DATE: March 20, 2008

RE: The legal requirements for operating an Opioid Antagonist Administration Program and potential liability in New Mexico.

INTRODUCTION

Naloxone, the standard treatment for heroin overdose, is a safe and effective prescription drug typically administered by emergency room personnel or first responders acting under standing orders of physicians. High numbers of overdose deaths and evidence that witnesses to heroin overdose are often unwilling or unable to call for help has motivated some public health professionals to institute programs that distribute naloxone directly to opiate drug users (ODUs). In such programs, drug users, their partners, or others are instructed in resuscitation techniques and provided a “take-home” dose of naloxone for administration in cases when medical help is not immediately available.

Evidence from US and abroad indicates that naloxone distribution helps reduce opiate overdose deaths and results in cost-savings to society.\(^1\) Despite the high and rising incidence of overdose events in many US locales, however, both the number and the scope of overdose programs remain inadequate. Legal concerns about provider and program liability act as one of the most important limiting factors, often complicating or derailing authorization, expansion, funding and implementation of these programs.

We were funded by the Drug Policy Alliance to analyze the legal issues for naloxone distribution programs in the fifty United States. New Mexico has responded to the overdose problem by authorizing interventions to promote the use of naloxone and to clearly authorize distribution to and administration by non-medical personnel. The New Mexico Administrative Code\(^2\) and New Mexico Department of Health (“NMDOH”) *Naloxone Distribution Policy Administrative Manual*,\(^3\) regulate how an Opioid Antagonist Administration Program (“program”) is to be established and how non-medically licensed people can

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\(^2\) NM ADC 7.32.7.1 (West 2007).

become trained targeted responders\(^4\) in order to be prescribed and dispensed naloxone.

This Memorandum addresses the following issues:

I. Operating a naloxone program in New Mexico.
   A. What is required for a training program?
   B. Who is trained?
   C. What is required for the prescription and dispensation of naloxone?

II. Potential Liability

   **Executive Summary**

   From a legal standpoint, naloxone is no different than any other prescription drug. Authorized medical professionals can prescribe and dispense naloxone in the same way they would any other drug. Naloxone is indicated for patients\(^5\) who, upon examination,\(^6\) are at risk of opiate overdose and who are judged by the professional to be capable of benefiting from naloxone administration. The amount of naloxone prescribed or dispensed depends upon the prescriber’s assessment of need. Thus there are no legal barriers anywhere in the US to qualified medical personnel prescribing naloxone to patients at risk of overdose.

   In most states, however, naloxone distribution programs are limited by the requirement that a clinician may generally only prescribe medications for his or her own patients. Providing naloxone to third parties who are themselves not at risk of overdose, or deputizing third parties (whether or not they are themselves at risk) to treat non-patients, is an effective way to save lives, but violates general prescription rules. Moreover, those third parties who undertake to treat others face at least a theoretical risk of being charged with the illegal practice of medicine. Rules on dispensing drugs to patients may also create uncertainty or inconvenience to naloxone programs, which work best when the drug is provided directly to the patient at the time it is prescribed.

   New Mexico has addressed this problem by clearly authorizing naloxone distribution programs involving third parties, and providing liability immunity for


\(^5\) We will refer to a person who has received a legal prescription for naloxone as a “patient.”

\(^6\) We will define examination generally as an interaction sufficient to allow the physician to determine the patient's diagnosis and treatment needs in the context of the service being sought or medical issues being raised.
non-medically licensed individuals who respond to overdoses by ODUs. After training by a program, trained targeted responders may be prescribed and dispensed naloxone. According to the Department of Health, the prescribing clinician may prescribe and distribute two pre-filled syringes of naloxone to trained responders at the program or three pre-filled syringes from public health offices (“PHO”). As part of the process of dispensation, trained responders should be given information about when and how to use the drug and other steps that are advisable in responding to an overdose.

