DATE: September 13, 2007

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

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.
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 Vermont is governed by the Medical Practice Act,\(^4\) with regulations in the Code of Vermont Rules.\(^5\) The Board of Medical Practice (the "Board") has the authority to license physicians\(^6\) 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.\(^7\) Vermont statutes do not explicitly define the basis or scope of the physician's general authority to prescribe. However, Vermont case law authorizes the Board to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.\(^8\)

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.\(^9\) Naloxone is not a controlled substance under state or federal law.\(^10\) 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 and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically.\(^11\) This reflects physicians' broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. In the absence of

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\(^5\) Code Vt. R. 04 13 141-001 (2007), et seq.
\(^10\) Naxolone is excluded from Schedule II of controlled substances, so it is a prescription drug. Vt. Stat. Ann. tit. 18, § 4228 ("For the purposes of this section, a 'controlled' drug or substance shall mean those drugs or substances listed under schedules I through V in the federal Controlled Substances Act, 21 U.S.C. § 801 et seq.").
\(^11\) According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances: "[a] physician ... licensed under this chapter, in good faith and in the course of his professional practice only, may prescribe, administer and dispense regulated drugs."12

In determining whether a prescription arises within the usual course of professional practice, courts, in general, may consider such factors 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 and efforts to provide other harm reducing services.13 The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.14

B. Analysis

While not explicitly required by Vermont law, 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 as appropriate, 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 ODU patient is consistent with the standard for a valid prescription under Vermont 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 in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice registered nurses (APRNs) can write prescriptions, if it is within their collaborative agreement with their supervising physician.\textsuperscript{15} Physician assistants (PAs) can also prescribe prescription drugs, but must do so under the supervision of a 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 Vermont 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.

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


\textbf{Error! Main Document Only.} The APRN performs medical acts independently within a collaborative practice with a licensed physician under practice guidelines which are mutually agreed upon between the APRN and collaborating physician and which are jointly acceptable to the medical and nursing professions. Practice guidelines will be reviewed and approved by the Board of Nursing and kept on file in the workplace and be made available to the Board of Nursing at any time upon request.

\textsuperscript{16} Code Vt. R. 13-141-001(7.4) (2007):

The certified physician assistant may prescribe only those drugs utilized by the primary supervising physician and permitted by the scope of practice submitted to and approved by the Board. The prescription form used by the PA must include:

(a) The printed name of the physician assistant
(b) The printed name of the supervising physician
(c) The practice address and telephone number
(d) A space for the physician assistant's signature
(e) A space for the physician assistant's DEA number
A healthcare provider must formulate a therapeutic plan for their patient and discuss that plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.\textsuperscript{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 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 Vermont 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 Vermont is governed by the statutory code\textsuperscript{18} with regulations found in the Code of Vermont


Rules. 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 can dispense prescription drugs. APRNs presumably can dispense prescription drugs, if this is agreed upon in their collaborative agreement with their supervising physician. PAs can dispense prescription drugs, if the supervising physician permits this within their scope of practice. Finally, healthcare providers directly dispensing prescription drugs

   The physician's assistant's scope of practice shall be limited to that delegated to the physician's assistant by the supervising physician and for which the physician's assistant is qualified by education, training and experience. At no time shall the practice of the physician's assistant exceed the normal scope of the supervising physician's practice.
   The scope of practice document shall cover at least the following:
   (a) Narrative: A brief description of the practice setting, the types of patients and patient encounters common to this practice and a general overview of the role of the physician assistant in that practice.
   (b) Supervision:
      (1) The mechanisms for on-site and off-site physician supervision and communication;
      (2) How back-up and secondary supervising physicians will be utilized, and the means by which communication with them will be managed;
      …
      (4) How ongoing supervision of the PA's activities are reviewed;
      …
      (7) The methods for in-practice consultation for patients who are not improving in a reasonable manner or time frame, including the ways in which the PA will access the supervising physician's expertise in determining diagnostic treatment and referral plans for a patient whose progress is not satisfactory;
   (c) Sites of Practice: A description of any and all practice sites (e.g. office,
from the provider’s office must place the drug in a "suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug."\textsuperscript{23}

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, it should 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{24}

Conclusion: Dispensing naloxone by valid prescription does not violate Vermont 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?

\begin{itemize}
\item clinic, hospital outpatient, hospital inpatient, industrial sites, schools). For each site, a description of the PA's activities.
\item (d) Tasks/Duties: A list of the PA's tasks and duties in the supervising physician's scope of practice. This list should express a sense of involvement in the level of medical care in that practice. The supervising physician may only delegate those tasks for which the physician assistant is qualified by education, training and experience to perform. … At no time should a particular task assigned to the PA fall outside of the scope of practice of the supervising physician.
\item …
\item (f) At no time shall the scope of practice of the physician assistant exceed the normal scope of either the primary or secondary supervising physician(s)’ practice.
\end{itemize}

These statutes have been interpreted to allow PAs to dispense prescription drugs. Natl. Assn. Bd. of Pharm., Natl. Assn. Bd. of Pharm. (2002).


