DATE: August 16, 2007

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

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 Nebraska is governed by the Medical Practice Act, with regulations found in the Nebraska Administrative Rules and Regulations. The Board of Medicine and Surgery (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. No provision of the Medical Practice Act explicitly defines the basis or scope of the physician's general authority to prescribe, nor did we locate any case-law discussing physicians’ general authority to prescribe drugs and devices, but the law has been interpreted to authorize the Board 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.

Nebraska law nowhere sets out an explicit standard for assessing the legality of a prescription, however, the definition of unprofessional conduct for medical practitioners includes:

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5 172 NE ADC Ch. 88, § 001 (2007), et seq.
8 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
Failure to keep and maintain adequate records of treatment or service; adequate records means legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment; … \(^{12}\)

Presumably this would be the standard, or equivalent to the standard, that a court would apply in assessing the propriety of a prescription.

**B. Analysis**

Nebraska statutes do not provide standards for prescriptions, but presumably the standards of professional conduct that require proper documentation of a patient’s treatment and the discussion of the treatment plan with the patient would apply. 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 Nebraska 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**

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,\(^ {13}\) who may delegate prescriptive

\(^{12}\) 172 NE ADC Ch. 88, § 013(24) (2007).

(1) Notwithstanding any other provision of law, a physician assistant may perform medical services when he or she renders such services under the supervision of a licensed physician or group of physicians approved by the board, in the specialty area or areas for which the physician assistant shall be trained or experienced. Any physician assistant licensed under sections 71-1,107.15 to 71-1,107.30 to perform services may perform those services only:

(a) In the office of the supervising physician where such physician maintains his or her primary practice;
authority to the PA.\textsuperscript{14} The supervising physician does not need to be on-site with the PA when the PA is not working in the physician’s primary place of practice, so long as the arrangement has been approved of by the Board.\textsuperscript{15} Nurse practitioners (NPs) may diagnose and treat patients, and may prescribe medication within their scope of practice.\textsuperscript{16}

\textbf{B. Analysis}

(b) In any other office which is operated by the supervising physician with the personal presence of the supervising physician. The physician assistant may function without the personal presence of the supervising physician in an office other than where such physician maintains his or her primary practice as provided in subsection (2) of this section and when approved on an individual basis by the board. Any such approval shall require site visits by the supervising physician, regular reporting to the supervising physician by the physician assistant, and arrangements for supervision at all times by the supervising physician which are sufficient to provide quality medical care;

(c) In a hospital, with the approval of the governing board of such hospital, where the supervising physician is a member of the staff and the physician assistant is subject to the rules and regulations of the hospital. Such rules and regulations may include, but need not be limited to, reasonable requirements that physician assistants and the supervising physician maintain professional liability insurance with such coverage and limits as may be established by the hospital governing board, upon the recommendation of the medical staff; or

(d) On calls outside such offices, when authorized by the supervising physician and with the approval of the governing board of any affected hospital.

(2) The board shall adopt and promulgate rules and regulations establishing minimum requirements for the personal presence of the supervising physician, stated in hours or percentage of practice time. The board may provide different minimum requirements for the personal presence of the supervising physician based on the geographic location of the supervising physician's primary and other practice sites and other factors the board deems relevant.

A physician assistant may prescribe drugs…as delegated to do so by a supervising physician. Any limitation placed by the supervising physician on the prescribing authority of the physician assistant shall be recorded on the physician assistant's scope of practice agreement established pursuant to rules and regulations adopted and promulgated under section 71-1,107.24. All prescriptions and prescription container labels shall bear the name of the supervising physician and the physician assistant.

\textsuperscript{15} \textit{Supra}, fn. 13.

