MEMORANDUM

DATE: June 7, 2007

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

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 IDU patient?
2. May an allied health professional other than physician prescribe naloxone to an IDU patient?
3. What instructions should accompany naloxone prescription/dispensation?
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 IDU Patient?

A. Professional Licensure Law

The practice of medicine in Arizona is governed by AZ Stat. § 32-1401 et seq., with regulations found in chapter 16 of title R4 of the Arizona Administrative Code. The Board of Medical Examiners 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 Arizona Board of Medical Examiners 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.

8 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Uniform Controlled Substances Act, AZ Stat. § 36-2501 to 36-2553 (2007), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. AZ Stat. § 13-3401(28) (2007).
9 AZ ADC R4-16-303(A) (2006) (prescribing and dispensing requirements):
   A physician shall record on the patient's medical record the name, strength, dosage, and form, of the controlled substance, prescription-only drug, or prescription-only device dispensed, the quantity or volume dispensed, the date the controlled substance, prescription-only drug, or prescription-only device is dispensed, the medical reasons for dispensing the controlled substance, prescription-only drug, or prescription-only device, and the number of refills authorized.
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.\textsuperscript{10} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

Arizona medical licensure law sets is silent on the physician's general authority to write prescriptions for drugs. However, regulations for prescribing controlled substances presumably provide a general guideline. The rules of professional conduct require that controlled substance prescriptions be issued only for "accepted therapeutic purposes."\textsuperscript{11} Medical practitioners may prescribe controlled substances "while acting in the course of their professional practice, in good faith and in accordance with generally accepted medical standards."\textsuperscript{12} In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters 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 and so on.\textsuperscript{13}

The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. Disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances. These cases apply the familiar standard under which a prescription is valid if it is written for a legitimate medical purpose, in the normal course of professional practice.\textsuperscript{14}

B. Analysis

Physicians are required to follow certain procedures when issuing prescriptions to all prescription drugs. The law does not specify the length or intensity of these interactions, leaving the precise contours of the examination and discussion to the judgment of the physician. 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. 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 IDU patient is consistent with the standard for a valid prescription under Arizona laws governing the

\textsuperscript{10} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
\textsuperscript{13} See generally, United States v. Moore, 423 U.S. 122 (1975).
\textsuperscript{14} State v. Marcus, 450 P.2d 689 (Ariz. 1969).
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?

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 may examine patients, develop plans of care, and run tests. ANPs may also be authorized by the medical board to prescribe drugs. A physician may

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16 AZ ADC R4-19-511 (2006):

A. The Board shall authorize an RNP to prescribe and dispense (P & D) drugs and devices within the RNP's specialty area and category of practice only if the RNP does all of the following:
1. Obtains authorization by the Board to practice as a registered nurse practitioner;
2. Applies for prescribing and dispensing privileges on the application for registered nurse practitioner certification;
3. Submits a completed application on a form provided by the Board that contains all of the following information:
   a. Name, address, and home telephone number;
   b. Arizona registered nurse license number, or copy of compact license;
   c. Nurse practitioner specialty;
   d. Nurse practitioner certification number issued by the Board;
   e. Business address and telephone number; and
   f. A sworn statement verifying the truthfulness of the information provided;
4. Submits evidence of a minimum of 45 contact hours of education within the three years immediately preceding the application, covering one or both of the following topics:
   a. Pharmacology, or
   b. Clinical management of drug therapy, and
5. Submits the required fee.

AZ ADC R4-19-512 (2006):

A. An RNP granted P & D authority by the Board may:
1. Prescribe drugs and devices;
2. Provide for refill of prescription-only drugs and devices for one year from the date of the prescription.
F. An RNP with P & D authority shall ensure that all prescription orders contain the following:
1. The RNP's name, address, telephone number, and specialty area;
2. The prescription date;
3. The name and address of the patient;
4. The full name of the drug, strength, dosage form, and directions for use;
5. The letters "'DAW', "'do not substitute", "'medically necessary" or any similar statement on the face of the prescription form if intending to prevent substitution of the drug;
6. The RNP's DEA registration number, if applicable; and
7. The RNP's signature.
delegate tasks to a collaborating physician assistant, such as obtaining patient histories, performing examinations, and developing a treatment plan.\textsuperscript{17} The physician may also delegate to a PA the authority to prescribe medication.\textsuperscript{18}

\textbf{B. Analysis}

\begin{footnotesize}
\textsuperscript{17} AZ Stat. § 32-2531 (2007).
\textsuperscript{18} AZ Stat. § 32-2532 (2007):

B. All prescription orders issued by a physician assistant shall contain the name, address and telephone number of the supervising physician.

E. Prescription-only drugs shall not be dispensed, prescribed or refillable for a period exceeding one year.

J. The board shall advise the state board of pharmacy and the United States drug enforcement administration of all physician assistants who are authorized to prescribe or dispense drugs and any modification of their authority.

K. The state board of pharmacy shall notify all pharmacies at least quarterly of physician assistants who are authorized to prescribe or dispense drugs.


