly using a dose appropriate auto-injector, or needle and syringe, or intranasally. **Individuals must be monitored for a recurrence of symptoms of opioid overdose after receiving naloxone, and additional doses of naloxone administered if needed.**

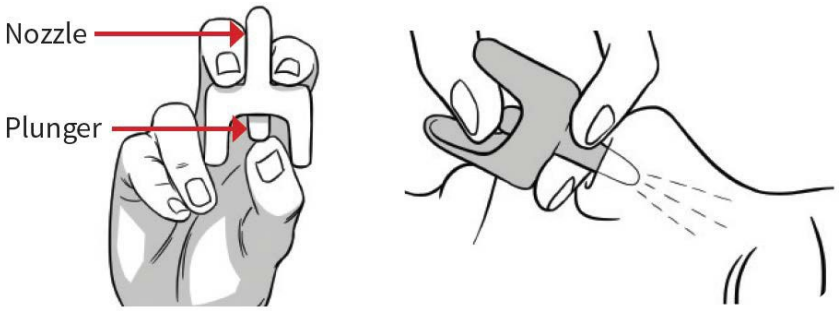
Standardized Procedure for Naloxone Administration

1. Confirm signs and symptoms of potential opioid overdose.

2. Call 9-1-1 and administer naloxone as follows **(select dispensed dosage form):**

Single-Step Intranasal Naloxone:

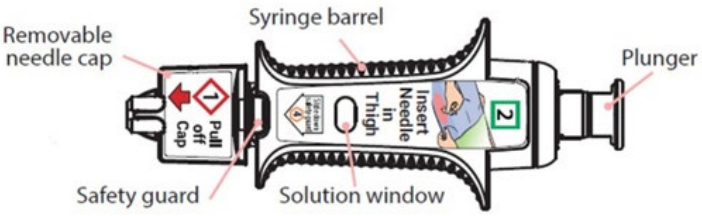
- The device is ready to use, no assembly required.
- Peel back the package to remove the device.
- Do not test the nasal spray. It has only one dose and cannot be reused.
- Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.
- Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
- Press the plunger firmly to release the dose into the patient's nose.
- Repeat, using the alternate nostril, if there is no response after 2 - 3 minutes using a new nasal spray.



- If there is still no response and additional doses are available, administer additional doses of nasal spray every 2 - 3 minutes until emergency medical assistance arrives. Use a new nasal spray in alternate nostrils with each dose.

Auto-injector Naloxone:

- ZIMHI is intended to be administered by individuals 12 years of age or older. Younger individuals or those with limited hand strength may find the device difficult to use.
- Place the individual on their back.



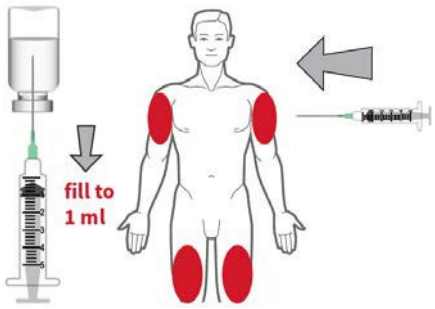
- Pull auto-injector from outer case and pull off red safety guard.
- Place the black end of the auto-injector against the outer thigh, through clothing if needed, press firmly, and hold in place for 5 seconds.

- Immediately after injection, using one hand with fingers behind the needle, slide the safety guard over the needle. Do not use two hands to activate the safety guard.

- Place the individual on their side (recovery position).
- Repeat, if there is no response after 3 minutes.
- Tell the EMS personnel that you administered an injection of naloxone and show them where the injection was administered.

Intramuscular Naloxone (single or multi-dose vials):

- Uncap the naloxone vial and uncap the intramuscular (IM) needle (23-25 gauge) and syringe (3mL).
- Insert the IM needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1 ml of naloxone liquid, and withdraw the needle.
- Insert the needle into the muscle of the upper arm or thigh of the victim, through clothing if needed, and push on the plunger to inject the naloxone.
- Repeat the injection if there is no response after three minutes.



3. For all victims, responders should perform compressions and rescue breaths for opioid-associated emergencies if they are trained and have a disposable rescue breathing device or perform Hands-Only CPR if not trained to perform rescue breaths.

Contraindications

There are no absolute contraindications to the use of naloxone in an emergency. The only relative contraindication is known hypersensitivity to naloxone.

Adverse Reactions

- Adverse reactions are related to precipitating opioid withdrawal. They include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, yawning, and sneezing.
- These symptoms may appear within minutes of naloxone administration and subside in approximately 2 hours.

- The severity and duration of the withdrawal syndrome is related to the dose of naloxone and the degree of opioid dependence.
- Some individuals may display responses not related to withdrawal such as temporary amnesia, physical discomfort or aggression when an opioid overdose is treated.
- **Adverse effects beyond opioid withdrawal are rare.**

Nalmefene Hydrochloride

Nalmefene nasal spray is an opioid antagonist indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids, as manifested by respiratory and/or central nervous system depression. It is safe to give this medication to adults and pediatric patients aged 12 years and older, with symptoms of opioid overdose, even if you are not sure if they overdosed on opioids.

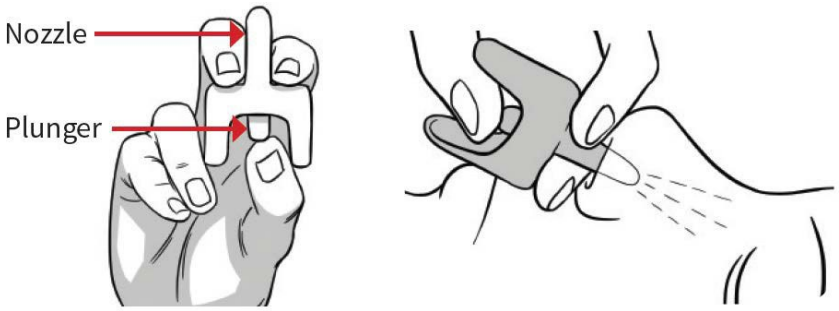
Following nalmefene administration individuals must be monitored for signs of a recurrence of symptoms of opioid overdose, and an additional dose of nalmefene administered if needed.

Standardized Procedure for Nalmefene Administration

1. Confirm signs and symptoms of potential opioid overdose

2. Call 9-1-1 and administer nalmefene as follows:

   <u>Single-Step Intranasal nalmefene</u>:
   - The device is ready to use, no assembly required.
   - Peel back the package to remove the device.
   - Do not test the nasal spray. It has only one dose and cannot be reused.
   - Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.
   - Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
   - Press the plunger firmly to release the dose into the patient's nose.
   - Repeat, using the alternate nostril, if there is no response after 2 - 5 minutes using a new nasal spray.



   - If there is still no response and additional doses are available, administer additional doses of nasal spray every 2 - 5 minutes until emergency medical assistance arrives. Use a new nasal spray in alternate nostrils with each dose.

3. For all victims, responders should perform compressions and rescue breaths for opioid-associated emergencies if they are trained and have a disposable rescue breathing device or perform Hands-Only CPR if not trained to perform rescue breaths.

Contraindications

There are no absolute contraindications to the use of nalmefene in an emergency. The only relative contraindication is known hypersensitivity to nalmefene.

Adverse Reactions

- The safety and tolerability of nalmefene is similar to naloxone.
- In studies most individuals (82%) did not experience adverse reactions.
- The main side effects are related to (non-severe, not life-threatening) opioid withdrawal: nausea, vomiting, rapid heart rate, hypertension, pain, fever, and dizziness.
- Some individuals may display responses not related to withdrawal such as temporary amnesia, physical discomfort, or aggression when an opioid overdose is treated.

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
69 West Washington Street, Suite 3500 • Chicago, Illinois 60602-3027 • www.dph.illinois.gov

Illinois Opioid Reversal Agent Standing Order

This Standing Order is issued by the Director of the Illinois Department of Public Health, effective on the date below. It authorizes Naloxone Entities to obtain and/or distribute opioid reversal agents, syringes, and other components of the naloxone or nalmefene kit to those who may assist an individual suffering opioid-related overdose. Naloxone Entities may include pharmacies, pharmacists, opioid overdose education and naloxone distribution (OEND) programs, or schools registered with the Illinois State Board of Education (ISBE). This Standing Order is made pursuant to the Substance Use Disorder Act (20 ILCS 301/5-23), and Executive Order 17-05, and should be used in conjunction with the Illinois Opioid Reversal Agent Standardized Procedure.

Intramuscular Naloxone Kits containing, at a minimum (links to package insert):

- Two (2) 1 ml single-use vials naloxone hydrochloride (0.4 mg/ml) or one (1) 10 ml multi-use vial of naloxone hydrochloride (0.4 mg/ml)
- Two (2) 23–25 gauge, 1-1.5 inch intramuscular sterile needles with Two (2) 3 mL syringes
- One (1) case containing one (1) ZIMHI™ (naloxone HCL injection, USP) 5mg/0.5 mL single-dose, prefilled syringe
- One (1) carton containing two (2) cases, each of which contains one (1) ZIMHI™ (naloxone HCL injection, USP) 5m/.0.5 mL single-dose, prefilled syringe
- Overdose prevention information pamphlet with step-by-step instructions for use

Single-step Intranasal Naloxone Kits containing, at minimum (links to package inserts):

- One (1) box containing two (2) NARCAN® Nasal Spray Devices (4 mg/0.1mL)
- One (1) box containing two (2) KLOXXADO™ Nasal Spray Devices (8mg/0.1mL)
- One (1) box containing two Sandoz (generic) naloxone nasal spray devices (4mg/0.1mL)
- One (1) box containing two Teva (generic) naloxone intranasal spray devices (4mg/0.1mL)
- Overdose prevention information pamphlet with step-by-step instructions for use

- Single-step Internasal Nalmefene Kits containing, at minimum (links to package insert):
- One (1) box containing two (2) OPVEE® Nasal Spray Devices (3 mg/0.1mL)
- Overdose prevention information pamphlet with step-by-step instructions for use

Standing Order

Dispense at minimum two (2) naloxone or nalmefene kits to the entity trained to receive the medication in accordance with the Illinois Opioid Overdose Reversal Agent Standardized Procedure. Unlimited refills are authorized.

License: 036135164
NPI: 1841585783

Physician's Signature and License No. and NPI No. **Date**

Sameer Vohra, MD, JD, MA
Physician's Name (Print):

Order Effective Date: 02/09/2024
Revision Date(s): 01/15/2024
Order Expiration Date: 02/08/2025

Indiana Department of Health

Eric J. Holcomb
Governor

Lindsay M. Weaver, MD, FACEP
State Health Commissioner

CSO-24-01

Statewide Standing Order ("Standing Order") for Naloxone Standing Order

Purpose: Naloxone is a medication indicated for reversal of opioid-related overdose event. This statewide standing order is intended ensure naloxone is readily available to any eligible recipients or providers that comply with IC 16-42-27. Attached is the *Indiana Statewide Naloxone Standing Order Toolkit for Naloxone Entities (Toolkit)*, which is incorporated by reference.

Definitions: "Overdose intervention drug" means an opioid antagonist approved by the FDA for the reversal of an opioid overdose which may be delivered intranasally with a mucosal atomizer device, intranasally with a nasal spray, or intramuscularly with a needle and any components necessary for the administration of the drug.

"Naloxone entity/entities" means an entity that obtains its naloxone rescue kit through this standing order and complies with the following requirements from IC 16-42-27-2:

(1) Annually register at https://optin.in.gov/ in a manner prescribed by the Department of Health (IDOH).

(2) Provide substance use education and training on drug overdose response and treatment, including the administration of an overdose intervention drug and the requirement to call **9-1-1** immediately before or after the administration of the drug.

(3) Provide substance use treatment information and referrals to substance use treatment programs, including programs in the local areas and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, nonaddictive medication for the treatment of opioid or alcohol dependence.

(4) Submit an annual report to IDOH containing:

(i) the number of sales of naloxone dispensed;

(ii) the dates of sale of naloxone dispensed;

(iii) any additional information required by IDOH

"Naloxone rescue kit" means a kit containing an overdose intervention drug, any components needed to administer the drug, and a quick guide of opioid overdose symptoms and assembly instructions.

Procedure: A naloxone entity or an individual may, in accordance with IC 16-42-27 and the Toolkit, receive, dispense, maintain, and/or administer an overdose intervention drug as part of a naloxone rescue kit. The naloxone entity or individual may distribute the naloxone rescue kit to those who may be able to assist an individual suffering an opioid-related overdose.

Geographic Region: This Standing Order is applicable statewide.

Standing Orders Authorization: This Standing Order is being issued pursuant to IC 16-42-27-2 which requires the Department to ensure there is a statewide standing order issued for the dispensing of an overdose intervention drug.

This Standing Order shall be reviewed annually by the state department of health and revised as needed. This Standing Order is effective January 1, 2024 through December 31, 2024.

Lindsay M. Weaver, MD, FACEP
Physician License No. 01069654A

Indiana Statewide Naloxone Standing Order Toolkit for Naloxone Entities
IC 16-42-27

Introduction

Individuals and entities that wish to obtain, administer or dispense naloxone under Indiana's Statewide Naloxone Standing Order must annually register as "Naloxone Entities" with the Indiana State Department of Health on the **OptIN** website found here: *https://optin.in.gov*.

The Statewide Standing Order, authorized by I.C. § 16-42-27, is renewed each year. Naloxone Entities must at all times remain compliant with Indiana law to act under the Statewide Standing Order and abide by the attestations made on the OptIN website.

This Toolkit includes: (1) substance use/dependence education; (2) training on overdose response and naloxone administration; and (3) treatment and referral information. The Toolkit may be a helpful resource for Naloxone Entities seeking compliance with I.C. § 16-42-27.

Naloxone Entities will automatically receive renewed Standing Orders and other important communications as long as they maintain current contact information on OptIN. **Naloxone Entities are required by law to annually renew their registration, comply with reporting requirements, and to update their registration throughout the year as changes occur (*e.g.*, input changes in address, contact information, etc.).**

***Note*: Neither this Toolkit nor the Indiana Statewide Standing Order guarantees coverage or prior authorization under Medicaid or other insurance programs.**

Naloxone Overview

Naloxone is an opioid antagonist indicated to reverse central nervous system depression in an individual suffering from an opioid-related oversedation, poisoning or overdose. Naloxone is the generic form of Narcan. Naloxone does not cause euphoric effects, is non-addictive, and is not a drug of abuse. Since 1971, naloxone has been successfully used to reverse opioid overdoses. Naloxone is a legend drug, but not a controlled substance.

Naloxone Effects

Naloxone reverses opioid-related oversedation, poisoning or overdose by replacing and blocking agonists from attaching to the brain's opioid receptors. Naloxone has a stronger affinity to the opioid receptors than do agonists. When administered to a person with opioids in their system, naloxone neutralizes the opioids' effect, allowing the body to return to more normal function. However, because many opioid overdoses are caused by high doses of opioid drugs or opioid drugs that are long-acting, rescuers may need to administer

multiple doses of naloxone. For this reason and pursuant to Indiana Code § 16-42-27, seeking immediate medical assistance **(calling 9-1-1)** is a required part of overdose response education.

Naloxone does not reverse drug overdoses in people without opioids in their system or produce any effect and does not interact with any medications other than opioids. The only contraindication to administering naloxone is if the recipient has a known sensitivity or allergy to naloxone or its components, which is rare. Because opioids remain in the person's system, naloxone cannot be used to disrupt a urine screen.

