

PHARMACIST PRESCRIPTIVE AUTHORITY OF NALOXONE RESCUE KIT PROTOCOL

A. Title:

New Mexico Pharmacist prescriptive authority of naloxone rescue kits (NRKs), 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 NRKs 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 NRKs 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 NRKs 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 community pharmacy setting when prescribed by a Pharmacist with the appropriate NRK prescriptive authority certification.

E. Guidelines:

A guide for prescribing and dispensing of NRKs in a community 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 an NRK may include the following contents (the pharmacy will be responsible for the assembly of the NRKs):
 - i. Naloxone 2mg/2ml syringes
 - ii. Intranasal trumpet device
 - iii. Educational handout
3. Other secondary options of NRKs as approved by the FDA 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 NRK.
3. Notify the patient's primary care provider with the consent of the patient (if available) 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.
3. Prescribed opiates or opioid use greater than 30 days.
4. History of or current polyopioid use.
5. Opioid use with certain concurrent diseases such as: renal dysfunction, liver disease, respiratory infection, sleep apnea, COPD, emphysema or other respiratory/airway disease that can lead to potential airway obstruction.
6. 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.
7. Known or suspected substance use, such as alcohol and/or marijuana.
8. Elderly patients (> 65) receiving an opioid prescription.
9. Teens receiving an opioid prescription.
10. Households with people at risk of overdose, such as children and/or someone with a substance abuse disorder.
11. Patients who may have difficulty accessing emergency medical services (distance, remoteness, lack of transportation, homelessness, and/or without phone services).
12. 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, tremulousness, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest which may result in death.
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. Liver disease; naloxone is primarily metabolized in the liver; use with caution.
7. 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

1. Cardiac Disorders: pulmonary edema, cardiac arrest or failure, tachycardia, ventricular fibrillation, and ventricular tachycardia. Death, coma, and encephalopathy have been reported as sequelae of these events.
2. Gastrointestinal Disorders: vomiting, nausea.
3. Nervous System Disorders: convulsions, paraesthesia, grand mal convulsion.
4. Psychiatric Disorders: agitation, hallucination, tremulousness.
5. Respiratory, Thoracic, and Mediastinal Disorders: dyspnea, respiratory depression, hypoxia.
6. Skin and Subcutaneous Tissue Disorders: nonspecific injection site reactions, sweating.
7. Vascular Disorders: hypertension, hypotension, hot flashes, or flushing.

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 NRK.
2. Face-to-face education is required on the proper use of the NRK, 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 members and/or caregivers are encouraged to attend the appointment to also receive training at the time the patient receives the NRK.
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 NRK 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 NRK use and to determine whether appropriate medical follow-up was completed, as required.

M. Records

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