DATE: October 8, 2007

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

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 federal or state law, but is a prescription drug subject to the general laws and regulations that govern all prescriptions in regular medical practice.
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 who are not patients of the prescriber. 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

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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.
lay persons, and to protect medical professionals from tort and other liability. Such legislation can 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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in Arkansas is governed by the Medical Practice Act, and regulations in the administrative code. The Board of Medical Examiners (the "Board") has the authority to license physicians, and to punish licensed physicians who behave in ways that violate the law or fall below 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 Board 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 there case-law challenging the legality of prescription of naloxone specifically.

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5 060 CARR 00 001 (Lexis 2007), et. seq.
10 "Controlled substance" means a drug classified in any of the schedules (I through V) of the Uniform Controlled Dangerous Substances Act, AR Stat. §§ 5-64-101 to 5-64-1303 (2006), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. AR Stat. § 20-64-503 (2006).
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

Arkansas medical licensure law is silent on a physician's general authority to write prescriptions for or dispense drugs. According to case law, the only standard for a prescription under Arkansas law is the standard governing the prescription of controlled substances set forth in the Code of Federal Regulations.\(^\text{12}\) This states that a prescription for a controlled substance is valid only if issued for a legitimate medical purpose by a properly licensed medical practitioner acting in the usual course of professional practice.\(^\text{13}\) In determining whether a prescription arises within the usual course of professional practice, courts, in general, consider such indicia 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, efforts to provide other harm reducing services, follow up care, and so on.\(^\text{14}\) We assume that a court or medical board would apply this same general, common-sense standard to the prescribing of drugs that are not controlled substances.

**B. Analysis**

While not explicitly required by Arkansas statutes, 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 as appropriate, 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 Arkansas laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

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


\(^{13}\) *Id.*

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 practice nurses (APNs) may be certified by the Arkansas State Board of Nursing to prescribe medicine to patients, if they have a collaborative practice agreement with a physician.\(^{15}\) Physician assistants (PAs) must work with a supervising physician, who may delegate prescribing authority to physician assistants.\(^{16}\)

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\(^{15}\) AR Stat.§ 17-87-310 (2006):
(a) The Arkansas State Board of Nursing may grant a certificate of prescriptive authority to an advanced practice nurse who:
   (1) Submits proof of successful completion of a board-approved advanced pharmacology course that shall include preceptorial experience in the prescription of drugs, medicines, and therapeutic devices; and
   (2) Has a collaborative practice agreement with a physician who is licensed under the Arkansas Medical Practices Act, §§ 17-95-201--17-95-207, 17-95-301--17-95-305, and 17-95-401--17-95-411, and who has a practice comparable in scope, specialty, or expertise to that of the advanced practice nurse on file with the board.
(b)(1) An advanced practice nurse with a certificate of prescriptive authority may receive and prescribe drugs, medicines, or therapeutic devices appropriate to the advanced practice nurse's area of practice in accordance with rules established by the board.
(c) A collaborative practice agreement shall include, but not be limited to, provisions addressing:
   (1) The availability of the collaborating physician for consultation or referral, or both;
   (2) Methods of management of the collaborative practice, which shall include protocols for prescriptive authority;
   (3) Coverage of the health care needs of a patient in the emergency absence of the advanced practice nurse or physician; and
   (4) Quality assurance.
(d) If a collaborative practice results in complaints of violations of the Arkansas Medical Practices Act, §§ 17-95-201--17-95-207--17-95-301--17-95-305, and 17-95-401--17-95-411, the Arkansas State Medical Board may review the role of the physician in the collaborative practice to determine if the physician is unable to manage his or her responsibilities under the agreement without an adverse affect on the quality of care of the patient.
(e) If a collaborative practice results in complaints of violations of this chapter, the Arkansas State Board of Nursing may review the role of the advanced practice nurse in the collaborative practice to determine if the nurse is unable to manage his or her responsibilities under the agreement without an adverse affect on the quality of care of the patient. (emphasis added)

\(^{16}\) AR Stat. § 17-105-108 (2006):
(a) Physicians supervising physician assistants may delegate prescriptive authority to physician assistants to include prescribing, ordering, and administering...all legend drugs, and all nonschedule prescription medications and medical devices. All prescriptions and orders issued by a physician assistant shall also identify his or her supervising physician.
(b) At no time shall a physician assistant's level of prescriptive authority exceed that of the supervising physician.

physician does not need to be physically present while the physician assistant is
providing medical services. 17

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Arkansas 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: Allied health professionals may replace a physician in specific functions during the prescription process. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

According to the licensure law described in sections I and II, a healthcare provider may issue prescriptions in the usual course of practice to a patient for

(a) Supervision of physician assistants shall be continuous but shall not be construed as necessarily requiring the physical presence of the supervising physician at the time and place that the services are rendered.
(b) It is the obligation of each team of physicians and physician assistants to ensure that:
   (1) The physician assistant's scope of practice is identified;
   (2) The delegation of medical task is appropriate to the physician assistant's level of competence;
   (3) The relationship and access to the supervising physician is defined; and
   (4) A process of evaluation of the physician assistant's performance is established.
(c) The physician assistant and supervising physician may designate back-up physicians who are agreeable to supervise the physician assistant during the absence of the supervising physician.

A physician desiring to supervise a physician assistant must:
(1) Be licensed in this state;
(2) Notify the Arkansas State Medical Board of his or her intent to supervise a physician assistant; and
(3) Submit a statement to the board that he or she will exercise supervision over the physician assistant in accordance with any rules adopted by the board.

17 Id.
legitimate medical purposes. This means that a prescription for naloxone is subject to general professional standards, which would include the requirements that proper records are kept and that the patient is instructed in the indications, risks and proper administration of the prescribed medication.