'Dispense' or 'dispensing' shall mean the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

\textsuperscript{24} The statutory and administrative codes of Vermont do not include dispensing standards for non-pharmacists; however, we recommend that healthcare professionals adhere to the same dispensing standards followed by pharmacists in Vermont, since healthcare professionals are subject to the Vermont pharmacy code. Code Vt. R. 04 030 230-14.1.2. (In order to dispense a prescription drug, a pharmacist must include “\textit{Error! Main Document Only.}}, the name and location of the patient, name and dosage of the drug, directions for use, date of order, and signature of the physician or his or her authorized designee”).
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 be properly dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to license sanctions. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing pharmacy or 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 found no provision that made it a crime to possess a legend drug without a prescription.

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(a) If a majority of the members of the board vote in favor of finding the person complained against guilty of unprofessional conduct as specified in the charges, or any of them, the board shall prepare written findings of fact, conclusions and order, a copy of which shall be served upon the person complained against.
(b) In such order, the board may reprimand the person complained against, as it deems appropriate; condition, limit, suspend or revoke the license or practice of the person complained against; or take such other action relating to discipline or practice as the board determines is proper.

(a) It shall be unlawful for any person to engage in the practice of pharmacy unless licensed to so practice under the provisions of this chapter provided, however, physicians … or other practitioners of the healing arts who are licensed under the laws of this state may dispense and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by statute of this state.
(b) Any person who shall be found by the board after hearing to have unlawfully engaged in the practice of pharmacy shall be subject to disciplinary action. For the purpose of enforcing this section, the attorney general may commence a criminal action against any person unlawfully engaging in the practice of pharmacy, and upon conviction the person may be punished by imprisonment not to exceed six months or by a fine not to exceed $1,000.00, or both.

A person who, not being licensed, advertises or holds himself out to the public as described in section 1311 of this title, or who, not being licensed, practices medicine or surgery as defined in section 1311 of this title, or who practices medicine or surgery under a fictitious or assumed name, or who impersonates another practitioner or signs a certificate of death for the purpose of burial or removal, shall be imprisoned not more than three months or fined not more than $200.00 nor less than $50.00, or both.
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\textsuperscript{28} may carry license sanctions.\textsuperscript{29} 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,


(a) The board shall find that any one of the following, or any combination of the following, whether or not the conduct at issue was committed within or outside the state, constitutes unprofessional conduct:

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(7) conduct which evidences unfitness to practice medicine;

(8) willfully making and filing false reports or records in his or her practice as a physician;

\ldots

(17) offering, undertaking or agreeing to cure or treat disease by a secret method, procedure, treatment or medicine;

(18) consistent improper utilization of services;

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(25) failure to comply with an order of the board or violation of any term or condition of a license which is restricted or conditioned by the board;

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(27) failure to comply with provisions of federal or state statutes or rules governing the practice of medicine or surgery;

(b) The board may also find that failure to practice competently by reason of any cause on a single occasion or on multiple occasions constitutes unprofessional conduct. Failure to practice competently includes, as determined by the board:

(1) performance of unsafe or unacceptable patient care; or

(2) failure to conform to the essential standards of acceptable and prevailing practice.

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.\textsuperscript{30} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{31}

**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.”\textsuperscript{32} 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

\textsuperscript{30} 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).
\textsuperscript{32} Pepin v. Averill, 32 A.2d 665 (Vt. 1943); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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. 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.

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

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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.\textsuperscript{36} 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 program is low. Conceptually, this risk is no different from any other healthcare context. By following state rules and general standards of practice, providers can protect themselves from the imposition of tort liability. Malpractice insurance and laws that apply specifically to volunteer providers may provide additional protection.

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state. However, as with any healthcare practice, institutions and professionals providing this service should follow the relevant rules and regulations that govern their practice to avoid professional, civil, and criminal liability.

The following is a summary of the program guidelines dictated by Vermont 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{36} 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.37

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.