DATE: September 10, 2007

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

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 Virginia is governed by chapter 29 of title 54.1 of the statutory code, "Medicine and Other Healing Arts," with regulations in the Virginia Administrative Code. The Board of Medicine (the "Board") 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. Virginia statutes and the administrative code do not explicitly define the basis or scope of the physician's general authority to prescribe. However, Virginia 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.

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.

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. 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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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 govern prescriptions for controlled substances: a physician “shall only prescribe [or] dispense … controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.”

In determining whether a prescription arises within the usual course of professional practice, courts 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. The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.

B. Analysis

While not explicitly required by Virginia 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.

Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Virginia 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.

Nurse practitioners (NPs) with prescriptive authority can write prescriptions, but must do so within the terms of the practice agreement between the nurse practitioner and the supervising\textsuperscript{15} physician.\textsuperscript{16} Physician assistants (PAs) can also prescribe, but they must do so within the written protocol established between the PA and the supervising physician.\textsuperscript{17}

\textsuperscript{15} 18 Va. Admin Code 90-40-10 (2007) ("'Supervision' means that the physician documents being readily available for medical consultation by the licensed nurse practitioner or the patient, with the physician maintaining ultimate responsibility for the agreed-upon course of treatment and medications prescribed").

\begin{itemize}
  \item A. A nurse practitioner with prescriptive authority may prescribe only within the scope of a written practice agreement with a supervising physician.
  \item C. The practice agreement shall contain the following:
    \begin{enumerate}
      \item A description of the prescriptive authority of the nurse practitioner within the scope allowed by law and the practice of the nurse practitioner.
      \item An authorization for categories of drugs and devices within the requirements of § 54.1-2957.01 of the Code of Virginia.
      \item The signatures of the primary supervising physician and any secondary physician who may be regularly called upon in the event of the absence of the primary physician.
    \end{enumerate}
\end{itemize}

A nurse practitioner’s prescriptive authority is broad, with few restrictions beyond the terms of the practice agreement. Va. Admin. Code 90-40-30 (2007):
\begin{itemize}
  \item A. No licensed nurse practitioner shall have authority to prescribe certain controlled substances and devices in the Commonwealth of Virginia except in accordance with this chapter and as authorized by the boards.
  \item B. The boards shall approve prescriptive authority for applicants who meet the qualifications set forth in 18 VAC 90-40-40 of this chapter.
\end{itemize}

\begin{itemize}
  \item A. Prior to initiation of practice, a physician assistant and his supervising physician shall submit a written protocol which spells out the roles and functions of the assistant. Any such protocol shall take into account such factors as the physician assistant's level of competence, the number of patients, the types of illness treated by the physician, the nature of the treatment, special procedures, and the nature of the physician availability in ensuring direct physician involvement at an early stage and regularly thereafter. The protocol shall also provide an evaluation process for the physician assistant's performance, including a requirement specifying the time period, proportionate to the acuity of care and practice setting, within which the supervising physician shall review the record of services rendered by the physician assistant.
  \item B. The board may require information regarding the level of supervision, i.e. "direct," "personal" or "general," with which the supervising physician plans to supervise the physician assistant for selected tasks. The board may also require the supervising physician to document the assistant's competence in performing such tasks.
  \item C. If the role of the assistant includes prescribing for drugs … the written protocol shall include those schedules and categories of drugs and devices that are within the scope of practice and proficiency of the supervising physician.
\end{itemize}

\textsuperscript{18} Va. Admin. Code 85-50-140:
\begin{itemize}
  \item A. The approved drugs and devices which the physician assistant with prescriptive authority may prescribe … or dispense manufacturer's professional
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Virginia 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. NPs and PAs could both staff a naloxone program off-site, as long as this is included in written protocol or practice agreement for each.

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

According to the licensure law described in sections I and II, 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.\(^{18}\)

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

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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 Virginia 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 Virginia is governed by chapter 33 of title 54.1 of the statutory code entitled "Pharmacy" with regulations found in the Virginia Administrative Code. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

Physicians can dispense drugs to patients with the approval of the Board of Pharmacy or the Board of Medicine. Physicians can either obtain a special

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   For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician … so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.
   A. Pursuant to § 54.1-3304 of the Code of Virginia, physicians licensed by the board to dispense drugs, when pharmacy services are not reasonably available, shall be subject to the following sections of this chapter. For purposes of this section, the terms "pharmacist," "pharmacist-in-charge," and "PIC" in the following shall be deemed to mean the physician permitted by the board:
license to dispense based on the lack of availability of a pharmacy\textsuperscript{23} or by demonstrating that "degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service."\textsuperscript{24} However, physicians can dispense drug samples\textsuperscript{25} without approval of

1. 18 VAC 110-20-110 C and D; 
2. 18 VAC 110-20-130 A; 
3. 18 VAC 110-20-140 A and C; 
4. 18 VAC 110-20-150 except that these requirements shall not apply to physicians licensed prior to August 25, 2004, unless the dispensing area is relocated or remodeled; 
5. 18 VAC 110-20-160; 
6. 18 VAC 110-20-180; 
7. 18 VAC 110-20-190 A, B and C; 
8. 18 VAC 110-20-200; 
9. 18 VAC 110-20-210; and 
10. 18 VAC 110-20-240 through 18 VAC 110-20-410. 

