DATE: August 14, 2007

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

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:

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1. Naloxone is not a controlled substance as defined by the 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

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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.
naloxone by 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 Texas is governed by the "Medical Practice Act,"\textsuperscript{4} with regulations found in the Texas Administrative Code.\textsuperscript{5} The Texas Medical Board (the "Board") has the authority to license physicians\textsuperscript{6} and to punish licensed physicians who behave in ways that violate the law or fall beneath the standards of good faith and regular practice of medicine.\textsuperscript{7} The Texas Administrative Code does not explicitly define the basis or scope of the physician's general authority to prescribe. However, Texas case law authorizes the Board to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.\textsuperscript{8}

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.\textsuperscript{9} Naloxone is not a controlled substance under state or federal law.\textsuperscript{10} 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

\textsuperscript{5} Tex. Admin. Code tit. 22 § 161.1 (2007), et seq.
\textsuperscript{7} Tex. Occ. Code Ann. §164.059(b) (2007).
\textsuperscript{10} Tex. Health & Safety Code Ann. §481.002(5) (West 2007) ("Controlled substance’ means a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Groups 1, 1-A, or 2 through 4. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance"); Tex. Health & Safety Code Ann. §481.033 (West 2007) (Naxalone is excluded from the schedule of controlled substances, so it is a prescription or legend drug).
This reflects physicians' broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles govern prescriptions for controlled substances:

A practitioner may not prescribe, dispense, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision except for a valid medical purpose in the course of medical practice.

In determining whether a prescription arises within the usual course of professional practice, courts consider such factors as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors and efforts to provide other harm reducing services. The medical board is

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11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
   (39) "Practitioner" means:
   (A) a physician, … or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;
   (B) a pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state;
   (D) an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under Section 157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542, Occupations Code.
   Prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient:
   (A) After a documented medical history, which may be provided orally or in writing by the patient, and physical examination by the physician providing the medication including an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance;
   (B) Pursuant to a written treatment plan tailored for the individual needs of the patient by which treatment progress and success can be evaluated with stated
authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{15}

\textbf{B. Analysis}

While not explicitly required by Texas statutes, it is prudent for physicians as a general matter to law to follow certain procedures when issuing prescriptions to all prescription drugs, including providing a physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription.

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

\textbf{II. May Anyone Other Than Physician Issue A Prescription For Naloxone?}

\textbf{A. Professional Licensure Law}

Allied health professionals and medical residents in this state are authorized to replace physicians in some or all aspects of a prescription program. Generally, the regulations allow licensed allied health professionals to step in to collect routine sections of a medical history, conduct some medical

\begin{quote}
...Management of these patients may require closer monitoring by the physician managing the pain and consultation with appropriate health care professionals.
\end{quote}

examinations, and issue actual prescriptions by following clear and documented “standing order” guidelines issued by the supervising physician. 16 A certified nurse practitioner and a physician assistant can write prescriptions under standing delegated orders from a physician, but they must do so under the "adequate" supervision of a physician 17 and they must adhere to labeling and record keeping requirements. 18

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16 At the physician’s primary practice site, the law is flexible on the level of supervision exercised. See infra fn 17. Functions may also be delegated at a site that is not the physician’s primary practice location. This is governed by Tex. Occ. Code Ann. §157.0542 (West 2007):
(a) On determining that the conditions of Subsection (b) have been met, the board may waive or modify any of the site or supervision requirements for a physician to delegate the carrying out or signing of prescription drug orders to an advanced practice nurse or physician assistant under Sections 157.052, 157.053, 157.054, and 157.0541, or under board rules. The board may not waive the limitation on the number of primary or alternate practice sites at which a physician may delegate the carrying out or signing of prescription drug orders or the number of advanced practice nurses or physician assistants to whom a physician may delegate the carrying out or signing of prescription drug orders.
(b) The board may grant a waiver under Subsection (a) if the board determines that:
(1) the practice site where the physician is seeking to delegate prescriptive authority is unable to meet the requirements of this chapter or board rules or compliance would cause an undue burden without a corresponding benefit to patient care;
(2) safeguards exist for patient care and for fostering a collaborative practice between the physician and the advanced practice nurses and physician assistants; and
(3) if the requirement for which the waiver is sought is the amount of time the physician is on-site, the frequency and duration of time the physician is on-site when the advanced practice nurse or physician assistant is present is sufficient for collaboration to occur, taking into consideration the other ways the physician collaborates with the advanced practice nurse or physician assistant, including at other sites.
At an alternate site, a physician licensed by the board may delegate to an advanced practice nurse or physician assistant, acting under adequate physician supervision, the act of administering, providing, or carrying out or signing a prescription drug order as authorized through a physician's order, a standing medical order, a standing delegation order, or another order or protocol as defined by the board.

