STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

ELIZABETH HERTEL
DIRECTOR

# Standing Order Information Packet-Naloxone Prescription for Opioid Overdose Prevention

## I. OVERVIEW

Naloxone hydrochloride (naloxone) is a medication intended for reversal of an overdose that is the result of consumption or use of one or more opioids or opioid-related substances. This includes morphine, heroin, oxycodone, hydromorphone, and synthetic analogues such as fentanyl and carfentanil. Naloxone will not reverse drug overdoses related to non-opioid substances.

## II. PURPOSE

This standing order is intended to ensure that individuals within the State of Michigan who are at risk of experiencing an opioid overdose, or who are family members, friends or other persons who are able to assist a person at risk of experiencing an opioid-related overdose (henceforth referred to as "Eligible Individuals"), are able to obtain naloxone. This order is not intended to be used by organizations that employ or contract with a prescriber who is authorized to write prescriptions. Such organizations should utilize the medical professionals with whom they have a relationship to write prescriptions specific to personnel who would be expected to administer naloxone.

## III. AUTHORITY

This standing order is issued pursuant to Michigan law which allows the Chief Medical Executive (CME) to issue a standing order that does not identify particular patients at the time it is issued, for the purpose of a pharmacist dispensing the opioid antagonist naloxone. MCL 333.17701 *et seq*., (click here for Standing Order provisions).

## IV. AUTHORIZATION

**This standing order may be used by pharmacists to generate a prescription for Eligible Individuals to obtain naloxone from a pharmacy. This order is authorization for pharmacists to dispense naloxone and devices for its administration SOLELY in the FDA-approved naloxone formulations and devices prescribed herein. Eligible Individuals, as defined in Michigan Administrative R. 338.201(c), means individuals within the State of Michigan who are seeking opioid antagonists.**

## V. INSTRUCTIONAL MATERIALS FOR ELIGIBLE INDIVIDUALS- USE OF NALOXONE

**Under the related administrative rules, pharmacists will be required to follow the Standing Order stipulations as outlined.**

### A. PHARMACIST TRAINING

It is required that prescribers and dispensers of naloxone are appropriately trained in its administration and will educate individual recipients of such prescriptions.

### B. PHARMACISTS PROVISION OF EDUCATIONAL MATERIALS WITH EACH PRESCRIPTION

It is recommended that pharmacies advertise the availability of naloxone at their locations through visible postings. Prior to dispensing naloxone under this standing order, pharmacists shall advise Eligible Individuals to review educational materials approved by the Michigan Department of Health and Human Services (MDHHS) found online at the MDHHS website: http://www.michigan.gov/bhrecovery.

Pharmacists will provide educational and safety information from the website to each Eligible Individual when dispensing Naloxone, which is summarized below.

## C. INFORMATION FOR ELIGIBLE INDIVIDUALS

- If you believe someone is experiencing an opioid overdose**, first call 911**!
  - Remain with the person until first responders arrive.
  - When any individual calls 911, be prepared to provide all necessary information and remain with the person in distress.
  - Michigan law provides certain protections from civil liability for dispensing naloxone under a standing order.
- Become familiar with how to use naloxone before someone needs it, through the pharmacist, your healthcare provider, or online training.
- Individuals who administer naloxone should provide treatment information to the person. Information about accessing opioid use disorder treatment is available at: http://www.michigan.gov/bhrecovery
- For questions about the proper use of naloxone, they should ask the pharmacist, contact their health care provider, or go to the MDHHS website at: http://www.michigan.gov/bhrecovery
- Up-to-date information about opioid overdoses and how naloxone can help treat and prevent them is available at: Opioid Overdose | SAMHSA.

## D. PEOPLE AT HIGHEST RISK OF AN OPIOID OVERDOSE

- People who previously overdosed on an opioid
- People taking high doses of opioids or who are undergoing treatment for chronic pain
- People who recently stopped taking opioids due to detoxification or recent incarceration
- People who use opioids with other sedating substances (such as benzodiazepines)
- People who use opioids and have other underlying medical conditions such as heart, liver or lung disease

## E. INDICATIONS FOR USE OF NALOXONE

Persons who may require naloxone will be those who exhibit SIGNS AND SYMPTOMS OF OPIOID OVERDOSE, which include:

- Unresponsive or unconscious individuals
- Not breathing or slow/shallow respirations
- Snoring or gurgling sounds (due to partial upper airway obstruction)
- Blue lips and/or nail beds
- Pinpoint pupils
- Clammy skin

Note: Individuals in cardiac arrest from all causes share many symptoms with someone with an opioid overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue

skin/nail beds).

## F. APPROPRIATE USE AND DIRECTIONS FOR FDA-APPROVED NALOXONE

Eligible Individuals should be aware of the following information, specific to the drug that is dispensed to them by the Pharmacist, when interacting with a person who is suspected of experiencing an opioid overdose event:

1. NARCAN® (naloxone hydrochloride) Nasal Spray
   - 4 mg of naloxone hydrochloride in 0.1 mL intranasally

   DOSAGE AND ADMINISTRATION
   - NARCAN Nasal Spray is for intranasal use only.
   - Seek emergency medical care immediately after use.
   - Administer a single spray of NARCAN Nasal Spray intranasally into one nostril.
   - Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance (see F. Step 3 below).

