

PHARMACIST PRESCRIPTIVE AUTHORITY FOR NALOXONE

A. Title:

New Mexico Pharmacist prescriptive authority for naloxone, as intended to support and pursuant to, New Mexico Board of Pharmacy Regulation.

B. Purpose:

This is the protocol by which the Pharmacist will educate, prescribe, and dispense naloxone in order to prevent and/or decrease opioid drug overdose deaths for patients in New Mexico. This tool is intended to ensure safety, efficacy, and provision to meet the needs of the public welfare by decreasing death due to drug overdose.

C. Definitions:

1. *Opiate*: the natural derivatives of opium, which are morphine and codeine.
2. *Opioid*: includes the opiates and related synthetic and semi-synthetic compounds that act at the opioid receptor. **for the purposes of this document, opioid will be used exclusively.
3. *Naloxone*: a potent opioid antagonist used in the reversal of opioid overdoses. The primary route of naloxone administration is by injection, but it can also be administered through the nasal spray; this is the preferred method when used by someone other than a medical professional.

D. Introduction:

New Mexico is a leader in the nation for drug overdose deaths (CDC, 2011); however, the current reach of naloxone distribution in New Mexico is limited through the Department of Health (DOH) Harm Reduction Program. The New Mexico Department of Health (NMDOH) Public Health Division currently supports the distribution of naloxone and overdose prevention training to persons at high risk of opioid overdose and/or friends/family of persons at risk of opioid overdose. The addition of Pharmacist prescriptive authority of naloxone will add to this established program and allow for increased access for patients throughout the state. Historically, these services have only been provided in syringe exchange venues and, as such, have primarily been directed to illicit drug users. However, prescription drugs, especially opioid medications such as oxycodone, hydrocodone, methadone, and fentanyl are major contributors to the problem of unintentional drug overdose. Prescription drugs can be harmful or fatal when abused, misused, or mixed with other sedative medications (CDC, 2011). In 2007, the prescription drug-associated overdose death rate overtook that of heroin and other illicit drugs that are associated with the increase in overdose deaths in New Mexico. Prescription drug-associated overdose deaths have continued to dominate overdose deaths in this state through 2011. The added Pharmacist prescriptive authority of naloxone to appropriate patients will allow for increased patient access, additional educational opportunities for patients, and a potential for decreased harm due to opioid overdose in New Mexico. Strategies employed will make naloxone available in the pharmacy setting when prescribed by a Pharmacist with the appropriate naloxone prescriptive authority certification.

E. Guidelines:

A guide for prescribing and dispensing of naloxone in a pharmacy will occur as stated below.

a. Pharmacist Education/Training

1. Participating Pharmacists will successfully complete a certification prescriptive authority training approved by the Board of Pharmacy and maintain this certification with the Board of Pharmacy by completing 2 hours of live continuing education in this area every two years.

2. A primary option of naloxone administration may include the following contents (the pharmacy will be responsible for the assembly of the desired delivery system):
 - i. Naloxone 2mg/2ml prefilled syringes
 - ii. Intranasal trumpet device
 - iii. Educational handout
3. Other FDA approved products may be used.

b. Consent/Screening/Prescriber Notification

1. Patient is screened and evaluated by the Pharmacist for the risk of overdose.
2. Patient consent form must be completed and signed before the prescribing and dispensing of naloxone.
3. Notify the patient's primary care provider with the consent of the patient within 15 days of the original prescription.

F. Patient Screening Criteria

1. Prescribed long-acting opioid (oxycodone ER, oxymorphone ER, morphine ER, transdermal fentanyl, methadone or buprenorphine).
2. A high daily dose of opioid prescribed. Inclusion and exclusion criteria will be included in the Pharmacist's training
3. Prescribed opiates or opioid use greater than 30 days.
4. History of or current polyopioid use.
5. Concurrent prescription or OTC medication that could potentiate the CNS and respiratory depressant properties of opioid medications, such as benzodiazepines, antipsychotics, carisoprodol, and/or antihistamine use.
6. Elderly patients (> 65) receiving an opioid prescription.
7. Households with people at risk of overdose, such as children and/or someone with a substance abuse disorder.
8. Patients who may have difficulty accessing emergency medical services (distance, remoteness, lack of transportation, homelessness, and/or without phone services).
9. Patients as determined by the Pharmacist using their professional judgment.

G. Mechanism of Action

Naloxone is an opioid antagonist with greatest affinity for the mu receptor. It acts by competing for the mu, kappa, and sigma opioid receptor sites in the CNS.

H. Indication

Naloxone is indicated for known or suspected overdose of an opioid and for the reversal of opioid activity, respiratory depression, with therapeutic opioid use.

I. Contraindications

Hypersensitivity to naloxone.

J. Precautions/Warnings

1. Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, and tremulousness. .
2. Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute withdrawal syndrome which may include, but not limited to the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or

vomiting, abdominal cramps, increased blood pressure, and tachycardia.

3. Known or suspected physical dependence on opioids; naloxone will precipitate withdrawal symptoms within minutes after administration and will subside in about 2 hours; observe patients for recurrence of respiratory depression and other narcotic effects for at least 2 hours after the last dose of naloxone.
4. Acute toxicity caused by levopropoxyphene; naloxone is not effective.
5. Agitation; excessive doses of naloxone may result in significant reversal of analgesia.
6. Newborns of mothers suspected of long-term opioid use; do not administer naloxone due to risk of seizures and/or acute withdrawal.

K. Adverse Reactions (rare, less than 10% patients)

1. Naloxone produces no adverse effects in opioid naïve or nondependent patients.
2. Rapid reversal of acute opioid overdose in the nondependent patient may precipitate an adrenergic response seen clinically as mydriasis, tachycardia, tremor, and a mild increase in blood pressure.
3. Rapid reversal may precipitate opioid withdrawal in opioid dependent patients. Manifestations of opioid withdrawal include body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia.

L. Patient Education

1. Once the patient is identified to be at high risk, the Pharmacist will provide overdose prevention education and training, which includes proper administration of nasal naloxone and the required immediate medical follow-up after proper use of naloxone.
2. Face-to-face education is required on the proper use of the naloxone, including a plan for overdose prevention and adverse effects. A designated rescue person or persons must be identified by the patient.
3. Patients will be provided with educational materials and a handout describing caregiver medication administration.
4. Family member, caregiver, and/or friend are strongly encouraged to attend the appointment at the discretion of the prescribing Pharmacist, to also receive training at the time the patient receives the naloxone.
5. Follow-up training and reinforcement is encouraged, the Pharmacist will provide their contact information for any questions or concerns.
6. In the event the naloxone is used or expired, the patient will return to the Pharmacist to request a new prescription; a thorough evaluation will be completed by the Pharmacist regarding the events leading to naloxone use and to determine whether appropriate medical follow-up was completed, as required.
7. On site documentation of reported use to summarize approximate time/date naloxone was used, number of doses used, name of patient naloxone was used on, name of suspected drug resulting in potential for overdose.

M. Records

- a. Consent form and patient visit information.
- b. Primary care provider notification of the prescription.
- c. Prescription order.