NALOXONE DISTRIBUTION POLICY

I. PURPOSE:

This New Mexico Department of Health (NMDOH) policy establishes guidelines for the dispensing of Naloxone through NMDOH Public Health Offices (PHO) and Contractors in order to reduce fatal opioid overdose as stated in Chapter 24, Article 23, Sections 24-23-1 and 24-23-2, NMSA 1978, and 7.32.7.1 through 7.32.13 NMAC, 9/13/2001.

The primary reason for establishing an Opioid Antagonist Administration Program (OAAP) is to improve response to drug overdose, which may prevent unnecessary loss of life. While opioid antagonist administration does not automatically guarantee to reverse the effects of overdose due to substance abuse, it is the only definitive care currently available for reversing the effects of opioid substances. Therefore, persons suffering from an overdose, when an opioid is a suspected substance, should be administered an opioid antagonist as quickly as possible.

II. POLICY STATEMENT

The objective is to authorize persons, other than a licensed health care professional permitted by law to administer an opioid antagonist, to administer naloxone to another person if: (1) he/she, in good faith, believes the other person is experiencing an opioid drug overdose; and (2) he/she acts with reasonable care in administering the drug to the other person. Further, this policy shall provide recommended guidelines to prevent opioid overdose death.

Naloxone is a specific opioid antagonist drug that rapidly reverses the effects of opiate drugs, including heroin. Respiratory depression and arrest is the primary reason for death due to an opioid overdose. Naloxone is often effective in reversing an opioid/heroin overdose death if administered no more than three to five minutes after the person who has
overdosed has stopped breathing, though Naloxone should be viewed as one of several tools and skills that can be taught and employed to prevent an opioid/heroin overdose death. Training Injection Drug Users (IDU) to prevent and/or properly respond to an overdose makes this population the primary target of this intervention since they are likely to be the people at the scene of an overdose. This training helps to provide them with the skills to function as peer educators within their drug using communities, which will ultimately decrease overdose deaths by spreading prevention education.

Trained Targeted Responders (TTR) are non-medical first responders (e.g. law enforcement or volunteer fire fighters) are also included as a target population, since they may be the first to arrive at a medical emergency call, especially in rural areas of the state.

Overdose Prevention Training Programs should include discussion of strategies for reducing the likelihood of overdose, the importance of providing rescue breathing to a person who is overdosing, the importance of quickly contacting professional medical help in the event of an overdose, and the appropriate use of Naloxone to reverse the effects of opiate overdose.

Naloxone is a prescription medication. Naloxone is not a DEA-scheduled drug. The Naloxone prescription may be provided directly to the opiate user, family members, friends, or domestic partners of the active opiate user for the purpose of ensuring greater community access to Naloxone and decreasing opiate overdose fatalities statewide. The New Mexico Board of Pharmacy (NMBOP) requires that a prescription for Naloxone specify:

1) The name of the individual to whom the medication is prescribed;
2) The name of the clinician with the authority to prescribe the medication;
3) An entry into the medical record that defines the prescribing event and the medical indications for the prescription.

III. NMDOH Procedure:

1. NMDOH personnel with independent prescribing authority as defined by the NMBOP (The NMDOH Regional Health Officers, Medical Doctors, Doctors of Osteopathy, Family Nurse Practitioners) are authorized to prescribe Naloxone to opiate users in the context of NMDOH-sanctioned overdose prevention and treatment education programs. The NMDOH clinician authorized to prescribe Naloxone will hereafter be referred to as the “prescribing clinician”.

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2. Naloxone must be added to the PHD/Pharmacy dispensing formulary.

3. Opiate users who have participated in a NMDOH-sanctioned Overdose Prevention Training Program are eligible to receive Naloxone from a local PHO clinic. The opiate user who is eligible to receive Naloxone will hereafter be referred to as the “participant”. NMDOH-sanctioned Overdose Prevention Training Programs include those conducted by PHO’s and NMDOH Contractors. Contractors must be trained and certified by the Harm Reduction Program to provide overdose education and Naloxone prescription and use the training guidelines and best practices provided by NMDOH.

4. Prior to prescribing and dispensing Naloxone, the prescribing clinician and the participant must discuss in person the indications, contraindications, potential adverse reactions and administration of the medication.

