

Temple University Beasley School of Law

Project on Harm Reduction in the Health Care System

MEMORANDUM

DATE: January 7, 2008

RE: Legality of Prescribing Take-Home Naloxone to Treat Opiate Overdose in North 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 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.**

¹ See, e.g. Karen H. Seal, et al, *Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study*, 82(2), J. of Urban Health, 303–311 (2005).

- 2. Prescribing naloxone to ODU 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 patients² who, upon examination,³ 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 ODU 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. (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 lay persons, and to protect medical professionals from tort and other liability.

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.

Such legislation can help lower legal barriers and increase access to naloxone here. (See “Conclusion.”)

In 2007, the North Carolina Medical Board endorsed a pilot overdose prevention program aimed at prescription opioid users, and including the prescription of naloxone. Based on our analysis, formal approval for the program was not required because naloxone would only be provided to patients for whom it was indicated based on a risk of overdose. Medical Board approval was, however, a valuable asset in moving the project forward and getting the assistance of licensed medical personnel.⁴

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 North Carolina is governed by the Medical Practice Act, N.C. Gen. Stat. §§ 90-1 to 90-21, with regulations found in chapter 32 of title 21 of the North Carolina Administrative Code. The Act vests in the North Carolina Medical Board of Examiners (the “Board”) power to “prescribe such regulations as it may deem proper.”⁵

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.⁶ Naloxone is not a controlled substance under state or federal law.⁷

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.⁸ This reflects physicians’ broad discretion in prescribing and dispensing medical

⁴ See Nabarun Dasgupta, Fred Wells Brason II & Su Albert, Project Lazarus: Overdose Prevention and Responsible Pain Management (2007), available at <http://www.ncmedboard.org/Clients/NCBOM/Public/PublicMedia/lazarus.pdf>.

⁵ N.C.G.S.A. § 90-6 (West 2007).

⁶ F.D.A. Bulletin, 37 Fed. Reg. 16, 503 (1972).

⁷ “Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Substances Act, N.C.G.S.A. § 90-87 (West 2007), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is excluded as a controlled substance and is thus a legend drug requiring a prescription. N.C.G.S.A. § 90-90 (West 2007).

⁸ According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.

agents such as naloxone in this state and elsewhere in the US. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances, whereby a prescription is only valid if it is written (1) with a valid medical purpose, and (2) in the course of professional practice.⁹ We assume that this standard, similar to the standards used throughout the nation, would be applied to assess the validity of a prescription for naloxone.

In determining whether a prescription arises within the usual course of professional practice, courts may consider such factors as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors and efforts to provide other harm reducing services.¹⁰ According to the Medical Practice Act, the Board has the authority to discipline physicians for professional misconduct.¹¹

B. Analysis

While not explicitly required by North Carolina law, 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 if necessary, 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 North Carolina laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

⁹ N.C.G.S.A. § 90-14 (West 2007); *In re Wilkins*, 242 S.E.2d 829 (N.C. 1978).

¹⁰ *In re Wilkins*, 242 S.E.2d 829 (N.C. 1978) (To prescribe a drug "for a complete stranger, without making any examination of the patient or any inquiry as to his medical history or current symptoms and complaints, constitutes" unprofessional conduct). *See generally, United States v. Moore*, 423 U.S. 122, 142-43 (1975) ("The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of 'professional practice.'... inadequate physical examinations or none at all .. ignored the results of the tests he did make ... did not regulate the dosage at all").

¹¹ N.C.G.S.A. § 90-14 (West 2007).

II. May Anyone Other Than Physician Issue A Prescription For Naloxone?

A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. With a delegation agreement, physician assistants (“PAs”) may prescribe drugs under the supervision of a physician, who must be available but does not have to be physically on site.¹² Nurse practitioners may prescribe drugs within a collaborative relationship with a physician, who does not have to physically present but must be available by telecommunications.¹³

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under North Carolina law. Provided that the requirements of collaboration or supervision are satisfied, a naloxone prescription program may be staffed by allied health professionals.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. Physician assistants may work in collaboration with physicians to issue prescriptions. Nurse practitioners may prescribe drugs within a collaborative relationship with a physician. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

¹² 21 NC ADC 32S.0110 (West 2007):

(a) A physician assistant may perform medical acts, tasks, or functions only under the supervision of a physician. Supervision shall be continuous but, except as otherwise provided in the rules of this Subchapter, shall not be construed as requiring the physical presence of the supervising physician at the time and place that the services are rendered.

