DATE: July 23, 2007

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

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 IDU patient?
2. May an allied health professional other than physician prescribe naloxone to an IDU patient?
3. What instructions should accompany naloxone prescription/dispensal?
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 Idaho is governed by the Medical Practice Act of 1977, with regulations found in the Idaho Administrative Code. The Board of Medical Examiners 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. The law has been interpreted to authorize the Idaho Board of Medical Examiners 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.

State pharmacy law defines prescribing powers and prohibitions:

A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription, must be for a legitimate medical purpose.

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5 Idaho Admin. Code 22.01.02.000 through 22.01.13.050 (2007).
10 "Controlled substance" means a drug classified in any of the schedules (I through V) of the Uniform Controlled Substances Act, Idaho Code §§ 37-2701 to 37-2751 (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. Idaho Code § 54-1705(28) (2007).
prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.  

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.  

**B. Analysis**

Physicians are required 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 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 Idaho 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 may replace physicians in some or all aspects of a prescription program. Physician Assistants (PAs) may apply to and receive authorization from the Board of Medicine to prescribe medications under the supervision of a physician.  

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

13 Idaho Admin. Code 22.01.03.042 (2007)”

01. Approval And Authorization Required. A physician assistant may issue written or oral prescriptions for legend drugs…only in accordance with approval and authorization granted by the Board and in accordance with the current delegation of services agreement and shall be consistent with the regular prescriptive practice of the supervising physician.

02. Application. A physician assistant who wishes to apply for prescription writing authority shall submit to the Board an application for such purpose on
take primary responsibility for the care of patients, which allows them to diagnose, manage, and treat their patients.\textsuperscript{14} APNs may apply to and receive authorization from the Board of Nursing to independently prescribe medication.\textsuperscript{15}

forms supplied by the Board. In addition to the information contained in the general application for physician assistant approval, the application for prescription writing authority shall include the following information:

\begin{enumerate}
\item Documentation of all pharmacology course content completed, the length and whether a passing grade was achieved (at least thirty (30) hours).
\item A statement of the frequency with which the supervising physician will review prescriptions written or issued.
\item A signed affidavit from the supervising physician certifying that, in the opinion of the supervising physician, the physician assistant is qualified to prescribe the drugs for which the physician assistant is seeking approval and authorization.
\end{enumerate}

03. Prescription Forms. Prescription forms used by the physician assistant must be printed with the name, address, and telephone number of the physician assistant and of the supervising physician. A physician assistant shall not write prescriptions or complete or issue prescription blanks previously signed by any physician.

04. Record Keeping. The physician assistant shall maintain accurate records, accounting for all prescriptions issued and medication delivered.

\textsuperscript{14} Idaho Admin. Code 23.01.01.271 (2007); Idaho Code § 54-1402(1)(c) (2007).

\textsuperscript{15} Idaho Admin. Code 23.01.01.315 (2007):

01. Initial Authorization. An application for the authority to prescribe and dispense pharmacologic and non-pharmacologic agents may be made as part of initial licensure application or by separate application at a later date.

\begin{enumerate}
\item An advanced practice professional nurse who applies for authorization to prescribe pharmacologic and non-pharmacologic agents within the scope of practice for the advanced practice category, shall:
\item Be currently licensed as an advanced practice professional nurse in Idaho; and
\item Provide evidence of completion of thirty (30) contact hours of post-basic education in pharmacotherapeutics obtained as part of study within a formal educational program or continuing education program, which are related to the applicant's advanced practice category scope of practice and include:
\begin{enumerate}
\item Pharmacokinetic principles and their clinical application;
\item The use of pharmacologic agents in the prevention of illness, restoration, and maintenance of health;
\item Federal and state laws relating to the purchasing, possessing, prescribing, administering, and disposing of pharmacologic and nonpharmacologic agents;
\item Prescription writing;
\item Drug selection, dosage and route of administration; and
\item Drug interactions.
\end{enumerate}
\item Submit a completed, notarized application form provided by the board; and
\item Remit fees prescribed in Subsection 901.05 of these rules.
\end{enumerate}

b. Exceptions to the pharmacotherapeutic education may be approved by the board.

c. Prescriptions written by authorized advanced practice professional nurses shall comply with all applicable state and federal laws and be signed by the prescriber with the abbreviation for the applicable category of advanced nursing practice, the identification number assigned by the board

d. Advanced practice professional nurse authorization shall expire and may be renewed at the same time as the advanced practice professional nurse license.