5. If medically indicated, the prescribing clinician is authorized to prescribe and distribute to the participant two (2) pre-filled 2.0 mg doses of Naloxone. Three (3) doses, or more, may be provided depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability. Each box containing the Naloxone must be labeled with a NMDOH Pharmacy label indicating the name of the participant, the name of the prescribing clinician, the date and the instruction for the use of the medication. Community Based Organizations (CBO’s) providing the same service must also follow these guidelines.

6. The prescribing clinician should inform the participant about the expiration date of the medication and instruct the participant to return for a new prescription before the currently prescribed syringes expires, and not to use the drug if the solution is cloudy. Naloxone should be stored in a relatively stable environment, avoiding direct sunlight or excessive freezing or heat.

7. The prescription of Naloxone must be documented in the approved NMDOH short form record/chart, which will be maintained by the PHO. The written record will document the name of the participant, the name of the prescribing clinician, the medical indication for the prescription if Naloxone, and documentation that the participant has been informed and understands the indications, contraindications, potential adverse reactions, and proper administration of the drug.

8. “Enrollment/Record of Use” forms should be sent to the Harm Reduction Program by the 10th of every month. The Harm Reduction Program does not receive or maintain the participant record/chart.
IV. Overdose Prevention Training Program

1. An Overdose Prevention Training Program should prepare a participant or Trained Targeted Responder to administer Naloxone as recommended by NMDOH for the OAAP.

2. The program must provide overdose education; what is and what causes an overdose, how overdoses can be avoided, how to identify and properly respond to an opioid overdose, which must include universal safety precautions, rescue breathing, activating EMS, and the administration of Naloxone.

3. Due to the small nature of many of the rural PHO’s where it is not uncommon for there to be only two or three NMDOH staff available to provide all services, and that some CBO’s do not have a medical component that allows them to store and prescribe Naloxone, collaboration is essential. If cooperation can be proven and maintained, a CBO or PHO may provide the educational component to the participants and another CBO or PHO may provide the Naloxone prescriptions and subsequent refills.

V. Overdose Prevention Prescription Program Guidelines

1. A Program Director shall be identified who manages the overdose prevention program. The Program Director shall:
   a) Identify a Physician Medical Director to oversee the OAAP;
   b) Select and identify program participants;
   c) Maintain Naloxone administration training records for all program participants while they are active in the program, and for at least three (3) years thereafter;
   d) Maintain OAAP records including Naloxone inventory records, program participant training records, and Overdose Prevention Program usage records;
   e) Ensure that all program participants are trained by the Overdose Prevention Training Program approved by the NMDOH – Harm Reduction Program.
   f) Provide evidence of coordination of the OAAP with local Emergency Medical Services and emergency dispatch agencies, including 911 dispatch agencies;
   g) Register the OAAP with the NMDOH using the application format;
   h) Report all administrations of Naloxone to the NMDOH using the required reporting format;
i) Assist the Physician Medical Director with quality assurance review of all Naloxone administrations; and,

j) Ensure the Naloxone is maintained and stored in accordance with the manufacturer’s guidelines.

2. **A Physician Medical Director** shall be identified by each OAAP who provides oversight of the program in accordance with the requirements of the NMBOP. The selected physician shall:
   a) Provide medical leadership, expertise, and oversee the program;
   b) Serve as an advocate and spokesperson for the OAAP;
   c) Ensure that all program participants are properly trained and their skills are maintained;
   d) Develop and approve medical protocols for the OAAP;
   e) Ensure quality assurance review for all administrations of Naloxone;
   f) Assume overall responsibility for how the OAAP is planned and conducted; and,
   g) Ensure compliance with the NMBOP requirements for the issuance, control and storage of medications.

3. Each Overdose Prevention Program will identify a **Consulting Pharmacist** who will be responsible for maintaining NMDOH/PHO licensure and compliance in accordance with NMBOP requirements for the ordering, inventory, issuance, control and storage of medications. NMDOH has a centralized **State Pharmacy and Pharmacy Director** who provides oversight and maintains the ordering, inventory and shipping of supplies and medications, including Naloxone, to the PHO’s and the programs they support. The Pharmacy Director, for the purposes of NMDOH OAAP, will be the Consulting Pharmacist. Each PHO usually assigns one **Nurse** who is responsible for the duties of the Pharmacy Director for that location and who is responsible for the Naloxone provided through the State Pharmacy. Both the Program Director and the Physician Medical Director shall work through the Nurse, or other individual, who is identified as being responsible as the PHO State Pharmacy representative.

