Background

In April 2015, Colorado passed a new law, Senate Bill 15-053, expanding access to the life-saving drug naloxone, which is used to reverse overdoses to narcotic drugs, such as certain prescription medications and heroin. As a result of the new law, a physician - or any medical professional with prescriptive authority - can write a standing order for naloxone that can be dispensed by other designated individuals (such as pharmacists and harm reduction organizations).

With these standing orders, pharmacists and harm reduction organizations can now provide naloxone to those who might benefit from it the most including:

- A family member, friend or other person in a position to assist a person at risk of overdose
- An employee or volunteer of a harm reduction organization.
- A first responder
- An individual at risk of overdose.

As a licensed physician in Colorado, the Chief Medical Officer of the Colorado Department of Public Health and Environment (CDPHE) may issue standing orders for naloxone prescriptions to be filled by pharmacists, to help expand statewide naloxone access to those who need it most.

Standing Order Information

Pharmacies can contact cdphe_naloxone@state.co to request a Standing Order for naloxone prescriptions. Attached is a template standing order that will be used by CDPHE in response to these requests. These standing orders are intended pharmacies that do not have their own medical providers. Those who do have affiliated medical providers should use their prescriptive authority and signature to create their own standing orders.
Naloxone/Narcan is 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 naloxone hydrochloride. It may be delivered intramuscularly with a needle or intranasally with a mucosal atomizer device.

This standing order covers the possession and distribution of naloxone kits, to include naloxone hydrochloride, intramuscular syringes, injection supplies, nasal atomizers, or commercial naloxone auto-injectors and any other naloxone product approved for opioid overdose treatment, as long as appropriate training is given.

This standing order authorizes pharmacists at ___ pharmacy in the state of Colorado to possess and distribute naloxone/narcan kits for the purpose of dispensing them, in accordance with the attached Protocol, to any of the following:

- a person at risk of experiencing an opiate-related overdose,
- a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose, or
- a first responder or employee or volunteer of a harm reduction organization.

Order to Dispense
Upon satisfactory assessment, as described in the attached Protocol, that the person to receive the naloxone is 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 an opiate-related overdose, and upon completion of training regarding recognizing and responding to suspected opioid overdose, dispense one naloxone kit.

Intramuscular naloxone kits contain the following at a minimum:
- Two single-use 1ml vials naloxone hydrochloride (0.4 mg/ml)
- Two intramuscular needle syringes
- Overdose prevention information pamphlet
- Step-by-step instructions for administration of intramuscular naloxone

Intranasal naloxone kits contain the following at a minimum:
- Two 2 ml Luer-Jet Luer-lock syringes prefilled with naloxone hydrochloride (2mg/2ml)
- Two mucosal atomization devices
- Overdose prevention information pamphlet
- Step-by-step instructions for administration of nasal naloxone

Auto-injector kits contain the following at a minimum:
- Naloxone HCL 0.4 mg/ml- pre-packaged kits (Evzio, NDC 60842-030-01) containing 2 auto-injectors with audio instructions and 1 training device
- Step-by-step instructions for administration of naloxone via auto-injector
STANDING ORDERS FOR NALOXONE DISTRIBUTION FOR OVERDOSE PREVENTION 10/1/16

Directions for Use

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

2. Administer naloxone as follows:
   - **Intramuscular Naloxone:**
     - Uncap the naloxone vial and uncap the muscle needle-syringe
     - Insert the muscle needle through the rubber membrane on the naloxone vial, turn the vial upside down, draw up 1cc 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
   - **Intranasal Naloxone:**
     - 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 top of the syringe
     - Spray half (1ml) of naloxone in one nostril and the other half (1ml) in the other nostril
     - Repeat if there is no response after three minutes
   - **Auto-injector Naloxone:**
     - Pull auto-injector from outer case 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
     - Repeat if there is no response after three minutes
   - **Narcan:**
     - Peel foil
     - Hold with index and middle fingers on either side, thumb on plunger
     - Do not prime plunger
     - Insert nasal atomizer until backs of fingers are against nostril
     - Push plunger until it stops
     - Give rescue breaths
     - If no response in 3-5 minutes, use additional atomizer in other nostril

3. Continue rescue breathing and monitor respiration and responsiveness of the naloxone recipient until emergency help arrives.

Larry Wolk, MD, MSPH
Chief Medical Officer

PROTOCOL FOR NALOXONE STANDING ORDER
**Indications and Usage**

Naloxone is indicated for the complete or partial reversal of opioid overdose induced by natural or synthetic opioids and exhibited by respiratory depression or unresponsiveness.

**Assessment**

**Subjective Findings**

- Individual is at risk of experiencing an opiate-related overdose or is in a position to assist a family member, friend, or other person at risk of experiencing an opiate-related overdose
- Individual reports no known sensitivity or allergy to naloxone hydrochloride

**Objective findings**

- Client is oriented to person, place, and time and able to understand and learn the essential components of overdose response and naloxone administration.

**Provider Actions**

- Screen individual for contraindications/precautions to prescription or dispensing.
- If a contraindication/precaution exists, refer individual to medical provider for evaluation.
- Provide opioid overdose training information/resources or referral to training (links to free educational materials are available on CDPHE’s website) Opioid overdose training for the individual shall cover the following at a minimum:
  - Risk factors for opioid overdose and possible prevention actions
  - Recognition of opioid overdose
  - Calling 911
  - Rescue breathing
  - Administration of naloxone as described in Standing Order
- Pharmacist will dispense naloxone kit and explain contents to individual
- Pharmacist is encouraged to log all dispensed kits on a form approved by the ordering physician.
- Provide information and/or referral for substance abuse or behavioral health treatment options.

**Follow Up Requirements**

- Instruct individual/parent/guardian to call medical provider if questions, concerns or problems arise
- Instruct individual/parent/guardian to return for refill as needed, subject to use and expiration of naloxone (18 months)
- Encourage opioid user to communicate with primary care provider regarding overdose, use of naloxone, and availability of behavioral health services

**Contraindications**
- Patients known to be hypersensitive to naloxone hydrochloride.

**Precautions**
- Pre-existing cardiac disease or seizure disorder
- Persons who are known or suspected to be physically dependent on opioids (including newborns of mothers with narcotic dependence. Reversal of narcotic effect will precipitate acute abstinence syndrome.)
- Use in Pregnancy
  - Teratogenic Effects: pregnancy category C, no adequate or well-controlled studies in pregnant women.
  - Non-teratogenic Effects: Pregnant women known or suspected to have opioid dependence often have associated fetal dependence. Naloxone crosses the placenta and may precipitate fetal withdrawal symptoms as well.
- Nursing Mothers: caution should be exercised when administering to nursing women due to transmission in human milk. Risks and benefits must be evaluated.
- Geriatric Use: choose lower range doses taking precautions for potential decreased hepatic, renal and cardiac function, as well as, concomitant disease and other drug therapy.

**Adverse Reactions**
- Adverse reactions are related to reversing dependency and precipitating withdrawal and include fever, hypertension, tachycardia, agitation, restlessness, diarrhea, nausea/vomiting, myalgias, diaphoresis, abdominal cramping, yawning, 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.
- Adverse effects beyond opioid withdrawal are rare.