Assuming the program follows the applicable rules and regulations and acts competently, there is no risk of criminal or civil liability arising out of naloxone prescription and dispensation activities beyond the medically licensed person standard of care applicable to their title.

The Legal Analysis in Detail

I. Operating A Naloxone Program In New Mexico.

A. What Is Required For A Training Program?

With the approval of the Department of Health, a program may be established to improve response to drug overdoses and prevent unnecessary loss of life through the training and deployment of “trained targeted responders.” Programs are managed by a program director. The program director must

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8 NM ADC 7.32.7.12 (West 2007).
9 NM ADC 7.32.7.9 (West 2007) (“The primary reason for establishing an Opioid Antagonist Administration Program by trained targeted responders is to improve response to drug overdose, which may prevent unnecessary loss of life”).
10 NM ADC 7.32.7.10(A) (West 2007): A Program Director shall be identified who manages the Opioid Antagonist Administration Program. The Program Director shall: (1) Identify a Physician Medical Director to oversee the Opioid Antagonist Administration Program; (2) Select and identify persons as Trained Targeted Responders; (3) Maintain Opioid Antagonist administration training records for all Trained Targeted Responders while they are active in the program, and for at least three (3) years thereafter; (4) Maintain Opioid Antagonist Administration Program records including opioid antagonist inventory records, Trained Targeted Responder training records, and Opioid Antagonist Administration Program usage records; (5) Ensure that all Trained Targeted Responders are trained using an Opioid Antagonist Training Program, which may be recommended by the Department; (6) Provide evidence of coordination of the Opioid Antagonist Administration Program with local EMS services and emergency dispatch agencies, including 911 dispatch agencies; (7) Register the Opioid Antagonist Administration Program with the Department using the application format outlined in Appendix A; (8) Report all administrations of an opioid antagonist to the Department using the reporting format outlined in Appendix B; (9) Assist the Physician Medical Director with quality assurance
identify a physician as the medical director, and a pharmacy director, if the program is going to dispense naloxone on premises. Commonly, a nurse is identified as the pharmacy director. Lastly, local emergency medical services (“EMS”) must be notified of the activation and existence of the program.

B. Who is Trained?

Any adult may be trained to work as a targeted responder. ODU and their families, friends and domestic partners are the primary target of this policy. Other targets are non-medical personnel who might encounter an overdose victim while performing their duties, like police officers. Trained targeted responders are those people that have been trained by a program.

review of all opioid antagonist administrations; and, (10) Ensure that the opioid antagonist is maintained and stored in accordance with the manufacturer's guidelines.

11 Id.; NM ADC 7.32.7.10(B) (West 2007):
Each Opioid Antagonist Administration Program shall have a Physician Medical Director who provides oversight of the Opioid Antagonist Administration Program in accordance with the requirements of the New Mexico Board of Pharmacy. The selected physician shall:
(1) Provide medical leadership, expertise, and oversee the program;
(2) Serve as an advocate and spokesperson for the Opioid Antagonist Administration Program;
(3) Ensure that all Trained Targeted Responders are properly trained and their skills are maintained;
(4) Develop and approve medical protocols for the Opioid Antagonist Administration Program;
(5) Ensure quality assurance review for all administrations of an opioid antagonist;
(6) Assume overall responsibility for how the Opioid Antagonist Administration Program is planned and conducted; and,
(7) Ensure compliance with the New Mexico Board of Pharmacy requirements for the issuance, control and storage of medications.


14 NM ADC 7.32.7.10(D) (West 2007):
Local EMS services and emergency dispatch agencies shall be notified of the activation and existence of the Opioid Antagonist Administration Program. The notification shall include the name of the Opioid Antagonist Administration Program Director, Physician Medical Director, location of the program, telephone number, and a copy of medical director approved protocols. The local emergency services and dispatch agencies shall also be notified if an existing Opioid Antagonist Administration Program stops or cancels the Opioid Antagonist Administration Program.


