DATE: August 14, 2007

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

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.**

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

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

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

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

This Memorandum addresses the following specific questions:

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

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

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

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

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

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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 IDU Patient?

A. Professional Licensure Law

The practice of medicine in Minnesota is governed by the Board of Medical Practice, with regulations in the Minnesota Administrative Code. The Board of Medical Practice (the "Board") has the authority to license physicians. The Board also punishes licensed physicians who behave in ways that violate the law or fall beneath the standards of good faith or outside the course of professional practice. The Board is authorized to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription 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: "[a] licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug." This is similar to the standard set out in case law for prescribing controlled substances. In applying this standard, courts, in general, may consider such factors as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records

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4 Minn. Stat. Ann. § 147.001 (West 2007), et seq.
5 Minn. R. 5600.0100 (2007), et seq.
10 Minn. Stat. Ann. § 152.01(4) (West 2007) (" Controlled substance' means a drug, substance, or immediate precursor in Schedules I through V of section 152.02"). Under the "Permanent Rules Relating to Pharmacists" (2002) for the Board of Pharmacy, naloxone is excluded from Schedule II of the Controlled Substances Act; therefore, it is treated as a prescription drug. http://www.phcybrd.state.mn.us/Newrules2002.htm.
12 The requirement that prescribing be in “the course of a physician's professional practice” is similar to the standard set out in case law for controlled substances. Padilla v. Minn. State Bd. of Med. Examiners, 382 N.W.2d 876 (Minn. App. 1986).
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.\textsuperscript{13}

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.\textsuperscript{14} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

\textbf{B. Analysis}

While not explicitly required by Minnesota statutes, it is prudent for physicians as a general matter to law to follow certain procedures when issuing prescriptions to all prescription drugs, including 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.

\textbf{Conclusion:} A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Minnesota laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

\section*{II. May Anyone Other Than Physician Issue A Prescription For Naloxone?}

\textbf{A. Professional Licensure Law}

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Certified nurse practitioners and advanced practice nurses are authorized in Minnesota to prescribe prescription drugs, as long as this is authorized in an agreement with a collaborating physician.\textsuperscript{15} Physician assistants can prescribe prescription drugs, but must do so under the supervision of a physician.\textsuperscript{16}

\begin{footnotesize}
\begin{enumerate}
\item United Stated v. Moore, 423 U.S. 122 (U.S. 1975).
\item According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
\end{enumerate}
\end{footnotesize}
Minnesota Medical Association that defines the delegated responsibilities related to the prescription of drugs … may prescribe and administer drugs … within the scope of the written agreement and within practice as a certified nurse practitioner. The written agreement required under this subdivision shall be based on standards established by the Minnesota Nurses Association and the Minnesota Medical Association as of January 1, 1996, unless both associations agree to revisions.

An advanced practice registered nurse who is authorized under this section to prescribe drugs is authorized to dispense drugs subject to the same requirements established for the prescribing of drugs. This authority to dispense extends only to those drugs described in the written agreement entered into under this section. The authority to dispense includes, but is not limited to, the authority to receive and dispense sample drugs.

Subdivision 1. Scope of practice. Physician assistants shall practice medicine only with physician supervision. Physician assistants may perform those duties and responsibilities as delegated in the physician-physician assistant agreement and delegation forms maintained at the address of record by the supervising physician and physician assistant, including the prescribing, administering, and dispensing of…drugs…

Patient service must be limited to:
(1) services within the training and experience of the physician assistant;
(2) services customary to the practice of the supervising physician;
(3) services delegated by the supervising physician; and
(4) services within the parameters of the laws, rules, and standards of the facilities in which the physician assistant practices.

Nothing in this chapter authorizes physician assistants to perform duties regulated by the boards listed in section 214.01, subdivision 2, other than the Board of Medical Practice, and except as provided in this section.

Subd. 2. Delegation. Patient services may include, but are not limited to, the following, as delegated by the supervising physician and authorized in the agreement:

…

(10) prescribing … legend drugs…if this function has been delegated by the supervising physician pursuant to and subject to the limitations of section 147A.18 and chapter 151.

Subdivision 1. Delegation. (a) A supervising physician may delegate to a physician assistant who is registered with the board, certified by the National Commission on Certification of Physician Assistants or successor agency approved by the board, and who is under the supervising physician's supervision, the authority to prescribe, dispense, and administer legend drugs…subject to the requirements in this section. The authority to dispense includes, but is not limited to, the authority to request, receive, and dispense sample drugs. This authority to dispense extends only to those drugs described in the written agreement developed under paragraph (b).

