TEMPELE UNIVERSITY BEASLEY SCHOOL OF LAW

Project on Harm Reduction in the Health Care System

MEMORANDUM

DATE: December 24, 2007

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

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 U.S. 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 U.S. 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 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.**

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2. Prescribing naloxone to ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.

3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.

4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODUs who are not patients.

5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensation?
4. How may naloxone be dispensed?
5. Is it legal to prescribe or dispense naloxone for recipients to give or administer to third parties who have not been prescribed the drug by a licensed professional?
6. What is the risk of disciplinary action by a professional board arising from naloxone prescription or distribution, and how can the risk be minimized?
7. What kind of malpractice liability may arise from naloxone prescription or distribution, and how can the risk of liability be minimized?
Executive Summary

From a legal standpoint, naloxone is no different than any other prescription drug. Authorized medical professionals can prescribe and dispense naloxone in the same way they would any other drug. Naloxone is indicated for patients who, upon examination, are at risk of opiate overdose and who are judged by the professional to be capable of benefiting from naloxone administration. The amount of naloxone prescribed or dispensed depends upon the prescriber’s assessment of need. (See Parts I & II describing who may prescribe naloxone.)

As part of the process of prescribing, the patient should be given information about when and how to use the drug, as well as other steps that are advisable in responding to an overdose. Because a person suffering an overdose may not be able to administer the drug him or herself, it is also appropriate to (1) teach groups of patients how to administer the drug so that they can assist each other in an overdose emergency; and (2) instruct—in person, or through written materials—friends, family members and others who may witness an overdose how to administer the drug to a patient. It is not uncommon for third parties to assist patients in administering their drugs, for all sorts of reasons. The key legal requirement is that the recipient have a valid prescription for the drug. (See Parts III & IV.)

Because a legal prescription requires some examination and a specific medical indication, naloxone may not be prescribed or dispensed to patients or program participants to hand out or administer to other ODUs who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws; the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

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

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 South Carolina is governed by the State Board of Medical Examiners (the Board), with regulations found in the South Carolina Administrative Code. 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.

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.

The medical practice act requires a physician to establish a proper physician-patient relationship before a physician can prescribe, which entails, at minimum, an appropriate physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. South Carolina case law authorizes the Board to set

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5 S.C. CODE ANN. REGS. 81-1 (2007), et seq.
10 Intra note 11.
   It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee:
further limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process. 12

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

B. Analysis

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 South Carolina 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?

(1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan;
(2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and
(3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.

(B) Notwithstanding subsection (A), a licensee may prescribe for a patient whom the licensee has not personally examined under certain circumstances including, but not limited to, writing admission orders for a newly hospitalized patient, prescribing for a patient of another licensee for whom the prescriber is taking call, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

(C) Prescribing drugs to individuals the licensee has never personally examined based solely on answers to a set of questions is unprofessional.

13 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the U.S.
A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. The State Board of Nursing permits nurse practitioners (NPs) and clinical nurse specialists (CNSs) to prescribe prescription drugs, provided they have obtained prescriptive authority from the State Board of Nursing, entered into an appropriate collaboration agreement with a physician and a supervising physician is readily available for consultation.14 Physician assistants (PAs) can prescribe prescription drugs, as

(B) An APRN is subject, at all times, to the scope and standards of practice established by the board-approved credentialing organization representing the specialty area of practice and shall function within the scope of practice of this chapter and must not be in violation of Chapter 47.
(C)(1) A licensed nurse practitioner … or clinical nurse specialist must provide evidence of approved written protocols, as provided in this section. A licensed NP … or CNS performing delegated medical acts must do so under the general supervision of a licensed physician or dentist who must be readily available for consultation.
(2) When application is made for more than three NP's or CNS's to practice with one physician or when a NP … or CNS is performing delegated medical acts in a practice site greater than forty-five miles from the supervising physician, the Board of Nursing and Board of Medical Examiners shall each review the application to determine if adequate supervision exists.
(D)(1) Delegated medical acts performed by a nurse practitioner … or clinical nurse specialist must be performed pursuant to an approved written protocol between the nurse and the physician and must include, but is not limited to:
(a) this general information:
(i) name, address, and South Carolina license number of the nurse;
(ii) name, address, and South Carolina license number of the physician;
(iii) nature of practice and practice locations of the nurse and physician;
(iv) date the protocol was developed and dates the protocol was reviewed and amended;
(v) description of how consultation with the physician is provided and provision for backup consultation in the physician's absence;
(b) this information for delegated medical acts:
(i) the medical conditions for which therapies may be initiated, continued, or modified;
(ii) the treatments that may be initiated, continued, or modified;
(iii) the drug therapies that may be prescribed;
(iv) situations that require direct evaluation by or referral to the physician.
(2) The original protocol and any amendments to the protocol must be reviewed at least annually, dated and signed by the nurse and physician, and made available to the board for review within seventy-two hours of request. Failure to produce protocols upon request of the board is considered misconduct and subjects the licensee to disciplinary action. A random audit of approved written protocols must be conducted by the board at least biennially.
(3) Licensees who change practice settings or physicians shall notify the board of the change within fifteen business days and provide verification of approved written protocols. NP's … and CNS's who discontinue their practice shall notify the board within fifteen business days.
(E)(1) A NP … or CNS who applies for prescriptive authority:
long as it is delegated by a supervising physician and within the written guidelines between the supervising physician and PA.\textsuperscript{15}