C. What Is Required For The Prescription And Dispensation Of Naloxone?

Naloxone is a prescription drug, excluded from controlled substance schedules.\(^\text{17}\) It may be prescribed by any clinician with the appropriate licensure. In New Mexico, this includes physicians; physician assistants (PAs) working under the direction of physicians, who must be available to supervise in person or by electronic means;\(^\text{18}\) and certified nurse practitioners (CNPs) with prescriptive authority, who may independently prescribe.\(^\text{19}\) A prescription for naloxone may

\[\text{\textsuperscript{17}}\text{NM ADC 16.19.20.66(A)(1) (West 2007). In NM, prescription drugs are referred to as ‘dangerous drugs.’ N.M. Stat. Ann. 1978, § 26-1-2(F) (West 2007): ‘[D]angerous drug’ means a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use cannot be prepared. ‘Adequate directions for use’ means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe the drug if it:}
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(3) \text{is limited by an approved application by Section 505 of the federal act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;}
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(4) \text{bears the legend: ‘Caution: federal law prohibits dispensing without prescription.’;}
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(6) \text{bears the legend ‘RX only.’}
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\[\text{\textsuperscript{18}}\text{N.M. Stat. Ann. 1978, § 61-6-7 (West 2007): ‘Physician assistants may prescribe, administer and distribute dangerous drugs other than controlled substances in Schedule I of the Controlled Substances Act pursuant to rules adopted by the board after consultation with the board of pharmacy if the prescribing, administering and distributing are done under the direction of a supervising licensed physician and within the parameters of a board-approved formulary and guidelines established under Subsection C of Section 61-6-9 NMSA 1978. The distribution process shall comply with state laws concerning prescription packaging, labeling and record keeping requirements. (emphasis added) NM ADC 16.10.15.7(D) (West 2007): ‘Effective supervision’ means the exercise of physician oversight, control, and direction of services rendered by a physician assistant. Elements of effective supervision include:}
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(1) \text{on-going availability of direct communication, either face-to-face or by electronic means;}
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(2) \text{active, ongoing review of the physician assistants services, as appropriate, for quality assurance and professional support;}
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(3) \text{delineation of a predetermined plan for emergency situations, including unplanned absence of the primary supervising physician; and}
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(4) \text{identification and registration of alternate supervising physicians, as appropriate to the practice setting.}
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be obtained by an ODU from medical personnel working with a NMDOH

(1) perform an advanced practice that is beyond the scope of practice of professional registered nursing;
(2) practice independently and make decisions regarding health care needs of the individual, family or community and carry out health regimens, including the prescription and distribution of dangerous drugs...and
(3) serve as a primary acute, chronic long-term and end of life health care provider and as necessary collaborate with licensed medical doctors, osteopathic physicians or podiatrists.

C. Certified nurse practitioners who have fulfilled requirements for prescriptive authority may prescribe in accordance with rules, regulations, guidelines and formularies for individual certified nurse practitioners promulgated by the board.
D. Certified nurse practitioners who have fulfilled requirements for prescriptive authority may distribute to their patients dangerous drugs...that have been prepared, packaged or fabricated by a registered pharmacist or doses of drugs that have been prepackaged by a pharmaceutical manufacturer in accordance with the Pharmacy Act and the New Mexico Drug, Device and Cosmetic Act.

NM ADC 16.12.2.13(O)(5)(a) (West 2007):
Requirements for prescriptive authority: In accordance with applicable state and federal laws, the CNP who fulfills the following requirements may prescribe and distribute dangerous drugs...
(i) Verifies 400 hours of work experience in which prescribing dangerous drugs has occurred within the two (2) years immediately preceding the date of the application. Individuals who have not fulfilled this requirement must provide documentation of successful completion of 400 hours of prescribing dangerous drugs in a preceptorship with a licensed CNP, CNS or physician. The preceptorship must be completed within six (6) months and a letter of authorization will be issued for the duration of the preceptorship.

