DATE: December 28, 2007

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

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.**

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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 define examination, generally, as an interaction sufficient to allow the physician to determine the patient's diagnosis and treatment needs in the context of the service being sought or medical issues being raised.
lay persons, and to protect medical professionals from tort and other liability. Such legislation can help lower legal barriers and increase access to naloxone here. (See “Conclusion.”)

The Legal Analysis in Detail

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

A. Professional Licensure Law

The practice of medicine in Louisiana is governed by the Medical Practice Act with regulations in the Louisiana Administrative Code. The State Board of Medical Examiners (the “Board”) has the authority to license physicians and to punish licensed physicians who behave in ways that violate the law or fall beneath the standards of good faith and regular practice of medicine. Leaving aside any limitations imposed by other laws, a physician is free to prescribe any drug she believes will benefit the patient and the prescription of which is consistent with the accepted standard of care. While no provision of the Medical Practice Act explicitly defines the basis or scope of the physician's general authority to prescribe, the law has been interpreted to authorize the Board to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices or through the disciplinary process.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. Louisiana law does not explicitly set out general requirements for a legal prescription of a non-controlled substance. However, other Louisiana provisions indicate that a prescription in this state must be based on an appropriate examination of the patient, and that the drug be

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8 In re DiLeo, 661 So. 2d 162 (La. App. 4 Cir. 1995).
prescribed for a legitimate medical purpose in the course of the provider’s regular professional practice.\textsuperscript{11}

Using standard research techniques, we identified no case-law challenging the legality of prescribing naloxone.\textsuperscript{12} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

\textbf{B. Analysis}

While not explicitly required by Louisiana statutes, it is prudent for physicians as a general matter of law to follow certain procedures when issuing prescriptions for all prescription drugs, including 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 naloxone 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 ODU patient is consistent with the standard for a valid prescription under Louisiana laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

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

\textbf{A. Professional Licensure Law}


“Prescription” means a written request for a drug or therapeutic aid issued by a licensed physician, dentist, veterinarian, osteopath, or podiatrist for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.


A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, is issued outside the context of a valid physician-patient relationship, and is not a valid prescription.

\textsuperscript{12} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
Allied health professionals are authorized to replace physicians in some aspects of medical care. Advanced practice registered nurses (“APRNs”) may apply to the Board of Nursing for authority to prescribe prescription drugs. The


Prescriptive and Distributing Authority. An Advanced Practice Registered Nurse (APRN) shall practice in a manner consistent with the definition of advanced practice set forth in R.S. 37:913(3). An APRN may be granted prescriptive authority to prescribe legend drugs, receiving and distributing a therapeutic regimen of prepackaged drugs prepared and labeled by a licensed pharmacist, and free samples supplied by a drug manufacturer, and distributing drugs for administration to and use by other individuals within the scope of practice as defined by the board in R.S. 37.913(3)(b).

1. The applicant shall:
   a. hold a current, unencumbered, unrestricted and valid registered nurse license in Louisiana with no pending disciplinary proceedings as stated in R.S. 37:921;
   b. hold a current, unencumbered, unrestricted and valid APRN license;
   c. submit a notarized application on a form provided by the board with a non-refundable fee as set forth in LAC 46:XLVII.3341;
   d. provide evidence of:
      i. 500 hours of clinical practice as a licensed APRN or APRN applicant within one year in the clinical specialty for which the applicant was educationally prepared as an APRN immediately prior to applying for prescriptive and distributing authority; practice in another state as a licensed APRN may be accepted to meet this requirement; or
      ii. 500 hours of clinical practice in medical management of patients in a preceptorship (student experience) in which the APRN applicant is precepted by a physician or another advanced practice registered nurse who has approval for medical management/prescriptive authority by the Board of Nursing. The student experience must occur in a formal board approved educational program preparing graduates to sit for the respective advanced practice specialty licensure exam and certification process; and
      iii. successful completion of a minimum of 45 contact hours of education (3 credit hour academic course) in advanced pharmacotherapeutics obtained as a component of a formal educational program preparing registered nurses for advanced practice, approved by the board;
      iv. successful completion of a minimum of 45 contact hours (3 credit hour academic course) in physiology/pathophysiology in a formal educational program approved by the board for preparation for advanced practice registered nurses;
      v. any deviation from Clause 1.d.i, ii or iii shall be submitted to the board for review and approval; and
      vi. a collaborative practice agreement as defined in § 4513.B.1, 2 and 3, with one or more licensed collaborating physicians which shall include, but not be limited to:
         (a). a plan of accountability among the parties that:
            (i). defines the prescriptive authority of the APRN and the responsibilities of the collaborating physician or physicians;
            (ii). delineates a plan for hospital and other healthcare institution admissions and privileges which includes a statement that the collaborating physician must have said privileges at the same institution before an APRN can receive this determination at said institution;
            (iii). delineates mechanisms and arrangements for diagnostic and laboratory requests for testing; and
(iv). delineates a plan for documentation of medical records;
(b). clinical practice guidelines as required by R.S. 37:913(9)(b) shall contain
documentation of the types or categories or schedules of drugs available and
generic substitution for prescription and be in accordance with current standards
of care and evidence-based practice for the APRN specialty and functional role
and be:
(i). mutually agreed upon by the APRN and collaborating physician;
(ii). specific to the practice setting;
(iii). maintained on site; and
(iv). reviewed and signed at least annually by the APRN and physician to reflect
current practice;
(c). documentation of the availability of the collaborating physician when the
physician is not physically present in the practice setting. Physicians shall be
available to provide consultation as needed:
(i). physician shall be available by telephone or direct telecommunications for
consultation, assistance with medical emergencies, or patient referral, as
delineated in the collaborative practice agreement; and
(ii). the secondary (back-up) physician or physicians shall be in good standing
and approved by the Louisiana State Board of Medical Examiners and sign the
collaborative practice agreement;
(iii). in the event the collaborating physician and any secondary (back-up)
collaborating physician(s) are unavailable, the APRN will not prescribe;
(d). documentation shall be shown that patients are informed about how to
access care when both the APRN and/or the collaborating physicians are absent
from the practice setting; and
(e). an acknowledgement of the mutual obligation and responsibility of the
APRN and collaborating physician to insure that all acts of prescriptive
authority are properly documented.

2. Prescriptive Authority
a. Prescribing...Legend Drugs
i. The LSBN shall review the application, reapplication or renewal, the
collaborative practice agreement for prescriptive authority and all related
materials and shall approve, modify, or deny the application, reapplication or
renewal for prescriptive authority. An APRN with prescriptive authority
approved by the board may prescribe drugs and therapeutic devices as
recommended by clinical practice guidelines and the parameters of the
collaborative practice agreement.
ii. Prior to granting an APRN prescriptive authority the collaborating physician
or physicians shall be approved by the Louisiana State Board of Medical
Examiners.
iii. Prescription Guidelines—All Medications
(a). The following guidelines apply to all prescriptions, whether or not said
prescriptions are for legend drugs, controlled substances or any other
medication. An APRN granted prescriptive authority shall comply with all
federal and state laws and rules in prescribing, distributing, and administering
drugs.
iv. The APRN who has been given proper authority to prescribe whether in
person or by an electronic means or over the Internet or over telephone lines
must meet the following requirements:
(a). perform and appropriately document a history and physical examination,
and make a diagnosis based upon the examination and all diagnostic and
laboratory tests;
(b). formulate a therapeutic plan that is discussed with the patient;
(c). state the availability of the APRN or coverage for the patient for follow-up
care;
APRN must have a collaborative practice arrangement with a physician, and the collaborative agreement must include the prescribing of drugs.\textsuperscript{14} The physician does not need to be on-site with the APRN but must be available by some form of direct communication for consultation.\textsuperscript{15} Physician assistants (“PAs”) may be delegated prescriptive authority by a supervising physician.\textsuperscript{16} There must be

(d). all of the above must be included in the collaborative practice agreement.

v. Each order for a prescription, whether written or oral shall include the following information.

(a). The prescription form shall not be less than 4 inches by 5 inches, and shall bear a single printed signature line.

(b). The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number ... In the event multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to a marked check box next to, or circling the authorizing prescriber's printed name.

(c). The prescription form shall clearly indicate the authorized prescriber's practice affiliation, and the collaborating physician's name, address, and telephone number shall appear on the prescription form.

(d). No prescription form shall contain more than four prescription drug orders.

(e). Each prescription drug order on the form shall provide the following:

(i). a check box labeled "dispense as written" or DAW or both; and

(ii). the number of refills, if any.

\textsuperscript{14} Id.

\textsuperscript{15} Id.


Legend Drugs/Medical Devices. To be eligible for registration of prescriptive authority for legend drugs...a physician assistant shall:
1. satisfy the licensure requirements of §1507 of this Chapter;
2. possess a current, unrestricted license to practice as a physician assistant duly issued by the board …
3. have received authority to prescribe legend drugs and/or medical devices to the extent delegated by a supervising physician;
4. have completed:
   a. a minimum of one year of clinical rotations during training and one year of practice under a supervising physician; or
   b. a minimum of two years of practice under a supervising physician;
5. practice under supervision as specified in clinical practice guidelines or protocols that shall, at a minimum, include:
   a. the methods to be employed by the supervising physician to insure supervision of the physician assistant's prescriptive authority;
   b. the nature, types and classifications of medication and/or medical devices a physician assistant is authorized to utilize by the supervising physician;
   c. a plan to accommodate immediate consultation by telephone or direct telecommunication with the supervising physician, or in his absence an approved locum tenens physician, to address medical emergencies, complications and other such matters;
   d. a predetermined plan for emergency services, after-hours, weekend, and vacation coverage;
   e. a predetermined plan for patient referrals to other physicians, emergency rooms and admission to hospitals at which the supervising physician holds privileges. Such plan shall include a statement that the physician assistant shall not seek privileges at any institution unless the supervising physician holds privileges at such institution;
established protocols for the method of review by the supervising physician and a protocol for directly contacting the physician when he or she is not on-site with the PA.\footnote{Id.}

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Louisiana law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. With the appropriate collaborative arrangement with a physician, an APRN or PA could prescribe naloxone in an overdose prevention program without on-site physician oversight.

**Conclusion:** PAs and APRNs may prescribe naloxone to participants in an overdose prevention program. A collaborative or supervisory arrangement with a physician is required, but on-site physician oversight is not. 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**

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

**B. Analysis**

The intended use of naloxone is to prevent opiate overdose. Indications for and methods of administration should be explained to patients, along with risks and benefits. Because of the nature of overdose, patients may not always be

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  \item f. an acknowledgment of the mutual obligations and responsibilities of the supervising physician and physician assistant to comply with all requirements of §4511 of these rules including, but not limited to, the review and countersigning of the physician assistant's written entry in the patient record of prescriptions for medication or medical devices; and
  \item g. confirmation that the physician assistant shall not prescribe medication or medical devices if the supervising physician, or in his absence an approved locum tenens physician, is neither physically present nor available by telephone or other telecommunication device.
\end{itemize}
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 Louisiana 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 Louisiana is governed by the Louisiana Pharmacy Practice Act\(^ {18}\) with regulations in the Louisiana Administrative Code.\(^ {19}\) Under these rules, pharmacists are expected to fill a prescription that meets regulatory guidelines. Except for samples,\(^ {20}\) a physician may not dispense prescription drugs at the point of service without having been licensed by the medical board as a “dispensing physician.”\(^ {21}\) Dispensing physicians are subject to detailed rules governing record-keeping,

\(^{20}\) La. Rev. Stat. Ann. § 46:2622 (West 2007) (“Bona fide medication sample’ means a drug, chemical, or medication packaged by the original manufacturer thereof in such quantity as does not exceed a reasonable therapeutic dosage for a period in excess of one week and provided at no cost to a physician for administration or dispensation to a patient at no cost to the patient.”).
labeling and storage of medications. A PA may deliver a medication sample. APRNs can dispense drugs that have been pre-packaged and labeled by a pharmacist, as well as samples provided free of charge by manufacturers.

