DATE: August 15, 2007

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

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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in Washington is governed by chapter 18.71 of title 18 of the statutory code, with regulations in the Washington Administrative Code. The Washington State Medical Quality Assurance Commission (the "Commission") 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. Washington case law authorizes the Commission 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] prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs."

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is

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10 Wash. Rev. Code Ann. §69.50.101(d) (West 2007) ("Controlled substance’ means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or board rules"); Naxalone is excluded from Schedule II of the "Uniform Controlled Substances Act," so it is a prescription drug. Wash Rev. Code Ann. §69.50.206 (West 2007).
there case-law challenging the legality of prescription of naloxone specifically.\textsuperscript{12} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

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. These cases apply the familiar standard under which a prescription is valid if it is written for a legitimate medical purpose, in the normal course of professional practice.\textsuperscript{13}

B. Analysis

While not explicitly required by Washington 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 when 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.

Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Washington laws governing the physician’s authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone. Some of the prescription tasks can be delegated to allied health professionals.

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

A. Professional Licensure Law

Allied health professionals and medical residents in this state are authorized to replace physicians in some or all aspects of a prescription program. Upon approval from the Commission, an advanced practice nurse (APNs) can write prescriptions and the supervision of a physician is not required by statute.\textsuperscript{14}

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

\textsuperscript{13} \textit{State v. Bell}, 83 Wash.2d 383 (Wash. 1974).

\textsuperscript{14} Wash. Rev. Code Ann. §18.79.050 (West 2007) ("Upon approval by the commission, an advanced registered nurse practitioner may prescribe legend drugs"); Wash Rev. Code Ann. §18.79.250 (West 2007):

An advanced registered nurse practitioner under his or her license may perform for compensation nursing care, as that term is usually understood, of the ill,
Physician assistants (PAs) have prescriptive authority, but they must receive Commission approval beforehand and be asked to prescribe by their supervising physician.\textsuperscript{15} Certified physician assistants (CPAs) also have prescriptive authority, but they need only approval from the commission before prescribing prescription drugs, not a direct assignment from a supervising physician.\textsuperscript{16}

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Washington law. In the same way, a prescription issued by an allied health professional in accordance with

\begin{itemize}
\item[(2)] Prescribe legend drugs.
\end{itemize}

A physician assistant may issue written or oral prescriptions as provided herein when approved by the commission and assigned by the supervising physician(s).
(1) A physician assistant may issue prescriptions for legend drugs for a patient who is under the care of the physician(s) responsible for the supervision of the physician assistant.
(a) Written prescriptions shall include the name, address, and telephone number of the physician or medical group; the name and address of the patient and the date on which the prescription was written.
(b) The physician assistant shall sign such a prescription using his or her own name followed by the letters 'P.A.'

\begin{itemize}
\item[(2)] A physician assistant employed or extended privileges by a hospital, nursing home or other health care institution may, if permissible under the bylaws, rules and regulations of the institution, order pharmaceutical agents for inpatients under the care of the physician(s) responsible for his or her supervision.
\item[(3)] The license of a physician assistant who issues a prescription in violation of these provisions shall be subject to revocation or suspension.
\item[(4)] Physician assistants may dispense medications the physician assistant has prescribed from office supplies. The physician assistant shall comply with the state laws concerning prescription labeling requirements.
\end{itemize}

A certified physician assistant may issue written or oral prescriptions as provided herein when approved by the commission or its designee.
(1) Written prescriptions shall include the name, address, and telephone number of the physician or medical group; the name and address of the patient and the date on which the prescription was written.
(a) The certified physician assistant shall sign such a prescription using his or her own name followed by the letters 'P.A.-C.'

\begin{itemize}
\item[(2)] A certified physician assistant employed or extended privileges by a hospital, nursing home or other health care institution may, if permissible under the bylaws, rules and regulations of the institution, order pharmaceutical agents for inpatients under the care of the sponsoring physician(s).
\item[(3)] The license of a certified physician assistant who issues a prescription in violation of these provisions shall be subject to revocation or suspension.
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 with Commission approval are authorized in Washington to prescribe medicine without the supervision of a physician.\textsuperscript{17} PAs with Commission approval are authorized to prescribe, as long as they are assigned this task by their supervising physician.\textsuperscript{18} While CPAs also require commission approval to have prescriptive authority, they can prescribe prescription drugs without an order from a supervision physician.\textsuperscript{19}

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

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

As noted in the licensure law described in sections I and II, in general it is recommended that a healthcare provider must 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:

\textsuperscript{17} Supra fn 14.  
\textsuperscript{18} Supra fn 15.  
\textsuperscript{19} Supra fn 16.
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 Washington 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 Washington is governed by chapter 18.64 of title 18 entitled “Pharmacists,”20 with regulations found in the Washington administrative code.21 Pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing healthcare provider may also dispense the agent at the point of service. Physicians in Washington can dispense prescription drugs,22 with the only restrictions on dispensing being labeling23 and record keeping requirements.24 APNs may dispense prescription drugs under the supervision of a physician.25 PAs can dispense prescription drugs, but they must do so under the supervision of a physician and must receive Commission approval to dispense.26

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23 *Infra* fn 36.
24 *Infra* fn 30.

(1) A physician assistant may perform only those services as outlined in the standardized procedures reference and guidelines established by the commission. If said assistant is being trained to perform additional procedures beyond those established by the commission, the training must be carried out
If physician assistants wanted to dispense at a remote site, they would need additional Commission approval. CPAs can dispense directly from a physician's office and are not constrained from practicing at a remote site, unlike physician assistants. 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.

under the direct, personal supervision of the supervising physician or a qualified person mutually agreed upon by the supervising physician and the physician assistant. Requests for approval of newly acquired skills shall be submitted to the commission and may be granted by a reviewing commission member or at any regular meeting of the commission.

