DATE: August 6, 2007

RE: Legality of Prescribing Take-Home Naloxone to Treat Opiate Overdose in the District of Columbia

INTRODUCTION

Naloxone, the standard treatment for heroin overdose, is a safe and effective prescription drug typically administered by emergency room personnel or first responders acting under standing orders of physicians. High numbers of overdose deaths and evidence that witnesses to heroin overdose are often unwilling or unable to call for help has motivated some public health professionals to institute programs that distribute naloxone directly to opiate drug users (ODUs). In such programs, drug users, their partners, or others are instructed in resuscitation techniques and provided a “take-home” dose of naloxone for administration in cases when medical help is not immediately available.

Evidence from US and abroad indicates that naloxone distribution helps reduce opiate overdose deaths and results in cost-savings to society. Despite the high and rising incidence of overdose events in many US locales, however, both the number and the scope of overdose programs remain inadequate. Legal concerns about provider and program liability act as one of the most important limiting factors, often complicating or derailing authorization, expansion, funding and implementation of these programs.

We were funded by the Drug Policy Alliance to analyze the legal issues for naloxone distribution programs in the fifty United States. Our analysis finds that:

1. Naloxone is not a controlled substance as defined by federal or D.C. law, but is a prescription drug subject to the general laws and regulations that govern all prescriptions in regular medical practice.
2. Prescribing naloxone to ODUs in the District of Columbia is fully consistent with D.C. 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 the District of Columbia 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 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 the District of Columbia. A professional distributing naloxone in this way could be found to be violating professional licensure laws, and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license. (See Part V.)

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

---

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.
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 the District of Columbia is governed the Medical Practices Act, with regulations found in the District of Columbia Municipal Regulations. The Board of Medicine has the authority to recommend to the Mayor such regulations as are reasonably necessary to carry out the purposes of the licensure law, including promulgating regulations defining the accepted standard of care that all practitioners must meet or suffer disciplinary action from the Board. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the District of Columbia Board of Medicine 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 D.C. 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 D.C. or federal law. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug.

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs in the District of Columbia, nor is there case-law challenging the legality of prescription of naloxone specifically.

---

4 D.C. Code § 3-1201.01 (West 2007), et seq.
5 D.C. Mun. Regs. 17-4600 (Lexis 2007), et. seq.
6 D.C. Code § 3-1204.08.
7 Williamson v. District of Columbia Board of Dentistry, 647 A.2d 389 (D.C. Cir. 1994) (Prescriptive practices are within the Board’s expertise, and an agency’s decisions on such specialty areas are given deference by the court).
9 D.C. Code § 48-901.02(4) (West 2007) (“Controlled substance’ means a drug, substance, or immediate precursor, as set forth in Schedules I through V of subchapter II of this chapter”); D.C. Code § 48-902.06 (West 2007) (Naloxone is excluded from Schedule II of the Controlled Substances Act, so it is a prescription drug).
10 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in the District of Columbia and elsewhere in the US.

The law in the District of Columbia nowhere sets out an explicit standard for assessing the legality of a prescription. We presume that an analysis would look to the standard used for the prescription of controlled substances in the district. Under this standard, a prescription is valid if it is written “for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice”.

In determining whether a prescription arises within the usual course of professional practice, courts would probably consider such indicia as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on. The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.

B. Analysis

While not explicitly required by D.C. statutes, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination, 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. 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 District of Columbia laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in the District of Columbia apply to naloxone.

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

13 Salama v. District of Columbia Board of Medicine, 578 A.2d 693 (D.C. 1990).
A. Professional Licensure Law

Allied health professionals in the District of Columbia are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice registered nurses (APRNs) may diagnose and treat patients, and may independently prescribe medication.\(^{14}\) Physician assistants (PAs) must work with a supervising physician, who may either be on-site or be within a 15 mile radius of D.C. and available by telephone to assist the PA.\(^{15}\) PAs may diagnose, treat,

\(^{14}\) D.C. Code § 3-1201.02(2) (West 2007):

'Practice of advanced registered nursing' means the performance of advanced-level nursing actions by an advanced practice registered nurse certified pursuant to this chapter which, by virtue of post-basic specialized education, training, and experience, are proper to be performed. The advanced practice registered nurse may perform actions of nursing diagnosis and nursing treatment of alterations of the health status. The advanced practice registered nurse may also perform actions of medical diagnosis and treatment, prescription, and other functions which are identified in subchapter VI of this chapter and carried out in accordance with the procedures required by this chapter.

D.C. Code § 3-1206.04 (West 2007):

An advanced practice registered nurse may:

1. Initiate, monitor, and alter drug therapies;
2. Initiate appropriate therapies or treatments;
3. Make referrals for appropriate therapies or treatments; and
4. Perform additional functions within his or her specialty determined in accordance with rules and regulations promulgated by the board.