The most common side effect of naloxone in someone who has taken opioids is the induction of opioid withdrawal symptoms, including tachycardia, increased blood pressure, body aches, diarrhea, fever, and irritability.

Symptoms of Opioid Overdose

A person suffering an opioid overdose may present with some or all of the following symptoms:

- Decreased level of consciousness,
- Pinpoint pupils,
- Gurgling or choking noises,
- Body is limp,
- Breathing slows or stops,
- Heart rate slows or stops,
- Blue lips and/or nail beds,
- Clammy skin, or
- Cannot be woken or cannot speak, even after:
  - o Shaken, or
  - o Sternal rub.

Environmental Signs of an Opioid Overdose

In addition to the physical symptoms indicating an opioid overdose, the following items may indicate an opioid overdose:

- Needles,
- Spoons (especially bent spoons) or other cookers,
- Lighters,
- Tourniquets,
- Balloons or baggies,
- Pill bottles, or
- Pills (whole or crushed).

Naloxone Administration

If you believe that a person is suffering from an opioid overdose:

(1) Confirm your belief by checking for the symptoms and signs of opioid overdose found herein,

(2) **Call 9-1-1,**

(3) Administer naloxone,

(4) If the person has no pulse, give CPR if you know how and are comfortable doing so, (5) If there is no change in 3-5 minutes after giving naloxone, administer another dose, and

(6) Stay with the person until first responders arrive.

When administering naloxone, an individual may not be considered to be practicing medicine without a license in violation of I.C. § 25-22.5-8-2, if the individual, acting in good faith, does the following:

(1) Obtains naloxone from a prescriber (such as by participating in the Indiana Statewide Naloxone Standing Order);

(2) Administers naloxone to an individual who is experiencing an apparent opioid-related overdose; and

(3) Attempts to summon emergency services **(calls 9-1-1)** either immediately before or immediately after administering the naloxone.

Instructions on How to Give Naloxone

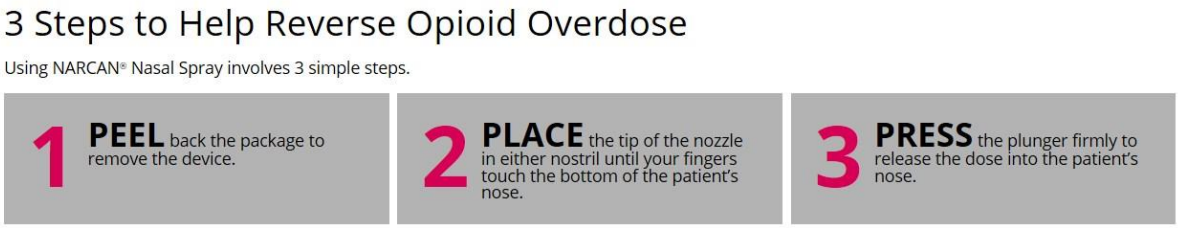
Naloxone Rescue Kits may be designed for nasal or muscular administration. Follow the instructions below based on the type of naloxone in your Naloxone Rescue Kit.

Intranasal Naloxone:

Follow steps 1 through 6 below for administering Naloxone Nasal Spray.

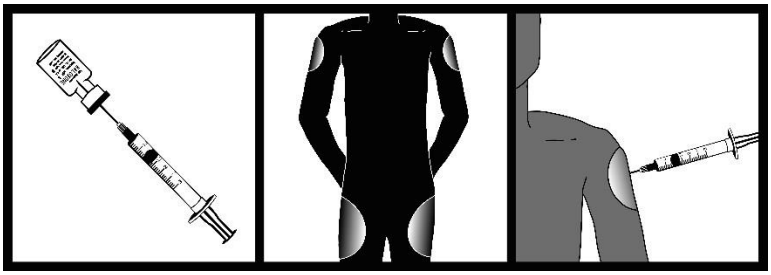
Intranasal Narcan:

Follow steps 1 through 3 below for administering Narcan Nasal Spray and watch the on-line video instructions at www.narcannasalspray.com before encountering an overdose emergency.



Intramuscular Naloxone via syringe:

Follow steps 1 through 3 below for administering injectable intramuscular Naloxone.



1. Take the orange cap off the vial and stick the needle through the rubber stopper,
2. Withdraw the indicated amount of medication, as directed on packaging, through the needle by pulling back on the plunger. Be sure the syringe fills with liquid — not air, and,
3. Insert syringe into muscle in the shoulder (like a flu shot) or into the front of the thigh. Push down on the plunger to empty the syringe

Intramuscular Naloxone via preloaded syringes:

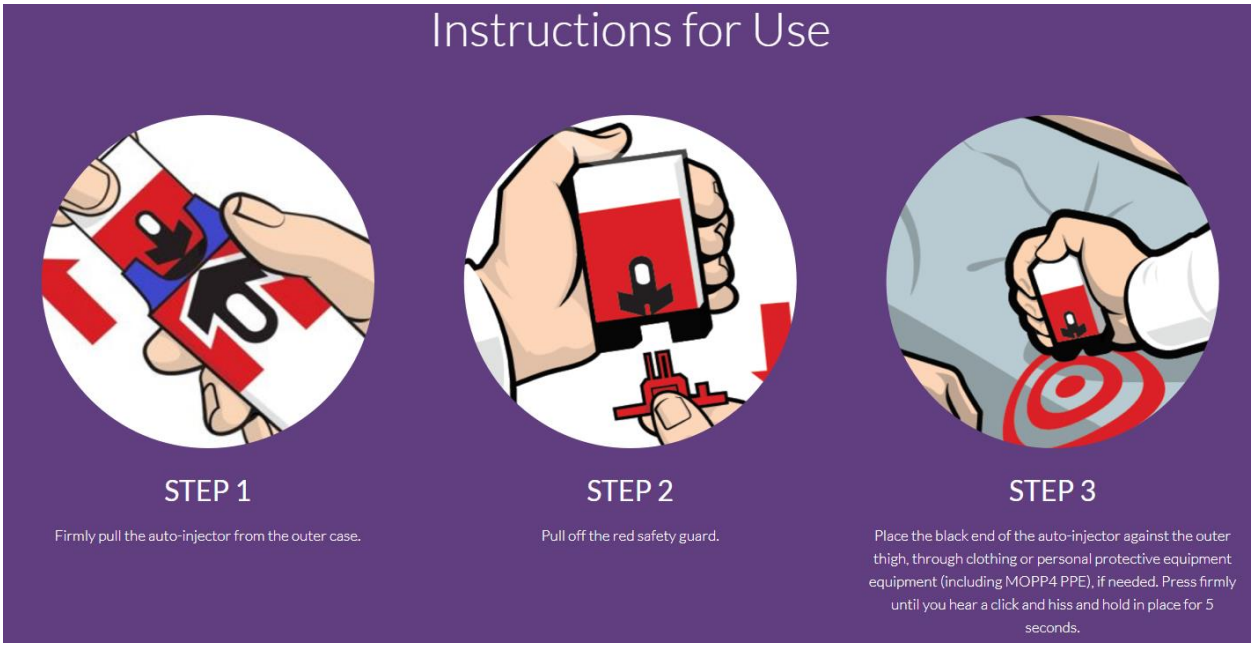
Follow steps 1 through 4 below for administering intramuscular Naloxone via preloaded syringes.

Syringe Assembly Instructions

1. Step 1 – Take the protective caps off the vial and injector
2. Step 2 – Thread the vial into the injector by using 3 half turns (or until the stopper is pierced by the metal cannula)
3. Step 3 – Remove the cover from the injection tip
4. Step 4 – Remove excess air before injecting the solution

Intramuscular Naloxone via auto-injector:

Follow steps 1 through 3 below for administering Naloxone via auto-injector.



Treatment Information

Several resources exist for locating treatment information:

- Indiana's Community Mental Health Centers: http://www.in.gov/fssa/dmha/files/DMHA_SOFs_and_CMHCs.pdf
- Substance Abuse and Mental Health Services Administration (SAMHSA) – See the Behavioral Health Treatment Services Locator and SAMHSA's National Helpline: https://findtreatment.samhsa.gov; 1-800-662-HELP (4357); 1-800-487-4889 (TDD)
- Indiana State Department of Health: https://www.in.gov/health/overdose-prevention/
- Indiana Governor's Task Force on Drug Enforcement, Treatment, and Prevention: http://www.in.gov/gtfdetp/index.htm
- Indiana Attorney General Prescription Drug Abuse Prevention Task Force: http://www.in.gov/bitterpill/
- Overdose Data to Action: https://www.cdc.gov/drugoverdose/od2a/funded-states.html
- Division of Mental Health and Addiction - Family and Social Services Administration: http://www.in.gov/fssa/dmha/index.htm#
- Connect 2 Help by dialing **2-1-1** or dial (317) 926-4357: https://in211.communityos.org/
- Overdose Lifeline: https://www.overdoselifeline.org/

Protocol for Dispensing Emergency Opioid Antagonists to Individuals at Risk of Experiencing, Witnessing, or Responding to an Opioid-Related Overdose

1. Authorization to Dispense Emergency Opioid Antagonists

This protocol is issued pursuant to K.S.A. 65-16,127 and K.A.R. 68-7-23, which allows the dispensing of emergency opioid antagonists ("EOAs") by pharmacists pursuant to a statewide protocol established and approved by the Kansas State Board of Pharmacy. A pharmacist shall engage in dispensing EOAs pursuant to this protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this protocol to dispense EOAs without a prescription to the following:

- An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose.
- A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.
- A first responder agency electing to provide an emergency opioid antagonist to its employees or volunteers.
- A school nurse.

If the eligible recipient is under 18 years of age, a parent or guardian shall provide consent.

2. Authorized Formulations, Quantities, Directions, and Supplemental Devices

A pharmacist may dispense any of the following prescription and nonprescription formulations of EOAs and supplemental drug delivery devices without a prescription. The pharmacist shall determine the appropriate EOA formulation to be dispensed.

The dispensed products shall be labeled in accordance with the Kansas Pharmacy Practice Act and any implementing regulations.

<u>Prepackaged intranasal naloxone (Examples include Narcan® Nasal Spray, Kloxxado®, and naloxone nasal spray.)</u>

- Formulation: FDA-approved naloxone 4mg to 8mg in a manufactured ready-to-use nasal spray device
- Quantity for individual dispensing: Dispense one carton of up to 2 devices per carton or up to two cartons of 1 device per carton
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1.

<u>Intramuscular naloxone (Examples include Narcan®, ZIMHI®, and naloxone for injection.)</u>

- Formulation: FDA-approved immediate release naloxone 0.4 mg/ml 1ml single dose vial or 5mg ready-to-use prefilled single-dose syringe
- Quantity for individual dispensing: Dispense up to 2 vials or prefilled syringes
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school

- Directions: Inject the contents of one vial or syringe into outer thigh for signs of opioid overdose. Call 911. May repeat x1.
- Supplemental devices to dispense: 3ml Syringe with a 25G ×1 inch needle
    - Quantity to dispense: One syringe for each single dose vial
    - Directions: Use as directed for naloxone administration.

Intramuscular naloxone auto-injector (subject to availability)

- Formulation: FDA-approved naloxone auto-injector for administration by lay persons
- Quantity for individual dispensing: Dispense one carton of up to 2 auto-injectors per carton or up to two cartons of 1 auto-injector per carton
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1.

Intranasal naloxone (non-FDA-approved delivery method)

- Formulation: FDA-approved naloxone 2 mg/2 ml prefilled luer lock syringe
- Quantity for individual dispensing: Dispense up to two prefilled syringes
- Quantity for first responder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1.
- Supplemental devices to dispense: Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Quantity to dispense: One device for each prefilled syringe
    - Directions: Use as directed for naloxone administration.

Prepackaged intranasal nalmefene (Examples include Opvee.)

- Formulation: FDA-approved nalmefene 2.7mg in a manufactured ready-to-use nasal spray device
- Quantity for individual dispensing: Dispense one carton of up to 2 devices per carton or two cartons of 1 device per carton
- Quantity for first resonder agency or school nurse: Dispense a quantity sufficient to meet the needs of the agency or school
- Directions: Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat x1.

3. Documentation and Record-keeping Procedures for Dispensing EOAs

Each pharmacist shall document the dispensing of an EOA by creating a prescription record for the individual or agency to whom it is dispensed. The pharmacist shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy for a period of five years from the date of dispensing.

4. Counseling, Training, and Educational Material Requirements

A pharmacist who dispenses an EOA shall instruct the individual to whom the EOA is dispensed to summon emergency medical services as soon as practicable either before or after administering the EOA. The individual should also be instructed to advise the emergency medical services personnel that an EOA has been administered.

A pharmacist shall provide in-person counseling, training, and written educational materials appropriate for the dosage form dispensed pursuant to K.A.R. 68-7-23. The person to whom an EOA is dispensed pursuant to this protocol may not be permitted to waive these consultation requirements. The pharmacist shall not dispense pursuant to this protocol if the person refuses counseling. This information shall include, but is not limited to, all the following:

1. Risk factors of opioid overdose; (See Appendix A)
2. Strategies to prevent opioid overdose;
3. Signs of opioid overdose; (See Appendix B)
4. Steps in responding to an overdose;
5. Information on EOAs, to include potential side effects or adverse effects;
6. Procedures for administering the EOA;
7. Proper storage, disposal, and expiration of the EOA product dispensed;
8. Information on where to obtain a referral for substance use disorder treatment (see Appendix C); and
9. If dispensed to a school nurse or first responder agency, information on

    a. the requirements to keep inventory records and report any administration of the EOA to the appropriate healthcare provider, and

    b. the requirement that any first responder, scientist, or technician that administers an EOA shall immediately summon emergency medical services, provide information related to the administration to the emergency medical services personnel and other involved treatment professionals (emergency room or treating physician, as appropriate), and notify the physician medical director for the first responder agency within 24 hours of administration, if applicable, and

    c. the requirement that any school nurse that administers an EOA shall notify/report such administration per the school district's policies and procedures, if applicable.

5. Documentation and Record-keeping Procedures for the EOA Protocol

Each pharmacist utilizing this protocol shall provide a copy of the signed and dated signature page of this protocol to the Board within five days of execution. A copy of this protocol shall be maintained for five years from the date of last dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has dispensed an EOA. Each pharmacist shall notify the Board in writing within 30 days of choosing to discontinue use of this protocol.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

☐ Yes ☐ No **Do you wish to be included on the K-TRACS website interactive map of pharmacies where EOA dispensing available?**

If yes, please provide the Pharmacy Name: _____

and Pharmacy Registration Number: **2-**_____

SIGNATURE _____ DATE SIGNED _____

PHARMACIST NOTICE OF DISCONTINUATION OF USE OF PROTOCOL*

Printed Name	Kansas License Number

SIGNATURE _____ DATE SIGNED _____

*Submit this page to the Board after signed and dated

Appendix A – Examples of Risk Factors for Opioid Overdose*

- Previous opioid intoxication or overdose.
- History of nonmedical opioid use.
- Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment.
- Higher-dose (>50 mg morphine equivalent/day) or long-acting opioid prescription.
- Receiving any opioid prescription plus:
    - Rotated from one opioid to another because of possible incomplete cross-tolerance.
    - Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, or other respiratory illness.
    - Renal dysfunction, hepatic disease, cardiac illness, or HIV/AIDS.
    - Known or suspected concurrent alcohol use.
    - Concurrent benzodiazepine or other sedative prescription.
    - Concurrent antidepressant prescription.
- Patients who may have difficulty accessing emergency medical services (distance, remoteness).

