MEMORANDUM

DATE: August 14, 2007

RE: Legality of Prescribing Take-Home Naloxone to Treat Opiate Overdose in Oklahoma

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. Our analysis finds that:

1. Naloxone is not a controlled substance as defined by state or federal law, but is a prescription drug subject to the general laws and regulations that govern all prescriptions in regular medical practice.

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2. Prescribing naloxone to ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.

3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.

4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODUs who are not patients.

5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensal?
4. How may naloxone be dispensed?
5. Is it legal to prescribe or dispense naloxone for recipients to give or administer to third parties who have not been prescribed the drug by a licensed professional?
6. What is the risk of disciplinary action by a professional board arising from naloxone prescription or distribution, and how can the risk be minimized?
7. What kind of malpractice liability may arise from naloxone prescription or distribution, and how can the risk of liability be minimized?
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 who, upon examination, 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. (See Parts I & II describing who may prescribe naloxone.)

As part of the process of prescribing, the patient should be given information about when and how to use the drug, as well as other steps that are advisable in responding to an overdose. Because a person suffering an overdose may not be able to administer the drug him or herself, it is also appropriate to (1) teach groups of patients how to administer the drug so that they can assist each other in an overdose emergency; and (2) instruct—in person, or through written materials—friends, family members and others who may witness an overdose how to administer the drug to a patient. It is not uncommon for third parties to assist patients in administering their drugs, for all sorts of reasons. The key legal requirement is that the recipient have a valid prescription for the drug. (See Parts III & IV.)

Because a legal prescription requires some examination and a specific medical indication, naloxone may not be prescribed or dispensed to patients or program participants to hand out or administer to other ODUs. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws; the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

Assuming the provider does not violate regulations that generally apply to drug prescription in this state, acts competently, and follows the additional guidelines we set out, criminal or civil liability is very unlikely to arise out of naloxone prescription activities. (See Parts VI and VII.) Presumably, few prosecutors would be hard-hearted enough to punish a person for saving a life, but an ODU who uses his or her own naloxone to save the life of a person who has not been prescribed the drug does, technically, break the law. A few states have taken positive action to clearly legalize emergency administration of naloxone by lay persons, and to protect medical professionals from tort and other liability. Such legislation can

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2 We will refer to a person who has received a legal prescription for naloxone as a “patient.”

3 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.
help lower legal barriers and increase access to naloxone here. (See “Conclusion.”)

### The Legal Analysis in Detail

#### I. May a Physician Legally Prescribe Naloxone to an IDU Patient?

##### A. Professional Licensure Law

The practice of medicine in Oklahoma is governed by the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, with regulations found in the Oklahoma Administrative Code. The State Board of Medical Licensure and Supervision has the authority to license physicians and to punish licensed physicians who behave in ways that violate the law or beneath the standards of good faith and regular practice of medicine. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the Oklahoma Board of Medical Licensure and Supervision to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug.

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is

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10 Okla. Stat. Ann. tit. 63, § 2-101 (West 2007) ("Controlled dangerous substance" means a drug, substance or immediate precursor in Schedules I through V of the Uniform Controlled Dangerous Substances Act, Section 2-101 et seq. of this title’); Although naloxone is not specifically excluded from Schedule II of the Uniform Controlled Dangerous Substances Act, Okla. Stat. Ann. tit. 63, § 2-312(A) (West 2007), naloxone is not considered a controlled substance by the State Board of Pharmacy. Personal communication with Gary LaRue (6/27/07).
there case-law challenging the legality of prescription of naloxone specifically.\textsuperscript{11} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances: "[a] physician … in good faith and in the course of such person's professional practice only, may prescribe … controlled dangerous substances."\textsuperscript{12}

In determining whether a prescription arises within the usual course of professional practice, courts may consider such factors as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors and efforts to provide other harm reducing services.\textsuperscript{13} The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{14}

B. Analysis

While not explicitly required by Oklahoma law, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Oklahoma laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone. Some of the prescription tasks can be delegated to allied health professionals.

II. May Anyone Other Than Physician Issue A Prescription For Naloxone?

\textsuperscript{11} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
\textsuperscript{13} United States v. Moore, 423 U.S. 122 (U.S. 1975).
A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) can prescribe, but must do so under the supervision of a physician, in accordance with their scope of practice.15

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Oklahoma law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A consultation with a non-physician healthcare provider may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued.

Conclusion: ARNPs and PAs may replace a physician in specific functions during the prescription process. The same rules that govern the prescription of any other prescription drug apply to naloxone.