(b) At a physician's primary practice site, a physician licensed by the board may delegate to a physician assistant or an advanced practice nurse acting under adequate physician supervision the act of administering, providing, or carrying out or signing a prescription drug order as authorized through a physician's order, a standing medical order, a standing delegation order, or another order or protocol as defined by the board.
(c) Physician supervision of the carrying out and signing of prescription drug orders must conform to what a reasonable, prudent physician would find consistent with sound medical judgment but may vary with the education and experience of the particular advanced practice nurse or physician assistant. A physician shall provide continuous supervision, but the constant physical presence of the physician is not required.
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Texas 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. Nurse practitioners and physician assistants are authorized in Texas to prescribe medicine with "adequate" physician supervision at a physician's primary practice. However, nurse practitioners and physician assistants can be authorized to prescribe without physician supervision beyond a physician's primary practice and, in those instances there are no specific or detailed conditions that govern the communication between the “collaborating physician,” a licensed non-physician provider, such as a physician assistant, and the patient.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. The same rules that govern the

(d) An alternate physician may provide appropriate supervision on a temporary basis as defined and established by board rule.
(e) A physician's authority to delegate the carrying out or signing of a prescription drug order is limited to:
(1) three physician assistants or advanced practice nurses or their full-time equivalents practicing at the physician's primary practice site or at an alternate practice site under Section 157.0541; and
(2) the patients with whom the physician has established or will establish a physician-patient relationship.

At an alternate site, like a naloxone program, “adequate supervision” means that the delegating physician:
(1) is on-site with the advanced practice nurse or physician assistant at least 20 percent of the time;
(2) reviews at least 10 percent of the medical charts at the site; and
(3) is available through direct telecommunication for consultation, patient referral, or assistance with a medical emergency.


Carrying out or signing a prescription drug order--Signing a prescription drug order, or completing a prescription drug order presigned by the delegating physician, by an advanced practice nurse or physician assistant after properly documented delegation of prescription authority. The following information shall be provided on each prescription: the patient's name and address; the drug to be dispensed; directions to the patient for taking the drug; dosage; the intended use of the drug, if appropriate; the name, address, and telephone number of the physician; the name, address, telephone number, identification number, and signature of the physician assistant or advanced practice nurse completing or signing the prescription drug order; the date; and the number of refills permitted. This also includes the ability of a physician assistant or advanced practice nurse to telephone prescriptions in to a pharmacy under his or her prescriptive authority.


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

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

B. Analysis

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

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

Naloxone distribution programs in Texas 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. The practice of pharmacy in Texas is governed by the "Texas Pharmacy Act"^{21} with regulations found in the Texas Administrative Code.^{22} Pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing healthcare provider may also dispense the agent at the point of service. In regard to physicians, Texas law provides that:

Except as otherwise provided in §169.5 of this chapter, a physician may provide, dispense, or distribute drugs for use or consumption by the patient away from the physician's office or after the conclusion of the physician-patient encounter only in quantities as are necessary to meet the patient's immediate needs. A physician shall comply personally with all appropriate labeling and record keeping requirements under state or federal law or shall oversee compliance by persons acting under his or her direction and supervision. A physician who provides, dispenses, or distributes drugs to a patient to meet his or her immediate needs may not charge a fee separate from that charged for medical services provided to the patient.^{23}

Physicians can be authorized to delegate dispensing, referred to as "carrying out"^{24} in the Texas statute, prescription drugs in the same manner and with the same limitations as apply to prescribing (see section II, supra). 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.^{25}

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone.^{26} Provided that the healthcare provider has followed the prescription

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^{24} Tex. Occ. Code Ann. §157.051(2) (2007) ("Carrying out or signing a prescription drug order' means completing a prescription drug order presigned by the delegating physician, or the signing of a prescription by a registered nurse or physician assistant").
(a) Before dispensing a prescription, a pharmacist shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist may not dispense a prescription drug if the
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 requirements for record keeping and proper labeling of the agent, including the patient’s name and other essential information.  