\begin{itemize}
\item[(a)] must be licensed by the board as a nurse practitioner, certified nurse-midwife, or clinical nurse specialist;
\item[(b)] shall submit a completed application on a form provided by the board;
\item[(c)] shall submit the required fee;
\item[(d)] shall provide evidence of completion of forty-five contact hours of education in pharmacotherapeutics acceptable to the board, within two years before application or shall provide evidence of prescriptive authority in another state meeting twenty hours in pharmacotherapeutics acceptable to the board, within two years before application;
\end{itemize}

\begin{itemize}
\item[(2)] The board shall issue an identification number to the NP … or CNS authorized to prescribe medications. Authorization for prescriptive authority is valid for two years unless terminated by the board for cause. Initial authorization expires concurrent with the expiration of the Advanced Practice Registered Nurse license.
\item[(3)] Authorization for prescriptive authority must be renewed after the applicant meets requirements for renewal and provides documentation of twenty hours acceptable to the board of continuing education contact hours every two years in pharmacotherapeutics. …
\end{itemize}

\begin{itemize}
\item[(F)(1)] Authorized prescriptions by a nurse practitioner … or clinical nurse specialist with prescriptive authority:
\item[(a)] must comply with all applicable state and federal laws;
\item[(b)] is limited to drugs and devices utilized to treat common well-defined medical problems within the specialty field of the nurse practitioner or clinical nurse specialist, as authorized by the physician and listed in the approved written protocols. The Board of Nursing, Board of Medical Examiners, and Board of Pharmacy jointly shall establish a listing of classifications of drugs that may be authorized by physicians and listed in approved written protocols; …
\item[(d)] must be signed by the NP … or CNS with the prescriber's identification number assigned by the board and the DEA number. The prescription form must include the name, address, and phone number of the NP … or CNS and physician and must comply with the provisions of Section 39-24-40. A prescription must designate a specific number of refills and may not include a nonspecific refill indication;
\item[(e)] must be documented in the patient record of the practice and must be available for review and audit purposes.
\item[(2)] A NP … or CNS who holds prescriptive authority may request, receive, and sign for professional samples … and may distribute professional samples to patients as listed in the approved written protocol, subject to federal and state regulations.
\end{itemize}

\textsuperscript{15} S.C. CODE ANN. §40-47-935 (1976):
Physician assistants may perform:

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\item medical acts, tasks, or functions with written scope of practice guidelines under \textit{physician supervision};
\item those duties and responsibilities, including the prescribing and dispensing of drugs and medical devices, that are lawfully delegated by their supervising physicians. However, only physician assistants holding a permanent license may prescribe drug therapy as provided in this article (emphasis added).
\end{enumerate}

While "physician supervision" is required for a PA to prescribe, there is no requirement for on-site supervision. S.C. CODE ANN. §40-47-910(7) (1976) ("Supervising' means overseeing the
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under South Carolina law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. NPs and CNSs can be authorized to prescribe prescription drugs without on-site physician supervision. Physician supervision is required for PAs to prescribe, but provided there were written guidelines, a PA could staff a naloxone program without the on-site supervision of a physician.

Conclusion: Appropriately credentialed advanced practice nurses and PAs may prescribe naloxone to participants in an overdose prevention program without on-site physician supervision. The same rules that govern the prescription of any other prescription drug apply to naloxone.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

According to the licensure law described in sections I and II, a healthcare provider must 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 activities of, and accepting responsibility for, the medical services rendered by a physician assistant in a manner approved by the board).
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 South Carolina 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 South Carolina is governed by the "South Carolina Pharmacy Practice Act,"\(^{19}\) and pharmacists are expected to fill a prescription that meets regulatory guidelines.