An advanced registered nurse practitioner in accordance with the scope of practice of the advanced registered nurse practitioner shall be eligible to obtain recognition as authorized by the Board to prescribe, as defined by the rules promulgated by the Board pursuant to this section and subject to the medical direction of a supervising physician. This authorization shall not include dispensing drugs, but shall not preclude, subject to federal regulations, the receipt of, the signing for, or the dispensing of professional samples to patients.

(a) A physician assistant may issue written and oral prescriptions and other orders for drugs and medical supplies … as delegated by and within the established scope of practice of the supervising physician and as approved by the Board.

... (c) Written prescriptions shall be issued in the format and in accordance with the Physician Assistant Drug Formulary, listed in Subchapter 11 of this Chapter, as established by the Board in consultation with the Oklahoma State Board of Pharmacy.
(d) All written prescriptions and orders for drugs shall be written on the prescription blank of the supervising physician and must bear the name and phone number of the physician, the printed name and license number of the physician assistant, the original signature of the physician assistant, and any other information the Board may require. If more than one physician name appears on the prescription blank, the physician assistant shall indicate which is the supervising physician.
(e) A physician assistant may not issue prescriptions or orders for drugs and medical supplies that the physician is not permitted to prescribe.
III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

While there is no explicit regulatory scheme, as noted in the licensure law described in sections I, in general it is recommended that a healthcare provider formulate a therapeutic plan for their patient and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.

B. Analysis

The intended use of naloxone is to prevent opiate overdose. Indications for and methods of administration should be explained to patients, along with risks and benefits. Because of the nature of overdose, patients may not always be able to self-administer the necessary dose. Some overdose prevention programs properly instruct pairs or groups of patients in naloxone administration and other emergency measures so that patients can assist each other. Prescribing staff may also provide written and oral instructions that patients can relay to their friends, family, or others who can help administer the drug in an event of an overdose. Such instructions parallel information given to patients who may need emergency injections of insulin or epinephrine and are entirely consistent with the legal prescription of the drug. These instructions should include:

1. information on how to spot symptoms of an overdose;
2. instruction in basic resuscitation techniques;
3. instruction on proper naloxone administration, and
4. the importance of calling 911 for help.

Naloxone distribution programs in Oklahoma should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

Conclusion: Program participants receiving a take-home dose of naloxone should receive verbal and written instructions on how and when to use this drug. Program staff should not instruct patients to administer naloxone to persons who do not have a valid prescription for the drug.

IV. How May Naloxone be Dispensed?

A. The Regulatory Scheme
Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. Under the Oklahoma Pharmacy Act, with regulations in the Oklahoma Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines. Physicians licensed as dispensers by the Oklahoma Pharmacy Board can dispense "dangerous drugs," which include prescription drugs, "for the expressed purpose of serving the best interests and promoting the welfare of such patients." Physicians can dispense professional samples without a dispensing license, but "sample" is defined to mean a dose of drug provided free to the practitioner, which would make this

   "Dangerous drug", "legend drug", "prescription drug" or "Rx Only" means a drug which:
   a. under federal law, is required, prior to being dispensed or delivered, to be labeled with one of the following statements:
      (1) "Caution: Federal law prohibits dispensing without prescription",
      (2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian",
      (3) "Rx Only",
   b. is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.
   A. Except as provided for in Section 353.1 et seq. of this title, only a licensed practitioner may dispense dangerous drugs to such practitioner's patients, and only for the expressed purpose of serving the best interests and promoting the welfare of such patients. The dangerous drugs shall be dispensed in an appropriate container to which a label has been affixed, such label to include the name and office address of the licensed practitioner, date dispensed, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength, not meaning ingredients, of the drug therein contained; provided, this requirement shall not apply to compounded medicines. The licensed practitioner shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years a record of every dangerous drug compounded or dispensed by the licensed practitioner.
   B. A licensed practitioner desiring to dispense dangerous drugs pursuant to this section shall register annually with the appropriate licensing board as a dispenser, through a regulatory procedure adopted and prescribed by such licensing board.
   C. A licensed practitioner who dispenses professional samples to patients shall be exempt from the requirement of subsection B of this section if:
      1. The licensed practitioner furnishes the professional samples to the patient in the package provided by the manufacturer;
      2. No charge is made to the patient; and
      3. An appropriate record is entered in the patient's chart.
   D. This section shall not apply to the services provided through the State Department of Health, city/county health departments, or the Department of Mental Health and Substance Abuse Services.
   'Professional samples' means complimentary drugs packaged in accordance with federal and state statutes and regulations and provided to a licensed practitioner free of charge by manufacturers or distributors and distributed free of charge in such package by the licensed practitioner to such practitioner's patients.
21 Supra fn 19.
exception of limited use in a naloxone program. ARNPs and PAs are limited to dispensing professional samples under the supervision of a physician. Finally, physicians must adhere to the dispensation regulations when directly dispensing prescription drugs from the physician's office.

