DATE: October 5, 2007

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

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 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. 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 lay persons, and to protect medical professionals from tort and other liability.

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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.
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 Pennsylvania is governed by the Medical Practice Act of 1985, with regulations found in the Pennsylvania Administrative Code. The State 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 beneath the standards of good faith and regular practice of medicine. The medical practice act does not define the basis or scope of the physician’s general authority to prescribe. However, Pennsylvania 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.

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 specific provisions, we presume a prescription for naloxone would be governed by the same broad principles govern prescriptions for controlled substances:

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10 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
A practitioner may prescribe, administer, or dispense a controlled substance or other drug or device only (i) in good faith in the course of his professional practice, (ii) within the scope of the patient relationship, and (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession.\(^\text{11}\)

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.\(^\text{12}\) The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\(^\text{13}\)

**B. Analysis**

While not explicitly required by Pennsylvania statutes, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing an appropriate 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 ODU patient is consistent with the standard for a valid prescription under Pennsylvania 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 are authorized to replace physicians in some or all aspects of a prescription program. Certified registered nurse practitioners (CRNPs), who have met the medical and nursing board program requirements, can prescribe prescription drugs without the direct supervision of a physician.\(^\text{14}\) Physician assistants (PAs) can also prescribe prescription drugs, but must do so under physician supervision and only for patients of the supervising physician.\(^\text{15}\)

A CRNP may prescribe and dispense drugs if the following requirements are met:

1. The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.
2. The CRNP has successfully completed at least 45 hours of course work specific to advanced pharmacology in accordance with the following:
   (i) The course work in advanced pharmacology may be either part of the CRNP education program or, if completed outside of the CRNP education program, an additional course or courses taken from an educational program or programs approved by the Boards.
   (ii) The course work in advanced pharmacology must be at an advanced level above a pharmacology course required by a professional nursing (RN) education program.
3. A CRNP who has prescriptive authority shall complete at least 16 hours of State Board of Nursing approved continuing education in pharmacology in the 2 years prior to the biennial renewal date of his or her CRNP certification. The CRNP shall show proof that she completed the continuing education when submitting a biennial renewal.
4. In prescribing and dispensing drugs, a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92–16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §§ 25.51–25.58, 25.61–25.81 and 25.91–25.95 (emphasis added).

CRNPs are required to work in a relationship with a collaborating or supervising physician. The relationship is defined as follows:

Direction—The incorporation of physician supervision to the certified registered nurse practitioner’s performance of medical acts in the following ways:

(i) Immediate availability of a licensed physician through direct communications or by radio, telephone or telecommunications.
(ii) A predetermined plan for emergency services which has been jointly developed by the supervising physician and the certified registered nurse practitioner.
(iii) A physician available on a regularly scheduled basis for:
   (A) Referrals.
   (B) Review of the standards of medical practice incorporating consultation and chart review.
   (C) Establishing and updating standing orders and drug and other medical protocols within the practice setting.
   (D) Periodic up-dating in medical diagnosis and therapeutics.
   (E) Co-signing records when necessary to document accountability by both parties.


(a) Prescribing, dispensing and administration of drugs.
A physician assistant may not practice in a location other than the primary practice location of the supervising physician unless that site has been registered with the Medical Board as a “satellite location.”

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Pennsylvania 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. With the necessary board approval and an appropriate collaboration agreement with a physician, a CRNP may staff a naloxone prescription program without direct, on-site physician oversight. A physician assistant may staff a naloxone program, but only in the company of a supervising physician and subject to the requirement of registration for satellite practice sites.

(1) The supervising physician may delegate to the physician assistant the prescribing, dispensing and administering of drugs …
(4) A physician assistant may only prescribe or dispense a drug for a patient who is under the care of the physician responsible for the supervision of the physician assistant and only in accordance with the supervising physician's instructions and written agreement.