2. KLOXXADO™ (naloxone hydrochloride) Nasal Spray
   - 8 mg of naloxone hydrochloride in 0.1 mL intranasally

   DOSAGE AND ADMINISTRATION
   - KLOXXADO™ Nasal Spray is for intranasal use only.
   - Seek emergency medical care immediately after use.
   - Administer a single spray of KLOXXADO™ Nasal Spray intranasally into one nostril.
   - Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

3. Intramuscular Naloxone Rescue Kit (syringe) should contain the following at a minimum:
   - A 1 mL (0.4 mg/mL) prefilled syringe, OR a single dose vial (0.4 mg/mL) with syringe
   - Intramuscular needle.

   DOSAGE AND ADMINISTRATION (1mL)
   - Pop off top of vial and insert syringe.
   - Remove 1 mL of Naloxone by pulling down on the plunger.
   - Insert syringe into a large muscle and push the plunger in.

## G. THE FIVE STEPS FOR RESPONDING TO AN OPIOID OVERDOSE WITH NALOXONE

### STEP 1: CALL FOR HELP (DIAL 911)

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the patient as soon as possible. If no emergency medical services (EMS) or other trained personnel are on the scene, dial 911 immediately. All you have to say is “Someone is not breathing.” Be sure to give a clear address and/or description of your location.

**STEP 2: CHECK FOR SIGNS OF OPIOID OVERDOSE**
Signs of OVERDOSE, which often result in death if not treated, are listed under Section V, Part of this Standing Order.

**STEP 3: SUPPORT THE PERSON'S BREATHING**
Ventilatory (breathing) support is an important intervention and may be lifesaving on its own. In situations where individuals are not breathing, rescue breathing can be effective in supporting respiration. Sudden cardiac arrest can resemble severe opioid overdose and should be treated with hands only CPR (see Section E above). Rescue breathing for adolescents and adults involves the following steps:

- Place one hand under the person's chin, tilt the head back and pinch the nose closed.
- Place your mouth over the person's mouth[1] to make a seal.
- Give one slow breath until the person's chest rises.
- Follow up with one breath every 5 seconds. The rescuer should avoid taking a deep breath prior to delivering rescue breaths.

**STEP 4: ADMINISTER NALOXONE**
Any patient who presents with signs of opioid overdose, or when this is suspected, should be administered an FDA-approved formulation of naloxone, see (V. E).

**STEP 5: MONITOR THE PERSON'S RESPONSE, ADDITIONAL DOSES MAY BE NEEDED**

- Regardless of response, remain with the patient to monitor for recurrence of signs and symptoms, particularly decreased breathing, of opioid overdose <u>until emergency personnel arrive.</u>
    - Most patients respond with an increase in rate and depth of spontaneous breathing. The response generally occurs within 2-3 minutes of naloxone administration. (Continue rescue breathing, if indicated, while waiting for the naloxone to take effect.)
    - Naloxone will likely continue to work for 30 to 90 minutes, but after that time, overdose symptoms may return. Therefore, it is strongly encouraged that <u>EMS transport the patient to an emergency department</u>, even if he or she revives after the initial dose of naloxone and seems to feel better.
    - After Giving Naloxone**:**
- Assure that 911 has been contacted and EMS is on their way.
- Continue to monitor breathing and pulse. If not breathing, give rescue breathing. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until arrival of EMS. If person does not wake up and is breathing effectively, place in recovery position (see Figure 1 below).
- Monitor for adverse reactions, particularly extreme agitation, or relapse. (See VI. D).

[1] Mouth to mouth rescue breathing is not without risk to the rescuer. In some locations, a face shield or barrier may be available.

*Figure 1. Recovery Position (source: https://en.wikipedia.org/wiki/Recovery)*

## VI. INSTRUCTIONAL MATERIALS FOR ELIGIBLE INDIVIDUALS -ADDITIONAL PATIENT INFORMATION

### A. NALOXONE CONTRAINDICATIONS

Do not administer naloxone to a person with known hypersensitivity to naloxone or to any of the other ingredients listed in the package insert of naloxone being administered. Do not administer naloxone in suspected cardiac arrest when the apparent cause is not an opioid overdose.

### B. NALOXONE PRECAUTIONS

#### 1. DRUG DEPENDENCE

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

#### 2. RESPIRATORY DEPRESSION DUE TO OTHER DRUGS

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

#### 3. PAIN CRISIS

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

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

Based on animal studies, no definitive evidence of birth defects in pregnant or nursing women exists to date. There also have not been adequate studies in humans to make a determination. However, the risks of low oxygen levels to the fetus and mother are generally considered to be greater than the potential risk to the fetus from the medication. Therefore, when indicated, it should be given.