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has obtained a dispensing license, he or she can dispense the drug directly to the clients. Allied health professionals would not be able to independently dispense naloxone in an overdose prevention program.

Conclusion: Dispensing naloxone by valid prescription does not violate Oklahoma law and may be done by a properly licensed physician on the premises of the distribution program.

V. Is It Legal To Prescribe Or Dispense Naloxone For Recipients To Give Or Administer To Third Parties Who Have Not Been Prescribed The Drug By A Licensed Professional?

A legal prescription requires a specific patient who has been examined and found to have a medical indication for the drug. Before the drug can properly be dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to heavy fines. The patient or volunteer who distributed or administered naloxone

   An advanced registered nurse practitioner in accordance with the scope of practice of the advanced registered nurse practitioner shall be eligible to obtain recognition as authorized by the Board to prescribe, as defined by the rules promulgated by the Board pursuant to this section and subject to the medical direction of a supervising physician. This authorization shall not include dispensing drugs, but shall not preclude, subject to federal regulations, the receipt of, the signing for, or the dispensing of professional samples to patients.

23 Supra fn 19.

to recipients who were not prescribed this agent could be charged with practicing medicine without a license\textsuperscript{25} or a violation of the Pharmacy Act.\textsuperscript{26} We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no provision that made it a crime to possess a legend drug without a prescription.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation. But a program in this state that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

VI. What Is The Risk Of Disciplinary Action By A Professional Board Arising Kind Of Medical Discipline Or Criminal Liability May Arise From Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules\textsuperscript{27} may carry license sanctions and fines.\textsuperscript{28} There is little or no risk of professional

\textsuperscript{25} Okla. Stat. Ann, tit. 59, § 491(2), which makes the practice of medicine without a license punishable by on the first offense of not less than $1,000 and not more than $5,000 and any succeeding offense is subject to a minimum of 30 days imprisonment and the maximum of 180 days imprisonment.


It shall be unlawful for any person, firm or corporation to:

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2. Sell, offer for sale, barter or give away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act or as otherwise provided by the Board of Pharmacy.


The words "unprofessional conduct" as used in Sections 481 through 514 of this title are hereby declared to include, but shall not be limited to, the following:

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12. Prescribing or administering a drug or treatment without sufficient examination and the establishment of a valid physician-patient relationship;
censure for participating in a naloxone prescription program. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct.29 Blatant non-compliance,

... Aiding or abetting, directly or indirectly, the practice of medicine by any person not duly authorized under the laws of this state.


A. RANGE OF ACTIONS: The State Board of Medical Licensure and Supervision may impose disciplinary actions in accordance with the severity of violation of the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act. Disciplinary actions may include, but are not limited to the following:
1. Revocation of the medical license with or without the right to reapply;
2. Suspension of the medical license;
3. Probation;
4. Stipulations, limitations, restrictions, and conditions relating to practice;
5. Censure, including specific redress, if appropriate;
6. Reprimand;
7. A period of free public or charity service;
8. Satisfactory completion of an educational, training, and/or treatment program or programs; and
9. Administrative fines of up to Five Thousand Dollars ($5,000.00) per violation.
Provided, as a condition of disciplinary action sanctions, the Board may impose as a condition of any disciplinary action, the payment of costs expended by the Board for any legal fees and costs and probation and monitoring fees including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. The Board may take such actions singly or in combination as the nature of the violation requires.

D. DISCIPLINARY ACTION AGAINST LICENSEES:
1. The Board shall promulgate rules describing acts of unprofessional or unethical conduct by physicians pursuant to the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act; and
2. Grounds for Action: The Board may take disciplinary action for unprofessional or unethical conduct as deemed appropriate based upon the merits of each case and as set out by rule. The Board shall not revoke the license of a person otherwise qualified to practice allopathic medicine within the meaning of the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act solely because the person's practice or a therapy is experimental or nontraditional.

29 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{30}

VII. What Kind of Tort or Civil Liability May Arise from Naloxone Prescription or Distribution; What Remedies Exist to Minimize Such Risk?