In South Carolina, physicians can dispense prescription drugs they have obtained, subject to state and federal labeling requirements.\(^{20}\) Physicians that dispense samples free of charge are exempt from labeling requirements, unless they dispense "more than one hundred twenty dosage units or a thirty-day supply of a drug in solid form or eight ounces of a drug in liquid form."\(^{21}\) NPs, CNSs

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\(^{19}\) S.C. CODE ANN. §40-43-10 (1976).
\(^{20}\) NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW (2007) (Physicians "may dispense drugs … that are the lawful property of the practitioner… Drugs or medicine dispensed must comply with the labeling requirements of state and federal laws and regulations"); cf. S.C. CODE ANN. §44-53-300 (1976) (Physicians' ability to dispense controlled substances).

(A) For purposes of this section, "sample" means a unit of a drug which is not intended by the manufacturer to be sold and which is intended to promote the sale of the drug.

(B) The department may not require the labeling of a prescription or nonprescription drug sample for which a physician does not require a federal or state controlled substance license to dispense, when the physician dispenses it to a patient for no charge. If the sample is not in the manufacturer's original package, the physician shall label it meeting all requirements of nonsample prescription medication. If adequate directions for usage are not provided on the
and PAs cannot dispense prescription drugs. NPs and CNSs can "distribute professional samples to patients as listed in the approved written protocol, subject to state and federal regulations."}

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has followed the prescription guidelines, he or she can dispense the drug directly to the clients, but NPs or CNSs would only be able to dispense samples provided by the manufacturer at no cost. If a program decides to dispense naloxone on premises, it should follow standard dispensation rules, which include the requirement to maintain a dispensation log, and proper labeling of the agent, including the patient’s name and other essential information.

Conclusion: Dispensing naloxone by valid prescription does not violate South Carolina law and may be done on premises of the distribution program by a physician or pharmacist.

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 heavy fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing

manufacturer's package, the physician shall give adequate written directions. (C) The labeling exemption established in this section does not apply when more than one hundred twenty dosage units or a thirty-day supply of a drug in solid form or eight ounces of a drug in liquid form is dispensed.

22 NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW (2007).
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, subject to a fine or imprisonment. Even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

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

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

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines. There is no risk of professional censure

A person who practices or offers to practice a regulated profession or occupation in this State in violation of this article or who knowingly submits false information for the purpose of obtaining a license is guilty of a misdemeanor and, upon conviction, must be imprisoned not more than one year or fined not more than fifty thousand dollars.

27 S.C. CODE ANN. §40-43-86(EE) ("A person who violates this subsection is guilty of a misdemeanor and, upon conviction, must be fined not more than five hundred dollars or imprisoned not more than two years, or both"); S.C. Code Ann. §16-1-100(B) (Possession or distribution of a prescription drug without a prescription is a Class B misdemeanor and violators are subject to not more than twenty-five years in prison).

"Misconduct" that constitutes grounds for disciplinary action is a showing to the board by the preponderance of evidence that a licensee has:

(7) knowingly performed an act that in any way assists an unlicensed person to practice;

(12) intentionally violated or attempted to violate, directly or indirectly, or is assisting in or abetting the violation of or conspiring to violate the medical practice laws;

(13) violated the code of medical ethics adopted by the board or has been found by the board to lack the ethical or professional competence to practice;

(14) violated a provision of this chapter or a regulation or order of the board.
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, 
pecific 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.\textsuperscript{30} Blatant non-compliance, 
cutting corners, cover-ups, and sloppy record-keeping have resulted in the 
imposition of professional censure and criminal charges.\textsuperscript{31}

**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.’’\textsuperscript{32} 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

\textsuperscript{30} 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).
Hartenbach, 768 S.W.2d 657 (Mo. App. E. Dist. 1989).
\textsuperscript{32} Jones v. Doe, 372 S.C. 53 (S.C. App. 2006); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 
(W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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.

“Loss of chance” doctrine in tort law establishes liability when negligent or otherwise harmful behavior substantially contributes to an injury, even if the injury may have also occurred from other causes. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the “loss of a chance” to receive medical care. However, the imposition of liability under this doctrine would be highly problematic if


programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

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

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

In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent and unless a state expressly rejects the protection offered by the VPA.

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 South Carolina 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. 38

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

38 N.Y. PUB. HEALTH LAW §3309 (McKinney 2006):
[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.
navigate the legal questions around dispensation of this life-saving agent to ODUs.