21 NC ADC 32S.0108 (West 2007):

(a) Physician assistants perform medical acts, tasks or functions with physician supervision pursuant to the supervisory arrangement as defined by Rule .0101(7) of this Section. Physician assistants perform those duties and responsibilities, including the prescribing and dispensing of drugs and medical devices, that are delegated by their supervising physician(s).

¹³ 21 NC ADC 32M.0110 (West 2007):

The primary or back-up supervising physician(s) and the nurse practitioner shall be continuously available to each other for consultation by direct communication or telecommunication. ... Collaborative Practice Agreement: (1) shall be agreed upon and signed by both the primary supervising physician and the nurse practitioner, and maintained in each practice site.

21 NC ADC 32M.0102 (West 2007) (a nurse practitioner with physician supervision and collaboration may be responsible for “prescribing, administering and dispensing therapeutic measures, tests, procedures and drugs”).

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 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 North 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 North Carolina is governed by the North Carolina Pharmacy Practice Act, N.C. Gen. Stat. §§ 90-85.2 to 90-85.40, with regulations found in chapter 46 of title 21. The Act vests in the State Board of Pharmacy all the duties, powers and authorities specifically granted by and necessary for the enforcement of the Pharmacy Practice Act.¹⁴ A physician may dispense drugs at the point of service without a pharmacy permit, and a physician's assistant or nurse practitioner may dispense drugs at the point of service if the site is covered by a pharmacy permit.¹⁵ A pharmacy permit can be obtained from the North Carolina Board of Pharmacy for a \$500 initial registration fee.¹⁶ Regulations governing dispensation of drugs are set by the board of pharmacy.¹⁷ If the population being served meets the statutory criteria of limited pharmaceutical access, naloxone may be dispensed from a mobile pharmacy.¹⁸

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. A program may arrange for naloxone to be directly dispensed by a physician at the point of service, but the program needs a permit for physician assistants and registered nurses to dispense. Regardless of who is dispensing

¹⁴ N.C.G.S.A. § 90-85.6 (West 2007).

¹⁵ 21 NC ADC 46.1703 (West 2007):

(a) The nurse practitioner may dispense any and all drugs that the nurse practitioner is authorized by law to prescribe. (b) The physician assistant may dispense any and all drugs that the physician assistant is authorized by law to prescribe. (c) The pharmacist shall prepare a plan to ensure that there are adequate amounts of each of the drugs dispensed by a nurse practitioner or physician assistant, and that such drugs are properly stored and packaged. (d) All drugs dispensed by a nurse practitioner or physician assistant must be dispensed from a place holding a current pharmacy permit from the Board.

National Association of Boards of Pharmacy, *Survey of Pharmacy Law 2002-2003* (Physicians may dispense prescriptions. Nurse practitioners and physician assistants may dispense under rules of the board of pharmacy).

¹⁶ <http://www.ncbop.org/>

21 NC ADC 46.1703 (West 2007) ("each pharmacy ... shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacy personnel").

¹⁷ N.C.G.S.A. § 90-85.26 (West 2007); 21 NC ADC 46.1703 (West 2007).

¹⁸ N.C.G.S.A. § 90-85.3 (West 2007):

"Mobile pharmacy" means a pharmacy that meets all of the following conditions: (1) Is either self-propelled or moveable by another vehicle that is self-propelled. (2) Is operated by a nonprofit corporation. (3) Dispenses prescription drugs at no charge or at a reduced charge to persons whose family income is less than two hundred percent (200%) of the federal poverty level and who do not receive reimbursement for the cost of the dispensed prescription drugs from Medicare, Medicaid, a private insurance company, or a governmental unit.

naloxone, the program must follow dispensation rules promulgated by the board of pharmacy.