A. The supervising physician is responsible for all aspects of the performance of a physician assistant, whether or not the supervising physician actually pays the physician assistant a salary. The supervising physician is responsible for supervising the physician assistant and ensuring that the health care tasks performed by a physician assistant are within the physician assistant's scope of training and experience and have been properly delegated by the supervising physician.

B. A supervising physician shall not supervise more than two physician assistants who work the same hours at the same employment location.

C. A supervising physician may designate a supervising physician's agent to provide consultation and supervise a physician assistant when the supervising physician is not immediately available. The supervising physician remains responsible for the acts of a physician assistant when the physician assistant is supervised by a supervising physician's agent.

E. In order to act as a supervising physician or a supervising physician's agent, a physician shall:

1. Complete an application as prescribed by the board.

2. Hold a license pursuant to chapter 13 or 17 of this title and not hold a license under probation, restriction or suspension unrelated to rehabilitation.

3. Submit a statement that the supervising physician or supervising physician's agent is familiar with the statutes and rules regarding the performance of health care tasks of physician assistants and accepts responsibility for supervising the physician assistant.

F. A physician who violates the provisions of this chapter shall not serve as a supervising physician or supervising physician's agent.

G. The supervising physician's agent is responsible for the acts of a physician assistant in the absence of the supervising physician if the board approves. The board considers the supervising physician's agent's signature on a physician assistant's current notification of supervision to be acknowledgement by the supervising physician's agent that the agent understands and is familiar with the physician assistant's approved health care tasks.

H. A supervising physician or supervising physician's agent shall not delegate to the physician assistant any health care task that the supervising physician or supervising physician's agent does not have training or experience in and does not perform.
\end{footnotesize}
We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Arizona 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. An advanced nurse practitioner may get authorization from the medical board to independently prescribe medicine. However, specific and detailed conditions govern the communication between the “collaborating physician,” and a physician’s assistant. These rules must be met for the prescription to be valid.

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 section I, a healthcare provider 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 Arizona 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 AZ Stat. § 32-1901 et seq., with regulations found in chapter 23 of title R4 of the Arizona Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines.

A prescribing advanced practice nurse, Physician’s assistant, or physician may also dispense the agent at the point of service. The Code states,

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19 AZ ADC R4-19-513 (2006):

A. A registered nurse practitioner (RNP) granted prescribing and dispensing authority by the Board may:

1. Dispense drugs and devices to patients;
2. Dispense samples of drugs packaged for individual use without a prescription order or additional labeling;
3. Only dispense drugs and devices obtained directly from a pharmacy, manufacturer, wholesaler, or distributor; and
4. Allow other personnel to assist in the delivery of medications provided that the RNP retains responsibility and accountability for the dispensing process.

B. If dispensing a drug or device, an RNP with dispensing authority shall:

1. Ensure that the patient has a written prescription that complies with R4-19-512(F) and inform the patient that the prescription may be filled by the prescribing RNP or by a pharmacy of the patient's choice;
2. Affix a prescription number to each prescription that is dispensed; and
3. Ensure that all original prescriptions are preserved for a minimum of seven years and make the original prescriptions available at all times for inspection by the Board of Nursing, Board of Pharmacy, and law enforcement officers in performance of their duties.

C. An RNP practicing in a public health facility operated by this state or a county or in a qualifying community health center under A.R.S. § 32-1921(F) may dispense drugs or devices to patients without a written prescription if the public health facility or the qualifying community health center adheres to all storage, labeling, safety, and recordkeeping rules of the Board of Pharmacy.

D. An RNP with dispensing authority shall ensure that a drug is dispensed with a label that contains all of the following information:

1. Dispensing RNP’s name and specialty area;
2. Address and telephone number of the location at which the drug is dispensed;
3. Date dispensed;
4. Patient's name and address;
5. Name and strength of the drug, quantity in the container, directions for use, and any cautionary statements necessary for the safe and effective use of the drug;
6. Manufacturer and lot number; and
7. Prescription order number.

E. An RNP with dispensing authority shall ensure that the following information about the drug or device is entered into the patient's medical record:
1. Name of the drug, strength, quantity, directions for use, and number of refills;
2. Date dispensed;
3. Therapeutic reason;
4. Manufacturer and lot number; and
5. Prescription order number.

F. An RNP with dispensing authority shall:
1. Keep all drugs in a locked cabinet or room in an area that is not accessible to patients;

G. If a prescription order is refilled, an RNP with P & D authority shall record the following information on the back of the prescription order or in the patient's medical record:
1. Date refilled,
2. Quantity dispensed if different from the full amount of the original prescription,
3. RNP's name or identifiable initials, and
4. Manufacturer and lot number.