4. **Overdose Prevention Selection, Supplies, and Medication Storage/Control**:
   a) Opioid Antagonist Selection: OAAP shall use Naloxone, as the opioid antagonist. The Physician Medical Director shall select the specific injection or administration device.
It is recommended that the 2 ml prefilled dose with an atomizer for intranasal delivery be used.

b) Response Supplies: OAAP shall provide and maintain at least the following minimum response equipment as selected by the Physician Medical Director:
   1) Medical exam gloves.
   2) Container approved for sharp medical waste.
   3) Mask or other barrier for use during rescue breathing.
   4) If an injectable delivery method is recommended, an agent to prepare skin before injection.

c) Medication Storage and Control: Medication storage and control shall be in accordance with the NMBOP and Federal Food and Drug Administration (FDA) rules and regulations.

5. **Record Keeping**: The OAAP shall establish and maintain a record keeping system that is available for audit. It shall include the following information:
   a) List of program participants;
   b) Dates of training for program participants;
   c) Copy of medical director approved medical protocols;
   d) Copy of the medical director contract/agreement;
   e) Copy of registration and EMS service notification forms;
   f) Naloxone Administration usage reports/Data collection forms;
   h) Quality assurance review documentation; and,
   g) Naloxone purchase/order and maintenance records.

6. **Registration of an Overdose Prevention Program**: Prior to beginning an OAAP, the Program Director shall submit an application for registration to the NMDOH using the format outlined below:
   a) Application Date;
   b) Program Start-up Date;
   c) Program Name;
   d) Program Director Name;
   e) Program Mailing Address;
   f) Program Physical Location;
   g) Program Telephone Number;
   h) Physician Medical Director Name;
   i) Physician Medical Director Mailing Address;
   j) Physician Medical Director Telephone Number;
   k) Physician Medical Director New Mexico License Number;
   l) Notification to local EMS/911 Dispatch Agency - Provide Date;
m) Name of Consulting Pharmacist;
n) Address of Consulting Pharmacist;
o) Telephone Number of Consulting Pharmacist.

7. **Participant Enrollment/Record of Use Report**: Every person who receives overdose prevention training and/or is prescribed and provided with Naloxone will have an Enrollment/Record of Use Form completed and signed by the trainer that will be sent to the Harm Reduction Program by the 10th of every month. Only forms for participants who have actually received Naloxone or reported an overdose reversal should be submitted. The report form shall be designated by the NMDOH Harm Reduction Program, and shall include at a minimum:
   a) Name of the OAAP;
   b) Name of the trainer submitting the report;
   c) Unique participant code of the participant;
   d) If reporting the use of Naloxone:
      1) Approximate date of Naloxone use;
      2) Amount of Naloxone administered;
      3) Amount of Naloxone replaced to the participant at the time of the report;
      4) If known, list the type of drugs (other than opioids) taken by the person to whom the Naloxone was administered; and,
      5) Circumstances relating to overdose (if known):
         1. Was EMS called, and if not, why;
         2. Was the person transported to a clinical facility;
         3. Was rescue breathing performed on the person who overdosed;
         4. Distance from nearest emergency department (in road miles);
         5. Clinical disposition of the incident (if known).

8. **Enrollment Cards**: It is preferred to avoid having trained participant obtain their naloxone by referral. In certain cases, such as a training provided in a detention facility, or in rural areas, where it is not possible to provide the Naloxone to a participant at the time of the training, an enrollment card should be given to the participant, along with information on suggested locations where the participant may redeem the card for their Naloxone and related equipment. When the card is redeemed, the original trainer should then send in the participants enrollment form. This card should have:
   a. The individuals unique participant code,
b. The date and location of the training,
c. The name and telephone number of the trainer (or the OAAP),

9. **Trained Targeted Responders**: This is the title given to non-medical, emergency personnel who are trained to intervene in an overdose situation and allowed to carry and administer Naloxone in the situation, such as the New Mexico State Police.

This section outlines the requirements in order for law enforcement, firefighters, some Emergency Medical Technicians, syringe exchange and outreach staff, and other non-medical personnel who may encounter an overdose situation while in performance of their duties. Such an effort has the same requirements as the other component of the OAAP, i.e., medical direction, a consulting pharmacist and a pharmacy where the medication may be stored in compliance with NMBOP. In this case, though, the Medical Director is responsible for:

a. Monitoring and updating responder training;
b. Checking the medication in and out of the pharmacy to the responders and monitoring compliance for care of the medication, and monitoring expiration dates;
c. Ensuring the activation of EMS during an overdose situation;
d. Ensuring the proper documentation of any performed intervention.