B. A physician may apply for a special or limited use permit in accordance with 18 VAC 110-20-120.

For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a \textit{special, limited or unusual nature} as compared to a regular pharmacy service (emphasis added). The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice. 
2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application. 
3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

The Board of Medicine shall have, with respect to practitioners of medicine, homeopathy, osteopathy, or podiatry, the same powers conferred upon the Board of Pharmacy with respect to pharmacists, to revoke or suspend the license to dispense drugs issued under § 54.1-3304 or § 54.1-3304.1 or to prescribe the medicines to be possessed or dispensed by such practitioner.


the aforementioned boards. NPs can dispense drug samples that are included within their written protocol with their supervising physician. PAs can dispense drug samples that are included in their practice agreement with their supervising physician. Finally, regulations governing the dispensation of drugs directly from the provider’s office for physicians set basic standards for storage and record-keeping that must accompany such practice.

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. A physician can dispense naloxone if he or she has obtained a license to dispense prescription medications. NPs, PAs and physicians without a dispensing license can only dispense drug samples of naloxone, which would be limited to naloxone doses provided at no cost by the manufacturer. If a program is able 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.

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25 We did not find a definition of drug samples in Virginia law; however, it appears from the related provisions that drug samples would be interpreted to mean drugs provided free by a manufacturer, and thus would not encompass purchased naloxone distributed free by a physician, PA or NP. Cf. Va. Code Ann. § 54.1-3401.1 (West 2007).
27 18 Va. Admin. Code 90-40-120 (2007) ("A nurse practitioner may dispense only those manufacturers' samples of drugs that are included in the written practice agreement as is on file with the board").
28 Supra fn 17.
30 We were unable to find any case or agency law describing what constitutes a "good cause" to issue a special or limited pharmacy permit. However, the pharmacy services required for a naloxone program could constitute the "special, limited or unusual nature" the pharmacy board envisioned. If so, a physician operated naloxone program would be legal in Virginia.
31 Supra fn 25.
   A drug shall be dispensed only in packaging approved by the current U.S.P.-N.F. for that drug. In the absence of such packaging standard for that drug, it shall be dispensed in a well-closed container.
   B. Drugs may be dispensed in compliance packaging for self-administration when requested by the patient or for use in hospitals or long-term care facilities provided that such packaging meets all current U.S.P.-N.F. standards for packaging, labeling and record keeping.
Any drug dispensed by filling or refilling a written or oral prescription of a prescriber shall be exempt from the requirements of § 54.1-3462 except subdivisions 1, 9, and 10, and the packaging requirements of subdivision 7, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.
Conclusion: Dispensing naloxone by valid prescription does not violate Virginia law and may be done on premises of the distribution program.

V. Is It Legal To Prescribe Or Dispense Naloxone For Recipients To Give Or Administer To Third Parties Who Have Not Been Prescribed The Drug By A Licensed Professional?

A legal prescription requires a specific patient who has been examined and found to have a medical indication for the drug. Before the drug can properly be dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to license sanctions. The patient or volunteer who 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 found no provision that made it a crime to possess or distribute 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 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{35} may carry license sanctions.\textsuperscript{36} 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.\textsuperscript{37} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{38}

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

\subsection*{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

\textsuperscript{35} Va. Code Ann. §54.1-2915:

A. The Board may refuse to admit a candidate to any examination; refuse to issue a certificate or license to any applicant; reprimand any person; place any person on probation for such time as it may designate; suspend any license for a stated period of time or indefinitely; or revoke any license for any of the following acts of unprofessional conduct:

\begin{itemize}
  \item \ldots
  \item 3. Intentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients;
  \item \ldots
  \item 12. Conducting his practice in a manner contrary to the standards of ethics of his branch of the healing arts;
  \item 13. Conducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public;
  \item \ldots
  \item 17. Violating any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing, or administration of drugs.
\end{itemize}


\textsuperscript{37} 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).

of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

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

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

B. Analysis

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

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

39 Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
impaired, 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.41

“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.42 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.43 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.44

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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 Virginia 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.

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 ODU’s via trained patients or volunteers (“Trained Overdose Responders” under NYS law); establish immunity for providers participating in such programs; and establish
immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.\textsuperscript{45}

\section*{C. Cooperation with First Responders}

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

\textsuperscript{45} N.Y. Pub. Health Law §3309 (McKinney 2006):

[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.