H. Under the supervision of an RNP with P & D authority, other personnel may:
1. Receive and record a prescription refill request from a patient or a patient's representative;
2. Receive and record a verbal refill authorization from the RNP including:
   a. The RNP's name;
   b. Date of refill;
   c. Name, directions for use, and quantity of drug; and
   d. Manufacturer and lot number;
3. Prepare and affix a prescription label; and
4. Prepare a drug or device for delivery, provided that the dispensing RNP:
   a. Inspects the drug or device and initials the label before issuing to the patient to ensure compliance with the prescription; and
   b. Ensures that the patient is informed of the name of the drug or device, directions for use, precautions, and storage requirements.

G. Except for samples provided by manufacturers, all drugs dispensed by a physician assistant shall be:
1. Prepackaged in a unit-of-use package by the supervising physician or a pharmacist acting on a written order of the supervising physician.
2. Labeled to show the name of the supervising physician and physician assistant.

H. A physician assistant shall not obtain a drug from any source other than the supervising physician or a pharmacist acting on a written order of the supervising physician. A physician assistant may receive manufacturers' samples if allowed to do so by the supervising physician.

21 AZ ADC R4-16-301 (2006):
A. A physician who wishes to dispense a controlled substance as defined in A.R.S. § 32-1901(12), a prescription-only drug as defined in A.R.S. § 32-1901(65), or a prescription-only device as defined in A.R.S. § 32-1901(64) shall
in part: "A doctor shall dispense only to the doctor's own patient and only for conditions being treated by that doctor."\textsuperscript{22}

Finally, regulations governing the dispensation of drugs directly from the provider's office set basic standards for storage and record-keeping must accompany such practice.\textsuperscript{23}

be currently licensed to practice medicine in Arizona and shall provide to the Board the following:
1. A completed registration form that includes the following information:
   a. The physician's name, license number, and field of practice;
   b. A list of the types of drugs and devices the physician will dispense; and
   c. The location or locations where the physician will dispense a controlled substance, a prescription-only drug, or a prescription-only device.
3. The fees required in A.R.S. § 32-1436.
B. A physician shall renew a registration to dispense a controlled substance, a prescription-only drug, or a prescription-only device by complying with the requirements in subsection (A) on or before June 30 of each year. If a physician has made timely and complete application for the renewal of a registration, the physician may continue to dispense until the Board approves or denies the renewal application.

A. A doctor of medicine may dispense drugs and devices kept by the doctor if:
1. All drugs are dispensed in packages labeled with the following information:
   (a) The dispensing doctor's name, address and telephone number.
   (b) The date the drug is dispensed.
   (c) The patient's name.
   (d) The name and strength of the drug, directions for its use and any cautionary statements.
2. The dispensing doctor enters into the patient's medical record the name and strength of the drug dispensed, the date the drug is dispensed and the therapeutic reason.
3. The dispensing doctor keeps all drugs in a locked cabinet or room, controls access to the cabinet or room by a written procedure and maintains an ongoing inventory of its contents.

AZ ADC R4-16-303 (2006):
A. A physician shall record on the patient's medical record the name, strength, dosage, and form, of the…prescription-only drug…dispensed, the quantity or volume dispensed, the date the…prescription-only drug…is dispensed, the medical reasons for dispensing the…prescription-only drug…and the number of refills authorized.
B. Before dispensing a…prescription-only drug…to a patient, a physician shall review the prepared…prescription-only drug…to ensure that:
1. The container label and contents comply with the prescription, and
2. The patient is informed of the name of the…prescription-only drug….directions for use, precautions, and storage requirements.
C. A physician shall purchase all dispensed…prescription-only drugs…from a manufacturer or distributor approved by the United States Food and Drug Administration, or a pharmacy holding a current permit from the Arizona Board of Pharmacy.
D. The person who prepares a…prescription-only drug…for dispensing shall countersign and date the original prescription form for the…prescription-only drug.
B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirement to maintain a dispensation log, and proper labeling of the agent, including the patient’s name and other essential information.\(^{24}\)

**Conclusion:** Dispensing naloxone by valid prescription does not violate Arizona law and may be done on 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 fines.\(^{25}\) 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\(^{26}\) or unlawful administration of a prescription drug.\(^{27}\) 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.

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\(^{24}\) AZ ADC R4-16-303 (2006).

\(^{25}\) AZ Stat. § 32-1401(27(j) (2007) (unprofessional conduct includes “prescribing, dispensing or administering any...prescription-only drug for other than accepted therapeutic purposes”).

\(^{26}\) AZ Stat. § 32-1455 (2007) makes the practice of medicine without a license a class 5 felony, punishable by a term of imprisonment for one and a half years under § 13-701 (2007) and a fine determined by the court under § 13-801 (2007).

Finally, the unauthorized recipient of the drug could be charged with illegal possession of a prescription (legend) drug, subject to fines. Even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

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.

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

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30 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist.); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
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 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, 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 will be extremely difficult to establish where the injury results from overdose, because at the moment naloxone was administered

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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.34

“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.35 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. Thus, 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 prescription or dispensation context 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 Arizona law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, advanced nurse practitioner, or licensed physician’s assistant 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 imperative to 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.37

**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 IDUs.

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37 N.Y. Pub. Health Law §3309 (McKinney 2006)(“the 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”).