*This list is for only for sample purposes to assist the pharmacist in developing counseling materials. It is not intended to be an all-inclusive list of the risk factors for opioid overdose, nor does it represent a list of mandatory counseling points.

Appendix B – Examples of Signs of Opioid Overdose*

Signs and symptoms of opioid-related overdose in a person:

- Fentanyl patches on skin or needle in the body
- Unresponsive or unconscious individuals
- Not breathing or slow/shallow respirations
- Snoring, gurgling, or choking sounds (due to partial upper airway obstruction)
- Blue lips and/or nail beds
- Heart rate slows or stops
- Pinpoint pupils
- Pale and clammy skin
- Vomiting

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.

Environmental signs of opioid-related overdose:

- Needles
- Spoons (especially bent spoons) or other cookers
- Lighters
- Tourniquets
- Balloons or baggies
- Pill bottles
- Pills (whole or crushed)

*This list is for only for sample purposes to assist the pharmacist in developing counseling materials. It is not intended to be an all-inclusive list of the signs of an opioid overdose, nor does it represent a list of mandatory counseling points.

Appendix C – Examples of Locations for Information on Substance use Disorder Treatment*

The Department for Children and Families Alcohol and Drug Abuse Hotline: 1-866-645-8216

Kansas Department for Aging and Disability Services Substance Use Treatment Division.

A google search of "Kansas resources for substance use disorder treatment" will provide many resources you can use.

*This list is for only for sample purposes to assist the pharmacist in developing counseling materials. It is not intended to be an all-inclusive list of resources for substance use disorder treatment, nor does it represent a list of mandatory counseling points.

Kentucky Statewide Physician Protocol to Initiate Dispensing of Opioid Antagonists for Opioid Overdose Prevention and Response

Purpose

This statewide physician protocol signed by a physician with the Kentucky Department for Public Health specifies the criteria and procedures for eligible pharmacists who have met the requirements and received certification from the Kentucky Board of Pharmacy, according to and in accordance with the Kentucky Board of Pharmacy administrative regulations 201 KAR 2:360 to initiate the dispensing of opioid antagonists. *This signed protocol is intended for pharmacists that **do not** have a medical provider to issue a protocol.*

<table>
<tr><th colspan="3">Opioid Antagonist Dispensing Protocol</th></tr>
<tr><td>Eligible Candidates</td><td colspan="2">▪ Persons with a history of receiving medical care for acute opioid poisoning or overdose
▪ Persons with a suspected history of substance abuse or nonmedical opioid use
▪ Persons receiving high-dose opioid prescriptions (e.g., >50mg morphine equivalent)
▪ Persons who are opioid naïve and receiving a first prescription for methadone for pain
▪ Persons starting buprenorphine or methadone for addiction treatment
▪ Persons on opioid prescriptions for pain in combination with:
◦ Smoking, chronic obstructive pulmonary disease (COPD), emphysema, sleep apnea, or other respiratory illness
◦ Renal dysfunction, hepatic disease, or cardiac disease
◦ Known or suspected alcohol use
◦ Concurrent benzodiazepine or other sedative prescriptions
◦ Concurrent antidepressant prescription
▪ Persons who may have difficulty accessing emergency medical services
▪ Voluntary request by a person or agency</td></tr>
<tr><td>Medication</td><td>Nasal Spray
Naloxone HCl 4 mg / 0.1 ml (Narcan)
or
Naloxone HCl 8 mg / 0.1 ml (Kloxxado)
or
Nalmefene 2.7 mg / 0.1 ml (Opvee) (for patients 12 and older)

Dispense #1 carton</td><td>Pre-filled Syringe
Naloxone 5 mg/0.5ml injection (Zimhi) (for patients 12 and older)

Dispense #1 carton</td></tr>
<tr><td>Directions for Use</td><td>◦ Call 911.
◦ Do not prime.
◦ Spray in nostril upon signs of opioid overdose.
◦ May repeat in 2–5 minutes in opposite nostril if no or minimal breathing, then as needed (if doses are available), every 2 – 5 minutes.</td><td>◦ Call 911.
◦ Administer into the anterolateral aspect of the thigh, through clothing if necessary upon signs of opioid overdose.
◦ May repeat in 2-3 minutes if no or minimal breathing and responsiveness, then as needed (if doses are available), every 2-3 minutes.</td></tr>
</table>

Education	▪ Pharmacist dispensing an opioid antagonist to a person or agency not operating a harm reduction program shall provide verbal counseling and written educational materials, appropriate to the product and dosage form of dispensed.
Documentation	▪ Provide education both verbally and in written form for take-home use. ▪ Include name and title of person providing education to recipient of the opioid antagonist prescription. ▪ Document via prescription record each person who receives an opioid antagonist prescription under this protocol.
Contraindications	▪ Patients with known hypersensitivity or allergy to naloxone hydrochloride or nalmefene. ▪ Naloxone crosses the placenta and may precipitate withdrawal in the fetus. The fetus should be evaluated for signs of distress after naloxone is used. Naloxone should only be used in pregnant women with opioid dependence in situations of life-threatening overdose. (Pregnancy Category C)
Notification of Participation	Pharmacists choosing to participate in opioid antagonist distribution under the authority of this Statewide Protocol shall notify the Department for Public Health when initiating their participation. A facsimile of this signed form shall be emailed to Naloxoneprotocol@ky.gov or faxed to 502-564-9377 within seven (7) days of dispensing naloxone.

Opioid Antagonist Statewide Physician Protocol Signatures:

Judy Ann Theriot, MD, CPE
Judith Ann Theriot, MD, CPE
Medical Director
Kentucky Department for Medicaid Services

National Provider ID: 1811990476

July 19, 2024 Date Signed
This order is effective immediately upon signing and may be revised or revoked by the Kentucky Department for Public Health according to their direction.

By signing this Statewide Physician Protocol, the pharmacist attests that he/she is naloxone-certified by the Kentucky Board of Pharmacy, and has read and understands this Protocol.

Pharmacist **Date Signed**

Printed Name

Pharmacy Name	**Store number(s)**
Pharmacy Address and email, if available	

- A copy of this Signed Protocol must be maintained on file and be readily retrievable at each participating pharmacy site.
- This Signed Protocol must be renewed **annually**.

July 17, 2024

Kentucky Public Health
Prevent. Promote. Protect.

STATE OF LOUISIANA

Standing Order for the Distribution or Dispensing of Naloxone or Other Opioid Antagonists

Background and Purpose

Naloxone, and other opioid antagonists, is a prescription medication indicated for the reversal of respiratory depression or unresponsiveness due to opioid overdose. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, it has been determind that widespread availability of opioid antagonists to addicts and their caregivers, as well as first responders in the community, would serve the public interest. For as long as naloxone, and other such opioid antagonists, remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe said drug products in order to dispense or distribute the drug product. Thus, the Lousiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone, or other opioid antagonists, beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose; specifically first responders, caregivers and family/ friends of potential patients.

According to La R.S. 40:978.2, a licensed medical practitioner may, directly or by **standing order** (emphasis added), prescribe or dispense the drug naloxone or another opioid antagonist without having examined the individual to whom it may be administered if two conditions are met. First, the licensed medical practitioner must provide the individual receiving and administering the naloxone or other opioid antagonist all training requirements for the safe and proper administration of naloxone or another opioid antagonist to individuals who are undergoing, or who are belived to be undergoing, an opioid-related drug overdose. According to the statute, the training, at a minimum, shall address (1) techniques on how to recognize signs of opioid-related overdose, (2) standards and procedures for the storage and administration of naloxone or another opioid antagonist and (3) emergency follow-up procedures including the requirement to summon emergency services either immediately before or immediately after administering the naloxone or other opioid antagonist to an individual apparently experiencing an opioid-related overdose. Second, the naloxone, or other opioid antagonist, must be prescribed or dispensed in such a manner that it shall be administered through a device approved for this purpose by the United States Food and Drug Administration.

Authorization

The standing order is issued in compliance with, and under the authority of, La. R.S. 40:978.2 and shall be deemed as a medical order for naloxone, or other opioid antagonist, as long as the conditions of the statute are met. This standing order shall be valid for one year from the date of issue below.

Training and Instructional Materials

In accordance with the Louisiana Board of Pharmacy's regulations (LAC 46:LIII.2541), the pharmacist distributing the naloxone, or other opioid antagonist, must verify the recipient's knowledge and understanding of the proper use of the drug product. At a minimum, this must include (1) techniques on how to recognize signs of an opioid-related drug overdose, (2) standards and procedures for the storage

and administration of the drug product, and (3) emergency follow-up procedures, including the requirement to summon emergency service either immediately before or immediately after administering the drug product to the individual experiencing the overdose.

Dosage and Refills

Further, refills may be obtained as needed pursuant to this order. Do not administer naloxone for usage on an individual with known hypersensitivity to naloxone, or to any other ingredient that may be referenced in the package insert of naloxone, or any other opioid antagonist prescribed and/or dispensed.

Reimbursement

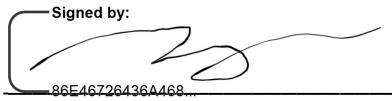
For reimbursement purposes, it may be necessary to have the medication dispensed in the name of the insured. This standing order authorizes the pharmacist to prepare a prescription for naloxone or other opioid antagonist, with refills authorized, in the name of the insured, and then dispense that product. This standing order, in and of itself, should not be relied upon as a guaranty or reimbursement from any payer source.

Recordkeeping

In order to comply with the recordkeeping requirements found in the Board of Pharmacy rules and regulations, the pharmacist shall attach a copy of this standing order to the invoice, or other record of sale of distribution. Further, the pharmacist shall store these transaction documents with the other distribution records in the pharmacy.

I hereby declare this standing order as a statewide medical order for the dispensing of naloxone, or opioid antagonist product, as long as the requirements of La. R.S. 40:978.2 and LAC 46:LIII.2541 are satisfied. Any pharmacy licensed by the Louisiana Board of Pharmacy may rely on this standing order for the distribution or dispensing of naloxone or other opioid antagonist to any Louisiana resident.

Signed by:



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Dr. Paula V. de la Cruz (NPI: 1114088697)

Date of Issue: 01/01/2025

MINNESOTA
BOARD OF PHARMACY

Pharmacist Prescribing Protocol
Opioid Antagonists

Background

Minn. Stats. §151.37, subd. 16, states the following:

> "A pharmacist is authorized to prescribe opiate antagonists for the treatment of an acute opiate overdose . . . the board shall develop a standardized protocol for the pharmacist to follow in prescribing an opiate antagonist. In developing the protocol, the board shall consult with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses."

This protocol was developed by Board staff after consulting with the above-mentioned agencies and professional associations. It was approved at the Board's December 30, 2020 meeting. Although the statutes use the phrase "opiate" antagonist, the more appropriate word to use is "opioid" – which includes both naturally occurring forms of opioids as well as synthetic forms such as fentanyl and methadone. Consequently, opioid will be used for this document. Pharmacists who independently prescribe opioid antagonists must follow *this* protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Pharmacists can continue to issue legally valid opioid antagonist prescriptions through the use of other protocols that they enter into with a physician, advanced practice registered nurse (APRN), or physician assistant (PA) as allowed by Minn. Stats. §151.01, subd. 27(6) and Minn. Stats. §151.37, subd. 2 They can also issue legally valid opioid antagonist prescriptions using the protocol that the Board developed for use by the Minnesota Department of Health, pursuant to Minn. Stats. §151.37, subd. 13. When doing so, they would enter into the protocol with a local community health board medical consultant or the MDH Medical Director. (Information is available at: https://www.health.state.mn.us/naloxone). When working under these other protocols, the practitioner, not the pharmacist, is the prescriber-of-record.

Definitions

1. "Opioid antagonist" means naloxone or other product approved by the U.S. Food and Drug Administration for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
2. "Recipient" means the person to whom an opioid antagonist is being supplied. The recipient might be someone other than the person for whom the use of the opioid antagonist is intended.

General considerations

1. Pharmacists who use this protocol must keep a written copy of it at each location at which they issue prescriptions for or dispense an opioid antagonist. They must make a copy of the protocol available upon the request of a representative of the Board of Pharmacy. This protocol must list the names of each pharmacist who is issuing prescriptions for opioid antagonists at the location.
2. Before pharmacists can prescribe an opioid antagonist under this protocol, they must successfully complete a training program *specifically developed for prescribing* opioid antagonists for the treatment of an acute opioid overdose. The program must be offered by a college of pharmacy, by a continuing education provider that is accredited by the Accreditation Council for Pharmacy Education (ACPE), or a program approved by the Board. Any training program approved by the Board must be based upon the most recent recommendations for management of opioid overdoses issued by the Centers for Disease Control and Prevention (CDC), Minnesota Department of Health (MDH), Minnesota Department of Human Services (DHS), or the Institute for Clinical Systems Improvement (ICSI).

    a. Upon the request of a representative of the Board, pharmacists must provide proof that they have completed the training.
    b. Pharmacists may request Board approval of a continuing education program by downloading the Continuing Education Program Approval Form for Non-ACPE Program Attendees, filling it out, and submitting it to the Board, along with information about the program. This form does *not* need to be submitted for a program offered by a college of pharmacy or by a continuing education provider that is accredited by ACPE.
    c. Note that the program must be developed for the *prescribing* of opioid antagonists. For example, a continuing education program that deals only with the pharmacology of an opioid antagonist would not be sufficient.

3. Pharmacists and pharmacies are encouraged to post a notice or to otherwise alert customers that pharmacists may prescribe and dispense opioid antagonists.

Procedures

When an individual requests an opioid antagonist, or when a pharmacist in his or her professional judgement decides to advise an individual of the availability of opioid antagonist), the pharmacist shall complete the following steps:

1. Screen for the following (in the primary spoken language of the recipient, upon request and when possible):

    a. Does the recipient understand that opioid antagonists can only be used for opioid overdoses and cannot be used for other drug overdoses?
    b. Does the person to whom the opioid antagonist would be administered have a known hypersensitivity to the drug? (If yes, do not furnish).

c. Provide training in opioid overdose prevention and recognition, the administration of the opioid antagonist, and in the appropriate response to an opioid overdose, including the need to pursue immediate, follow-up treatment (e.g., calling 911).

2. When an opioid antagonist is dispensed:

   a. The pharmacist shall provide the recipient with appropriate written information and with counseling on the product dispensed:
      i. administration, including
         a) an opioid antagonist may be administered in cases of unknown or mixed substance overdoses
         b) an opioid antagonist should be administered if the patient's sensitivity to the drug is unknown
      ii. effectiveness
      iii. adverse effects
      iv. storage conditions and shelf-life
      v. information concerning "Steve's Law" which provides immunity from prosecution when an individual calls emergency services for an overdose
      vi. a recommendation that 911 be called if the opioid antagonist is administered
      vii. and any other information deemed necessary in the professional judgment of the pharmacist.

      A pharmacist dispensing an opioid antagonist pursuant to this protocol shall not permit the recipient to waive the provision of the written information or the counseling required by this protocol. Whenever possible, the pharmacist should provide information, whether written or oral, to the recipient in the primary language of the recipient.
   b. The pharmacist shall provide the recipient with information about, and/or referrals to, substance abuse treatment resources if the recipient indicates interest in substance abuse treatment or recovery services.
   c. The pharmacist shall provide the recipient with information and appropriate resources concerning proper disposal of medications and needles/syringes. The pharmacist may also inform the recipient that the pharmacy is allowed to sell up to ten clean needles/syringes without a prescription.
   d. When applicable, the pharmacist should encourage the patient to discuss the risks of opioid overdose with prescribers who have issued opioid prescriptions.

Authorized drugs

1. Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved opioid antagonist products. A pharmacist may not prescribe or dispense a compounded version of an opioid antagonist. A pharmacist may also recommend optional items when appropriate, such as alcohol pads, rescue breathing masks, and protective gloves.
2. In selecting a product for which a prescription will be issued, the pharmacist shall obtain sufficient information from the recipient to make a decision that is based on: products available; recipient or patient preference; how well the product can be administered by the individuals likely to be involved in administering the product; insurance coverage and other cost factors; and any other pertinent factor.

Records

The pharmacist must generate a written or electronic prescription for any opioid antagonist dispensed. The prescription must include all of the information required by Minn. Stats. §151.01, subd. 16a. The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of two years, as required by the rules of the Minnesota Board of Pharmacy. Pharmacists are reminded that prescriptions paid for by Medicare and Medicaid must be kept on file for even longer periods of time.

Names of Pharmacists Who Will Be Prescribing Pursuant to this Protocol

Location at which prescribing will occur

Pharmacy or facility name: _____

Pharmacy of facility address: _____

Names of Prescribing pharmacists:

1) _____
2) _____
3) _____
4) _____
5) _____
6) _____
7) _____
8) _____
9) _____
10) _____

Docusign Envelope ID: 06AB0559-F8AA-4CBF-9982-D7C230851C0A

MISSISSIPPI STATE DEPARTMENT OF HEALTH

Mississippi Statewide Opioid Antagonist Standing Order

Authority

Naloxone is indicated for the reversal of opioid overdose induced by natural or synthetic opioids in the setting of respiratory depression or unresponsiveness. It is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Nalmefene is indicated for emergency treatment of known or suspected overdose induced by natural or synthetic opioids in patients 12 years and older, as manifested by respiratory and/or central nervous system depression. It is contraindicated in patients known to be hypersensitive to nalmefene or any of its other ingredients.

§ 41-29-319 of the Mississippi Code of 1972 Annotated allows a practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner to directly or by standing order prescribe an opioid antagonist to a person at risk of experiencing an opioid-related overdose or to a registered pain management clinic, family member, friend or other person in a position to assist such person at risk of experiencing an opioid-related overdose; further, a practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner may issue a standing order to one or more individual pharmacies that authorizes the pharmacy to dispense an opioid antagonist to a person at risk of experiencing an opioid-related overdose or to a family member, friend or other person in a position to assist such person at risk of experiencing an opioid–related overdose, without the person to whom the opioid antagonist is dispensed needing to have an individual prescription; and a pharmacist acting in good faith and in compliance with the standard of care applicable to pharmacists may dispense an opioid antagonist under a prescription or a standing order issued in accordance with the law. This standing order by the Mississippi State Health Officer covers the dispensing and administration of naloxone or nalmefene by a pharmacist licensed to practice in the state of Mississippi as authorized under § 41-29-319 of the Mississippi Code of 1972 Annotated (“The Pharmacist”). Dispensing and/or administration shall be in full compliance with Mississippi Pharmacy Practice Regulations.

The pharmacist is authorized to dispense naloxone or nalmefene in accordance with § 41-29-319 of the Mississippi Code of 1972 Annotated.

Order to dispense:
The pharmacist is authorized to dispense the below formulations of naloxone to any person regardless of age:

Formulation (Generic or Brand Name acceptable)	Directions for Use	Quantity to Dispense
Naloxone 2 mg/2mL single dose Luer-Lock prefilled syringe *Dispense with two intranasal mucosal atomizer devices for intranasal administration or two 1-1.5 inch, 23-25g needles for intramuscular/subcutaneous administration.	Intranasal using atomizer: Spray one-half of syringe (1 mL) into each nostril. May repeat every 2-3 minutes if no response.	Two syringes
	Injection using needle: Inject 2 mL intramuscularly or subcutaneously into the shoulder or thigh. May repeat every 2-3 minutes if no response.	
Naloxone 0.4 mg/mL single dose vial *Dispense with 3cc, 23g-25g, 1-1.5 inch syringes.	Inject 1 mL into the shoulder or thigh. May repeat every 2-3 minutes if no response.	Two vials
Narcan® Nasal Spray (4 mg/0.1 mL)	Spray into one nostril. May repeat with new device every 2-3 minutes if no response.	Two pack kit
Kloxxado™ Nasal Spray (8 mg/0.1 mL)	Spray into one nostril. May repeat with new device every 2-3 minutes if no response.	Two pack kit

The pharmacist is authorized to dispense the below formulations of opioid antagonists to persons 12 years and older:

Formulation (Generic or Brand Name acceptable)	Directions for Use	Quantity to Dispense
OPVEE (nalmefene) nasal spray (2.7 mg/0.1 mL)	Administer a single spray into one nostril. May repeat with new device every 2-5 minutes if no response.	One carton containing two devices
ZURNAI (nalmefene) autoinjector (1.5 mg/0.5 mL)	Administer ZURNAI to the outer thigh, through clothing if necessary. May administer additional doses using a new autoinjector for each dose every 2-5 minutes as needed until emergency medical assistance arrives.	One carton containing one single-dose auto-injector

ZIMHI™ (One carton containing two cases, each of which contains one ZIMHI™ (naloxone HCL injection, USP) 5 mg/0.5 mL single-dose, prefilled syringe)	Inject intramuscularly or subcutaneously in thigh with the needle facing downwards. May repeat every 2-3 minutes if no response.	One carton

Recordkeeping:

1. A copy of the standing order signed by the Mississippi State Epidemiologist must be maintained on file and readily retrievable at each participating pharmacy.
2. Prescriptions shall be maintained by the pharmacy in accordance with Mississippi Pharmacy Practice Regulations.

Justin Turner, MD
Chief Medical Officer
State of Mississippi

Date: 10/29/2024
Order Expiration Date: 10/28/2025

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

North Carolina State Health Director's Opioid Antagonist Standing Order for Pharmacists

This standing order signed by the North Carolina State Health Director authorizes any pharmacist practicing in the state of NC and licensed by the NC Board of Pharmacy to dispense opioid antagonists, indicated for the treatment of opioid overdose, to persons as directed below.

Dispensing Protocol for Opioid Antagonists	
Eligible Candidates	▪ Persons who voluntarily request an opioid antagonist and are at risk of experiencing an opiate-related overdose, including, but not limited to: – Current illicit or non-medical opioid users or persons with a history of such use – Persons with a history of opioid intoxication or overdose and/or recipients of emergency medical care for acute opioid poisoning – Persons with a high dose opioid prescription (>50 morphine milligram equivalents per day) – Persons with an opioid prescription and known or suspected concurrent alcohol use – Persons from opioid detoxification and mandatory abstinence programs – Persons entering methadone maintenance treatment programs (for addiction or pain) – Persons with opioid prescription and smoking/COPD or other respiratory illness or obstruction – Persons with an opioid prescription who also suffer from renal dysfunction, hepatic disease, cardiac disease, HIV/AIDS – Persons who may have difficulty accessing emergency medical services – Persons enrolled in prescription lock in programs ▪ Persons who voluntarily request an opioid antagonist and are the family member or friend of a person at risk of experiencing an opiate-related overdose. ▪ Persons who voluntarily request an opioid antagonist and are in the position to assist a person at risk of experiencing an opiate-related overdose.
Medication to be Dispensed	FDA-approved opioid antagonists, indicated for the treatment for opioid overdose, used in accordance with approved directions. List of approved products and directions maintained here. Product selection should be made based on patient preference, availability, insurance coverage, and other pertinent factors.
Refills	PRN
Contraindications	For naloxone products: a history of known hypersensitivity to naloxone or any of its components. For nalmefene products: a history of known hypersensitivity to nalmefene or to any of the other ingredients.
Precautions	*Pregnancy:* naloxone crosses the placenta and may precipitate withdrawal in the fetus. Naloxone should only be used in pregnant women with opioid dependence in situations of life-threatening overdose (pregnancy category C). The fetus should be evaluated for signs of distress after naloxone is used for the mother. Careful monitoring is needed until the fetus and mother are stabilized. There are no available data on nalmefene for use in pregnant women, however, treatment for opioid overdose with nalmefene should not be withheld because of potential concerns regarding the effects on the fetus. *Precipitation of opioid withdrawal:* abrupt reversal of opioid depression may result in acute withdrawal symptoms such as but not limited to the following: nausea/vomiting, diarrhea, fever, myalgias, diaphoresis, increased blood pressure, and irritability. Use with caution in neonates and ensure close monitoring for the development of opioid withdrawal.
Patient Education	Every person provided an opioid antagonist under this standing order shall receive education regarding the risk factors of overdose, signs of an overdose, overdose response steps, and the use of the opioid antagonist. Examples of educational materials that incorporate the above information may be found at http://www.naloxonesaves.org.
Notification of Participation	Pharmacies choosing to participate in opioid antagonist dispensing under the authority of this standing order shall notify the Division of Public Health when initiating their participation; see directions for notification at http://www.naloxonesaves.org.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

North Carolina State Health Director's Opioid Antagonist Standing Order for Pharmacists

Kelly Kimple, MD, MPH
National Provider ID: 1508091919

1/17/2025
Date Signed

Legal Authority GS 90-12.7; SL 2023-15. This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. The statewide standing order signed by the North Carolina State Health Director does not expire. It will be renewed upon change in the State Health Director or updated if any relevant information regarding opioid antagonist administration becomes available.

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

129 PLEASANT STREET, CONCORD, NH 03301
603-271-9544 1-800-852-3345 Ext. 9544
Fax: 603-271-4912 TDD Access: 1-800-735-2964
www.dhhs.nh.gov

Jonathan R. Ballard
Chief Medical Officer

Standing Order for Community Organizations Dispensing of Opioid Antagonists

Naloxone and nalmefene are indicated for the reversal of opioid overdose induced by natural or synthetic opioids in the setting of respiratory depression or unresponsiveness. It should not be given to anyone known to be hypersensitive to the agent. This standing order authorizes community organizations in New Hampshire to dispense opioid antagonists to any person who is:

- Either a person at risk of experiencing an opiate-related overdose; OR a family member, friend, or other person in a position to assist a person at risk of experiencing such an overdose; AND who has been provided opioid overdose response training.

1. **Intranasal Naloxone**:

- Naloxone HCl Nasal Spray 4mg (**Narcan** – brand name)

  Dispense up to four two-pack boxes of single-step Naloxone HCl Nasal Spray 4mg (Narcan – brand name) which contains two (2) 4mg doses of naloxone HCl in 0.1 ml of nasal spray. Dispensing instructions: Call 911. Spray the contents of one sprayer (0.1ml) into one nostril. May repeat every 2-3 minutes if symptoms of an opioid emergency persist, alternating nostrils.

- Naloxone HCl 1mg/ml delivered with mucosal atomizer

  Dispense two 2ml Luer-lock needleless syringes prefilled with Naloxone HCl 1mg/mL and equivalent quantity mucosal atomizing devices. Dispensing instructions: Call 911. Administer naloxone in accordance with written step-by-step instructions for administration of intranasal naloxone provided by organization personnel.

- Naloxone HCl Nasal Spray 8mg (**Kloxxado** – brand name)
  - Dispense one package of Naloxone HCl Nasal Spray 8mg (Kloxxado – brand name). Dispensing instructions: Call 911. Spray the contents of a new sprayer into one nostril. May repeat every 2-3 minutes with a new sprayer if symptoms of an opioid emergency persist, alternating nostrils. Written step-by-step instructions for administration of intranasal naloxone must be given to patient and reviewed with patient by organization personnel.

2. **Intranasal Nalmefene**

- Nalmefene Nasal Spray 2.7mg (**OPVEE** – brand name)
  a. Dispense one package of Nalmefene nasal spray only for use on persons age 12 and older. Dispensing instructions: Call 911. Spray the contents into one nostril. May repeat every 2-5 minutes with a new sprayer if symptoms of an opioid emergency persist. Written step-by-step instructions for use of nalmefene must be given to patient and reviewed with patient by organization personnel.

3. **Intramuscular Naloxone**:

- Naloxone HCl 0.4mg/ml delivered intramuscularly

  Dispense 1x 10ml vial or 2 x 1ml single dose vials; and 1 intramuscular (IM) single packaged syringe and 1-1 ½ inch size needle.

  Dispensing instructions: Call 911. Draw up and administer 1ml naloxone in accordance with written step-by-step instructions for administration of intramuscular naloxone as reviewed by agency personnel. May repeat in 2-3 minutes if symptoms of an opioid emergency persist.

4. **Agency Instructions:** Written step-by-step instructions for administration of opioid antagonists must be given to persons and reviewed with persons by agency personnel. Instructions must provide opioid overdose response counseling covering, at a minimum: 1.) Recognition of an opioid overdose; 2.) Calling 911; 3.) Administration of opioid antagonists; and 4.) Orientation to and explanation of the contents of the opioid antagonist package. In accordance with NH RSA 318-B:15, IV, New Hampshire law allows an organization to dispense or distribute opioid antagonists pursuant to a prescription or standing order, when acting in good faith and with reasonable care, and in accordance with specific procedures, training and safeguards, as outlined in this Standing Order.

Jonathan Ballard MD

Jonathan Ballard, MD, MPH, MPhil
Chief Medical Officer

Expiration Date: 12/31/2025
Unlimited refills authorized
NH Med License: 15614

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

2nd REVISED STANDING ORDER FOR PHARMACISTS TO DISPENSE OPIOID ANTIDOTE FOR OVERDOSE PREVENTION

CONTROL NUMBER: 2021-01 (2nd Revised)

This revised standing order is issued pursuant to P.L.2021, c.152 ("Act"), which provides that the Commissioner of Health, or, if the commissioner is not a duly licensed physician, the Deputy Commissioner for Public Health Services, "shall issue a standing order authorizing all licensed pharmacists in the State to dispense an opioid antidote to any individual or entity, regardless of whether the individual or entity holds an individual prescription for the opioid antidote."

The purpose of this standing order is to make opioid antidotes as easily accessible and as widely available as possible in order to provide treatment to people experiencing a suspected overdose. Nothing in this standing order shall be construed to restrict in any way the ability of any individual or entity to be dispensed an opioid antidote.

The Act defines the following terms:

- "Opioid antidote" as "any drug, regardless of dosage amount or method of administration which has been approved by the United States Food and Drug Administration (FDA) for the treatment of an opioid overdose. 'Opioid antidote' includes, but is not limited to naloxone hydrochloride, in any dosage amount, which is administered through nasal spray or any other FDA-approved means or methods. "

- "Drug overdose" means "an acute condition including, but not limited to, physical illness, coma, mania, hysteria, diminished consciousness, respiratory depression, or death resulting from the consumption or use of a controlled dangerous substance or another substance with which a controlled dangerous substance was combined and that a layperson would reasonably believe to require medical assistance."

- "Recipient" means "any individual who or entity that is prescribed or dispensed an opioid antidote" in accordance with N.J.S.A. 24:6J-4 or N.J.S.A. 45:14-67.2

including, but not be limited to, "private citizens, emergency medical responders, emergency medical response entities, law enforcement officers, law enforcement agencies, recognized places of public access, employees and volunteers providing services at, through, or on behalf of a recognized place of public access, public and nonpublic schools, school nurses and other staff at a public or nonpublic school, sterile syringe access programs, and staff and employees of a sterile syringe access program. The term 'recipient' shall not include a prescriber or a licensed pharmacist acting within a professional capacity."

I. AUTHORIZATION

A. This standing order may be used by any recipient as a prescription or third-party prescription to obtain an opioid antidote from a pharmacy. This standing order authorizes pharmacists who maintain active licenses to practice pharmacy in the State of New Jersey and who are in good standing with the New Jersey Board of Pharmacy to dispense an opioid antidote, as defined herein, to any recipient regardless if the recipient has an individual prescription for an opioid antidote. A pharmacist dispensing an opioid antidote shall furnish the recipient with the overdose prevention information set forth in Section III below.

II. ORDER TO DISPENSE FOR PHARMACISTS

A. Unlimited refills are authorized with opioid antidotes.
B. A pharmacist may dispense any other items necessary for the administration of opioid antagonists as determined by the pharmacist's professional judgment (including but not limited to, syringes and mucosal atomization devices), consistent with State and federal law.
C. The dissemination of overdose prevention information, as required by Section III below, shall be documented by the dispensing pharmacist in the recipient's medical record or another appropriate record, log or other similar recordkeeping location.

III. INFORMATION

Upon dispensing an opioid antidote, a pharmacist shall provide the following overdose prevention information to the person receiving the opioid antidote, which information shall include, but is not limited to, the following:

A. Information on opioid overdose prevention and recognition;
B. Instructions on how to perform rescue breathing and resuscitation;
C. Information on dosage and instructions regarding administration in conjunction with the packaging insert included with the opioid antidote;
D. Information describing the importance of calling 911 for assistance with an

opioid overdose;

E. Instructions regarding appropriate care of an overdose victim after administration of an opioid antidote; and

F. Information on contraindications and precautions.

IV. ADDITIONAL INFORMATION

In addition to the required information provided by a pharmacist to a recipient pursuant to Section III above, a pharmacist may also direct the recipient to the following website for additional information regarding opioid overdose prevention and opioid antidotes: https://nj.gov/humanservices/dmhas/initiatives/naloxone.html.

V. EXPIRATION AND REVIEW

This revised standing order supersedes the standing orders issued on August 31, 2021 and August 24, 2022.

This revised standing order shall not expire unless and until all forms of opioid antidotes have been approved as over-the-counter medications or until otherwise withdrawn in writing by the Department of Health. This revised standing order will be reviewed periodically and updated as relevant developments in the law or science about opioid antidote administration occur.

A pharmacist dispensing an opioid antidote shall maintain records as required by the Board of Pharmacy.

New Jersey Department of Health
Issuing Official

Margaret C Fisher

Margaret Fisher, MD
Acting Deputy Commissioner
Public Health Services
New Jersey Department of Health
NPI Number: 1932165701
NJ License Number: 25MA07136300

9/7/22
Date

NEW MEXICO
Department of Health
Public Health Division

MICHELLE LUJAN GRISHAM
Governor

DAVID R. SCRASE, M.D.
Acting Cabinet Secretary

New Mexico Statewide Standing Order for Registered Pharmacist Naloxone or other FDA approved opioid antagonist for rescue use

Authority: NMSA 24-23-1.F: A licensed prescriber may directly or by standing order prescribe, dispense, or distribute an opioid antagonist to: 1) a person at risk of experiencing an opioid-related drug overdose; 2) a family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose; 3) an employee, volunteer or representative of a community-based entity providing overdose prevention and education services that is registered with the department; 4) a first responder.

Section A: Purpose:

Opioid overdose death is preventable through administering, dispensing, and prescribing naloxone to people who are at risk of experiencing or witnessing an opioid overdose. As trusted and accessible health care professionals, pharmacists are in a unique position to educate individuals on opioid overdose and dispense naloxone when indicated.

This standing order authorizes registered pharmacists in New Mexico to dispense naloxone or other FDA approved opioid antagonist for rescue use to:

1. Any person who uses an opioid, regardless of how the opioid is used or obtained.
2. Any person in a position to assist a person at risk of experiencing an opioid overdose.

Section B: Order and Dispensing Procedures

1. Assessment and Eligibility Criteria

Indication: Naloxone is an opioid antagonist that reverses the effects of opioids, including respiratory and central nervous system depression. It is indicated for emergency treatment of a known or suspected opioid overdose. It is not a substitute for emergency medical care. Other FDA approved opioid antagonist(s) for rescue use will be authorized under this standing order, when available.

Eligibility:

1. People who voluntarily request naloxone (or other opioid antagonist) and meet criteria as described in Section A are eligible to receive naloxone (or other opioid antagonist).
2. Pharmacists, using their professional judgment, may offer naloxone (or other opioid antagonist) to individuals identified to be at increased risk of experiencing an opioid overdose. Factors to consider that may increase risk of overdose: High dose of opioids, using opioids for more than 3 months, using opioids and benzodiazepines simultaneously, being treated for opioid use disorder with buprenorphine, methadone, or naltrexone, history of opioid overdose.

Contraindications: Known hypersensitivity to naloxone (or other opioid antagonist, as applicable). Anaphylactic shock may occur in those allergic to naloxone or any of its components. Contraindication(s) to other FDA approved opioid antagonist(s), if any, based on manufacturer's drug information (approved product labeling) must be observed by pharmacist in determination of whether the product is appropriate.

Warnings/Precautions: Naloxone and other opioid antagonists may cause opioid withdrawal symptoms such as: nausea/vomiting, diarrhea, chills, sweating, anxiety, and combativeness/disorientation.

Naloxone and other opioid antagonists are not effective in reducing respiratory and central nervous system depression caused by non-opioid substances.

2. Order to Dispense

Product Selection and Labeling

The pharmacist may dispense one of the following products based on product availability and preference.
Naloxone HCl Solution 1 mg/mL prefilled Luer-Lock Syringe Dispense: 2 x 2 mL syringes (4 mL total) with two nasal mucosal atomization devices. Directions for use: Spray 1 mL (one-half of syringe) in each nostril. Repeat after 3 minutes if no response. Call 911. ***Note: DO NOT dispense naloxone product available with a fixed needle (NDC 76329-1469-01). The needle is fixed on the syringe barrel and the individual will not be able to attach the nasal mucosal atomization device.***
Narcan®Nasal Spray (naloxone HCl) 4 mg/0.1 mL Nasal Spray Dispense: 1 box containing two 4 mg/0.1 mL doses of naloxone Directions for use: Administer a single spray of Narcan® in one nostril. Repeat after 3 minutes if no response. Call 911.
Any other naloxone preparation or opioid antagonist commercially available and FDA approved for the emergency treatment of known or suspected opioid overdose. Label with directions for use consistent with drug monograph. Call 911.

Prescription Label Requirements: Name of recipient/person requesting naloxone, date dispensed, naloxone product and quantity, licensed prescriber name: *Chris Novak, MD*, directions for use, refills: PRN.

3. Opioid Overdose and Naloxone Administration Education

Required Counseling and Educational Information: Pharmacists dispensing under this standing order must provide individuals receiving naloxone with opioid overdose and naloxone administration education. The pharmacist should be familiar with opioid overdose prevention, using opioid medications safely, and naloxone administration instructions.

Education must, at a minimum, include:

Opioids and what causes opioid overdose:	• Most opioids are narcotic pain relievers such as: oxycodone, hydrocodone, oxymorphone, hydromorphone, codeine, morphine, fentanyl, methadone, and buprenorphine. Heroin is also an opioid drug. • Opioids can have severe adverse reactions that slow or stop breathing. This can happen when a person ingests too much of the opioid medication or mixes an opioid medication with another substance. Opioid overdoses can be fatal because they slow or stop breathing.
Factors that increase risk for overdose:	• Mixing opioids with alcohol, benzodiazepines, or other drugs. • Taking opioids more often or in higher quantities than prescribed. • Restarting opioids after a period of abstinence.
Naloxone overview:	• Naloxone is a safe medication that reverses and blocks the effects of opioids and can be used to treat a known or suspected opioid overdose. • Naloxone only reverses the effects of opioids. It will not have an effect on an overdose caused by another substance (e.g., alcohol, benzodiazepines, stimulants, etc.).

	• Naloxone may cause opioid withdrawal symptoms such as: nausea/vomiting, diarrhea, chills, sweating, anxiety, and combativeness/disorientation. People who use opioids chronically are more likely to experience these effects. • Naloxone will not have an effect on a person who has not taken opioids.
How to recognize an opioid overdose:	• Person is unresponsive or unconscious; will not wake up even when shaken. • Person is not breathing or breathing is very slow and shallow. • Person's lips or fingernails are blue/grey and skin is pale and clammy.
What to do in case of an overdose:	1. **Call 911 as soon as possible and follow dispatcher instructions.** Naloxone is not a substitute for emergency medical services. 2. Follow dispatcher instructions for rescue breathing, if appropriate. 3. Administer naloxone. If no response in 3 minutes, give a second dose. 4. Once revived, place person in recovery position and stay until help arrives.
How to administer naloxone:	• Refer to attached educational handout in Section C: *User Guide - Information on Opioid Safety and How to Use Naloxone* • Pharmacist should review naloxone administration instructions for the naloxone product being dispensed.

Refer to the attached educational handout in Section C of this documents as a guide to educate and counsel individuals receiving naloxone. Review with each individual and provide a written copy with the naloxone product being dispensed.

Pharmacists dispensing naloxone under this standing order must comply with dispensing procedures and associated opioid overdose and naloxone education as detailed in this section.

Licensed Prescriber:
Name: Chris Novak, MD
Address: 1190 S St. Francis Dr., Ste. S-1057, Santa Fe, NM 87505
NPI: 1508834110 License#: MD2009-0030

_____ Date:_____01/11/2022_____

Christopher Novak, MD, MPH
New Mexico Department of Health

Section C: Additional Information and Attached Documents

Educational handout: Review with each individual and provide a written copy with the naloxone product being dispensed.
User Guide - Information on Opioid Safety and How to Use Naloxone

Helpful information and resources for pharmacists dispensing naloxone under this standing order.
Pharmacist Naloxone Dispensing Guide

Overdose Prevention and Rescue Breathing in 20 minutes or less
https://nmhealth.org/publication/view/help/1706/

Distribution of Overdose Reversal Drugs in Ohio

Updated 8/20/2024

To assist Ohioans in understanding laws governing the distribution of overdose reversal drugs (ORDs), the Ohio Board of Pharmacy developed this comprehensive guide. The guide is divided into sections based upon the type of entity engaged in the distribution of ORDs.

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: www.pharmacy.ohio.gov/contact.

IMPORTANT: The requirements listed in this guide DO NOT APPLY to overdose reversal drugs that have been approved for over-the-counter use. Rather, the requirements apply to ORDs that have not been approved for over-the-counter use by the FDA (e.g., usually requires a prescription).

REMINDER: The State of Ohio developed a dedicated website to order naloxone for personal and organizational use. For more information, please visit: www.naloxone.ohio.gov.

Section 1 – What is an Overdose Reversal Drug?

An overdose reversal drug (ORD) is defined in ORC 4729.01 as both of the following:

> (1) Naloxone;
>
> (2) Any other drug that the state board of pharmacy, through rules adopted in accordance with Chapter 119. of the Revised Code, designates as a drug that is approved by the U.S. Food and Drug administration for the reversal of a known or suspected opioid-related overdose.

Effective 10/31/23: Nalmefene (OPVEE®) was added as an overdose reversal drug per OAC 4729-8-01.

Manufacturers of FDA-approved overdose reversal drugs may submit a request for consideration to the Board by sending an email to: contact@pharmacy.ohio.gov.

IMPORTANT: The naloxone and nalfemene approved for distribution in Ohio are not limited to a specific formulation, brand, or method of delivery.

Section 2 – Liability Protections for Administration of an Overdose Reversal Drug

The liability protections for those administering an overdose reversal drug are now found in ORC 3715.504. This section specifically states:

> *(B) An individual who administers an overdose reversal drug under the authority conferred by division (A) of this section is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from administering the drug, and not subject to administrative action or criminal prosecution for an act or omission that arises from administering the drug, if the individual, acting in good faith, does all of the following:*
>
> *(1) Obtains the overdose reversal drug under section 3715.50, 3715.501, 3715.502, or 3715.503 or the Revised Code;*
>
> *(2) Administers the overdose reversal drug to an individual who is apparently experiencing an opioid-related overdose;*
>
> *(3) Attempts to summon emergency services as soon as practicable either before or after administering the overdose reversal drug, except that making such an attempt is not required if the individual administering the drug knows that emergency services already have been summoned or are present.*

Section 3 – Distributing Overdose Reversal Drugs without a Protocol

Ohio law (ORC 3715.50) permits **any** person or government entity to purchase, possess, personally furnish, and distribute an overdose reversal drug (ORD) without a prescriber-authorized protocol if all the following conditions are met:

(1) The overdose reversal drug is in its original manufacturer's packaging.

(2) The overdose reversal drug's packaging contains the manufacturer's instructions for use.

(3) The overdose reversal drug is stored in accordance with the manufacturer's or distributor's instructions.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Distributing Overdose Reversal Drugs without a Protocol	
How does the law define a person?	The law permits a person or government entity to distribute an ORD without a prescriber approved protocol. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
Are there any legal protections for persons and government entities distributing ORDs?	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from exercising that authority.* *After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
Does this law now permit me to treat an overdose	Yes, if the person, company, or government entity distributing overdose reversal drug meets the three

reversal drug like an over-the-counter medication?	requirements listed above. For example, pharmacies can now offer overdose reversal drug on store shelves rather than having it behind the pharmacy counter. However, pharmacies that are dispensing overdose reversal drug pursuant to a prescriber authorized protocol for insurance reimbursement should consult **Section 4** of this guide.
What type of overdose reversal drug can be distributed?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
I am licensed as a terminal distributor of dangerous drugs. Is there a patient-specific record keeping requirement or labeling requirement for the distribution of overdose reversal drug in accordance with this section?	No. In February 2023, the Board adopted the following resolution: *The Board hereby suspends all patient-specific record keeping requirements of division 4729:5 of the Administrative Code for personally furnishing or selling overdose reversal drug from a site licensed as a terminal distributor of dangerous drugs.* Therefore, a terminal distributor engaged in the distribution of overdose reversal drug in accordance with this section is not required to maintain patient logs or apply patient-specific labels to the drug.
How does this law change impact Service Entities?	The law authorizing Service Entities is repealed effective 4/6/23. The service entity law was replaced with ORC 3715.50, which provides more expansive authority for overdose reversal drug distribution (and no longer requires a prescriber protocol). A previous Service Entity that still wishes to distribute via a prescriber protocol (for example, for insurance billing) may still do so if they comply with the requirements in **Section 5** of this guide.

Section 4 – Dispensing Overdose Reversal Drugs in a Pharmacy

On April 6, 2023, section 4729.44 was officially renumbered to section 3715.502 of the Revised Code. This section governs the ability of pharmacist and pharmacy interns to dispense overdose reversal drugs (ORDs) pursuant to a prescriber-authorized protocol.

IMPORTANT: If you are a pharmacy that was dispensing overdose reversal drugs pursuant to a prescriber-authorized protocol prior to 4/6/23, you will not have to modify your current processes.

NOTE: This section applies to the dispensing of ORDs pursuant to a prescriber-authorized protocol. Nothing in Ohio law prohibits the dispensing of an ORD pursuant to a patient-specific prescription.

The Board has developed a sample protocol that can be used by pharmacies. The sample protocol can be accessed here: www.pharmacy.ohio.gov/sample.

Additionally, pharmacies may distribute overdose reversal drug without meeting the requirements for dispensing (see **Section 3** of this guide). The ability to dispense pursuant to a prescriber-authorized protocol is maintained in the law to allow for insurance reimbursement by the pharmacy.

To assist pharmacists and pharmacy personnel, the Board developed the following frequently asked questions:

Frequently Asked Questions - Dispensing Overdose Reversal Drugs in a Pharmacy	
Who may authorize a pharmacy dispensing protocol?	Physician (MD/DO), Physician Assistant, Advance Practice Registered Nurse **NOTE:** Prior to April 6, 2023, only a physician was permitted to authorize a dispensing protocol.
Who is eligible to receive an overdose reversal drug pursuant to a pharmacy dispensing protocol?	(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; (2) A family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

What are the requirements for the dispensing protocol? ***See:* *OAC 4729:1-3-04 (B)***	(1) A description of the clinical pharmacology of the overdose reversal drug. (2) Indications for use of the overdose reversal drug as rescue therapy, including criteria for identifying persons eligible to receive overdose reversal drug under the protocol. (3) Precautions and contraindications concerning dispensing an overdose reversal drug. (4) Overdose reversal drugs authorized to be dispensed, including all of the following information: (a) Name of product; (b) Dose; (c) Route of administration and required delivery device; and (d) Directions for use. (5) Any patient instructions in addition to the required patient training.
Is there a requirement to instruct individuals receiving an ORD to summon emergency services?	Yes. A pharmacist or pharmacy intern who dispenses an overdose reversal drug under this section shall instruct the individual to whom the drug is dispensed to summon emergency services as soon as practicable either before or after administering the drug.
What type of overdose reversal drug can be dispensed pursuant to a prescriber-approved protocol?	The law does not specify or limit the type of overdose reversal drug that can be dispensed pursuant to an approved protocol. However, the type of overdose reversal drug that may be dispensed is subject to the formulations specified within the protocol. If new formulations are developed, they may be added to the protocol.
If I dispense overdose reversal drug, am I required to notify the Board?	Yes. OAC 4729:1-3-04 requires a pharmacy to submit notification to the Board within 30 days of establishing an approved protocol. The Board uses this documentation to create a list on its web site to facilitate access to the medication. Please be advised, that a pharmacy that discontinues their protocol will also be required to notify the Board. The Notification Form, including submission instructions, can be accessed here.

	NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov. **REMINDER:** The notification requirement does not apply to institutional facilities that only provide ORDs upon discharge.
Can a pharmacist delegate the required training to a designee (such as a technician)?	Yes. The pharmacy is required to ensure that all pharmacist designees are appropriately trained on the use of overdose reversal drugs and can meet the training requirements.
What are the patient training requirements prior to dispensing an overdose reversal drug pursuant to a protocol? ***See: OAC 4729:1-3-04(D)***	In addition to requirements specified in the protocol, rule 4729:1-3-04 requires a pharmacist, pharmacy intern under the direct supervision of a pharmacist, or a pharmacist's designee that is appropriately trained to provide the following in-person training and written educational materials to the individual to whom an overdose reversal drug is dispensed: (1) Risk factors of opioid overdose; (2) Strategies to prevent opioid overdose; (3) Signs of opioid overdose; (4) Steps in responding to an overdose; (5) Information on the overdose reversal drug dispensed; (6) Procedures for administering the overdose reversal drug dispensed; (7) Proper storage and expiration of the overdose reversal drug dispensed; and (8) Information on where to obtain a referral for substance abuse treatment. ***Additionally, the patient receiving overdose reversal drug must be instructed, either verbally or in writing, that emergency services must be summoned as soon as practicable before or after administering overdose reversal drug.***
When does a prescriber authorized protocol expire?	The protocols shall be renewed by on a biennial basis.

See: OAC 4729:1-3-04(J)	
Is an offer to counsel the patient required if dispensing pursuant to a protocol?	Yes. An offer to counsel if still required. However, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.
Is there a limit to the amount of an overdose reversal drug that can be dispensed pursuant to a protocol?	A pharmacist or pharmacy intern should refer to their protocol to determine if there are any established limits. If no such limits exist, they should exercise their professional judgement.
Is there written information available to assist pharmacists, pharmacy interns and pharmacist designees with meeting the training requirements?	Yes. The Board has developed a brochure that covers all of the required training. The Board has a printed supply of these brochures that can be requested by a pharmacy free-of-charge by visiting: www.pharmacy.ohio.gov/NalBrochure The brochure is also available electronically (in the following languages: Nepali, Spanish, Somali, Arabic, and Simplified Chinese) by visiting: www.pharmacy.ohio.gov/naloxone
Are there any legal protections for pharmacists, interns, and authorizing prescribers?	Yes. ORC 3715.502 (E) states: *A physician, physician assistant, or advanced practice registered nurse who in good faith authorizes a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription, as provided in this section, is not liable for or subject to any of the following for any act or omission of the individual to whom the drugs are dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.* *A pharmacist or pharmacy intern authorized under this section to dispense overdose reversal drugs without a prescription who does so in good faith is not liable for or subject to any of the following for any act or omission of the individual to whom the drugs are dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*

Are there record keeping requirements for pharmacists and pharmacy interns dispensing an overdose reversal drug pursuant to a protocol?	All laws and rules regarding the dispensing of drugs by a pharmacy would apply to an ORD dispensed pursuant to a protocol.
Are there any age restrictions for dispensing an overdose reversal drug pursuant to a protocol?	Unless specified in the signed protocol, there are no restrictions on the age for dispensing an overdose reversal drug. A pharmacist must use their professional judgement to determine if a minor is sufficiently mature with respect to intellect and emotions to carry out all the responsibilities to effectively respond to a suspected overdose, including the administration of an ORD.
I am a prescriber that will be authorizing several pharmacies to dispense ORDs pursuant to a protocol. Do I need to have a signed protocol for every pharmacy?	No. The protocol issued by the prescriber can be signed once and include a list of all the authorized pharmacies. That protocol should then made available to all participating pharmacies.
Are there any substance abuse resources available to patients and their families?	The Ohio CareLine (1-800-720-9616) is a toll-free emotional support call service created by the Ohio Department of Mental Health and Addiction Services and administered in community settings. Behavioral health professionals staff the CareLine 24 hours a day, 7 days/week. They offer confidential support in times of personal or family crisis when individuals may be struggling to cope with challenges in their lives. When callers need additional services, they will receive assistance and connection to local providers.
I am a pharmacy dispensing overdose reversal drugs pursuant to a prescription. Do I need to comply with the requirements of OAC 4729:1-3-04?	No. The requirements in OAC 4729:1-3-04 are only for pharmacies that dispense overdose reversal drugs pursuant to a prescriber approved protocol. It does not apply to pharmacies that provide overdose reversal drug pursuant to a prescription or an order by a licensed prescriber.

Are there any additional training requirements for pharmacies that offer overdose reversal drugs without a prescription?	Yes. A pharmacy that has submitted notification of overdose reversal drug dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of overdose reversal drugs dispensing pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.
Does my pharmacy need to keep overdose reversal drugs on-site?	Yes. Except in the event of a drug shortage, a pharmacy that has submitted notification of overdose reversal drug dispensing shall ensure the drug is made available for patients who request it.
Do I need to comply with the standard record keeping requirements for dispensing a dangerous drug?	Yes. Any drug that is dispensed (even if dispensed via protocol) must comply with the Board's record keeping requirements for the dispensing of dangerous drugs.

Section 5 – Personally Furnishing Overdose Reversal Drugs via Prescriber Protocol

Previous sections of the Ohio Revised Code that governed the distribution of overdose reversal drug via a prescriber protocol have been consolidated into section 3715.503 of the Revised Code. This section governs the ability of lay persons to dispense ORDs pursuant to a prescriber-authorized protocol.

Please be advised that a protocol IS NOT REQUIRED for the distribution of naloxone and other ORDs (see Section 3). However, the ability to distribute via a prescriber protocol was retained in the law to allow for the billing of an overdose reversal drug via a patient's insurance. Facilities that previously considered themselves "Service Entities" are no longer required to distribute via a prescriber issued protocol (see Section 3).

To assist those seeking to distribute overdose reversal drugs in accordance with a prescriber protocol, the Board developed the following frequently asked questions:

Frequently Asked Questions - Personally Furnishing Overdose Reversal Drugs via Prescriber Protocol	
Who may authorize a protocol to personally furnish an ORD?	Physician (MD/DO), Physician Assistant, Advance Practice Registered Nurse
Who is eligible to receive an ORD pursuant to a prescribe authorized protocol?	The law provides no specifics. The eligibility criteria should be established in the protocol.
What are the requirements for a protocol to personally furnish an ORD? ***See: ORC 3715.503 (B)***	A protocol established by a physician, physician assistant, or advanced practice registered nurse for purposes of this section shall include all of the following: (1) Any limitations to be applied concerning the individuals to whom the overdose reversal drug may be personally furnished; (2) The overdose reversal drug dosage that may be personally furnished and any variation in the dosage based on circumstances specified in the protocol;

	(3) Any labeling, storage, recordkeeping, and administrative requirements; (4) Training requirements that must be met before a person will be authorized to personally furnish overdose reversal drugs; (5) Any instructions or training that the authorized person must provide to an individual to whom an overdose reversal drug is personally furnished.
Is there a requirement to instruct individuals receiving an ORD to summon emergency services?	Not specifically. However, the immunity protections in ORC 3715.504 for those administering an ORD are contingent on the summoning of emergency services. Therefore, it is strongly recommended. (See **Section 2** for Liability Protections)
What type of overdose reversal drugs can be personally furnished pursuant to a prescriber-approved protocol?	The law does not specify or limit the type of overdose reversal drug that can be personally furnished pursuant to an approved protocol. However, the type of overdose reversal drug that may be dispensed is subject to the formulations specified within the protocol. If new formulations are developed, they may be added to the protocol.
What are the patient training requirements prior to personally furnishing overdose reversal drugs pursuant to a protocol?	There are no specific training requirements. Rather, the law requires the authorizing prescriber to establish those requirements in the protocol.
When does a prescriber authorized protocol expire?	The law does not require the protocols to be renewed once they have been authorized.
Are there any legal protections for authorizing prescribers?	Yes. ORC 3715.503 (C) states: *A physician, physician assistant, or advanced practice registered nurse who in good faith authorizes an individual to personally furnish a supply of an overdose reversal drug in accordance with a protocol established under this section, and*

	an individual who in good faith personally furnishes a supply under that authority, is not liable for or subject to any of the following for any act or omission of the individual to whom the overdose reversal drug is personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.
Is there a patient-specific record keeping requirement or labeling requirement for lay distributors personally furnishing pursuant to a protocol?	No. There is no requirement in the law. Additionally, the Board issued the following resolution for licensed terminal distributors of dangerous drugs that are personally furnishing overdose reversal drugs in accordance with a prescriber protocol: *The Board hereby suspends all patient-specific record keeping requirements of division 4729:5 of the Administrative Code for personally furnishing or selling an overdose reversal drug from a site licensed as a terminal distributor of dangerous drugs.* Therefore, a terminal distributor distributing an ORD in accordance with this section is not required to maintain patient logs or apply patient-specific labels to the drug.
Are there any age restrictions for dispensing an overdose reversal drug pursuant to a protocol?	Unless specified in the signed protocol, there are no age restrictions.
Is there written information available to assist with the training of patients?	Yes. The Board has developed a brochure that covers many of the typical training requirements for providing an overdose reversal drug to laypersons. The brochure is available electronically by visiting: www.pharmacy.ohio.gov/naloxone. Additionally, the Ohio Department of Health's Project DAWN Program has several training resources available.
Are there any substance abuse resources available to patients and their families?	The Ohio CareLine (1-800-720-9616) is a toll-free emotional support call service created by the Ohio Department of Mental Health and Addiction Services and administered in community settings. Behavioral health professionals staff the CareLine 24 hours a day, 7 days/week. They offer confidential support in times of personal or family crisis when individuals may be struggling to cope with challenges in their lives. When

	callers need additional services, they will receive assistance and connection to local providers.

Section 6 – Overdose Reversal Drugs for Emergency Use (Naloxboxes)

Section 3715.50 of the Revised Code permits any person or government entity to obtain and maintain a supply of an overdose reversal drug for use in an emergency. Prior to April 6, 2023, only a licensed terminal distributor of dangerous drugs could obtain and maintain a supply of an overdose reversal drug for use in an emergency.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Overdose Reversal Drugs for Emergency Use	
How does the law define a person?	The law permits a person or government entity to obtain and maintain a supply of an overdose reversal drug for use in an emergency. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
What are the requirements for obtaining and maintaining an ORD for emergency use? ***See: ORC 3715.50 (C)***	In the case of a supply of an overdose reversal drug obtained and maintained for use in an emergency situation, a person or government entity shall do all of the following: (1) Provide to any individual who accesses the drug instructions regarding emergency administration of the drug, including a specific instruction to summon emergency services as necessary; (2) Establish a process for replacing within a reasonable time period any overdose reversal drug that has been accessed; (3) Store the overdose reversal drug in accordance with the manufacturer's or distributor's instructions. **NOTE:** It is up to the person or government entity to determine a reasonable time period for replacing an ORD that has been accessed.
Are there any legal protections for persons and government entities	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is*

maintaining ORDs for emergency use?	*not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from exercising that authority.* *After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
What type of overdose reversal drug can be maintained for emergency use?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
Do I need a prescriber protocol or prescription to access and use the emergency overdose reversal drug?	No. Section 3715.50 of the Revised Code does not require a prescriber protocol or prescription to access and use the emergency overdose reversal drug.
I obtained a terminal distributor of dangerous drugs license from the Board of Pharmacy to maintain overdose reversal drugs for emergency use. Do I need to maintain my license?	If you obtained a terminal distributor of dangerous drugs license for the **sole purpose** of maintaining overdose reversal drugs for emergency use, then you may discontinue your license. To do so, please following the instructions on this form: www.pharmacy.ohio.gov/DCB.