…A nurse practitioner shall function by establishing collaborative, consultative, and referral networks as appropriate with other health care professionals. Patients who require care beyond the scope of practice of a nurse practitioner shall be referred to an appropriate health care provider. Nurse practitioner practice means health promotion, health supervision, illness prevention and diagnosis, treatment, and management of common health problems and chronic conditions, including:

(a) Assessing patients, ordering diagnostic tests and therapeutic treatments, synthesizing and analyzing data, and applying advanced nursing principles;

…

(c) Prescribing therapeutic measures and medications relating to health conditions within the scope of practice…
We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Nebraska law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. An overdose prevention program including prescription could be staffed by a NP. PAs may prescribe drugs, and could staff an overdose prevention program if they follow the appropriate regulations and receive proper authorization.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

While there is no explicit regulatory scheme for prescription, as noted in the licensure law described in sections I and II, in general it is recommended that healthcare providers follow the regulations of professional conduct. This requires the documentation of a therapeutic plan for the patient and the discussion of such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before beginning treatment.17

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

17 Cf., 172 NE ADC Ch. 88, § 013(24) (2007).
4. the importance of calling 911 for help.

Naloxone distribution programs in Nebraska 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 pharmacy laws and regulations, pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing physician may dispense the agent at the point of service, however, “if such practitioner regularly engages in dispensing such drugs...to his or her patients for which such patients are charged, such practitioner shall obtain a pharmacy license.”

NPs and PAs may dispense free samples of drugs. Physicians, registered nurses, licensed practical nurses, and PAs are all authorized to dispense medication at a public health clinic that has a delegated dispensing permit, which requires supervision and training by a pharmacist.

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19 172 NE ADC Ch. 128, § 001 (2007), et seq.
   As authorized by the Uniform Licensing Law, the practice of pharmacy may be engaged in by a pharmacist, a pharmacist intern, or a practitioner with a pharmacy license. The practice of pharmacy shall not be construed to include:
   ...
   (2) Practitioners, other than... nurse practitioners, who dispense drugs...as an incident to the practice of their profession, except that if such practitioner regularly engages in dispensing such drugs...to his or her patients for which such patients are charged, such practitioner shall obtain a pharmacy license...
   ...
   Nurse practitioner practice means health promotion, health supervision, illness prevention and diagnosis, treatment, and management of common health problems and chronic conditions, including:
   ...
   (b) Dispensing, incident to practice only, sample medications which are provided by the manufacturer and are provided at no charge to the patient...
unable to locate specific labeling and record-keeping requirements for dispensing legend drugs from the provider’s office, but we recommend that they dispense according to local custom.

**B. Analysis**

Under a delegated dispensing permit for a public health clinic, approved formulary drugs and devices may be dispensed by a public health clinic worker or a health care professional licensed in Nebraska to practice medicine and surgery or licensed in Nebraska as a registered nurse, licensed practical nurse, or physician assistant without the onsite services of a pharmacist if:

1. The initial dispensing of all prescriptions for approved formulary drugs and devices is conducted by a health care professional licensed in Nebraska to practice medicine and surgery or pharmacy or licensed in Nebraska as a registered nurse, licensed practical nurse, or physician assistant;
2. The drug...is dispensed pursuant to a prescription written on site by a practitioner;
3. ...Prescriptions are accompanied by patient instructions and written information approved by the Director of Regulation and Licensure;
4. All drugs...are prepackaged by the manufacturer or at a public health clinic by a pharmacist into the quantity to be prescribed and dispensed at the public health clinic;
5. All drugs...stored, received, or dispensed under the authority of public health clinics are properly labeled at all times. For purposes of this subdivision, properly labeled means that the label affixed to the container prior to dispensing contains the following information:
   a. The name of the manufacturer;
   b. The lot number and expiration date from the manufacturer or, if prepackaged by a pharmacist, the lot number and calculated expiration date. Calculated expiration date means the expiration date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier;
   c. Directions for patient use;
   d. The quantity of drug in the container;
   e. The name, strength, and dosage form of the drug; and
   f. Auxiliary labels as needed for proper adherence to any prescription;
7. The following additional information is added to the label of each container when the drug or device is dispensed:
   a. The patient's name;
   b. The name of the prescribing health care professional;
   c. The prescription number;
   d. The date dispensed; and
   e. The name and address of the public health clinic;
8. The only drugs...allowed to be dispensed or stored by public health clinics appear on the formulary approved pursuant to section 71-1,147.48; and
9. At any time that dispensing is occurring from a public health clinic, the delegating pharmacist for the public health clinic or on-call pharmacist in Nebraska is available, either in person or by telephone, to answer questions from clients, staff, public health clinic workers, or volunteers. This availability shall be confirmed and documented at the beginning of each day that dispensing will occur. The delegating pharmacist or on-call pharmacist shall inform the public health clinic if he or she will not be available during the time that his or her availability is required. If a pharmacist is unavailable, no dispensing shall occur.
Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has followed the prescription guidelines, she can dispense the drug directly to the clients. It is unlikely that a physician working with a naloxone program would be required to obtain a pharmacy license for “regular” dispensing. NPs and PAs could staff a naloxone program that distributes naloxone as samples.