(ii) Once prescriptive authority requirements are met, the board will notify the board of pharmacy of completion of prescriptive authority requirements.
(b) Formulary. It is the CNP's responsibility to maintain a formulary of dangerous drugs...that may be prescribed; the only drugs to be included in the formulary are those relevant to the CNP's specialty and practice setting. The board of nursing reserves the right to audit the formulary of the CNP. Licensees may be subject to disciplinary action by the board of nursing if non compliant with the audit.
(c) Prescription pads. The CNP's name, address, and telephone number must be imprinted on the prescription pad. In the event that a CNP is using a prescription pad printed with the names of more than one CNP, the name of the CNP for the individual prescription shall be indicated.
(d) Distributing: CNPs, who have fulfilled requirements for prescriptive authority as stated in these rules, may distribute to their patients dangerous drugs...which have been prepared, packaged, or fabricated by the registered pharmacist or doses which have been pre-packaged by a pharmaceutical manufacturer in accordance with the Pharmacy Act [61-11-22] and the Drug, Device and Cosmetic Act for the benefit of the public good.
(e) Labeling: CNPs may label only those drugs which the CNP prescribes and distributes to patients under the CNP's care. The medication shall be properly labeled with the patient's name, date of issue, drug name and strength, instructions for use, drug expiration date, number dispensed and name, address and telephone number of the CNP. Labeling may be handwritten or a pre-printed fill-in label may be used. All information shall be properly documented in the patient record.
program. An ODU at risk of overdose may of course also obtain a prescription from authorized personnel not associated with a program. Prescriptions of naloxone within an authorized program must be documented in an approved NMDOH record. Prescriptions outside a program must be documented in the normal course of medical practice.

Naloxone dispensation is subject to the regulations set out by the NMDOH, the New Mexico Administrative Code, and the general rules covering dispensing of prescription drugs under the New Mexico Pharmacy Act. Physicians are authorized to dispense drugs. CNPs may independently dispense prescription drugs that have been prepared by a pharmacist or prepackaged by a pharmaceutical manufacturer and labeled according to New Mexico law. PAs working under the supervision of a physician may dispense prescription drugs that have been prepackaged by a pharmacist. Physician supervision of the PA does not need to be on-site and may be through electronic means.

Naloxone may be dispensed on program premises or through PHO. In either case it is offered without charge. Of course, patients wishing to buy naloxone themselves may take a valid prescription to a pharmacy. Each trained

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20 New Mexico Department of Health, Naloxone Distribution Policy Administrative Manual (2007) (“NMDOH personnel with independent prescribing authority … are authorized to prescribe naloxone to opiate users in the context of NMDOH-sanctioned heroin overdose prevention and treatment education programs”).
21 New Mexico Department of Health, Naloxone Distribution Policy Administrative Manual (2007) (“This New Mexico Department of Health (NMDOH) policy establishes guidelines for the dispensing of naloxone through NMDOH Public Health Offices (PHO) and contracted providers”) (emphasis added).

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.

24 NM ADC 7.32.7 (West 2007).
26 N.M. Stat. Ann. 1978, § 61-6-6(J)(3) (“‘[T]he practice of medicine’ consists of… offering or undertaking to give or administer, dispense or prescribe a drug or medicine for the use of another person, except as directed by a licensed physician”).
27 Supra, FN 19.
28 Supra, FN 18; N.M. Stat. Ann. 1978 § 61-6-7.1(c) (West 2007) (“‘[D]istribute’ means to administer or supply directly to a patient under the direct care of the distributing physician assistant one or more doses of drugs prepackaged by a licensed pharmacist and excludes the compounding or repackaging from a bulk or original container”).
29 Supra, FN 18.
targeted responder should be dispensed naloxone immediately after completing the program. In cases where that is not possible, participants are given a prevention and response card that allows them to receive naloxone from a program or PHO without a referral. Providers acting outside a naloxone program may also dispense the medication.