Section 7 – Vending Machines for Overdose Reversal Drugs

Section 3715.50 of the Revised Code permits any person or government entity to obtain and maintain a supply of an overdose reversal drug for distribution through an automated mechanism (e.g., a vending machine). Prior to April 6, 2023, only a licensed terminal distributor of dangerous drugs could distribute an overdose reversal drug through an automated mechanism.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Vending Machines for Overdose Reversal Drugs	
How does the law define a person?	The law permits a person or government entity to obtain and maintain a supply of an overdose reversal drug for distribution through an automated mechanism. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
What are the requirements for distribution of an ORD through an automated mechanism? ***See: ORC 3715.50 (C)***	In the case of a supply of an overdose reversal drug obtained and maintained for distribution through an automated mechanism, a person or government entity shall do all of the following: (1) Ensure that the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location; (2) Provide to any individual who accesses the drug instructions regarding emergency administration of the drug, including a specific instruction to summon emergency services as necessary; (3) Develop a process for monitoring and replenishing the supply maintained in the automated mechanism; (4) Store the overdose reversal drug in accordance with the manufacturer's or distributor's instructions.

Are there any legal protections for persons and government entities distributing ORDs through an automated mechanism?	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from exercising that authority.* *After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
What type of overdose reversal drug can be provided via automated mechanism?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
Do I need a prescriber protocol or prescription to access an overdose reversal drug via an automated mechanism?	No. Section 3715.50 of the Revised Code does not require a prescriber protocol or prescription to distribute an overdose reversal drug through an automated mechanism.
I obtained a terminal distributor of dangerous drugs license from the Board of Pharmacy to install an automated mechanism. Do I need to maintain my license?	If you obtained a terminal distributor of dangerous drugs license for the **sole purpose** of distributing overdose reversal drugs, then you may discontinue your license. To do so, please following the instructions on this form: www.pharmacy.ohio.gov/DCB.

4729-8-01 **Overdose Reversal Drugs.**

Pursuant to section 4729.01 of the Revised Code, the state board of pharmacy hereby designates the following dangerous drugs, which have been approved by the federal food and drug administration for the reversal of a known or suspected opioid-related overdose, as overdose reversal drugs:

(A) Naloxone; and

(B) Nalmefene.

Effective: 10/31/2023

Five Year Review (FYR) Dates: 10/31/2028

CERTIFIED ELECTRONICALLY

Certification

10/20/2023

Date

Promulgated Under: 119.03
Statutory Authority: 4729.01
Rule Amplifies: 4729.26, 3715.50, 3715.501, 3715.502, 3715.503, 3715.504, 3715.505

State of Utah

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

Department of Health & Human Services

TRACY S. GRUBER
Executive Director

NATE CHECKETTS
Deputy Director

DR. MICHELLE HOFMANN
Executive Medical Director

DAVID LITVACK
Deputy Director

NATE WINTERS
Deputy Director

Utah Statewide Standing Order
Dispensing Opioid Antagonists for Opioid Overdose Prevention

Purpose:
Opioid overdose can be reversed and death prevented by timely administration of an opioid antagonist. As authorized by State law, this standing order is intended to increase access to FDA approved opioid antagonists for those who might be at risk of an overdose or who might be in a position to assist someone at risk of an overdose.

Authority:
This standing order shall be considered a prescription for a FDA approved opioid antagonist for an eligible person or entity. This standing order authorizes a pharmacist to dispense a FDA approved opioid antagonist to any eligible person or entity. This standing order authorizes any eligible person or entity in the State of Utah, including but not limited to any wholesaler licensed in the State of Utah, to possess, store, deliver, distribute, or administer FDA approved opioid antagonists.

Pursuant to the authority provided in UCA §26B-4-510(2), this standing order authorizes a pharmacist licensed under UCA §58-17b Pharmacy Practice Act to dispense an opioid antagonist according to the provisions of UCA §26B-4-510 and R156-17b-625 and the requirements of this standing order.

Immunity:
UCA §26B-4-510 provides protection from civil liability for a pharmacist who dispenses an opioid antagonist according to this standing order.

Dispensing Guidelines:
The following individuals may receive a FDA approved opioid antagonist under this standing order:

- an individual who is at increased risk of experiencing an opioid overdose;
- a family member, friend or other person who could assist an individual at increased risk of an opioid overdose, including an individual on behalf of:
    - a law enforcement agency or correctional setting;
    - the Utah Department of Health and Human Services;
    - a Utah local health department;
    - a community based organization (e.g., 501c3, churches, YMCAs, public libraries);
    - an organization that provides substance abuse or mental health treatment, recovery or support services;
    - an organization that provides services to the homeless;
    - an organization that provides training in proper administration of an opioid antagonist;
    - an organization that provides harm reduction services;
    - Native American Tribal Communities;
    - first responders (e.g., fire, emergency medical services);

    - educational facilities;
    - schools; or
- an individual on behalf of an overdose outreach provider for use as provided in UCA §26B-4-511.

Authorized Products:
Opioid antagonist formulations may be dispensed under this standing order as long as they have been approved by the FDA. When dispensing a commercially packaged take-home kit, proper care should be given to make sure the recipient is aware of the type of kit they have and where instructions for the take home kit are located. Administration of these kits should be as directed.

Prices vary widely for the different products and reimbursement practices vary by insurer.

- Currently, some insurance plans cover naloxone, but not other forms of opioid antagonists. Check coverage and dispense based on coverage and pharmacy benefit criteria.
- Medicaid patients of record may be covered by their insurance. All forms of an opioid antagonist are covered by Medicaid without prior authorization for their patients.
- For patients without insurance coverage, referral can be made to any other local resource for which the pharmacy is aware. The Utah Department of Health and Human Services Executive Medical Director will not submit prior authorization forms for this standing order. If prior authorization is required for a particular product, another type of product should be provided that does not require prior authorization. The patient may also work with their healthcare provider to submit a prior authorization form on their behalf.

Reporting:
As required in R156-17b-625, the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee that dispenses an opioid antagonist under this standing order shall affirm that the pharmacy licensee has complied with the protocol in UCA §26B-4-510 and shall report the following information:

- the total number of single doses dispensed during the reporting period; and
- the name of each product dispensed along with the total number of single doses of that particular product.

The report must be submitted no later than 10 days after December 31 of each calendar year through a link that will be provided to enrolled pharmacies by the Utah Department of Health and Human Services.

Registration:
Pharmacies that plan to dispense an opioid antagonist under this standing order are asked to voluntarily enroll with the Utah Department of Health and Human Services at https://pubredcap.health.utah.gov/surveys/?s=JJ7D8FYDAM.

In addition to any other requirements under Utah or federal law, the pharmacy licensee must keep the data specified in R156-17b-625(5).

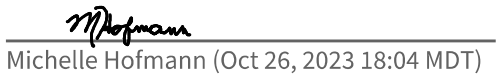
Education:
Pharmacists who dispense an opioid antagonist under this order should understand the key warnings established by the FDA's Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee, including:

- risk of recurrent respiratory and CNS depression as the duration of effect of an opioid antagonist may be shorter than the opioids being antagonized. It is recommended that medical care is sought, surveillance maintained, and additional doses administered, if needed;
- risk of limited efficacy with partial agonists or mixed agonists/antagonists;

- abrupt postoperative reversal of opioid depression may result in adverse cardiovascular effects, primarily in patients who had preexisting cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects; and
- precipitation of severe opioid withdrawal, particularly in opioid dependent patients and neonates. It is recommended these patients be monitored for the development of opioid withdrawal.

Educational materials to provide to an individual when an opioid antagonist is dispensed and educational materials for dispensers can be found at https://opidemic.utah.gov/resources/. Naloxone training can be found at https://opidemic.utah.gov/naloxone/naloxone-training/.

Effective Period for this Order:
The Utah Department of Health and Human Services will review this standing order and request input from the Utah Board of Pharmacy as new information becomes available to provide recommendations and support of revisions prior to a re-issue as needed or at least every 2 years.


Michelle Hofmann (Oct 26, 2023 18:04 MDT)

10/26/2023

Michelle G. Hofmann, MD, MPH, MHCDS, FAAP
Executive Medical Director
Utah Department of Health and Human Services

Date

DEA Number: BH8966321
NPI Number: 1760550628

Statewide Standing Order for Naloxone and Other Opioid Reversal Agents
Virginia Department of Health
109 Governor Street, 13th Floor
Richmond, VA 23219

Date Issued: March 5, 2024

The persons identified below are authorized to dispense and administer naloxone and other opioid antagonists, referred to as opioid reversal agents (ORA), pursuant to this standing order and in accordance with protocols by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. Additionally, this standing order authorizes a licensed pharmacy, wholesale distributor, third party logistics provider or manufacturer to distribute the ORA formulations specified below via invoice to entities designated by this standing order in accordance with Virginia Board of Pharmacy Guidance Document §110-44.

Authorized Dispensers:

The following individuals may dispense and administer ORAs pursuant to this standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow Board of Pharmacy protocol when dispensing naloxone as authorized in §54.1-3408 (X):

- Pharmacists who maintain a current active license practicing in a pharmacy located in Virginia that maintains a current active pharmacy permit,
- Health care providers providing services in a hospital emergency department
- Emergency medical services personnel as defined in §32.1-111.1, and
- Law-enforcement officers as defined in §9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in §53.1-1,
- Employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers,
- Employees of regional jails,
- School nurses,
- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees, or individuals contracted by a school board to provide school health services, and
- Firefighters.

Authorized ORAs for Persons Authorized to Dispense Pursuant to §54.1-3408 (X)			
Intranasal	Auto-injector	Intranasal	Intranasal
Naloxone 2mg/2mL prefilled syringe, #2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. **Mucosal Atomization Device (MAD)** Directions: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	**Naloxone 2mg or 5mg auto-injector, #1 twin pack** Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	**Naloxone 4mg or 8mg nasal spray, #1 twin pack** Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	**Nalmefene 2.7mg nasal spray, #1 twin pack** Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 5 minutes until emergency medical assistance arrives.

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to this standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow Board of Pharmacy protocol when dispensing naloxone as authorized in §54.1-3408 (Y)

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;
- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.
- **Note: Virginia Code §54.1-3408 (Y) does not currently authorize the dispensing of opioid antagonists other than naloxone.**

Authorized Naloxone Formulations for Persons Authorized to Dispense Pursuant to §54.1-3408 (Y)

Intranasal		Auto-injector	Injection*
Naloxone 2mg/2mL prefilled syringe, #2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. **Mucosal Atomization Device (MAD)** Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	**Naloxone 4mg or 8mg nasal spray, #1 twin pack** Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	**Naloxone 2mg or 5mg auto-injector, #1 twin pack** Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	**Naloxone 0.4mg/mL, #2 single-use 1 mL vials** Directions: inject 0.4mg (1mL) in shoulder or thigh muscle upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. Must dispense with 2 single-use 1 mL vials, 2 (3 ml) syringes and 2 (23-25 gauge) hypodermic needles and instructions for administration. Directions: Use as directed for naloxone administration.

*Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organizations has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes.

This order is effective for two (2) years from the date issued, unless otherwise discontinued by the Commissioner or upon his resignation, removal, or retirement. Any individual dispensing ORAs pursuant to this order must maintain a copy of the standing order for two (2) years from the last date of dispensing.

Please call the Office of the Commissioner at (804) 864-7001 with questions about this standing order. Please call the Board of Pharmacy at (804) 367-4456 with questions about the dispensing protocol. For questions about the REVIVE! Training program, please call the Department of Behavioral Health and Developmental Services at (804) 786-0464.

May refill as long as order remains effective.

Prescriber: _____ Date: 03/05/2024

Karen Shelton, MD, FACOG
NPI Number: 1619926680
Virginia Medical License Number: 0101260180
Virginia Department of Health

WEST VIRGINIA
OFFICE OF THE COMMISSIONER & STATE HEALTH OFFICER
STANDING ORDER
OPIOID ANTAGONIST PRESCRIPTION FOR OVERDOSE PREVENTION

Opioid antagonist medications are 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 State of West Virginia who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons, that are in a position to assist a person at risk of experiencing an opioid-related overdose (Eligible Persons), are able to obtain opioid antagonists. This order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Organizations with a medical staff should rely on those medical professionals to write prescriptions or issue standing orders specific to the personnel who would be expected to administer opioid antagonists.

II. AUTHORITY

This standing order is issued in accordance with West Virginia Code §16-46-7, which permits the State Health Officer to prescribe an opioid antagonist by one or more standing orders to Eligible Persons.

III. AUTHORIZATION

This standing order may be used by Eligible Persons as a prescription or third-party prescription to obtain an opioid antagonist from a pharmacy. This order is authorization for pharmacists to dispense opioid antagonists and devices for its administration in the forms prescribed herein.

IV. ADMINISTRATION

Eligible Persons may administer, provide, or make available opioid antagonists to a person who the Eligible Person suspects of experiencing an opioid overdose event.

V. FORMULATION AND DIRECTIONS

Any opioid antagonists FDA approved for the treatment of a suspected opioid overdose and necessary paraphernalia for their administration may be dispensed to Eligible Persons.

A. For Intranasal Administration
Administer dosage according to the package insert. Repeat after three (3) minutes if no or minimal response.

B. For Intramuscular Injection (vial)
Administer dosage according to the package insert. Inject the recommended dose IM into the shoulder or thigh. Repeat after three (3) minutes if no or minimal response.

C. For Intramuscular or Subcutaneous Injection
Administer dosage according to the package insert. Inject the recommended dose into the outer thigh. Repeat after three (3) minutes if no or minimal response.

VI. REVIEW OF ORDER

This standing order will be reviewed and may be updated as additional information or changes to legislation/training materials occur. This standing order may be withdrawn by the State Health Officer at any time.

EXECUTED on this the 1 day of Dec, 2023.

Matthew Q. Christiansen, MD, MPH
Commissioner & State Health Officer
Bureau for Public Health

sbt Testimony SB0793 – Public Health - Opioid Over
Uploaded by: Stephen Thomas
Position: FAV

UNIVERSITY OF MARYLAND
SCHOOL OF PUBLIC HEALTH
Maryland Center for Health Equity

2242 SPH Building (# 255)
College Park, Maryland 20742-2611
301.405.2438 TEL 301.405.8397 FAX
www.sph.umd.edu

February 18, 2025

Senator Pamela Beidle, Chair
Senator Antonio Hayes, Vice Chair
Finance Committee
East Miller Senate Building, Room 3
Annapolis, Maryland 21401

SUBJECT: SB0793 – Public Health - Opioid Overdose Reversal Drugs

Chair Beidle,

I am Dr. Stephen B. Thomas, Professor of Health Policy and Management and Director, the University of Maryland Center for Health Equity. I speak in my personal capacity today. I appreciate the opportunity to hear my support for SB0793 – Public Health - Opioid Overdose Reversal Drugs. I urge a favorable report on Senate Bill 0793.

As you are aware, in recent years the opioid epidemic has impacted too many people and families across Maryland and the United States. It is vital that our first responders, health care providers, and average citizens have the education and tools to help their fellow citizens in life threatening overdose situations. Fentanyl has emerged as the leading cause of overdose deaths in Maryland – according to U.S. Attorney's Office and DEA, in more than 2,000 overdose deaths from July 2023 through June 2024 – more than 1,600 were fentanyl related.

Scientists and health professionals are constantly looking to improve the responses to these overdoses, and it is important that Maryland include any formulation of any opioid reversal drug approved by the federal Food and Drug Administration in the standing order. It is my understanding that several other states have already taken the same step.

By updating the standing order to include all FDA approved opioid reversal drugs, we will be ready for the introduction of new, more effective, or less expensive medicines that may be approved in the future. As the state's standing order is only updated annually, we do not want to be left in a situation where there is a new, more effective, or less costly reversal drug that is not available to Maryland's first responders, health professionals and citizens.