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 Arkansas 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 pharmacy laws, with regulations in the administrative code, pharmacists are expected to fill a prescription that

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20 070 CARR 00 001 (Lexis 2007), et seq.
meets regulatory guidelines. Physicians are able to dispense legend drugs in injectable form, but may not dispense other drugs “without prior approval by the Arkansas State Medical Board after application to the board and on the showing of need.”\textsuperscript{21} This authority cannot be delegated to APNs or PAs.\textsuperscript{22}

\textsuperscript{21} AR Stat. § 17-95-102 (2006):
(a) A dispensing physician is a physician licensed under the Arkansas Medical Practices Act, §§ 17-95-201-17-95-207, 17-95-301-17-95-305, and 17-95-401-17-95-411, who purchases legend drugs to be dispensed to his or her patients for the patients' personal use and administration outside the physician's office.
(b) \textit{This section shall not apply to physicians who only dispense drugs in injectable form} unless they are controlled substances, in which case the section shall fully apply (emphasis added).
(c) The dispensing physician shall:
   (1) \textit{Personally dispense legend drugs and the dispensing of such drugs may not be delegated} (emphasis added);
   (2) Keep records of all receipts and distributions of legend drugs. The records shall be subject to inspection by the proper enforcement authority and shall be readily accessible for inspection and maintained in a central registry; and
   (3) Label legend drugs with the following information:
      (A) Patient's name and address;
      (B) Prescribing physician's address…
      (C) Date of dispensing; and
      (D) Directions and cautionary statements, if any, as required by law.
(d) No physician licensed under the Arkansas Medical Practices Act, §§ 17-95-201-17-95-207, 17-95-301-17-95-305, and 17-95-401-17-95-411, shall dispense legend drugs without prior approval by the Arkansas State Medical Board after application to the board and on the showing of need. Licensed physicians who were dispensing in the ordinary course of their practice for the twelve (12) months immediately prior to July 4, 1983, shall be exempt from the requirements of this subsection.
(e) The board shall enforce the provisions of this section and is authorized and directed to adopt regulations to carry out its purpose…

\textsuperscript{22} 060 00 CARR 001 § 12 (Lexis 2007):
1. Pursuant to other provisions of Act 515 of 1983 any physician licensed to practice medicine in the state of Arkansas who is a "dispensing physician" as defined by Act 515 of 1983 shall comply with all provisions of the Act and shall register with the Arkansas State Medical Board on a form provided by it for that purpose.
2. Any physician desiring to dispense legend drugs, who is not exempt by the terms of Act 515 of 1983 from the requirement of prior approval of the Arkansas State Medical Board shall apply to the Board on a form provided for it for that purpose and shall be required to demonstrate the need for such dispensing of legend drugs prior to receiving approval.
3. All records maintained by a dispensing physician pursuant to the requirements of Act 515 of 1983 shall be subject to inspection by a designated inspector of the Arkansas State Medical Board and at its direction during all regular business hours.
4. Violation of the provision of Act 515 of 1983 or violations of these regulations shall constitute "unprofessional conduct" and shall subject the violator to disciplinary action as provided by Ark. Code Ann. 17-95-409.

We were unable to find an explanation of what would be required for a “showing of need” to dispense non-injectable drugs.

governing the dispensation of drugs directly from the provider’s office set basic standards for record-keeping that have to accompany such practice, which include the requirement to maintain a dispensation log, and proper labeling of the agent, including the patient’s name and cautionary information.\textsuperscript{23}

\textbf{B. Analysis}

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Naloxone is generally used in injectable form, so provided that the physician has followed the prescription guidelines, she can dispense the drug in directly to the clients. For a physician to dispense naloxone in a non-injectable form, such as a nasal spray, she must receive authorization as a dispensing physician from the Medical Board. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

\textbf{Conclusion: Dispensing naloxone by valid prescription does not violate Arkansas law and may be done on premises of the distribution program.}

\textbf{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 physician who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to fines.\textsuperscript{24} The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license.\textsuperscript{25} We cannot say that a person who saved a life in this way would

\textsuperscript{23} Supra fn. 21.
\textsuperscript{24} AR Stat. § 17-95-401 (2006).
\textsuperscript{25} AR Stat. § 17-95-401 (2006):

If any person who does not possess a valid license to practice medicine within this state and who is not exempted from the licensing requirements does any of the acts constituting the practice of medicine, he or she shall be deemed to be practicing medicine without complying with the provisions of the Arkansas Medical Practices Act.
actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We were unable to find any provision that makes it illegal to distribute or possess prescription drugs.

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, or may be called upon to assist another patient. 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 may carry license sanctions and fines. There is no risk of professional censure for participating in a naloxone prescription program run as described here. 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. Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.

Under AR Stat. § 17-95-402 (2006) such acts constitute a misdemeanor and:

(2) Upon conviction he or she shall be punished by a fine of not less than two hundred fifty dollars ($250) nor more than five hundred dollars ($500) or by imprisonment in the county jail for a period of not less than one (1) month nor more than eleven (11) months, or by both fine and imprisonment. Each day of such a practice shall constitute a separate offense.


26 Williams v. Ohio Board of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993);
Sermchief v Gonzales, 660 S.W.2d 683 (Mo. banc 1983).

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.” 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 ODU 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, and, in an actual case, by 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\textsuperscript{31} 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.\textsuperscript{32}

“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.\textsuperscript{33} 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. A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is arguably 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. Arkansas state law provides similar liability protections from damages caused by physicians and health care professionals providing free health care services. It appears that under Arkansas law, 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 Arkansas 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;

34 42 U.S.C.A. § 14503.
35 AR Stat. § 16-6-201 (2006).
• 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.36

**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.

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[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.