(b) The agreement between the physician assistant and supervising physician and any alternate supervising physicians must include a statement by the supervising physician regarding delegation or nondelegation of the functions of prescribing, dispensing, and administering of legend drugs…to the physician assistant. The statement must include a protocol indicating categories of drugs for which the supervising physician delegates prescriptive and dispensing authority. The delegation must be appropriate to the physician assistant's practice and within the scope of the physician assistant's training. Physician
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Minnesota 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. Certified nurse practitioners and advanced nurse practitioners can prescribe, as long as both are authorized to do so by a supervising physician. Physician assistants can prescribe under the supervision of a physician.

Conclusion: Provided the appropriate arrangements with a physician are in place, allied health professionals may staff a naloxone prescription program. 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

Although not required by the regulatory scheme for prescribing noted in the licensure law described in sections I and II, in general it is recommended assistants who have been delegated the authority to prescribe, dispense, and administer legend drugs…shall provide evidence of current certification by the National Commission on Certification of Physician Assistants or its successor agency when registering or reregistering as physician assistants.

…

(c) The board may establish by rule:
   (1) a system of identifying physician assistants eligible to prescribe, administer, and dispense legend drugs…

   …

   (3) a method of determining the categories of legend [drugs] … that each physician assistant is allowed to prescribe, administer, and dispense; and
   (4) a system of transmitting to pharmacies a listing of physician assistants eligible to prescribe legend [drugs]…

Subd. 2. Termination and reinstatement of prescribing authority. (a) The authority of a physician assistant to prescribe, dispense, and administer legend drugs…shall end immediately when:
   (1) the agreement is terminated;
   (2) the authority to prescribe, dispense, and administer is terminated or withdrawn by the supervising physician; or
   (3) the physician assistant reverts to inactive status, loses National Commission on Certification of Physician Assistants or successor agency certification, or loses or terminates registration status.

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 Minnesota 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 Minnesota is governed by the Minnesota Board of Pharmacy, with regulations found in the administrative code. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

18 Minn. Stat. Ann. § 151.01 (West 2007), et seq.
19 Minn. R. 6800.0100 (2007), et seq.
The prescribing healthcare provider may also dispense the agent at the point of service. Physicians in Minnesota are given broad discretion to practice their profession, which includes dispensing prescription drugs. Advanced nurse practitioners can dispense prescription drugs, although certified nurse practitioners cannot. Physician assistants can dispense prescription drugs, but they must do so under the supervision of a physician. Finally, healthcare providers are given broad discretion in dispensing prescription drugs directly from the provider’s office.

B. Analysis

A licensed practitioner in the course of professional practice only, may … dispense a legend drug … and may cause a person who is an appropriately certified, registered, or licensed health care professional to … dispense … the same within the expressed legal scope of the person’s practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9 [or] physician assistant … to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. … This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

An advanced practice registered nurse who is authorized under this section to prescribe drugs is authorized to dispense drugs subject to the same requirements established for the prescribing of drugs. This authority to dispense extends only to those drugs described in the written agreement entered into under this section. The authority to dispense includes, but is not limited to, the authority to receive and dispense sample drugs.

Supra fn 20.


… Patient services may include, but are not limited to, the following, as delegated by the supervising physician and authorized in the agreement … … (10) … dispensing legend drugs…if this function has been delegated by the supervising physician pursuant to and subject to the limitations of section 147A.18 and chapter 151.

Nothing in [the Pharmacy Act] shall subject a person duly licensed in this state to practice medicine … to inspection by the State Board of Pharmacy, nor prevent the person from administering drugs, [or] medicines … in the person’s practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, [or] medicines … as may be considered appropriate in the treatment of such patient; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection.

Except for the provisions of section 151.37, nothing in this chapter applies to or interferes with the dispensing, in its original package and at no charge to the patient, of a legend drug…that was packaged by a manufacturer and provided to the dispenser for distribution as a professional sample.
Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients, whether it be a physician, advanced nurse practitioner or physician assistant.

Conclusion: Dispensing naloxone by valid prescription does not violate Minnesota 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 license sanctions. The patient or volunteer who dispensed naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license and/or illegal dispensing of a prescription drug. 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 imprisonment and/or a fine. While this is not a serious crime, even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

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27 Minn. Stat. Ann. § 151.37(1) (West 2007) (“Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug”); Minn. Stat. Ann. § 151.34 (West 2007) (“It shall be unlawful to … (11) dispense a legend drug without first obtaining a valid prescription for that drug”).
29 Minn. Stat. Ann. § 151.29 (West 2007) (“Any person violating any of the provisions of this chapter, or rules hereunder, shall be guilty of a misdemeanor, unless otherwise provided”).
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 or fines. There is no risk of professional censure for

30 Minn. Stat. Ann. § 141.091:

Subdivision 1. Grounds listed. The board may refuse to grant a license … or may impose disciplinary action as described in section 147.141 against any physician. The following conduct is prohibited and is grounds for disciplinary action:

(a) Failure to demonstrate the qualifications or satisfy the requirements for a license contained in this chapter or rules of the board. The burden of proof shall be upon the applicant to demonstrate such qualifications or satisfaction of such requirements.

