DATE: July 23, 2007

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

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.

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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 IDU patient?
2. May an allied health professional other than physician prescribe naloxone to an IDU 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. (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.

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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.
The Legal Analysis in Detail

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

A. Professional Licensure Law

The practice of medicine in Iowa is governed by Iowa Code Ann. §§ 147.2 et seq. and 148.1 et seq., with regulations found in sections 653-10.1 et seq. of volume 17 of the Iowa Administrative Code. The Board of Medical Examiners has the authority to license physicians,4 and to punish licensed physicians who behave in ways that violate the law or beneath the standards of good faith and regular practice of medicine.5 No provision of the medical practice act explicitly defines the basis or scope of the physician’s general authority to prescribe, but the law has been interpreted to authorize the Iowa Board of Medical Examiners to set limits on allowable practices, either by enacting specific regulations banning certain practices, or through the disciplinary process.6

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.7 Naloxone is not a controlled substance under state or federal law.8

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.9 This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. Leaving aside any limitations imposed by other laws, a physician is free to prescribe any drug she believes will benefit the patient and the prescription of which is consistent with the accepted standard of care. Iowa law does not set out a general standard for a

6 Miller v. Board of Medical Examiners of State of Iowa, 609 N.W.2d 478 (Iowa 2000).
8 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Uniform Controlled Substances Act, Iowa Code Ann. §§ 124.201 to 124.602 (2007), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. Iowa Admin. Code 641-111.7(135) (2007).
9 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
valid prescription, but such a standard may be inferred from the controlled substances and medical practice laws. Controlled substances law requires a "medical purpose" and limits validity to prescriptions written in the usual course of professional practice.  

Medical licensure law requires that all physicians live up to the professional standard of care. In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on.

The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. Disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances.

B. Analysis

While not explicitly required by Iowa statutes, it is prudent for physicians as a general matter of law to follow certain procedures when issuing prescriptions to all prescription drugs, including providing a physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. The law does not further specify the length or intensity of these interactions, leaving the precise contours of the examination and discussion to the judgment of the physician. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. 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 IDU patient is consistent with the standard for a valid prescription under Iowa 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

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Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced registered nurse practitioners may engage in “nursing assessment, intervention, and management within the boundaries of the nurse-client relationship” as well as provide additional delegated medical services when working in a collaborative practice.\(^{13}\) ARNPs may prescribe medications directly without the authorization of a physician.\(^{14}\) Physician Assistants may conduct patient examinations, assess and treat medical problems, counsel patients, and provide other medical services as delegated by a supervising physician.\(^{15}\) Physician Assistants may also work in collaboration with physicians to issue prescriptions upon the physician’s authorization.\(^{16}\)

**B. Analysis**


\(^{14}\) Iowa Code Ann. § 147.107(8) (2007):

[A] registered nurse who is licensed and registered as an advanced registered nurse practitioner and who qualifies for and is registered in a recognized nursing specialty may prescribe substances…if the nurse is engaged in the practice of a nursing specialty regulated under rules adopted by the board of nursing in consultation with the board of medical examiners and the board of pharmacy examiners.


\(^{16}\) Iowa Admin. Code 645-327.1(148C) (2007) (conditions under which PAs may prescribe):

1. The physician assistant shall have passed the national certifying examination conducted by the National Commission on the Certification of Physician Assistants or its successor examination approved by the board.

2. Physician assistants with a temporary license may order drugs…only with the prior approval and direction of a supervising physician. Prior approval may include discussion of the specific medical problems with a supervising physician prior to the patient’s being seen by the physician assistant.

3. A physician assistant shall not prescribe substances that the supervising physician does not have the authority to prescribe except as allowed in 327.1(1)"n."

4. The physician assistant may prescribe, supply and administer drugs…in all settings including, but not limited to, hospitals, health care facilities, health care institutions, clinics, offices, health maintenance organizations, and outpatient and emergency care settings…

Iowa Admin. Code 645-327.6(147) (2007) (Record requirements):

1. Each written prescription drug order issued by a physician assistant shall contain the following:
   a. The date of issuance.
   b. The name and address of the patient for whom the drug is prescribed.
   c. The name, strength, and quantity of the drug, medicine, or device prescribed and directions for use.
   d. A supervising physician's name, the physician assistant's name and the practice address.
   e. The signature of the physician assistant followed by the initials "PA."

2. Each oral prescription drug order issued by a physician assistant shall include the same information required for a written prescription, except for the written signature of the physician assistant and the address of the practitioners.
We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Iowa law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A consultation with a non-physician healthcare provider may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued. ARNP’s have independent prescribing authority, and PAs working under supervision of a physician may prescribe medications. However, specific and detailed conditions govern the communication between the “collaborating physician” and the Physician’s Assistant.\footnote{Iowa Code Ann. § 148C.3 (2007): 2. Rules shall be adopted by the board pursuant to this chapter requiring a licensed physician assistant to be supervised by physicians. The rules shall provide that not more than two physician assistants shall be supervised by a physician at one time. The rules shall also provide that a physician assistant shall notify the board of the identity of the physician assistant’s supervising physician and of any change in the status of the supervisory relationship.} These rules must be met for the prescription to be valid.

Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. A program can operate using an ARNP; a PA can dispense prescriptions with a collaborating physician’s authorization. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

According to the licensure law described in sections I and II, a healthcare provider may prescribe medications for a medical purpose in the usual course of professional practice.\footnote{Iowa Code Ann. §§ 124.308(4) and 124.401(5) (2007).} This means that a prescription for naloxone is subject to general professional standards, which would include the requirements that proper records are kept and that the patient is instructed in the indications, risks and proper administration of the prescribed medication.

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 imperative to calling 911 for help.

Naloxone distribution programs in Iowa 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 Iowa Pharmacy Practice Act, Iowa Code Ann. §155A.1 et seq., with regulations found in 657-1.1 et seq, pharmacists are expected to fill a prescription that meets regulatory guidelines.

A physician may also dispense the agent at the point of service. If the physician dispenses drugs other than samples, she must register the fact that she dispenses with her examining board. A PA or ARNP may, upon direct orders of a supervising physician, supply prepackaged and prepared medications when pharmacist services are not available or when doing so serves the best interests of the patient.  

19 Iowa Code Ann. § 147.107 (2007):

1. A person, other than a pharmacist, physician…who dispenses as an incident to the practice of the practitioner's profession, shall not dispense prescription drugs…
2. A pharmacist, physician…who dispenses prescription drugs…for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the prescription is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical
Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that must accompany such practice. This includes the requirement to maintain a record of drugs dispensed to a patient, and proper labeling of the agent, including the patient’s name, physician’s name, and essential information about the drug.  

presence. However, the physical presence requirement does not apply when a pharmacist or practitioner is utilizing an automated dispensing system…

A…physician…who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall register the fact that they dispense prescription drugs with the practitioner's…examining board at least biennially.

A physician…who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall offer to provide the patient with a written prescription that may be dispensed from a pharmacy of the patient's choice or offer to transmit the prescription orally, electronically, or by facsimile in accordance with section 155A.27 to a pharmacy of the patient's choice.

3. A physician's assistant or registered nurse may supply when pharmacist services are not reasonably available or when it is in the best interests of the patient, on the direct order of the supervising physician, a quantity of properly packaged and labeled prescription drugs…necessary to complete a course of therapy. However, a remote clinic, staffed by a physician's assistant or registered nurse, where pharmacy services are not reasonably available, shall secure the regular advice and consultation of a pharmacist regarding the distribution, storage, and appropriate use of such drugs…

4. Notwithstanding subsection 3, a physician assistant shall not dispense prescription drugs as an incident to the practice of the supervising physician or the physician assistant, but may supply, when pharmacist services are not reasonably available, or when it is in the best interests of the patient, a quantity of properly packaged and labeled prescription drugs…necessary to complete a course of therapy. However, a remote clinic, staffed by a physician assistant, where pharmacy services are not reasonably available, shall secure the regular advice and consultation of a pharmacist regarding the distribution, storage, and appropriate use of such drugs…Prescription drugs supplied under the provisions of this subsection shall be supplied for the purpose of accommodating the patient and shall not be sold for more than the cost of the drug and reasonable overhead costs, as they relate to supplying prescription drugs to the patient, and not at a profit to the physician or the physician assistant. If prescription drug supplying authority is delegated by a supervising physician to a physician assistant, a nurse or staff assistant may assist the physician assistant in providing that service. Rules shall be adopted by the board of physician assistant examiners, after consultation with the board of pharmacy examiners, to implement this subsection.


13.1(2) A label shall be affixed to a container in which a prescription drug is dispensed by a physician which shall include:  
1. The name and address of the physician.  
2. The name of the patient.  
3. The date dispensed.
B. Analysis

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. Under circumstances of need and under supervision of a physician, a PA or ARNP may also supply drugs to the clients. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

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

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

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

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this manner was guilty of a crime.

4. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician.
5. The name and strength of the prescription drug in the container.
13.1(3) The provisions of subrules 13.1(1) and 13.1(2) shall not apply to packaged drug samples.
13.1(4) A physician shall keep a record of all prescription drugs dispensed by the physician to a patient which shall contain the information required by subrule 13.1(2) to be included on the label. Noting such information on the patient's chart or record maintained by the physician is sufficient.

22 Iowa Code Ann. § 155A.4 (“A person shall not dispense prescription drugs unless that person is a licensed pharmacist or is authorized by section 147.107 to dispense or distribute prescription drugs”). A violation is a simple misdemeanor under § 155A.22, punishable under § 903.1(1)(a) by a fine between $65 and $625, and/or imprisonment up to 30 days.
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. 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 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. Blatant non-compliance,

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23 Iowa Code Ann. § 155A.21 (2007) (“A person found in possession of a drug or device limited to dispensation by prescription, unless the drug or device was so lawfully dispensed, commits a serious misdemeanor”). Iowa Code Ann. § 903.1(1)(b) make serious misdemeanors punishable by a fine between $315 and $1,875, and a possible imprisonment up to one year.


25 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist.); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{26}

\section*{VII. What Kind of Tort or Civil Liability May Arise from Naloxone Prescription or Distribution; What Remedies Exist to Minimize Such Risk?}

\subsection*{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{27} 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.

\subsection*{B. Analysis}

Naloxone is the drug of choice for overdose. Assuming that the patient is an IDU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone,\textsuperscript{28} 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


29 Berte v. Bode, 692 N.W.2d 368 (Iowa 2005).
31 Mead v. Adrian, 670 N.W.2d 174 (Iowa 2003).
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. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. It appears that 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 prescription or dispensation context 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 Iowa law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, an advanced registered 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.

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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 imperative to 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.34

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 IDUs.

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"[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."