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

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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 fines.\(^{24}\) 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.\(^{25}\) 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 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.


\(^{25}\) Neb. Rev. Stat. § 71-102(1) (2006) (“No person shall engage in the practice of medicine…[or] pharmacy…unless such person has obtained a license from the Department of Health and Human Services Regulation and Licensure for that purpose”).

\(^{26}\) Neb. Rev. Stat. § 28-1437(1) (2006): It shall be unlawful for any person knowingly or intentionally to possess or to acquire or obtain or to attempt to acquire or obtain by means of misrepresentation, fraud, forgery, deception, or subterfuge possession of any drug substance not classified as a controlled substance under the Uniform Controlled Substances Act, but which can only be lawfully distributed, under
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 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.

federal statutes in effect on April 16, 1996, upon the written or oral order of a practitioner authorized to prescribe such substances.


A license, certificate, or registration to practice a profession may be denied, refused renewal, limited, revoked, or suspended or have other disciplinary measures taken against it in accordance with section 71-155 when the applicant, licensee, certificate holder, or registrant is guilty of any of the following acts or offenses:

…
(10) Unprofessional conduct
…
(13) Distribution of...drugs for any other than lawful purposes.

For purposes of section 71-147, unprofessional conduct means any departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or occupation or the ethics of the profession or occupation, regardless of whether a person, patient, or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest, including, but not limited to:

…
(6) Assisting in the care or treatment of a patient without the consent of such patient or his or her legal representative;
…
(19) Failure to keep and maintain adequate records of treatment or service;
(20) Prescribing, administering, distributing, dispensing, giving, or selling any controlled substance or other drug recognized as addictive or dangerous for other than a medically accepted therapeutic purpose.
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.28 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.29

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

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

B. Analysis

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).
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.\(^\text{34}\) Nebraska state law provides similar liability protections from damages caused by health care providers at a “free clinic or other facility operated by a not-for-profit organization…by an agency of the state, or by any political subdivision…unless such damage or injury was caused by the willful or wanton act or omission of such practitioner.”\(^\text{35}\) It appears that under Nebraska 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.

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

\(^{34}\) 42 U.S.C.A. § 14503 (West 2000).


A person credentialed under the Uniform Licensing Law to practice as a physician, … physician assistant [or] nurse…who, without the expectation or receipt of monetary or other compensation either directly or indirectly, provides professional services, of a kind which are eligible for reimbursement under the medical assistance program established pursuant to the Medical Assistance Act, as a volunteer in a free clinic or other facility operated by a not-for-profit organization as defined in section 25-21,190, by an agency of the state, or by any political subdivision shall be immune from civil liability for any act or omission which results in damage or injury unless such damage or injury was caused by the willful or wanton act or omission of such practitioner.
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 Nebraska 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.

C. Cooperation with First Responders

[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.
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.