Each TTR should:

a) Complete the initial Overdose Prevention Training Program recommended by the Department;
b) At least every two (2) years, TTR’s should complete a refresher Overdose Prevention Training Program from a NMDOH recommended training program;
c) Activate the EMS using pre-established methods (e.g. contact 911 public safety) during any response to a suspected overdose.
d) Comply with Physician Medical Director protocols for response to individuals experiencing a suspected overdose;
e) Report all responses to suspected overdose to the OAAP Program Director and Physician Medical Director and complete an enrollment/record of use report form report as listed in section 7. A copy of the report shall be submitted to the Department by the 10th of each month;
f) Ensure that the opioid antagonist drugs and other supplies are maintained and used in accordance with the manufacturer’s guidelines, and inspect the Naloxone expiration date at least monthly.

10. **Notification:** Local EMS agencies shall be notified of the activation and existence of the OAAP. The notification shall include the name of the OAAP Program Director, Physician Medical Director, location of the program, telephone number, and a copy of medical director approved protocols. The local EMS agencies shall also be notified if an existing OAAP stops or cancels the Overdose Prevention Program.

11. **Applicability:** This policy applies to all NMDOH employees and contract providers who are certified to provide overdose prevention training with Naloxone prescription to both current and former injection drug users, their family members and friends, treatment providers, and other non-medical first responders, such as law enforcement personnel, who may encounter an overdose situation while performing their duties.

13. **Responsibility:**
   a) NMDOH leadership has the ultimate responsibility for assuring this policy is enforced.
   b) NMDOH leadership has the ultimate authority to accept or reject the recommendations of the Harm Reduction Program.
   c) The Harm Reduction Program is responsible for monitoring, reviewing and certifying both DOH and contracted providers and the quality of the training being provided.

14. **Definitions:**
   1. **“Administration of Opioid Antagonist”** means the administration of an opioid antagonist by a person authorized pursuant to this regulation.
   2. **“Department”** means the New Mexico Department of Health (NMDOH).
   3. **“Emergency Medical Service (EMS)”** means the services rendered by licensed Emergency Medical Technicians, certified Emergency Medical Services First Responders or Emergency Medical Dispatchers in response to a person’s need for immediate medical care to prevent loss of life or aggravation of physical or psychological illness or injury.
4. **“Medical Direction”** means guidance or supervision for trained targeted responders provided by a physician for the administration of opioid antagonists. This includes overseeing training, emergency medical services coordination, protocol approval, quality assurance and reporting.

5. "**Opioid**" means containing or derived from opium, including but not limited to morphine, heroin, or pharmaceutical medications containing opiates, such as methadone, codeine, hydrocodone, and oxycontin.

6. **“Opioid antagonist”** means a drug that nullifies in whole or in part the administration of an opioid. The opioid antagonist is limited to Naloxone or other medications approved by the NMDOH, unless otherwise stated in this regulation and is limited to a dose less than or equal to 1.0mg by subcutaneous injection or a dose of 2.0mg by intramuscular injection, not to exceed a total overall dose of 2.0mg. (Need to clarify: separate out IM dose definition).

7. **“Opioid Antagonist Administration Program (OAAP)”** means an organized program to administer Naloxone in accordance with these regulations.

8. **“Overdose Prevention Training Program”** means a training program which teaches overdose prevention information and practices, and prepares a person to administer an opioid antagonist as recommended by the Department for an OAAP.

9. **“Participant”** is any qualified individual who has been trained and enrolled in the program.

10. **“Physician”** means a doctor of medicine or doctor of osteopathy who is licensed or otherwise authorized to practice medicine or osteopathic medicine in New Mexico.

11. **“Physician Medical Director”** means a physician who is responsible for oversight of an Opioid Antagonist Administration Program, including providing for or ensuring the medical control of trained targeted responders; the development, implementation, and evaluation of medical protocols; oversight of quality assurance activities, and compliance with the NMBOP requirements.

12. **“Protocols”** means predetermined, written medical care plans and includes standing orders.

13. **“Provider”** means a person or entity contracted to deliver services.
14. “Trained Targeted Responder (TTR)” means a person who has completed an authorized opioid antagonist training program and who administers opioid antagonists as defined in Harm Reduction Protocols.

15. References: