DATE: August 13, 2007

RE: Legality of Prescribing Take-Home Naloxone to Treat Opiate Overdoses in Alabama

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. 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, and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

Assuming the provider does not violate regulations that generally apply to drug prescription in this state, acts competently, and follows the additional guidelines we set out, criminal or civil liability is very unlikely to arise out of naloxone prescription activities. (See Parts VI and VII.) Presumably, few prosecutors would be hard-hearted enough to punish a person for saving a life, but an ODU who uses his or her own naloxone to save the life of a person who has not been prescribed the drug does, technically, break the law. A few states have taken positive action to clearly legalize emergency administration of naloxone by

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

The Legal Analysis in Detail

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

A. Professional Licensure Law

The practice of medicine in Alabama is governed by the health provisions of the Alabama statutory code, with regulations found in the Alabama Administrative Code. The Medical Licensure Commission has the authority to license physicians. The Medical Licensure Commission and the Board of Medical Examiners may punish licensed physicians who behave in ways that violate the law or fall below the standards of good faith and regular practice of medicine. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the Alabama Board of Medical Examiners to set limits on allowable practices, either by enacting specific regulations banning certain practices, or through the disciplinary process.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug.

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically.

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11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

The law in Alabama nowhere sets out an explicit standard for assessing the legality of a prescription. We presume that an analysis would look to the standard commonly used for the prescription of controlled substances in Alabama and other states. Under this standard, a prescription is valid if it is written (1) consistent with the accepted standard of care of the medical community, and (2) for a legitimate medical purpose.12 In determining the validity of a prescription, courts generally consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on.13 The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.14

B. Analysis

While not explicitly required by Alabama statutes, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination as appropriate, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Alabama 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

13 See e.g., United States v. Moore, 423 U.S. 122 (1975).
Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Physician assistants (PAs) must work with a supervising physician. They may prescribe legend drugs as authorized in a job description that has been approved by the physician and the board. If the supervising physician is not going to be on-site with the

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(1) Physician supervision requires, at all times, a direct, continuing and close supervisory relationship between a physician assistant and the physician to whom the assistant is registered.
(2) There shall be no independent, unsupervised practice by physician assistants.
(3) The supervising physician shall be available for direct communication or by radio, telephone or telecommunication.
(4) The supervising physician shall be available for consultation or referrals of patients from the physician assistant.
(5) In the event the physician to whom the physician assistant is registered is not available, provisions must be made for medical coverage by a physician pursuant to Rule 540-X-7-.24.
(6) If the physician assistant is to perform duties at a site away from the supervising physician, the application for registration must clearly specify the circumstances and provide written verification of physician availability for consultation and/or referral, and direct medical intervention in emergencies and after hours, if indicated. The Board, at its discretion, may waive the requirement of written verification upon documentation of exceptional circumstances. Employees of state and county health departments are exempt from the requirement of written verification of physician availability.
(7) The supervising physician and the physician assistant shall adhere to any written guidelines established by the Board to govern the prescription practices of physician assistants.
(8) If the physician assistant is to perform duties at a site away from the supervising physician, physician supervision requires the following:
(a) Supervising physician receives a daily status report to be made in person, by telephone, or by telecommunications from the assistant on any complications or unusual problems encountered;
(b) Supervising physician visits the clinic, in person, at least once a week during regular business hours to observe and to provide medical direction and consultation;
(c) Supervising physician, during weekly office visits, reviews with the assistant case histories of patients with unusual problems or complications;
(d) An appropriate physician personally diagnoses or treats patients requiring physician follow-up.
(9) The mechanism for quality analysis shall be as follows:
(a) A written plan for review of medical records and patient outcomes shall be submitted with the application for registration, with documentation of the reviews maintained.
(b) Countersignature by supervising physician must be pursuant to established policy and/or applicable legal regulations and accreditation standards.

(1) A physician assistant may prescribe a legend drug to a patient subject to both of the following conditions being met:
(a) The drug type, dosage, quantity prescribed, and number of refills are authorized in the job description which is signed by the supervising physician to whom the physician assistant is currently registered and which is approved by the Board;
PA, the methods of review must be included in their supervisory agreement and the PA’s job description.\(^{17}\) Certified registered nurse practitioners must work in collaboration with a physician.\(^{18}\) They may prescribe legend drugs that are

(b) The drug is included in the formulary approved under the guidelines established by the Board for governing the prescription practices of physician assistants.

…

(3) The supervising physician and the physician assistant shall adhere to and follow all requirements and procedures stated in written guidelines established by the Board to govern the prescribing practices of physician assistants.

…

(9) When prescribing legend drugs a physician assistant shall use a prescription form which includes all of the following:
(a) The name, medical practice site address and telephone number of the physician supervising the physician assistant;
(b) The physician assistant's name printed below or to the side of the physician's name;
(c) The medical practice site address and telephone number of the physician assistant, if different from the address of the supervising physician;
(d) The physician assistant's license number assigned by the Board;
(e) The words "Product Selection Permitted" printed on one side of the prescription form directly underneath a signature line;
(f) The words "Dispense as written" printed on one side of the prescription form directly underneath a signature line.

\(^{17}\) Supra, fn. 15.

1) The collaborating physician shall:
(a) Provide professional medical oversight and direction to the certified registered nurse practitioner.
(b) Be readily available for direct communication or by radio, telephone or telecommunications,
(c) Be readily available for consultation or referrals of patients from the certified registered nurse practitioner.
(2) In the event the collaborating physician is not readily available, provisions shall be made for medical coverage by a physician who is pre-approved by the State Board of Medical Examiners and is familiar with these rules.
(3) If the certified registered nurse practitioner is to perform duties at a site away from the collaborating physician, the written protocol shall clearly specify the circumstances and provide written verification of physician availability for consultation, referral, or direct medical intervention in emergencies and after hours, if indicated.
(4) The collaborating physician shall be present with the certified registered nurse practitioner in an approved collaborative practice site for not less than ten percent (10%) of the certified registered nurse practitioner's scheduled hours in the collaborative practice as specified in the protocol application. In addition, the collaborating physician shall visit each approved collaborative practice site not less than quarterly. The collaborating physicians with the Alabama Department of Public Health and county health departments are exempt from this requirement.
(5) The certified registered nurse practitioner's scheduled hours in licensed acute care hospitals, licensed skilled nursing facilities, licensed special-care assisted living facilities, and licensed assisted living facilities are not subject to the required minimum hours for physician presence.
included in their job protocol and have been approved by the physician and the
board.19

(6) If the certified registered nurse practitioner’s scheduled weekly collaborative
practice hours are:
(a) Thirty or more hours per week, the certified registered nurse practitioner
shall be present in an approved practice site with the collaborating or covering
physician for time equal to ten percent (10%) of the certified registered nurse
practitioner's scheduled weekly hours. Cumulative hours may accrue on a
monthly basis.
(b) Less than 30 hours per week, the certified registered nurse practitioner shall
be present in an approved practice site with the collaborating or covering
physician for time equal to ten percent (10%) of the certified registered nurse
practitioner's scheduled weekly hours. Cumulative hours may accrue on a
quarterly basis.
(7) The collaborating physician shall provide notice in writing to the State Board
of Medical Examiners of the commencement or termination of a collaborative
practice agreement as required by Rule 540-X-8.04(4).
(8) The Joint Committee may, at its discretion, waive the requirements of
written verification of physician availability upon documentation of exceptional
circumstances. Employees of the Alabama Department of Public Health and
county health departments are exempt from the requirements of written
verification of physician availability.

(1) Certified registered nurse practitioners engaged in collaborative practice with
physicians may be granted prescriptive authority upon submission of evidence
of completion of an academic course in pharmacology or evidence of integration
of pharmacology theory and clinical application in the certified registered nurse
practitioner curriculum.
(2) Certified registered nurse practitioners practicing under protocols approved
in the manner prescribed by Code of Ala. 1975, section 34-21-80 et seq. may
prescribe legend drugs to their patients, subject to the following conditions:
(a) The drug type, dosage, quantity prescribed, and number of refills shall be
authorized in an approved protocol signed by the collaborating physician and the
certified registered nurse practitioner. This requirement may be met if written
prescriptions adhere to the standard recommended doses of legend drugs as
identified in the Physician's Desk Reference or Product Information Insert, not
to exceed the recommended treatment regimen periods.
(b) The drug shall be included in the formulary recommended by the Joint
Committee and adopted by the Board of Nursing and the State Board of Medical
Examiners.

…
(5) The certified registered nurse practitioner in collaborative practice with
prescriptive privileges shall not engage in prescribing for:
(a) Self
(b) Immediate family members.
(c) Individuals who are not patients of the practice.

…
(7) When prescribing legend drugs a certified registered nurse practitioner shall
use a prescription format that includes all of the following:
(a) The name, medical practice site address and telephone number of the
collaborating physician or covering physician.
(b) The certified registered nurse practitioner's name printed below or to the side
of the physician's name.
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Alabama 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. Physician assistants and certified registered nurse practitioners may prescribe legend drugs to patients, in accordance with their job description as authorized by a collaborating physician.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. Physician assistants and certified registered nurse practitioners may prescribe legend drugs, but only with a collaborating physician’s authorization. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

According to the licensure law described in sections I and II, a healthcare provider may prescribe legend drugs to patients for legitimate medical purposes, and consistent with the standard of care of the medical community.20

(c) The medical practice site address and telephone number of the certified registered nurse practitioner if different from that of the collaborating physician.
(d) The certified registered nurse practitioner's registered nurse license number and identifying prescriptive authority number assigned by the Board of Nursing.
(e) The words "Product Selection Permitted" printed on one side of the prescription form directly beneath a signature line.
(f) The words "Dispense as written" printed on one side of the prescription form directly beneath a signature line.
(g) The date the prescription is issued to the patient.


(a) Certified registered nurse practitioners…engaged in collaborative practice with physicians practicing under protocols approved in the manner prescribed by this article may prescribe legend drugs to their patients, subject to both of the following conditions:
(1) The drug type, dosage, quantity prescribed, and number of refills shall be authorized in an approved protocol signed by the collaborating physician; and
(2) The drug shall be on the formulary recommended by the joint committee and adopted by the State Board of Medical Examiners and the Board of Nursing.

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 Alabama 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 Practice of Pharmacy Act\(^2\) and regulations found in the Alabama Administrative Code,\(^3\) 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.\(^3\) We were unable to locate any provision providing standards for storage and record-

\(^1\) Ala. Code 34-23-1 (2007), et. seq.
keeping that have to accompany the dispensing of prescription drugs, but we recommend that healthcare providers dispense according to local custom.

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients. Physicians, certified registered nurse practitioners, and physician assistants may dispense legend drugs.

Conclusion: Dispensing naloxone by valid prescription does not violate Alabama law and may be done on premises of the distribution program.

V. Is It Legal To Prescribe Or Dispense Naloxone For Recipients To Give Or Administer To Third Parties Who Have Not Been Prescribed The Drug By A Licensed Professional?

A legal prescription requires a specific patient who has been examined and found to have a medical indication for the drug. Before the drug can properly be dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to fines. 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.

25 Ala Code § 34-24-51 (2007): Any person who practices medicine...or offers to do so in this state without a certificate of qualification having been issued in his behalf by the State Board of Medical Examiners and without a license and certificate of registration from the State Licensing Board for the Healing Arts shall be guilty of a misdemeanor and, upon conviction, shall be fined for each offense not less than $100.00 nor more than $1,000.00 and may be imprisoned in the county jail for not less than one month nor more than six months.
subject to fines.\(^{26}\) Even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another patient. But a program in this state that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

VI. What Is The Risk Of Disciplinary Action By A Professional Board Arising Kind Of Medical Discipline Or Criminal Liability May Arise From Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\(^ {27}\) There no risk of professional censure for

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\(^{26}\) Ala. Code § 34-23-7 (2007):
Any person found in possession of a drug or medicine limited by law to dispensation by a prescription, unless such drug or medicine was lawfully dispensed, shall be guilty of a misdemeanor and, upon conviction, shall be fined not more than $1,000.00 and, in addition thereto, may be imprisoned in the county jail for hard labor for not more than one year.

\(^{27}\) Ala. Code § 34-24-360 (2007):
The Medical Licensure Commission shall have the power and duty to suspend, revoke, or restrict any license to practice medicine…in the State of Alabama or place on probation or fine any licensee whenever the licensee shall be found guilty on the basis of substantial evidence of any of the following acts or offenses:

- (2) Unprofessional conduct as defined herein or in the rules and regulations promulgated by the commission.
- (3) Practicing medicine…in such a manner as to endanger the health of the patients of the practitioner.
- (8) Distribution by prescribing, dispensing, furnishing, or supplying of controlled substances to any person or patient for any reason other than a legitimate medical purpose.
- (9) Gross malpractice or repeated malpractice or gross negligence in the practice of medicine…
- (11) Performance of unnecessary diagnostic tests or medical or surgical services.
- (13) Aiding or abetting the practice of medicine by any person not licensed by the commission.
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 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.

(22) Failure to maintain for a patient a medical record which meets the minimum standards stated in the rules and regulations promulgated by the commission.
(23) Failure to comply with any rule of the Board of Medical Examiners or Medical Licensure Commission.

28 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).
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 applied the rule of ‘‘superseding cause’’ to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.

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 under 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 Alabama law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, an advanced nurse practitioner, or a 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.35

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.