In addition, just as fentanyl has emerged as the preeminent killer in the state's overdoses, one day another drug will take its place. By updating the standing order, Maryland will be ready to ensure that reversal drugs better suited to reversing this next drug, or the one after that, can be quickly made available.

Opioids and overdoses are a public health crisis without question. It is critical that we mobilize our communities and trusted voices within them to help spread awareness messages to help prevent

overdose deaths. That also means equipping them with the education and tools to respond to overdoses as they happen so they can help save lives.

I have spent the last two decades working to spread awareness for colorectal cancer screenings and COVID vaccinations through trusted community leaders in Black and Brown communities. I helped build the HAIR program — Health Advocates In-Reach and Research — while working with barber shops in Pittsburgh around 2005 to spread awareness for colorectal cancer screenings to a population of mostly Brown and Black people, who have a history of mistrust with the health care system. I then brought the program to the University of Maryland in 2010 and expanded it to COVID vaccinations when the pandemic hit.

My current research at University of Maryland focuses on the translation of evidence-based science on chronic disease into community-based interventions designed to eliminate racial and ethnic disparities in health and health care. I have also focused on understanding how social context shapes attitudes and behaviors of underserved, poorly served, and never-served segments of our society toward participation in health promotion and disease prevention activities. Much of my research has been centered on how the legacy of the Syphilis Study at Tuskegee (1932–72) has impacted trust and influenced the willingness of African Americans to participate in medical and public health research.

Previously I was a member of the Maryland Health Quality and Cost Council's Health Disparity Work Group. The final report of our work was translated into legislation and passed into law as the Maryland Health Improvement and Disparities Reduction Act of 2012. In 2014, Democratic Gov. O'Malley appointed me to serve on the Maryland Health Care Commission and I was reappointed in 2019 by Gov. Larry Hogan.

I am deeply committed to helping to address the public health challenges of underserved communities across Maryland and the country, and ensuring these communities have trust in the health care system and public health systems. I believe that updating the standing order to include all FDA approved opioid reversal drugs is a smart move for Maryland and it will show our citizens that nothing is being held back from our first responders and health providers that could save lives because of where someone lives or the color of their skin.

Thank you for your consideration. Again, I urge a favorable report on Senate Bill 0793.

Sincerely,

Stephen B. Thomas
Professor, Department of Health Services Administration
Director, Maryland Center for Health Equity
Office Number: 301 405-8859
Email: sbt@umd.edu

SB793_RHTC_FAV.pdf
Uploaded by: Therese Hessler
Position: FAV

February 18, 2025

Senate Finance Committee

SB793 - Public Health - Opioid Overdose Reversal Drugs

POSITION: FAVORABLE

Recovery Housing & Treatment Center Coalition of Maryland (RHTC) strongly supports Senate Bill 793 (SB793) – Public Health – Opioid Overdose Reversal Drugs. Our coalition represents recovery residences, group homes, treatment centers, and other essential services that contribute to the continuum of care throughout Maryland. We work diligently to educate policymakers, stakeholders, and communities on the importance of maintaining and expanding recovery facilities and services to support individuals in their journey to long-term recovery.

SB793 is a crucial step forward in addressing the ongoing opioid crisis that continues to devastate communities across our state. By requiring licensed healthcare providers to allow individuals to choose any formulation of FDA-approved opioid overdose reversal drugs, this legislation ensures greater access and flexibility in obtaining life-saving medication. As providers of comprehensive recovery services, we understand firsthand that barriers to accessing overdose reversal drugs can mean the difference between life and death for individuals struggling with substance use disorder.

Additionally, this bill protects private and public entities that prescribe and dispense opioid overdose reversal drugs from being mandated to stock all formulations. Many treatment centers and recovery housing facilities operate on limited resources, and this measure ensures that we can continue providing essential care without excessive financial or operational burdens.

For individuals in recovery, stability, safety, and timely intervention are critical. The passage of SB 793 aligns with our mission to support those in recovery, protect communities, and uphold Maryland's commitment to combating the opioid epidemic. By expanding access to opioid overdose reversal drugs, this bill will empower treatment providers, protect individuals at risk, and ultimately save lives.

We ask the Committee to support SB793 and take a decisive step toward enhancing Maryland's public health infrastructure.

For more information call or email:
Therese M. Hessler, Ashlar Government Relations | 301-503-2576 | therese@ashlargr.com

SB0793_UNF_MedChi_PH - Opioid Overdose Reversal Dr
Uploaded by: Christine Krone
Position: UNF

MedChi

The Maryland State Medical Society
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Senate Finance Committee
February 18, 2025
Senate Bill 793 – *Public Health – Opioid Overdose Reversal Drugs*
POSITION: OPPOSE

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **opposes** Senate Bill 793. The bill proposes the inclusion of novel opioid reversal drugs as a mandatory part of Maryland's public health strategy. We appreciate the intent behind the bill to address the opioid overdose crisis, but we believe that this legislation, as written, could have unintended and harmful consequences for public health in our State.

The Maryland Department of Health (MDH) currently operates an evidence-based Overdose Education and Naloxone Distribution (OEND) strategy, which reflects best practice standards and is supported by a substantial body of scientific evidence. Naloxone remains the most widely accepted and proven treatment for opioid overdoses. Given this evidence, we are concerned that the proposed bill would divert resources from a successful, established program and create logistical and financial burdens that could ultimately reduce the effectiveness of overdose reversal efforts in Maryland.

One of the core elements of Senate Bill 793 is the inclusion of Nalmefene as an opioid reversal drug. However, we have significant reservations about its effectiveness and safety, particularly in community overdose settings. Nalmefene has not been adequately tested in real-world overdose situations, and the available evidence suggests that its efficacy is not yet sufficiently established. The drug's approval was granted through an abbreviated process based on an earlier formulation primarily tested in hospital settings. This raises concerns about whether Nalmefene is suitable for emergency use in the field.

Additionally, clinicians have raised alarms about Nalmefene's potential to induce more severe opioid withdrawal symptoms compared to Naloxone. Given that Nalmefene binds more strongly to opioid receptors and has a prolonged duration of action, there is a significant risk that its use in overdose reversal could complicate recovery and prolong withdrawal symptoms, which is especially problematic in emergency settings where immediate treatment is critical. There is also concern that these prolonged withdrawal symptoms could overwhelm emergency departments, leading to more extensive treatment requirements and longer observation times.

Multiple respected medical and professional organizations, including the MD-DC Society of Addiction Medicine, the American College of Medical Toxicology, and the American Academy of Clinical Toxicology, have voiced concerns about the safety and efficacy of Nalmefene. These organizations recommend that Nalmefene should not replace Naloxone as the primary opioid antidote at this time, as it does not meet the standards required to ensure patient safety and the best possible outcome in overdose situations.

In conclusion, while we share the goal of reducing opioid overdose deaths, we believe that Senate Bill 793 could undermine the State's existing, successful harm reduction strategies. For these reasons, we urge an unfavorable vote.

For more information call:
Christine K. Krone
J. Steven Wise
Danna L. Kauffman
Andrew G. Vetter
410-244-7000

SB793 - MOOR - LOO.docx.pdf
Uploaded by: Emily Keller
Position: UNF

Maryland

Maryland's Office of Overdose Response

Wes Moore, Governor · Aruna Miller, Lt. Governor · Emily Keller, Special Secretary of Overdose Response

February 18, 2025

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401

RE: SenateBill 793- Public Health - Opioid Overdose Reversal Drugs

Dear Chair Beidle:

Maryland's Office of Overdose Response (MOOR) respectfully submits this letter of opposition for Senate Bill (SB) 793, which aims to require a licensed health care provider, when issuing a standing order for an opioid overdose reversal drug, to allow an individual to choose any FDA-approved overdose reversal drug in any formulation, and which prohibits a requirement for certain public and private entities that prescribe and dispense opioid overdose reversal drugs to stock all FDA-approved overdose reversal drugs.

The Maryland Department of Health currently operates the Overdose Response Program (ORP) which provides naloxone to community-based organizations and other entities for distribution at no cost. Naloxone is safe, effective, and a proven life-saving tool in community-based environments. MOOR believes that MDH's efforts at overdose education and naloxone distribution are highly effective and rooted in best practices.

SB 793 would require the standing order issued by MDH to cover newer overdose reversal drugs, such as nalmefene. Nalmefene has not been used extensively in the community setting in the same way as naloxone, and nalmefene runs the risk of inducing more significant precipitated opioid withdrawal in patients. Opioid withdrawal may manifest moderate symptoms such as dysphoria or gastrointestinal problems, or it may manifest more severely with agitation or cardiac problems.[1] Precipitated withdrawal may lead someone who has just had an overdose reversed to avoid further treatment in the moment in favor of self-medicating. In 2023, the American College of Medical Toxicology and the American Academy of Clinical Toxicology released a joint position statement that expressed concern at the use of nalmefene and cautioned against using it in place of naloxone due to its potential to cause unintended harm.[2]

[1] Stolbach, A. I., Mazer-Amirshahi, M. E., Nelson, L. S., & Cole, J. B. (2023). American College of Medical Toxicology and the American Academy of Clinical Toxicology position statement: nalmefene should not replace naloxone as the primary opioid antidote at this time. Clinical Toxicology, 61(11), 952-955
[2] Ibid

Additionally, nalmefene and other newer opioid overdose reversal drugs may incur a higher cost on the State's efforts to address the overdose crisis. For these reasons, MOOR believes that SB 793 does not improve the state's overdose response efforts.

If you would like to discuss this further, please do not hesitate to contact Benjamin Fraifeld, Associate Director for Policy & Advocacy at MOOR, 443-346-3013.

Sincerely,

Emily Keller
Special Secretary of Overdose Response

SB 793 - MDH - FIN -LOO (1).pdf
Uploaded by: Meghan Lynch
Position: UNF

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 18, 2025

The Honorable Pamela Beidle
Chair, Finance Committee
3 East Miller Senate Office Building
Annapolis, Maryland 21401

RE: Senate Bill 793 – Public Health - Opioid Overdose Reversal Drugs – Letter of Opposition

Dear Chair Beidle and Committee Members:

The Maryland Department of Health (Department) respectfully submits this letter of opposition for Senate Bill (SB) 793 – Public Health - Opioid Overdose Reversal Drugs.

SB 793 would require health care providers, when writing standing orders for an opioid reversal drug, to allow an individual to choose any formulation of any opioid overdose reversal drug (OORDs) approved by the Food and Drug Administration (FDA).

While the Department acknowledges the intent of the legislation to expand access, the legislation is not required as an individual can currently request any formulation of opioid overdose reversal drugs approved by the FDA. The Department is dedicated to addressing the overdose crisis in Maryland and is actively providing overdose reversal medications via a statewide standing order, which includes all formulations of naloxone and technical support for pharmacists on how to educate individuals who access naloxone via the standing order on how best to utilize the medication, through the Overdose Response Program (ORP). In fiscal year 2024, we distributed more than 430,283 OORDs into the community.

MDH has concerns with the bill as currently drafted. Maryland's ORP, administered by the MDH Office of Harm Reduction, oversees the majority of community-level overdose education and naloxone distribution in the state. The program relies on licensed healthcare practitioners to issue standing orders that authorize non-medical staff—such as outreach workers and community health educators—to dispense naloxone. These standing orders allow prescribers to determine which formulations are most appropriate for the populations served, ensuring that individuals at risk of overdose receive products that are safe, effective, and easy to administer in high-stress situations.

By requiring that the end recipient be allowed to select any FDA-approved product, this bill undermines the prescriber's clinical authority and may compel harm reduction programs to distribute newer, more potent formulations that have limited real-world data on safety and

efficacy[1] when administered by non-medical personnel. Many prescribers who currently support ORP efforts may not be comfortable authorizing distribution of these products under their licenses, potentially leading them to withdraw from participation. Given that many prescribers serve in voluntary or unpaid roles, even a small reduction in participation could significantly impact the availability of standing orders across the state, threatening the operational integrity of ORP organizations.

MDH provides overdose reversal education technical assistance and distributes naloxone to community-based organizations at no cost to those organizations. Naloxone is a well-known opioid overdose reversal medication with a long-standing history of safe use in community-based settings through the Overdose Response Program (ORP). MDH has provided years of public health education to the community around the appropriate administration of this formulation in conjunction with the activation of the emergency medical system. The effectiveness of MDH's overdose education and naloxone distribution strategies (OEND), as described above, reflect best practice standards based on a large body of evidence within the scientific literature.[2]

HB 572, if passed as written, would require MDH to include novel formulations of overdose reversal medications approved by the FDA, which lack evidence of efficacy in community-based settings. New OORDs, namely nalmefene hydrochloride, have recently become available - however, in the case of nalmefene hydrochloride, clinicians have expressed concern about the use of the formulation in the community setting due to the increased likelihood of inducing opioid withdrawal and have urged further study of the formulation. This view has also been expressed by the American College of Medical Toxicology and the American Academy of Clinical Toxicology, which released a joint statement expressing concern about the utilization of nalmefene as an overdose reversal agent in community-based settings until additional studies supporting its utility can be conducted.[3]

The bill also affects standing orders for pharmacy dispensing issued by MDH and local health departments, including the statewide naloxone standing order issued by the MDH Secretary. To comply with the legislation, these standing orders would need to be reissued to cover all FDA-approved formulations, regardless of whether state or local public health officials determine them to be the most effective and accessible options.

Additionally, the bill creates potential conflicts with payer policies, particularly Maryland Medicaid's Preferred Drug List (PDL). Medicaid recipients who request an OORD that is not included on the PDL may face significant out-of-pocket costs, limiting access to overdose reversal medications and introducing new barriers for vulnerable populations. Expanding access to overdose reversal medications is a critical component of Maryland's harm reduction strategy, however HB 572 introduces logistical, financial, and clinical challenges that could reduce the effectiveness of current naloxone distribution efforts.

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[1] https://www.marylandmacs.org/media/som/microsites/macs/documents/Nalmefene-Evidence-Brief-Final-1.pdf

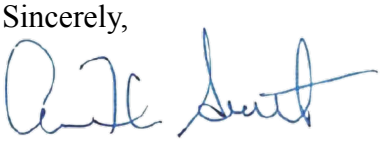
[2] Razaghizad, A., Windle, S. B., Filion, K. B., Gore, G., Kudrina, I., Paraskevopoulos, E., ... & Eisenberg, M. J. (2021). The effect of overdose education and naloxone distribution: an umbrella review of systematic reviews. American journal of public health, 111(8), e1-e12.

[3] Stolbach, A. I., Mazer-Amirshahi, M. E., Nelson, L. S., & Cole, J. B. (2023). American College of Medical Toxicology and the American Academy of Clinical Toxicology position statement: nalmefene should not replace naloxone as the primary opioid antidote at this time. Clinical Toxicology, 61(11), 952-955.
https://www.marylandmacs.org/media/som/microsites/macs/documents/Nalmefene-Evidence-Brief-Final-1.pdf

Given these dynamics, MDH believes HB 572 would not be helpful to the state's efforts to reduce overdose mortality and may create additional harm. The newer formulations of overdose reversal agents should undergo additional study in community-based settings prior to being incorporated into public health strategy.

For these reasons, MDH respectfully urges an unfavorable report on House Bill 572. If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,



Laura Herrera Scott, M.D., M.P.H.
Secretary