The program must follow legislated rules governing the dispensation of naloxone from the program, including basic standards for storage and record-keeping. The prescribing clinician should inform the participant about storing naloxone and instruct the participant to return for new prescriptions before the expiration date, and not to use the drug if the solution is cloudy. Additionally,

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‘Prevention and Response’ Cards: All effort should be made by the provider to ensure participants receive the Naloxone immediately after their overdose prevention training. Participants should not have to obtain Naloxone by referral. In certain cases, such as a training provided in a detention facility, where it is not possible to provide the Naloxone to a participant at that time, a “Prevention and Response” card should be given to the participant. When the card is redeemed, the original trainer should be contacted by the prescribing clinician and the original trainer will send in the participants enrollment form. This card should have: a. The participants personalized ID code, b. The date and location of the training, c. The name and telephone number of the trainer, d. Suggested locations where the participant may redeem the card for their Naloxone and related equipment.

**32** NM ADC 7.32.7.10(E) (West 2007):

1. Opioid Antagonist Selection: Opioid Antagonist Administration Programs shall use naloxone, or other medications approved by the Department, as the opioid antagonist. The Physician Medical Director shall select the specific injection device. It is recommended that single dose, pre-filled syringes with attached safety needles be used.
2. Response Supplies: Opioid Antagonist Administration Programs shall provide and maintain at least the following minimum response equipment as selected by the Physician Medical Director:
   a. Medical exam gloves.
   b. Container approved for sharp medical waste.
   c. Mask or other barrier for use during rescue breathing.
   d. Agent to prepare skin before injection.
3. Medication Storage and Control: Medication storage and control shall be in accordance with the New Mexico Board of Pharmacy and Federal Food and Drug Administration rules and regulations.

authorized medical personnel must talk with the participant about the indications, contraindications, potential adverse reactions and administration of the medication. 34

Conclusion: Naloxone may be prescribed by physicians, PAs and CNPs. A prescription of naloxone may be obtained by a trained targeted responder from a program or medical personnel with prescribing authority associated with a program. Presumably, an individual may obtain a prescription from authorized personnel not associated with a program. Naloxone may be dispensed on program premises or through PHO. In either case it is offered without charge. Outside an organized program, physicians, PAs and CNPs may dispense naloxone to their patients. Of course, patients wishing to buy naloxone themselves may take a valid prescription to a pharmacy.

II. Liability

The potential for liability for health care providers prescribing naloxone to ODU patients inside or outside an authorized training program is extremely low throughout the United States. 35 New Mexico’s overdose prevention legislation nonetheless provides immunity for both licensed health care providers 36 and trained targeted responders 37 furnishing or using naloxone. Trained targeted

36 N.M. Stat. Ann. 1978, § 24-23-2 (“A licensed health care professional who is permitted by law to prescribe an opioid antagonist, if acting with reasonable care, may prescribe, dispense, distribute or administer an opioid antagonist without being subject to civil liability or criminal prosecution”).
A. A person authorized under federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist, may administer an opioid antagonist to another person if:
   (1) he, in good faith, believes the other person is experiencing a drug overdose; and
   (2) he acts with reasonable care in administering the drug to the other person.
B. A person who administers an opioid antagonist to another person pursuant to Subsection A of this section shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug.

NM ADC 7.32.7.8 (West 2007):
INDIVIDUAL AUTHORIZATION TO ADMINISTER OPIOID ANTAGONIST: Persons, other than a licensed health care professional permitted by law to administer an opioid antagonist, are authorized to administer an opioid antagonist to another person if he, in good faith, believes the other person is experiencing an opioid drug overdose and he acts with reasonable care in administering the drug to the other person. It is strongly recommended that any person administering an opioid antagonist to another person immediately call for Emergency Medical Services.
responders are safe from liability as long as they believe in good faith that the person to whom they administer naloxone is having an opioid drug overdose and the administration of naloxone, provided the responder is acting with reasonable care. This immunity includes protection from criminal charges of unauthorized practice of medicine. Licensed health care providers are immune from professional discipline, criminal charges or malpractice liability provided they meet the professional standard of care. New Mexico also protects individuals at an overdose event who call 911 for assistance from some criminal charges possession charges.