D.C. Mun. Regs. 17-5909 (Lexis 2007):

1. A nurse-practitioner shall have authority to prescribe legend drugs…
2. A nurse-practitioner shall have authority to prescribe drugs only while certified in accordance with this chapter.
3. Prescriptions for drugs shall comply with all applicable District of Columbia and federal laws.
4. A nurse-practitioner who … prescribes a prescription drug shall enter in the patient's chart on the date of the transaction or, if the chart is not available, no later than the next office day, the following information:
   a. Each prescription that a nurse-practitioner orders …
5. Pursuant to § 514 of the Act, D.C. Official Code § 3.1205.14 (a) (19), the Board may suspend or revoke the license or take other disciplinary action against any applicant or licensee who prescribes, dispenses, or administers drugs when not authorized to do so.

\(^{15}\) D.C. Mun. Regs. 17-4914 (Lexis 2007):

1. A supervising physician has ultimate responsibility for the medical care and treatment given to a patient by a physician assistant to whom the supervising physician has delegated authority to perform health care tasks.
2. Subject to the limitations of the Act and this chapter, a physician who is registered as a supervising physician by the Board may delegate to a physician assistant medical procedures and other tasks that are usually performed within the normal scope of the supervising physician's practice.
3. A supervising physician shall not permit a physician assistant to practice medicine independently, and shall ensure that all actions undertaken by a physician assistant are as follows:
   a. Governed by a standard or advanced job description registered by the Board;
   b. Performed in immediate collaboration with the supervising physician; or
   c. Performed pursuant to § 4911.5.
and prescribe medication for patients, within the scope of practice and delegated authority of the supervising physician.\textsuperscript{16}

\begin{itemize}
  \item[(4)] A supervising physician may delegate to a physician assistant only those tasks and duties that are consistent with sound medical practice, taking into account the following:
    \begin{itemize}
      \item The physician assistant's education, skill, training, and experience;
      \item The patient's health and safety;
      \item The degree of supervision provided by the supervising physician;
      \item The qualifications of the supervising physician; and
      \item The nature of the supervising physician's practice.
    \end{itemize}
  \item[(5)] A supervising physician shall be responsible for supervising a physician assistant at all times that a physician assistant performs health care tasks delegated by a supervising physician. Unless a job description registered by the Board expressly requires a greater level of supervision, a supervising physician shall do the following:
    \begin{itemize}
      \item Be present within a fifteen (15) mile radius of the District;
      \item Be available for consultation by voice communication;
      \item Countersign all medical orders and progress notes within forty-eight (48) hours; and
      \item Provide immediate collaboration for health care tasks that are not governed by a job description registered by the Board.
    \end{itemize}
  \item[(6)] A supervising physician who is temporarily unavailable to supervise a physician assistant shall designate a back-up supervising physician to provide substitute supervision during the supervising physician's absence.
\end{itemize}

\begin{itemize}
  \item[(11)] A health care facility, organization, association, institution, or group practice which employs a physician assistant shall designate one physician to supervise the physician assistant. The physician who is designated has ultimate responsibility for the care and treatment of a patient attended by the physician assistant regardless of whether the designated supervising physician actually pays the salary of the physician assistant.
  \item[(12)] Except as provided in § 4914.13, a physician shall not supervise more than two (2) physician assistants at one time.
  \item[(13)] A supervising physician employed by a health care facility that provides in-patient treatment may supervise four (4) physician assistants; Provided, that the health care tasks delegated to the physician assistants are restricted to the case and treatment of the facility's in-patient population.
\end{itemize}

\textsuperscript{16} D.C. Code § 3-1201.02(13) (West 2007)

Practice by physician assistants' means the performance, in collaboration with a licensed physician or osteopath, of acts of medical diagnosis and treatment, prescription, preventive health care, and other functions which are authorized by the Board of Medicine pursuant to § 3-1202.03

D.C. Mun. Regs. 17-4912 (Lexis 2007):

\begin{itemize}
  \item[(1)] All prescription orders issued by a physician assistant shall be written on a prescription pad that bears the printed names of the physician assistant and the supervising physician. A physician assistant may sign the prescription order.
  \item[(5)] A physician assistant who administers, dispenses, or prescribes a prescription drug shall enter a progress note in the patient's chart on the date of the transaction which shall include the following information:
    \begin{itemize}
      \item Each prescription that a physician assistant orders; and
      \item The name, strength, and quantity of each drug that a physician assistant dispenses or administers.
    \end{itemize}
\end{itemize}
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under District of Columbia 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. However, specific and detailed conditions govern the communication between the “collaborating physician,” a licensed non-physician provider such as the Physician’s Assistant, and the patient. These rules must be met for the prescription to be valid.