### D. NALOXONE ADVERSE REACTIONS

1. **Potential Adverse reactions in people who have OPIOID-induced respiratory DEPRESSION** Abrupt reversal of opioid-induced respiratory depression may result in nausea, vomiting, sweating, abnormal heart beats, and fluid development in the lungs, acute opioid withdrawal syndrome, increased blood pressure, shaking, shivering, seizures and hot flashes.
2. **Potential Adverse reactions in people with OPIOID DEPENDENCE**

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

3. **Acute withdrawal syndrome** may include, but not be limited to, the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, yawning, weakness, shivering or trembling, nervousness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and fast heart beats. Most often the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.
4. **Potential adverse reactions in people who are also using stimulants** Occasionally people combine opioids with stimulants (e.g., methamphetamine or cocaine). When naloxone reverses the depressive effects of the opioid, the stimulant effects of the other drug take over. This can result in extreme agitation and **even violent behavior** and may present a risk to the caregiver.
5. **Potential adverse reactions in people taking opioids with prolonged actions** In some cases, a longer acting opioid may be involved. This could result in the person waking up after naloxone but then relapsing as the duration of action of the naloxone is less than the particular drug. This could result in the return of life-threatening respiratory depression and death. **Always call EMS when administering naloxone.**

## VII. PHARMACIST COUNSELING: REFERRAL AND/OR FOLLOW-UP CARE

Regional Prepaid Inpatient Health Plan (PIHP) Resources should be provided to Eligible Individuals by the pharmacist utilizing this standing order. The resource pamphlet will list mental health and substance abuse services for people in that PIHP Region.

## VIII. PHARMACY REPORTING OF NALOXONE DISPENSING

Monitoring naloxone dispensing: Pharmacists dispensing naloxone under this standing order are required to provide quarterly reports to the Pharmacy Naloxone Registration site email MDHHS-Naloxoneorder@michigan.gov , on a quarterly basis. The report shall contain the total number of naloxone doses dispensed under this standing order under the delegating provider's NPI, along with the total of naloxone doses dispensed in total by the pharmacy for the time period, the number of each type of formulation dispensed, and the pharmacy name and license number. No protected health information specific to any Eligible Individuals may be included in the report.

## IX. REVIEW

This standing order will automatically expire on the date that the physician whose signature appears below has ceased to function in the capacity of CME, or until otherwise provided by law, whichever occurs first. MDHHS will distribute a notice to all licensed pharmacies if the standing order is altered or revoked. **The Standing Order- Naloxone Prescription for Opioid Overdose Prevention, was finalized October 19, 2021.**

Dates of Amendments: May 22, 2018, January 25, 2019, April 28, 2019, October 1, 2021

October 19, 2021

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**ADDENDUM - MICHIGAN STATEWIDE NALOXONE STANDING ORDER**

**Revised October 19, 2021**
**SAMPLE – UNSIGNED STANDING ORDER**

***The Chief Medical Executive does not provide prior authorizations under this standing order. Patients, pharmacists and insurance companies should work directly with the patient's primary care provider to obtain any prior authorization.***

This standing order issued by The Chief Medical Executive, effective on the date below, authorizes all FDA-approved formulations of Naloxone to be dispensed by a pharmacist, and to maintain and/or administer naloxone, mucosal atomizer devices (MADs), syringes, and other components of Naloxone Rescue Kits for the purpose of assembling and distributing kits to ELIGIBLE INDIVIDUALS that may be in a position to assist an individual suffering an opioid- related overdose.

**FDA -Approved Nasal Narcan Dispensing Kit must contain:**
- A pre-filled, ready-to-use dose of Narcan Nasal Spray.
- A guide of opioid overdose symptoms and assembly instructions.

**FDA- approved Nasal Kloxxado Dispensing Kit must contain:**
- A pre-filled, ready-to-use dose of Kloxxado Nasal Spray, and
- A guide of opioid overdose symptoms and assembly instructions.

**FDA- Approved Intramuscular Naloxone Rescue Kits (syringe) must contain**:
- A 1 mL (0.4 mg/mL) prefilled syringe or 2 mL (0.4 mg/mL or 1 mg/mL) pre-filled syringe or single dose vial (0.4 mg/mL) with syringe,
- Intramuscular needle, and
- A quick guide of opioid overdose symptoms and assembly instructions.

SIGNATURES:

_____ _____

Natasha Bagdasarian, MD, MPH
Chief Medical Executive

Date Signed/Effective Date

REGISTERED PHARMACY SIGNATURE

By signing this Naloxone Standing Order, the Pharmacy Manager of Record attests that all Registered Pharmacists at this location have read and understand both the State of Michigan Naloxone Standing Order and the reference materials provided with the Standing Order (also available online at: http://www.michigan.gov/bhrecovery)

| | |
|---|---|
| **Pharmacy Manager of Record's Signature** | **Date** |
| **Pharmacy Manager of Record's Name and License No. (print legibly)** | |
| **Pharmacy Name and Store Number** | |
| **Pharmacy Address** | |