In the case of volunteer providers, the U.S. Volunteer Protection Act shields volunteers for acts committed within the scope of their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent. This is effective so long as the agent responsible is acting voluntarily and without pay.

Conclusion: Trained targeted responders are safe from liability as long as they believe in good faith that the person they administer naloxone to is having an opioid drug overdose and the administration of naloxone is done with reasonable care. Licensed health care professionals are safe from liability as long as they possess and apply the knowledge and use the skill and care ordinarily used by other professionals with similar qualifications.

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38 Id.
OVERDOSE PREVENTION--LIMITED IMMUNITY.--
A. A person who, in good faith, seeks medical assistance for someone experiencing a drug-related overdose shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the seeking of medical assistance.
B. A person who experiences a drug-related overdose and is in need of medical assistance shall not be charged or prosecuted for possession of a controlled substance pursuant to the provisions of Section 30-31-23 NMSA 1978 if the evidence for the charge of possession of a controlled substance was gained as a result of the overdose and the need for medical assistance.
C. The act of seeking medical assistance for someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution pursuant to the Controlled Substances Act.
I. PURPOSE:

This New Mexico Department of Health (NMDOH) policy establishes guidelines for the dispensing of naloxone through NMDOH Public Health Offices (PHO) and contracted providers in order to reduce fatal opioid overdose as stated in 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 by trained targeted responders is to improve response to drug overdose, which may prevent unnecessary loss of life. While opioid antagonist administration does not automatically guarantee the reversal of overdose due to opiate use, 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 leading to respiratory 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 (ODU) and their families, friends, and domestic partners to prevent and/or properly respond to an overdose makes this population the primary target of this intervention. The aforementioned individuals are most likely to be at the scene of an overdose, The training provides ODU with the skills to function as peer educators within their drug using circles (communities), with a programmatic goal of decreasing overdose deaths through peer prevention education.

Targeted Responders, defined as non-medical first responders such as law enforcement or volunteer fire fighters, are also included as a target population, since they may be the first to arrive at a 911 emergency call in the rural and frontier areas of the state.

Overdose prevention and treatment education should include discussion of strategies for reducing the likelihood of overdose, the importance of providing rescue breathing to a person who has overdosed, the importance of quickly summoning professional medical help in the event of an overdose, and appropriate use of naloxone to reverse the effects of heroin overdose.

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

1) The named 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 heroin overdose prevention and treatment education programs. The NMDOH clinician authorized to prescribe naloxone will hereafter be referred to as the “prescribing clinician”.

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

3. Opiate users and others who have participated in NMDOH-sanctioned heroin overdose prevention and treatment education programs are eligible to receive Naloxone from a local public health office clinic. The trained individual who is eligible to receive Naloxone will hereafter be referred to as “the participant”. NMDOH-sanctioned heroin overdose prevention and treatment education programs include those conducted by NMDOH contractors. Contracted providers 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 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 syringes containing 0.4 milligrams of Naloxone contained in one milliliter of diluents. Each box containing the pre-filled syringes 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, though they may provide up to three (3) pre-filled syringes, or more, depending on the conditions indicated by the participant, such as lengthy travel or limited hours of availability.

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” forms and “Record of Use” forms should be sent to the Harm Reduction Program by the 15th of every month.

**IV. Training Program**

1. A training program should prepare a participant or targeted responder to administer Naloxone as shown by best practices or as recommended by NMDOH for an Overdose Prevention Program.