(b) Prescription blanks. The requirements for prescription blanks are as follows:
(1) Prescription blanks must bear the license number of the physician assistant and the name of the physician assistant in a printed format at the heading of the blank. The supervising physician must also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).
(2) The signature of a physician assistant shall be followed by the initials 'PA-C' or similar designation to identify the signer as a physician assistant. When appropriate, the physician assistant's DEA registration number must appear on the prescription.
(3) The supervising physician is prohibited from presigning prescription blanks.
(4) The physician assistant may use a prescription blank generated by a hospital provided the information in paragraph (1) appears on the blank.
…
(e) Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drug. A physician assistant shall comply with §§ 16.92–16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and Department of Health regulations in 28 Pa. Code §§ 25.51–25.58 (relating to prescriptions) and regulations regarding packaging and labeling dispensed drugs. See § 16.94 and 28 Pa. Code §§ 25.91–25.95 (relating to labeling of drugs, devices and cosmetics) (emphasis added).

See also, Pa. Code tit. 49 § 18.122 (2007) (defining “supervision” as not including the constant physical presence of the physician).

17 Supra notes 14-16.
Conclusion: A CRNP may independently staff a naloxone prescription program; a physician assistant may assist a physician in conducting naloxone prescription. 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, as noted in the licensure law described in section I, in general it is recommended that a healthcare provider must formulate a therapeutic plan for their patient and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.

B. Analysis

The intended use of naloxone is to prevent opiate overdose. Indications for and methods of administration should be explained to patients, along with risks and benefits. Because of the nature of overdose, patients may not always be able to self-administer the necessary dose. Some overdose prevention programs properly instruct pairs or groups of patients in naloxone administration and other emergency measures so that patients can assist each other. Prescribing staff may also provide written and oral instructions that patients can relay to their friends, family, or others who can help administer the drug in an event of an overdose. Such instructions parallel information given to patients who may need emergency injections of insulin or epinephrine and are entirely consistent with the legal prescription of the drug. These instructions should include:

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 Pennsylvania 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 Pennsylvania is governed by the "Pharmacy Act,"\(^\text{18}\) with regulations found in the Pennsylvania Administrative Code.\(^\text{19}\) Pharmacists are generally expected to fill a prescription that meets regulatory guidelines.

The prescribing healthcare provider may also dispense the agent at the point of service. Physicians,\(^\text{20}\) nurse practitioners,\(^\text{21}\) and physician assistants\(^\text{22}\) can dispense prescription drugs at the point of service; however, a physician assistant must do so under physician supervision.\(^\text{23}\) If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirement to maintain a dispensation log, and proper labeling of the agent, including the patient’s name and other essential information.\(^\text{24}\)

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. Regulations governing the dispensation

\(^{20}\) Pa. Stat. Ann. tit. 63, § 390-8(2) (West 2007) (“[N]othing herein shall be construed to prevent a duly licensed medical practitioner from dispensing, compounding or otherwise giving any drug to his own patients after diagnosis or treatment of said patient, if such compounding, preparing and dispensing is done by said licensee himself”).
\(^{21}\) Supra note 14.
\(^{22}\) Supra notes 15-16.
\(^{23}\) Id.

(a) The label on a dispensed drug container shall include the name of the drug, using abbreviations if necessary; the quantity; and the name of the manufacturer if the drug is a generic drug. If a practitioner specifically indicates that the name of the drug may not appear on the label, the recognized national drug code number shall be placed on the label if the number is available for the product. The label shall also bear the name and address of the practitioner, the date dispensed, the name of the patient and the directions for use of the drug by the patient.

(b) Drugs which, at the time of their dispensing, have full potency for less than 1 year, as determined by the expiration date placed on the original label by the manufacturer, may only be dispensed with a label that indicates the expiration date. The label shall include the statement, ‘Do not use after manufacturer’s expiration date,’ or similar wording.
of drugs directly from the provider’s office set basic standards for storage and record-keeping that must accompany such practice.

**Conclusion:** Dispensing naloxone by valid prescription does not violate Pennsylvania 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 heavy fines.\(^{25}\) The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine and/or pharmacy without a license.\(^{26}\) 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.