…

(f) Violating a rule promulgated by the board or an order of the board, a state, or federal law which relates to the practice of medicine, or in part regulates the practice of medicine including without limitation sections 148A.02, 609.344, and 609.345, or a state or federal narcotics or controlled substance law.

(g) Engaging in any unethical conduct; conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare or safety of a patient; or medical practice which is professionally incompetent, in that it may create unnecessary danger to any patient's life, health, or safety, in any of which cases, proof of actual injury need not be established.

…

(i) Aiding or abetting an unlicensed person in the practice of medicine, except that it is not a violation of this paragraph for a physician to employ, supervise, or delegate functions to a qualified person who may or may not be required to obtain a license or registration to provide health services if that person is practicing within the scope of that person's license or registration or delegated authority.

…

(k) Engaging in unprofessional conduct. Unprofessional conduct shall include any departure from or the failure to conform to the minimal standards of acceptable and prevailing medical practice in which proceeding actual injury to a patient need not be established.

participating in a naloxone prescription program. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, 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.32 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.33

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

When the board finds that a licensed physician or a physician registered under section 147.032 has violated a provision or provisions of sections 147.01 to 147.22, it may do one or more of the following:
(1) revoke the license;
(2) suspend the license;

(4) impose limitations or conditions on the physician's practice of medicine, including the limitation of scope of practice to designated field specialties; the imposition of retraining or rehabilitation requirements; the requirement of practice under supervision; or the conditioning of continued practice on demonstration of knowledge or skills by appropriate examination or other review of skill and competence;
(5) impose a civil penalty not exceeding $10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive the physician of any economic advantage gained by reason of the violation charged or to reimburse the board for the cost of the investigation and proceeding;
(6) order the physician to provide unremunerated professional service under supervision at a designated public hospital, clinic, or other health care institution; or
(7) censure or reprimand the licensed physician.

32 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).
patient’s companion, a failure to seek timely medical help after the administration of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

Generally, every tort claimant must establish that he or she suffered an injury that was actually caused by the defendant healthcare provider. A healthcare provider is required to practice his or her profession in a reasonably competent manner. Particular conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the “standard of care.” The essence of the inquiry is whether the provider’s treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances.

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

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an ODU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone, and, in an actual case, by expert testimony from clinicians and public health experts. If the prescription of naloxone is reasonable, there can be no tort liability even if the other elements of the case are established.

“But for” causation will be extremely difficult to establish where the injury results from overdose because at the moment naloxone was administered serious injury was already likely to happen. Where the injury is caused by the rare occurrence of side effects of naloxone, the causal connection is still tenuous: the behavior of the injured party, in overdosing on heroin, is the key causal factor that necessitated treatment with the agent. Injury was likely to be as severe, if not more so, had naloxone not been administered. It is not considered malpractice to

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34 See e.g. LaBorde v. Castleman, 2006 WL 2053158 (Minn. App. July 25, 2006); Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
prescribe a drug that carries a low risk of side effects to avert death or severe impairment, particularly if the patient is adequately informed of the risks. Even in the unlikely cases in which “but for” factual causation may be established, the provider’s actions must represent a major contributing factor to the injury for liability to arise. It is hardly fair to blame a prescribing professional for a harm primarily caused by a patient’s decision to inject heroin; courts have usually applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.  

“Loss of chance” doctrine in tort law establishes liability when negligent or otherwise harmful behavior substantially contributes to an injury, even if the injury may have also occurred from other causes. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the “loss of a chance” to receive medical care. However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

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

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population. In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent.

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38 Kroeger v. Lee, 270 Minn. 75 (Minn. 1965).
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 Minnesota law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician or licensed medical provider working in collaboration with a physician.
2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.
3. The prescription must be made out to the specific patient and must contain all the information required by law.
4. Each prescription should be accompanied by oral and/or written information on the following:
   • information on how to spot symptoms of an overdose;
   • instruction in basic resuscitation techniques;
   • instruction on proper naloxone administration, and
   • the 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.\textsuperscript{40}

\textbf{C. Cooperation with First Responders}

Programs should also work with police and EMTs to inform them about program goals and practices. Alerting first responders to the presence of take-home naloxone can help inform their work and alleviate resistance or roadblocks to program implementation. By building their programs according to the regulatory schemes we have referenced above, programs can successfully navigate the legal questions around dispensation of this life-saving agent to ODUs.

\textsuperscript{40} 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.