**Conclusion:** Dispensing naloxone by valid prescription does not violate Texas 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 license sanctions for a legal prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.

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27 Tex. Occ. Code Ann. §157.056 (West 2007): The following information must be provided on each prescription subject to this subchapter:
(1) the patient's name and address;
(2) the drug to be dispensed;
(3) directions to the patient regarding the taking of the drug and the dosage;
(4) the intended use of the drug, if appropriate;
(5) the name, address, and telephone number of the physician;
(6) the name, address, telephone number, and identification number of the registered nurse or physician assistant completing or signing the prescription drug order;
(7) the date; and
(8) the number of refills permitted.


29 Tex. Health & Safety Code Ann. §431.021 (2007) (“The following acts and the causing of the following acts within this state are unlawful and prohibited: … (ee) selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b)”).

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The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with illegally distributing a prescription drug or practicing medicine without a license.\(^{31}\) We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no provision that made it a crime to possess a legend drug without a prescription.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, 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\(^{32}\) may carry license sanctions\(^{33}\) or criminal prosecution.\(^{34}\) There is no risk of

A person commits an offense if the person violates any of the provisions of Section 431.021 relating to unlawful or prohibited acts. A first offense under this subsection is a Class A misdemeanor unless it is shown on the trial of an offense under this subsection that the defendant was previously convicted of an offense under this subsection, in which event the offense is a state jail felony; Tex. Penal Code Ann. \S 12.21 (2007) ("An individual adjudged guilty of a Class A misdemeanor shall be punished by: (1) a fine not to exceed $4,000; (2) confinement in jail for a term not to exceed one year; or (3) both such fine and confinement"). See also Tex. Health & Safety Code Ann. \S 431.021.


\(^{32}\) Tex. Occ. Code Ann. \S 164.052(a) (2007) ("A physician or an applicant for a license to practice medicine commits a prohibited practice if that person...(5) commits unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public"); Tex. Occ. Code Ann. \S 164.053 (2007):
(a) For purposes of Section 164.052(a)(5), unprofessional or dishonorable conduct likely to deceive or defraud the public includes conduct in which a physician:
(1) commits an act that violates any state or federal law if the act is connected with the physician's practice of medicine;
...
(9) delegates professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not
professional censure for participating in a naloxone prescription program. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct. 35 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges. 36

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.

If the disciplinary panel determines from the evidence presented to the panel that a person licensed to practice medicine would, by the person's continuation in practice, constitute a continuing threat to the public welfare, the disciplinary panel shall temporarily suspend or restrict the license of that person.

Tex. Occ. Code Ann. §164.101(a) (2007) (“The board on majority vote may probate an order canceling, revoking, or suspending a license or imposing any other method of discipline if the probationer conforms to each order, condition, and rule the board establishes as a term of probation”).


35 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).

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 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

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37 Condor .v Waltrip, 791 S.W.2d 537 (Tex. App. 1990); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).

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. 39

“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. 40 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-gap 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. 41 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 and unless a state expressly rejects the 
protection offered by the VPA. 42 Texas law provides similar immunity for a 
volunteer healthcare provider working for a charitable organization. 43 It appears

40 Martin v. E. Jefferson Gen. Hosp., 582 So.2d 1272 (La. 1991); see Lee v. Andrews, 545 
Corpus Christi 2006).
that volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

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

CONCLUSION

A. Guidelines

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

The following is a summary of the program guidelines dictated by Texas 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:

(c) Except as provided by Subsection (d) and Section 84.007, a volunteer health care provider who is serving as a direct service volunteer of a charitable organization is immune from civil liability for any act or omission resulting in death, damage, or injury to a patient if:
(1) the volunteer commits the act or omission in the course of providing health care services to the patient;
(2) the services provided are within the scope of the license of the volunteer; and
(3) before the volunteer provides health care services, the patient or, if the patient is a minor or is otherwise legally incompetent, the person responsible for the patient signs a written statement that acknowledges:
(A) that the volunteer is providing care that is not administered for or in expectation of compensation; and
(B) the limitations on the recovery of damages from the volunteer in exchange for receiving the health care services.
• 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. 44

C. Cooperation with First Responders

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

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