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. 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

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It shall be unlawful for:

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(2) Any person not duly licensed as a pharmacist, pursuant to section 3 hereof, to engage in the practice of pharmacy, including the preparing, compounding, dispensing, selling or distributing at retail to any person any drug, except by a pharmacy intern or such other authorized personnel under the direct and immediate personal supervision of a pharmacist.
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\(^{27}\) may carry license sanctions\(^{28}\) and fines.\(^{29}\) There is little or no risk of professional


(a) A physician who engages in unprofessional or immoral conduct is subject to disciplinary action under section 41 of the act (63 P. S. § 422.41). Unprofessional conduct includes, but is not limited to, the following:

…

(2) Violating a statute, or a regulation adopted thereunder, which imposes a standard for the practice of medicine in this Commonwealth. The Board, in reaching a decision on whether there has been a violation of a statute, rule or regulation, will be guided by adjudications of the agency or court which administers or enforces the standard.

…

(8) Knowingly permitting, aiding or abetting a person who is not licensed or certified, or exempt from license or certification requirements, to perform activities requiring a license or certification in a health care practice.

…

(11) Possessing, using, prescribing for use or distributing a … legend drug in a way other than for an acceptable medical purpose. An acceptable experimental purpose is considered an acceptable medical purpose.

…

(14) Delegating a medical responsibility to a person when the physician knows or has reason to know that the person is not qualified by training, experience, license or certification to perform the delegated task.


(a) Temporary suspensions.--A license or certificate issued under this act may be temporarily suspended under circumstances as determined by the board to be an immediate and clear danger to the public health and safety. The board shall issue an order to that effect without a hearing, but upon due notice, to the licensee or certificate holder concerned at his or her last known address, which shall include a written statement of all allegations against the licensee or certificate holder. The provisions of section 9 shall not apply to temporary suspension. The board shall thereupon commence formal action to suspend, revoke or restrict the license or certificate of the person concerned as otherwise provided for in this act. All actions shall be taken promptly and without delay. Within 30 days following the issuance of an order temporarily suspending a license, the board shall conduct or cause to be conducted a preliminary hearing to determine that there is a prima facie case supporting the suspension. The licensee or certificate holder whose license or certificate has been temporarily suspended may be present at the preliminary hearing and may be represented by counsel, cross-examine witnesses, inspect physical evidence, call witnesses, offer evidence and testimony and make a record of the proceedings. If it is determined that there is not a prima facie case, the suspended license shall be
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. 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

immediately restored. The temporary suspension shall remain in effect until vacated by the board, but in no event longer than 180 days.

(a) General rule.--Any person …who violates any provisions of this act or any rule or regulation of the board commits a misdemeanor of the third degree and shall, upon conviction, be sentenced to pay a fine of not more than $2,000 or to imprisonment for not more than six months, or both, for the first violation. On the second and each subsequent conviction, he or she shall be sentenced to pay a fine of not less than $5,000 nor more than $20,000 or to imprisonment for not less than six months nor more than one year, or both.
(b) Civil penalties.--In addition to any other civil remedy or criminal penalty provided for in this act, the board, by a vote of the majority of the maximum number of the authorized membership of the board as provided by law, or by a vote of the majority of the duly qualified and confirmed membership or a minimum of five members, whichever is greater, may levy a civil penalty of up to $1,000 on any current licensee who violates any provision of this act or on any person who practices medicine and surgery or other areas of practice requiring a license, certificate or registration from the board without being properly licensed, certificated or registered to do so under this act. The board shall levy this penalty only after affording the accused party the opportunity for a hearing, as provided in Title 2 of the Pennsylvania Consolidated Statutes (relating to administrative law and procedure).

30 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); Sermchief v. Gonzalez, 660 S.W.2d 683 (Mo. banc 1983).
patient’s companion, a failure to seek timely medical help after the administration of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

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

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

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an 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

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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.34

“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.35 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.36 A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary resuscitation procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population.

In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly

negligent and unless a state expressly rejects the protection offered by the VPA. Pennsylvania law provides similar liability protections for a volunteer medical professional, who acts in good faith. It appears that under the Pennsylvania law, 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 Pennsylvania. 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 Pennsylvania 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.

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A holder of a volunteer license who, in good faith, renders professional health care services under this act shall not be liable for civil damages arising as a result of any act or omission in the rendering of care unless the conduct of the volunteer licensee falls substantially below professional standards which are generally practiced and accepted in the community and unless it is shown that the volunteer licensee did an act or omitted the doing of an act which the person was under a recognized duty to a patient to do, knowing or having reason to know that the act or omission created a substantial risk of actual harm to the patient.
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 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.39

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.