2. The program must provide overdose education; what is and what causes an overdose, how it 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 short-staffing of many of the rural PHO’s there may be only two or three NMDOH staff available to provide all services, and 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 between a CBO and a PHO, CBO staff may provide the educational component to the participants and the PHO may provide the Naloxone prescriptions and subsequent refills.

**V. Overdose Prevention Prescription Program Guidelines**

1. A **Program Director** shall be identified to manage the overdose prevention program. The Program Director shall:
   a) Identify a Physician Medical Director to oversee the Overdose Prevention Program;
   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 a least three (3) years thereafter;
   d) Maintain Overdose Prevention Program records including Naloxone inventory records, program participant training records, and Overdose Prevention Program usage records;
e) Ensure that all program participants are trained using an Overdose Prevention Training Program, which may be recommended by the NMDOH.

f) Provide evidence of coordination of the Overdose Prevention Program with local Emergency Medical Services and emergency dispatch agencies, including 911 dispatch agencies;

g) Register the Overdose Prevention Program with the NMDOH using the application format;

h) Report all administrations of Naloxone to the NMDOH using the 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 Overdose Prevention Program 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 Overdose Prevention Program;
   c) Ensure that all program participants are properly trained and their skills are maintained;
   d) Develop and approve medical protocols for the Overdose Prevention Program;
   e) Ensure quality assurance review for all administrations of Naloxone;
   f) Assume overall responsibility for how the Overdose Prevention Program is planned and conducted;
   g) Ensure compliance with the NMBOP requirements for the issuance, control and storage of medications; and,
   h) Write Naloxone prescriptions and serve as clinical supervisor for mid-level clinicians (Family Nurse Practitioners) prescribing Naloxone.

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 Overdose Prevention Programming, 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: Overdose Prevention Programs shall use Naloxone, as the opioid antagonist. The Physician Medical Director shall select the specific injection or administration device. It is recommended that either single dose, pre-filled syringes with attached safety needles be used, or the 2 ml pre-filled dose with an atomizer for intranasal delivery;
   b) Response Supplies: Overdose Prevention Program shall provide trained participants 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) 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 Overdose Prevention Program 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;
   i) Quality assurance review documentation; and,
g) Naloxone purchase/order and maintenance records.

6. **Registration of an Overdose Prevention Program:** Prior to beginning an Overdose Prevention Program, 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) Notified and Coordinated with Local EMS Service(s), Provide Date;
   m) Notified and Coordinated with local 911 Dispatch Agency;
   n) Name of Consulting Pharmacist;
   o) Address of Consulting Pharmacist;
   p) Telephone Number of Consulting Pharmacist.

7. **Participant Enrollment form:** Every person who receives both overdose prevention training and is prescribed and provided with Naloxone will have an enrollment form signed by the provider/prescribing clinician that will be sent to the Harm Reduction Program by the 15th of every month. Only forms for participants who have actually received Naloxone should be submitted. At a minimum, the form shall contain the following information:
   a) The participant unique ID number, generated by the first letter of the first name, the first two letters of the last name, the full DOB in two digit format (xx/xx/xx), and sex (M or F);
   b) The participant's age;
   c) Sex;
   d) Race/ethnicity;
   e) County of Residence;
   f) Source of knowledge about the program’s existence;
   g) If participant is a syringe exchange client;
   h) Amount of Naloxone prescribed at this first visit;
   i) Date enrolled in the program, and;
j) The provider’s name (signature).