(2) The physician assistant may not practice in a remote site, or prescribe controlled substances unless specifically approved by the commission or its designee.

…

(4) A physician assistant and supervising physician shall ensure that, with respect to each patient, all activities, functions, services and treatment measures are immediately and properly documented in written form by the physician assistant. Every written entry shall be reviewed and countersigned by the supervising physician within two working days unless a different time period is authorized by the commission.

(5) It shall be the responsibility of the physician assistant and the supervising physician to ensure that adequate supervision and review of the work of the physician assistant are provided.

(6) In the temporary absence of the supervising physician, the supervisory and review mechanisms shall be provided by a designated alternate supervisor(s).

(7) The physician assistant, at all times when meeting or treating patients, must wear a badge identifying him or her as a physician assistant.

27 Id.

Certified physician assistants may dispense medications the certified physician assistant has prescribed from office supplies. The certified physician assistant shall comply with the state laws concerning prescription labeling requirements.


(1) A certified physician assistant may perform only those services as outlined in the standardized procedures reference and guidelines established by the commission. If said assistant is being trained to perform additional procedures beyond those established by the commission, the training must be carried out under the direct, personal supervision of the sponsoring physician or a qualified person mutually agreed upon by the sponsoring physician and the certified physician assistant. Requests for approval of newly acquired skills shall be submitted to the commission and may be granted by a reviewing commission member or at any regular meeting of the commission.

…

(3) It shall be the responsibility of the certified physician assistant and the sponsoring physician to ensure that appropriate consultation and review of work are provided.

(4) In the temporary absence of the sponsoring physician, the consultation and review of work shall be provided by a designated alternate sponsor(s).

(5) The certified physician assistant must, at all times when meeting or treating patients, wear a badge identifying him or her as a certified physician assistant.

B. Analysis

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. APNs\textsuperscript{31} and PAs\textsuperscript{32} can dispense from a physician’s office under the supervision of a physician. PAs can also dispense from a remote site with Commission approval.\textsuperscript{33} CPAs can dispense from a physician’s office\textsuperscript{34} or at a remote site.\textsuperscript{35} If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirements for record keeping and proper labeling of the agent, including the patient’s name and other essential information.\textsuperscript{36}

Conclusion: Dispensing naloxone by valid prescription does not violate Washington law and may be done on premises of the distribution program by properly certified practitioners.

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

\begin{quote}
A … practitioner who … dispenses, or distributes legend drugs shall maintain invoices or such other records as are necessary to account for the receipt and disposition of the legend drugs. The records maintained pursuant to this section shall be available for inspection by the board and its authorized representatives and shall be maintained for two years.
\end{quote}

\textsuperscript{31} \textit{Supra} fn 25.
\textsuperscript{32} \textit{Supra} fn 26.
\textsuperscript{33} \textit{Id.}
\textsuperscript{34} \textit{Supra} fn 28.
\textsuperscript{35} \textit{Supra} fn 29.
\textsuperscript{36} \textit{Wash Rev. Code Ann.} § 69.41.050 (West 2007):

(1) To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.

(2) A violation of this section is a misdemeanor.
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 heavy 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 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 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.

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

37 Wash Rev. Code Ann. § 48.30A.040 (West 2007): A violation of this chapter is cause for discipline and constitutes unprofessional conduct that could result in any regulatory penalty provided by law, including refusal, revocation, or suspension of a business or professional license, or right or admission to practice. Conduct that constitutes a violation of this chapter is unprofessional conduct in violation of RCW 18.130.180.


39 Wash. Rev. Code Ann. § 69.41.030(1) (West 2007) (“It shall be unlawful for any person to … possess any legend drug except upon the order or prescription of a physician”).


Everyone convicted of a misdemeanor for which no punishment is prescribed by any statute in force at the time of conviction and sentence, shall be punished by imprisonment in the county jail for a maximum term fixed by the court of not more than ninety days, or by a fine in an amount fixed by the court of not more than one thousand dollars or both such imprisonment and fine.
Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules\(^{41}\) may carry license sanctions and fines.\(^{42}\) There is no risk of professional censure for 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.\(^{43}\) Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\(^{44}\)

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


The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

...  
(6) The possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself;

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

...  
(10) Aiding or abetting an unlicensed person to practice when a license is required;

...  
(12) Practice beyond the scope of practice as defined by law or rule;


\(^{43}\) 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).

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.”45 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,46 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:

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45 *Douglas v. Bussabarger*, 73 Wash.2d 476 (Wash. 1968); see *Plaintiff v. City of Petersburg*, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).

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 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 and unless a state expressly rejects the protection offered by the VPA.\textsuperscript{50} Washington law provides similar liability for volunteer medical professionals, who are "not liable for civil damages resulting from any act or omission in the rendering of such care, other than acts or omissions constituting gross negligence or willful or wanton misconduct."\textsuperscript{51} This same standard applies to a volunteer rendering emergency medical services.\textsuperscript{52} It appears that volunteers working with naloxone distribution programs would be immune from any liability.

\textbf{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.}

\textbf{CONCLUSION}

\textbf{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 Washington 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 importance of calling 911 for help.

\textsuperscript{50} 42 U.S.C.A. § 14503 (West 2000).
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. 53

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.


[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.