DATE: January 20, 2008

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

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/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.”)

Naloxone Trial Program

Recognizing that deaths from opioid overdose are preventable, the California legislature instituted a trial period for opioid overdose prevention and treatment training programs. This is a three year trial program running from January 1, 2008 through January 1, 2010 in seven CA counties: Alameda, Fresno,

(a) For purposes of this section:
   (1) “Opioid antagonist” means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.
   (2) “Opioid overdose prevention and treatment training program” or “program” means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:
      (A) The causes of an opiate overdose.
      (B) Mouth to mouth resuscitation.
      (C) How to contact appropriate emergency medical services.
      (D) How to administer an opioid antagonist.
   (b) A licensed health care provider who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, without being subject to civil liability or criminal prosecution. This immunity shall apply to the licensed health care provider even when the opioid antagonist is administered by and to someone other than the person to whom it is prescribed.
   (c) Each local health jurisdiction that operates or registers an opioid overdose prevention and treatment training program shall, by January 1, 2010, collect, and report to the Senate and Assembly Committees on Judiciary, all of the following data on programs within the jurisdiction:
      (1) Number of training programs operating in the local health jurisdiction.
      (2) Number of individuals who have received a prescription for, and training to administer, an opioid antagonist.
      (3) Number of opioid antagonist doses prescribed.
      (4) Number of opioid antagonist doses administered.
      (5) Number of individuals who received opioid antagonist injections who were properly revived.
      (6) Number of individuals who received opioid antagonist injections who were not revived.
      (7) Number of adverse events associated with an opioid antagonist dose that was distributed as part of an opioid overdose prevention and treatment training program, including a description of the adverse events.
   (d) This section shall apply only to the Counties of Alameda, Fresno, Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz.
   (e) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted on or before January 1, 2011, deletes or extends that date.
Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz. The law allows local health jurisdictions to train individuals to prevent and respond to opioid overdose.

Significantly, the law provides immunity from civil and criminal charges for licensed healthcare providers who dispense or distribute naloxone with reasonable care in conjunction with a training program. Healthcare providers are protected whether or not the person who received or administered the naloxone was the person to whom it was prescribed. The immunity does not apply to lay people who receive or administer naloxone, and only applies to healthcare providers acting in conjunction with the training program.

The legal analysis this memo pertains most directly to the CA counties where this trial program is not in effect. Our research suggests that naloxone distribution is legal in CA, but the trial program alleviates healthcare providers in those counties of any feared risks of liability which are discussed below.

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 California is governed by the Medical Practice Act with regulations found in the Medical Practice Regulations. The Medical Board of California consists of two divisions, a Division of Medical Quality, and a Division of Licensing. The Medical Board has the authority 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 California Medical 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

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prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. State law offers no explicit standards for prescribing a prescription drug, but presumably the generic standards applicable to controlled substances provide a basic framework:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research.

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. This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

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.

B. Analysis

While not explicitly required by California 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. 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. Physicians who have an on-going relationship with

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11 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Uniform Controlled Substances Act, Cal. Health & Safety Code §§ 11000 to 11657, recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. Cal. Health & Safety Code § 111505 (West 2007).
13 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
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 California 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?

### 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 prescribe drugs in accordance with a standardized protocol developed by the APN and a supervising physician. This protocol must include

Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:
(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.
(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.
(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure...
(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.
(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

...
the drugs the APN may prescribe, under what circumstances, and the extent of physician supervision required. The physician does not have to be present at all times, but must at least be available by telephone when the APN is seeing patients. A supervising physician may also delegate prescriptive authority to a physician assistant (PA), but must provide a written protocol that specifies what drugs may be prescribed and the criteria for the prescribing and use of that drug.\textsuperscript{16}

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\textsuperscript{16} Cal. Bus. & Prof. Code § 3502.1:

(a) In addition to the services authorized in the regulations adopted by the board, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may…transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. The drugs listed shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) "Drug order" for purposes of this section means an order for medication which is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under California 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. PAs and APNs may be authorized to prescribe medicine by a supervising physician.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. APNs and PAs may be delegated authority to prescribe by a supervising physician. 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 must be treating a patient and have a legitimate medical purpose for issuing a prescription. 17

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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 California 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 Law, Cal. Bus. & Prof. Code §4000 et seq., with regulations found in Cal. Code Regs. Tit. 16, §1700 et seq., pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing physician may also dispense the agent at the point of service. ANPs and PAs may dispense drugs directly to a patient of the

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supervising physician, pursuant to the written protocol with the physician.\textsuperscript{19} The drugs dispensed by the ANP or PA must be packaged and labeled by a physician, by the manufacturer, or by a pharmacist.

Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that must accompany such practice.\textsuperscript{20} These regulations include the requirement to

\begin{itemize}
\item[(a)] No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:
\begin{enumerate}
\item The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
\item The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
\item The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
\item The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.
\end{enumerate}
\end{itemize}

\textsuperscript{19} Cal. Bus. & Prof. Code § 4170(8) (West 2007):
A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.


\begin{itemize}
\item[a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
\begin{enumerate}
\item either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used.
\item Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
\item The directions for the use of the drug.
\item The name of the patient or patients.
\item The name of the prescriber…
\item The date of issue.
\item The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
\item The strength of the drug or drugs dispensed.
\item The quantity of the drug or drugs dispensed.
\item The expiration date of the effectiveness of the drug dispensed.
\item The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.
\end{enumerate}
\end{itemize}
maintain a dispensation log, and proper labeling of the agent, including the patient’s name and other essential information.

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has followed the prescription guidelines, she can dispense the drug directly to the clients. A physician assistant or an advanced practice nurse can dispense at point of service prepackaged, pre-labeled prescriptions that have been approved by the supervising physician (see part II). If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.²¹

Conclusion: Dispensing naloxone by valid prescription does not violate California 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?

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a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

1. either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
2. The directions for the use of the drug.
3. The name of the patient or patients.
4. The name of the prescriber...
5. The date of issue.
6. The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
7. The strength of the drug or drugs dispensed.
8. The quantity of the drug or drugs dispensed.
9. The expiration date of the effectiveness of the drug dispensed.
10. The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.
11. Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules...
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. 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. 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.

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

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(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician
(b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both that fine and imprisonment.
(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.

23 Cal. Bus & Prof. Code § 2053.5(3) makes it unlawful practice of medicine for an unlicensed person to prescribe or administer legend drugs to another person, punishable under Cal. Bus. & Prof. Code § 2052 (West 2007):
(a) Notwithstanding Section 146, any person who practices or attempts to practice…without having at the time of so doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense, punishable by a fine not exceeding ten thousand dollars ($10,000), by imprisonment in the state prison, by imprisonment in a county jail not exceeding one year, or by both the fine and either imprisonment.
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?

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

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25 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).
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 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

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applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.  

“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. 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. 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

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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 California 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.\footnote{33}{N.Y. Pub. Health Law §3309 (McKinney 2006): [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.}

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.