8. **Report of Naloxone Administration, Record of Use form:**
   Any administration of Naloxone to another person by a program participant affiliated with an Overdose Prevention Program shall be reported to NMDOH. Any program participant who has knowledge of the administration of Naloxone by a non-program participant shall also report such administration to the NMDOH. As a minimum, the report shall contain the information listed below:
   a) Name of Overdose Prevention Program;
   b) Unique participant code submitting report;
   c) Relationship to the person whom the Naloxone was administered;
   d) Approximate date of Naloxone use;
   e) Amount of Naloxone administered;
   f) Amount of Naloxone replaced to the participant at the time of the report;
   g) If known, list the type of overdose drugs (other than opioids) taken by the person to whom the Naloxone was administered; and,
   h) Circumstances relating to overdose (if known):
      1) Was the Naloxone used on a person, and if not, what happened to it (lost, stolen, confiscated, etc);
      2) Signs and symptoms indicating overdose;
      3) Was Emergency Medical Services called, and if not, why;
      4) Was the person transported to a clinical facility;
      5) Was rescue breathing performed on the person who overdosed;
      6) Distance from nearest emergency department (in road miles);
      7) Location of injection site on the overdose person’s body;
      8) Was the person revived, or the clinical disposition of the overdose incident (if known).

9. **“Prevention and Response” Cards:** All effort should be made by the provider to ensure participants receive the Naloxone immediately after their overdose prevention training. Participants should not have to obtain Naloxone by referral. In certain cases, such as a training provided in a detention facility, where it is not possible to provide the Naloxone to a participant
at that time, a “Prevention and Response” card should be given to the participant. When the card is redeemed, the original trainer should be contacted by the prescribing clinician and the original trainer will send in the participants enrollment form. This card should have:
   a. The participants personalized ID code,
   b. The date and location of the training,
   c. The name and telephone number of the trainer,
   d. Suggested locations where the participant may redeem the card for their Naloxone and related equipment.

10. **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 Overdose Prevention Program, 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 Trained Targeted Responder should:
   a) Complete an initial Overdose Prevention Training Program, which may be recommended by the Department;
   b) At least every two (2) years, Trained Targeted Responders should complete a refresher Overdose Prevention training course from a NMDOH recommended training program;
c) Activate the EMS using pre-established methods (contact E-911 public safety answering point or local emergency number) during any response to a victim of suspected drug overdose, and advise that Naloxone is being used;
d) Comply with Physician Medical Director protocols for response to victims of suspected drug overdose;
e) Report all responses to victims of suspected drug overdose to the Overdose Prevention Program Director and Physician Medical Director and complete a report as listed below. A copy of the report shall be submitted to the Department within twenty (20) calendar days;
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.

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

12. **Trained Targeted Responder reporting form**: This form shall at a minimum capture the following information:
   a) Patient sex;
   b) Race/ethnicity;
   c) Date of use;
   d) Amount of Naloxone used;
   e) Was patient alone;
   f) Was rescue breathing used;
   g) Signs and symptoms;
   h) Presence of other drugs (if known);
   i) Miles from nearest hospital;
   j) Outcome of the incident;
   k) Comments, provider, facility, phone number.

13. **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 victim 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.  
   d) CBO’s and other organizations, such as the Department of Public Safety, shall receive their Naloxone and Pharmacy Consultant from a contracted pharmaceutical provider and not the NMDOH State Pharmacy.

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 0.4 mg by intramuscular injection, not to exceed a total overall dose of 0.8 mg. Intra-nasal administration is limited to a dose of less than or equal to 1.0 mg.

7. “**Overdose Prevention Program**” means an organized program to administer Naloxone in accordance with these regulations.

8. “**Overdose Prevention Training Program**” means a training program which prepares a person to administer an opioid antagonist as shown by best practices or recommended by the Department for an Opioid Antagonist Administration Program.

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

10. “**Person**” means any individual other than a licensed health care professional permitted by law to administer an opioid antagonist, including, but not limited to, private individuals, law enforcement personnel, and first responders who are not certified by the Department.

11. “**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.

12. “**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.

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

14. “**Provider**” means a person or entity delivering emergency medical services in New Mexico.

15. “**Trained Targeted Responder**” means a person who has completed an authorized opioid antagonist training program and who administers opioid antagonists as defined in Harm Reduction Protocols.