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

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

While there is no explicit regulatory scheme for prescribing legend drugs, as noted in the licensure law described in sections I and II, in general it is recommended 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,

17 D.C. Mun. Regs. 17-4911(8) (Lexis 2007):
A physician assistant shall wear an identification badge with lettering clearly visible to a patient bearing the name of the physician assistant and the title "Physician Assistant." In addition, a physician assistant shall, upon introduction to a patient and prior to rendering services, explain that the physician assistant is not a physician and that the supervising physician is ultimately responsible for the patient's care.
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 the District of Columbia 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 District of Columbia law. Under the pharmacy laws with regulations found in the D.C. Municipal Regulations, pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing physician may also dispense the agent at the point of service. APRNs are given broad authority to conduct the independent practice of medicine, which includes the dispensing of prescription drugs. We were unable to locate specific labeling and record-keeping requirements for physicians or APRNs, but we recommend that they dispense according to local custom.

PAs may dispense medication that is prepackaged by the manufacturer or by the supervising physician, and must note in the patient’s chart what medication

---

18 D.C. Code Ann. §47-2885.01 (West 2007), et seq.
19 D.C. Mun. Regs. 17-6500 (Lexis 2007), et. seq.
21 Supra, fn. 14.
was dispensed. They also must label the drug with the name and address of the PA, the supervising physician’s name, patient’s name, and directions for use.

**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. If a program decides to dispense naloxone on premises, PAs must follow standard dispensation rules, and physicians and APRNs should dispense according to local custom.

**Conclusion:** Dispensing naloxone by valid prescription does not violate District of Columbia 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

---

(2) A physician assistant shall not dispense drugs unless they are as follows:
(a) Packaged by the manufacturer as a sample; or
(b) Prepackaged in a unit of use package by a supervising physician.
(3) All drugs dispensed by a physician assistant shall be labeled to show the following:
(a) The name and address of the physician assistant;
(b) The name of the supervising physician;
(c) The name of the patient;
(d) The date dispensed;
(e) The name and strength of the drug;
(f) Directions for use;
(g) Cautionary statements, if appropriate;
(h) The lot and control number; and
(i) The expiration date of the drug.
(4) A physician assistant shall not dispense a drug from any source other than a supervising physician or a pharmacist acting on a written order of a supervising physician.
(5) A physician assistant who administers, dispenses, or prescribes a prescription drug shall enter a progress note in the patient’s chart on the date of the transaction which shall include the following information:
(a) Each prescription that a physician assistant orders; and
(b) The name, strength, and quantity of each drug that a physician assistant dispenses or administers.

24 Id.
drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We could not locate any District of Columbia law making it a crime to possess a prescription drug without a prescription.

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 the District of Columbia that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

VI. What Is The Risk Of Disciplinary Action By A Professional Board Arising Kind Of Medical Discipline Or Criminal Liability May Arise From Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines. There no risk of professional censure for participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

25 D.C. Code § 3-1205.14(19) (West 2007) (The board may discipline a practitioner who “[p]rescribes, dispenses, or administers drugs when not authorized to do so”).
26 D.C. Code § 3-1210.01 (West 2007) (“No person shall practice, attempt to practice, or offer to practice a health occupation licensed or regulated under this chapter in the District unless currently licensed, or exempted from licensing, under this chapter”); § 3-1210.07 (“Any person who violates any provision of this chapter shall, upon conviction, be subject to imprisonment not to exceed 1 year, or a fine not to exceed $10,000, or both”).
Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct. Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.

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

A. The Legal Scheme

Any practice of medicine implies a risk that something may go wrong. In the context of a naloxone prescription/dispensing program, a patient may suffer one of the rare side effects from the drug. An error in administration by a patient’s companion, a failure to seek timely medical help after the administration of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

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

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

B. Analysis

28 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist.); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
Naloxone is the drug of choice for overdose. Assuming that the patient is an 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 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 of their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent. Volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

Conclusion: The risk of tort liability in a naloxone program is low. Conceptually, this risk is no different from any other healthcare context. By following District of Columbia 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 the District of Columbia. 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 District of Columbia law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, an advanced nurse practitioner, or a licensed medical provider working in collaboration with a physician.

2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.

3. The prescription must be made out to the specific patient and must contain all the information required by law.

4. Each prescription should be accompanied by oral and/or written information on the following:
   - information on how to spot symptoms of an overdose;
   - instruction in basic resuscitation techniques;
   - instruction on proper naloxone administration, and
   - the importance of calling 911 for help.

B. Changes in District of Columbia Law

Under the current law of the District of Columbia, 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.\(^{36}\)

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.

[The 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.]