Conclusion: Dispensing naloxone by valid prescription does not violate North Carolina law. Subject to permit and personnel requirements, naloxone may be dispensed on the premises of the distribution program. A physician may dispense drugs at the point of service without a pharmacy permit, and a physician's assistant or nurse practitioner may dispense drugs at the point of service if the site is covered by a pharmacy permit.

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 or illegal distribution of a prescription drug (see section VI).¹⁹ Likewise, the patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with illegal distribution of a prescription drug or practicing medicine without a license.²⁰ We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no provision that made it a crime to possess a legend drug without a prescription.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another

¹⁹ 21 NC ADC 46.1805 (West 2007):

The dispensing of or any delivery of a prescription drug, including the surrender of control or possession in any manner which results in a delivery of a prescription drug, without a valid prescription order is unlawful. Refilling a prescription for a prescription drug without authorization is unlawful.

²⁰ *Id.*; N.C.G.S.A. § 90-18 (West 2007).

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.²¹ There is no risk of professional censure for participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct.²² Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.²³

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

²¹ N.C.G.S.A. § 90-14 (West 2007):

The Board shall have the power to place on probation with or without conditions, impose limitations and conditions on, publicly reprimand, assess monetary redress, issue public letters of concern, mandate free medical services, require satisfactory completion of treatment programs or remedial or educational training, fine, deny, annul, suspend, or revoke a license or other authority to practice medicine in this State.

²² *Williams v Ohio Bd. of Nursing*, 1993 WL 69465 (Ohio App. 10 Dist. 1993); *Sermchief v. Gonzales*, 660 S.W.2d 683 (Mo. banc 1983).

²³ *In re Wilkins*, 242 S.E.2d 829 (N.C. 1978); *Ethridge v. Ariz. State Bd. of Nursing*, 796 P.2d 899 (Ariz.App. 2 Div. 1989), *State v. Hartenbach*, 768 S.W.2d 657 (Mo. App. E. Dist. 1989).

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."²⁴ The essence of the inquiry is whether the provider's treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances.

In order to prove negligence, the plaintiff must prove that (1) the provider's failure to meet the professional standard of care (2) caused an injury, and that the defendant provider (3) had a duty to avoid harming the plaintiff. Tort doctrine requires the plaintiff to prove that the injury would not have occurred "but for" the healthcare provider's unreasonable behavior.

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an ODU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk-benefit analysis would suggest that the provider's decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone,²⁵ 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

²⁴ *Clark v. Perry*, 442 S.E.2d 57 (N.C. App. 1994); see Restatement (Second) of Torts, §282, 1993 Washington, DC: American Law Institute Publishers.

²⁵ See, e.g. John Strang, et al, *Heroin overdose: the case for take-home naloxone*, 312, BMJ, 1435-1436 (1996); Karen H. Seal, et al, *Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study*, 82(2), J. of Urban Health, 303-311 (2005); Bigg D. Opiate Overdose Prevention/Intervention Using Take-Home Naloxone. Paper presented at: 131st Annual Meeting of the American Public Health Association, November 18, 2003; San Francisco, California.

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.²⁶ 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.²⁷

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.²⁸ This is effective so long as the agent responsible is a licensed health care provider acting voluntarily and without pay in the scope of his or her license. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. Thus, it appears that under North Carolina law, volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

²⁶ *Liller v. Quick Stop Food Mart, Inc.*, 507 S.E.2d 602 (N.C. App. 1998).

²⁷ *Boykin v. Kim*, 620 S.E.2d 707 (N.C.App. 2005); *Speer v. U.S.*, 512 F.Supp. 670 (N.D. Tex. 1981); *Hobart v. Shin*, 705 N.E.2d 907 (Ill. 1998); *Walt’s Sheet Metal v. Deblar*, 826 P.2d 333 (AK 1992).

²⁸ 42 U.S.C.A. § 14503 (West 2000).

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 North Carolina law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by 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.²⁹

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 ODU's.

²⁹ 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.