06. Accountability. The advanced practice professional nurse when exercising prescriptive and dispensing authority is accountable for:
There is no provision in the state law that allows a collaborating physician to delegate prescription authority to an APN, so presumably the only way for an APN to prescribe is to get independent authorization from the board.

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Idaho 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. APNs can be authorized in Idaho by the board to prescribe medicine, and PAs can be authorized to prescribe under the supervision of a collaborating physician. However, specific and detailed conditions govern the communication between the supervising physician, the Physician’s Assistant, and the patient. These rules must be met for the prescription to be valid.

a. Patient selection;

b. Problem identification through appropriate assessment;

c. Medication...selection;

d. Evaluation of outcome; and

g. Recognition and management of complications and untoward reactions.


01. Responsibilities. The supervising physician accepts full responsibility for the medical acts of and patient services provided by physician assistants…and for the supervision of such acts which shall include, but are not limited to:

a. An on-site visit at least monthly to personally observe the quality of care provided;

b. A periodic review of a representative sample of medical records to evaluate the medical services that are provided. When applicable, this review shall also include an evaluation of adherence to the delegation of services agreement between the physician and physician assistant; and

c. Regularly scheduled conferences between the supervising physician and such licensees.

02. Patient Complaints. The supervising physician shall report to the Board of Medicine all patient complaints received against the physician assistant…which relate to the quality and nature of medical care or patient services rendered.

03. Pre-Signed Prescriptions. The supervising physician shall not utilize or authorize the physician assistant to use any pre-signed prescriptions.

04. Supervisory Responsibility. A supervising physician or alternate supervising physician shall not supervise more than three (3) physician assistants…contemporaneously. The Board, however, may authorize a supervising physician or alternate supervising physician to supervise a total of six (6) such licensees contemporaneously if necessary to provide adequate medical care and upon prior petition documenting adequate safeguards to protect the public health and safety. The responsibilities and duties of a supervising physician may not be transferred to a business entity, professional corporation or partnership, nor may they be assigned to another physician without prior notification and Board approval.
Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. A program can operate using an APN who has received authorization from the board to prescribe medicine; a PA can dispense prescriptions but only 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 must evaluate a patient sufficiently to support a diagnosis for a need for the treatment plan and monitor the patient’s condition.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 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;

05. Available Supervision. The supervising physician shall oversee the activities of the physician assistant… and must always be available either in person or by telephone to supervise, direct and counsel such licensees. The scope and nature of the supervision of the physician assistant and graduate physician assistant shall be outlined in a delegation of services agreement, as set forth in IDAPA 22.01.03, “Rules for the Licensure of Physician Assistants,” Subsection 030.03.

06. Disclosure. It shall be the responsibility of each supervising physician to ensure that each patient who receives the services of a physician assistant… is aware of the fact that said person is not a licensed physician. This disclosure requirement can be fulfilled by the use of nametags, correspondence, oral statements, office signs or such other procedures that under the involved circumstances adequately advise the patient of the education and training of the person rendering medical services.

3. instruction on proper naloxone administration, and
4. the imperative to calling 911 for help.

Naloxone distribution programs in Idaho 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 Idaho Pharmacy Act,\textsuperscript{18} with regulations found in the Idaho Administrative Code,\textsuperscript{19} pharmacists are expected to fill a prescription that meets regulatory guidelines.

Physicians may dispense prescription drugs directly to their patients.\textsuperscript{20} Advanced Practice Nurses may also dispense the agent to their patients at the point of service.\textsuperscript{21} Dispensation authority for Physician Assistants is limited to

\begin{footnotes}
\item[18] Idaho Code § 54-1702 (2007).
\item[19] Idaho Admin. Code 27.01.01.010 through 27.01.01.496 (2007).
\item[20] Idaho law does not explicitly authorize the dispensation of prescription drugs by a physician, but the authority can be presumed as PAs may be delegated some dispensation authority by a physician under Idaho Admin. Code  22.01.03.042 (2007). The authority is also implied in the Controlled Substances Act , Idaho Code § 54-1705(24) (2007) (“‘Practitioner’ shall mean a physician…licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state”). See also, State v. Kellogg, 568 P.2d 514 (Idaho 1977) (“the legislature intended only to mean those persons licensed to practice medicine in the State pursuant to I.C. s 54-1803 [may dispense prescription drugs]”).
\item[21] Idaho Admin. Code 23.01.01.315 (2007)
\end{footnotes}
pharmaceutical samples\textsuperscript{22} and providing a patient an “emergency period” supply of medications when a pharmacist is unavailable.\textsuperscript{23}

Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that have to accompany such practice, which include labeling of the medication with the patient’s name, indications for use, and the dispenser’s contact information.\textsuperscript{24}

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription

\textsuperscript{22}Idaho Admin. Code 22.01.03.042 (2007):
05. Pharmaceutical Samples. The physician assistant who has prescriptive authority may request, receive, sign for and distribute professional samples of drugs...in accordance with his current delegation of services agreement and consistent with the regular prescriptive practice of the supervising physician.

\textsuperscript{23}Idaho Admin. Code 22.01.03.043 (2007):
01. Pre-Dispensed Medication. The physician assistant may legally provide a patient with more than one (1) dose of a medication at sites or at times when a pharmacist is not available. The pre-dispensed medications shall be for an emergency period to be determined on the basis of individual circumstances, but the emergency period will extend only until a prescription can be obtained from a pharmacy.
02. Consultant Pharmacist. The physician assistant shall have a consultant pharmacist responsible for providing the physician assistant with pre-dispensed medication in accordance with federal and state statutes for packaging, labeling, and storage.
03. Limitation Of Items. The pre-dispensed medication shall be limited to only those categories of drug identified in the delegation of services agreement, except a physician assistant may provide other necessary emergency medication to the patient as directed by a physician.
04. Exception From Emergency Period. Physician assistants in agencies, clinics or both, providing family planning, communicable disease and chronic disease services under government contract or grant may provide pre-dispensed medication for these specific services and shall be exempt from the emergency period. Physician assistants in agencies, clinics or both, in remote sites without pharmacies shall be exempt from the emergency period, providing that they must submit an application and obtain formal approval from the Board.

\textsuperscript{24}Idaho Admin. Code 27.01.01.159 (2007):
02. Prescription Labels. Any drug dispensed shall bear a label containing the following: the name, address and telephone number of the dispenser (person or business), the serial number and date of the prescription or its filling, the name of the prescriber and the name of the patient, the directions for use, name (generic or brand) of the medication (including manufacturer's name if a generic), and any cautionary statements required to protect the consumer, including when advisable the manufacturer's original expiration date, the quantity of item dispensed and the initials of the person dispensing and the statement: "Warning: Federal or State law prohibits the transfer of this prescription to any person other than the person for whom it was prescribed." When appropriate, the prescriber may request "Do Not Label", in such cases the medication name will not appear.
guidelines, the physician or APN (see part II) can dispense the drug directly to the clients. PAs are limited to dispensing only professional samples and emergency supplies of medication. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

**Conclusion:** Dispensing naloxone by valid prescription does not violate Idaho 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 to fines. A 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 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

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26 Idaho Code § 54-1804(2) (2007): …it shall constitute a felony for any person to practice medicine in this state without a license and upon conviction thereof shall be imprisoned in the state prison for a period not to exceed five (5) years, or shall be fined not more than ten thousand dollars ($10,000), or shall be punished by both such fine and imprisonment.

27 Idaho Code § 54-1732(3)(c) (2007):

The possession or use of a legend drug or a precursor by any person unless such person obtains such drug on the prescription or drug order of a practitioner [is unlawful]. Any person guilty of violating this section shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars ($1,000) or by both such fine and incarceration.
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.28 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.29 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.30

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

29 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist.); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
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.” 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 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, 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.\(^{33}\) 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.\(^{34}\)

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 of their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent.\(^{35}\) 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 Idaho law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, an advanced practice nurse, 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 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{36}

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.

\textsuperscript{36} 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.