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Assuming that naloxone was not being offered without charge by the manufacturer in sample form, a naloxone program that wished to distribute the drug directly to patients, even free of charge, must either engage the services of a dispensing physician or arrange for a pharmacist to prepare pre-packaged doses

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No registrant shall dispense any medication, other than a bona fide medication sample, unless the bottle, package, or other container for such medication bear a securely-affixed indelible, legible, typewritten, or printed label including:
1. the name and address of the registrant;
2. the name of the patient to whom or for whom dispensed;
3. the generic chemical or trade name, quantity or amount, dosage form, and strength of the medication dispensed;
4. the date of dispensation; and
5. appropriate directions for self-administration, ingestion, insertion, application, or injection by the patient.

La. Admin. Code tit. 46, pt. XLV, § 6503 (“‘Registrant’—a physician who is registered with the board as a dispensing physician in accordance with Subchapter C of this Chapter.”).


… At the direction and under the supervision of the supervising physician, a physician assistant may hand deliver to a patient of the supervising physician a properly labeled prescription drug prepackaged by a physician, a manufacturer or a pharmacist. In any case, the medical record of any patient cared for by the physician assistant for whom the physician's prescription has been transmitted or carried out shall be reviewed, countersigned and dated by a supervising physician within 72 hours, or as otherwise required by law..


a. … An APRN may receive and distribute pre-packaged medications or samples of non-controlled substances for which the APRN has prescriptive authority.

b. An APRN must distribute the medication. For the purpose of this regulation "distribute" shall mean hand the pre-packaged medication to the patient or the patient's authorized agent.

c. All drug products which are maintained/stored at the site of practice of an APRN, shall be maintained/stored in the manufacturer's or re-packager's original package. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date.

d. All drug products shall be maintained, stored and distributed in such a manner as to maintain the integrity of the product.
for distribution by an APRN. If a program decides to dispense Naloxone on premises, it must follow applicable labeling, storage and record-keeping rules.

**Conclusion:** Dispensing naloxone by valid prescription does not violate Louisiana law and may be done on premises of the distribution program by a dispensing physician or an APRN working in collaboration with a pharmacist off-site.

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. 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. Finally, the unauthorized recipient of the drug could be charged with illegal possession of a prescription (legend) drug, resulting in up to five years of imprisonment and a fine not exceeding $5000.

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 little 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.

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 carries 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

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29 Holladay v. Louisiana State Bd. of Medical Examiners, 689 So.2d 718 (La. App. 4th Cir. 1997); see, Montalbano v. Board of Medical Examiners, 560 So.2d 1009 (La. App. 4th Cir. 1990).
circumstances, which is said to establish the “standard of care.”\textsuperscript{30} 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.\textsuperscript{31}

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,\textsuperscript{32} 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.\textsuperscript{33}

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

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

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

In the case of volunteer providers, the US Volunteer Protection Act (“VPA”) shields volunteers for acts committed within the scope of their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent.\textsuperscript{36} Thus, volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

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\item \textsuperscript{34} Martin v. East Jefferson Gen Hospital, 582 So.2d 1272 (La. 1991).
\item \textsuperscript{35} Alello v. Smith, 641 So.2d 664 (La. App. 5 Cir. 1994).
\item \textsuperscript{36} 42 U.S.C.A. § 14503 (West 2000).
\end{itemize}
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 Louisiana 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.\textsuperscript{37}

\textbf{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.

\textsuperscript{37} New York Public Health Law § 3309 (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.