A. The Legal Scheme

Any practice of medicine implies a risk that something may go wrong. In the context of a naloxone prescription/dispensing program, a patient may suffer one of the rare side effects from the drug. An error in administration by a patient’s companion, a failure to seek timely medical help after the administration of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

Generally, every tort claimant must establish that he or she suffered an injury that was actually caused by the defendant healthcare provider. A healthcare provider is required to practice his or her profession in a reasonably competent manner. Particular conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the “standard of care.”\textsuperscript{31} The essence of the inquiry is whether the provider’s treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances.

In order to prove negligence, the plaintiff must prove that (1) the provider’s failure to meet the professional standard of care (2) caused an injury, and that the defendant provider (3) had a duty to avoid harming the plaintiff. Tort doctrine requires the plaintiff to prove that the injury would not have occurred “but for” the healthcare provider’s unreasonable behavior.

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an IDU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone,\textsuperscript{32} and, in an actual case, by


\textsuperscript{32} See e.g. John Strang, et al, Heroin overdose: the case for take-home naloxone, 312, BMJ, 1435-1436 (1996); Karen H. Seal, et al, Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study,
expert testimony from clinicians and public health experts. If the prescription of naloxone is reasonable, there can be no tort liability even if the other elements of the case are established.

“But for” causation will be extremely difficult to establish where the injury results from overdose because at the moment naloxone was administered serious injury was already likely to happen. Where the injury is caused by the rare occurrence of side effects of naloxone, the causal connection is still tenuous: the behavior of the injured party, in overdosing on heroin, is the key causal factor that necessitated treatment with the agent. Injury was likely to be as severe, if not more so, had naloxone not been administered. It is not considered malpractice to prescribe a drug that carries a low risk of side effects to avert death or severe impairment, particularly if the patient is adequately informed of the risks. Even in the unlikely cases in which “but for” factual causation may be established, the provider’s actions must represent a major contributing factor to the injury for liability to arise. It is hardly fair to blame a prescribing professional for a harm primarily caused by a patient’s decision to inject heroin; courts have usually applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.33

“Loss of chance” doctrine in tort law establishes liability when negligent or otherwise harmful behavior substantially contributes to an injury, even if the injury may have also occurred from other causes. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the “loss of a chance” to receive medical care.34 However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable.35 A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary resuscitation


procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population.

In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent and unless a state expressly rejects the protection offered by the VPA.  Oklahoma law provides similar liability protections from damages caused by employees working within their official functions for non-profit or charitable organizations, so long as the "damage or injury was not caused by gross negligence or willful and wanton misconduct by the volunteer." Volunteer medical professional must act in "good faith, and, if licensed, the services provided [must be] within the scope of the license of the volunteer medical professional." It appears that volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

Conclusion: The risk of tort liability in a naloxone program is low. Conceptually, this risk is no different from any other healthcare context. By following state rules and general standards of practice, providers can protect themselves from the imposition of tort liability. Malpractice insurance and laws that apply specifically to volunteer providers may provide additional protection.

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state. However, as with any healthcare practice, institutions and professionals providing this service should follow the relevant rules and regulations that govern their practice to avoid professional, civil, and criminal liability.

The following is a summary of the program guidelines dictated by Oklahoma law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician or licensed medical provider working in collaboration with a physician.

2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.

3. The prescription must be made out to the specific patient and must contain all the information required by law.

4. Each prescription should be accompanied by oral and/or written information on the following:
   - information on how to spot symptoms of an overdose;
   - instruction in basic resuscitation techniques;
   - instruction on proper naloxone administration, and
   - the importance of calling 911 for help.

**B. Changes in State Law**

Under the current law of this state, dispensing or administering naloxone to third parties who have not been prescribed the drug is illegal. Passing legislation to allow these practices would help reduce overdose deaths and ease the concerns of providers and clients about possible legal penalties. New York’s legislature recently passed a law to provide clear authorization of medical providers to “prescribe” or “dispense” naloxone to unknown ODUs via trained patients or volunteers (“Trained Overdose Responders” under NYS law); establish immunity for providers participating in such programs; and establish immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.³⁹

**C. Cooperation with First Responders**

Programs should also work with police and EMTs to inform them about program goals and practices. Alerting first responders to the presence of take-home naloxone can help inform their work and alleviate resistance or roadblocks to program implementation. By building their programs according to the regulatory schemes we have referenced above, programs can successfully navigate the legal questions around dispensation of this life-saving agent to ODUs.

[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.