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.

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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: _____