

Temple University Beasley School of Law

Project on Harm Reduction in the Health Care System

MEMORANDUM

DATE: August 15, 2007

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

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.**
- 2. Prescribing naloxone to ODU in this state is fully consistent with state and federal laws regulating drug prescribing.**

¹ See, e.g. Karen H. Seal, et al, *Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study*, 82(2), J. of Urban Health, 303–311 (2005).

- 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 patients² who, upon examination,³ 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 ODU's 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, and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license. (See Part V.)

Assuming the provider does not violate regulations that generally apply to drug prescription in 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.

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 Massachusetts is governed by the Medical Practice Act,⁴ with regulations found in title 243, Sections 1.00 through 2.10 of the Code of Massachusetts Regulations. The Board of Registration in Medicine (the "Board") is authorized to promulgate regulations regarding physicians practice.⁵ No provision of the Medical Practice Act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the Board to set limits on allowable practices, either by enacting specific regulations banning certain practices, or through the disciplinary process.⁶

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.⁷ Naloxone is not a controlled substance under state or federal law.⁸

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 a prescription of naloxone specifically.⁹ This reflects physicians' broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. State law offers no explicit standards for prescribing a prescription drug, but presumably the generic standards applicable to controlled substances provide a basic framework. Under

⁴ Mass. Gen. Laws ch. 112 § 2 (West 2007) et seq.

⁵ Mass. Gen. Laws ch. 112 § 2 (West 2007).

⁶ *Sugarman v. Board of Registration in Medicine*, 662 N.E.2d 1020 (Mass. 1996).

⁷ F.D.A. Bulletin, 37 Fed. Reg. 16, 503 (1972).

⁸ Controlled substance means a drug classified in any of the schedules (I through V) of the Controlled Substances Act, recognized to have a potential for abuse or to lead to physical or psychological dependence. 105 MA ADC 700.002 (West 2007). Naloxone is excluded as a controlled substance and is thus a “legend drug,” which requires a prescription. 114.3 MA ADC 31.02 (West 2007).

⁹ According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.

this standard, a prescription is valid if it is issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.¹⁰

In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on.¹¹

B. Analysis

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

II. May Anyone Other Than A 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. The regulations allow licensed allied health professionals to step in to collect routine sections of a

¹⁰ Mass. Gen. Laws. ch. 94C § 19(a) (West 2007). A similar standard is used throughout the country.

¹¹ See *State v. Young*, 406 S.E.2d 758, 771 (W.Va. 1991) (prescription written on street to patient who had not been properly examined was not in course of professional practice); see generally *United States v. Moore*, 423 U.S. 122, 142-43 ("[R]espondent's conduct exceeded the bounds of professional practice. [H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make.").

medical history, conduct some medical examinations, and issue actual prescriptions by following written guidelines issued by the supervising physician.¹² Advanced nurse practitioners can order tests and prescribe medications in collaboration with a physician.¹³ Physician assistants can order tests and issue written prescriptions under the supervision of a physician. Such supervision does not require the physical presence of the physician.¹⁴

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Massachusetts 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

¹² 244 MA ADC 4.22 (West 2007):

All nurses practicing in an expanded role ... shall practice in accordance with written guidelines developed in collaboration with and mutually acceptable to the nurse and to: (a) a physician expert by virtue of training or experience in the nurse's area of practice in the case of the nurse in the physician's office and the nurse in private practice; or (b) the appropriate medical staff and nursing administration staff of the institution employing the nurse.

(2) In all cases the written guidelines shall designate a physician who shall provide medical direction as is customarily accepted in the specialty area. Guidelines may authorize the nurse's performance of any professional activities included within her area of practice. The guidelines shall: (a) specifically describe the nature and scope of the nurse's practice; (b) describe the circumstances in which physician consultation or referral is required; (c) describe the use of established procedures for the treatment of common medical conditions which the nurse may encounter; and (d) include provisions for managing emergencies.

(3) In addition to the requirements of 244 CMR 4.22(2) the guidelines pertaining to prescriptive practice shall: (a) include a defined mechanism to monitor prescribing practices, including documentation of review with a supervising physician at least every three months;

¹³ M.G.L.A. 112 § 80B (West 2007) (“Advanced practice nursing [includes] the ordering of tests, therapeutics and prescribing of medications.”).

¹⁴ M.G.L.A. 112 § 9E (West 2007):

[A] physician assistant may perform medical services when such services are rendered under the supervision of a registered physician. Such supervision shall be continuous but shall not require the personal presence of the supervising physician or physicians. A registered physician shall supervise no more than two physician assistants at any one time.

A physician assistant may order tests and ... issue written prescriptions for patients. ... Any prescription of medication made by a physician assistant must include the name of the supervising physician.

If a physician assistant is employed by a physician or group of physicians, the assistant shall be supervised by and shall be the legal responsibility of the employing physician or physicians. The legal responsibility of such assistant shall remain that of the employing physician or physicians at all times including occasions when the assistant, under the direction and supervision of the employing physician or physicians, aids in the care and treatment of patients in health care facilities.

meet with a physician before a naloxone prescription is issued. A physician need not be present during the operation of a naloxone prescription program.

Conclusion: Allied health professionals may replace a physician the day to day operation of a naloxone prescription program. Advanced nurse practitioners and physician assistants may prescribe medications in collaboration with a physician. 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 may issue a prescription only for a legitimate medical purpose and in accordance with ordinary professional practice.¹⁵

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 Massachusetts 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

¹⁵ Cf. M.G.L.A. 94C § 19 (West 2007).

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 Massachusetts is governed by the Pharmacy Act,¹⁶ and the Code of Massachusetts Regulations.¹⁷ Physicians, physician assistants and advanced practice nurses may also dispense the agent at the point of service.¹⁸

If dispensing naloxone from a clinic¹⁹ there are regulations governing storage and record-keeping that must accompany such practice.²⁰ We were

¹⁶ Mass. Gen. Laws ch. 112 § 24 (West 2007).

¹⁷ Code of Massachusetts Regulations title 247, Sections 1.00 through 11.15, and title 105, Sections 722.001 through 722.100 (West 2007).

¹⁸ National Association of Boards of Pharmacy, *Survey of Pharmacy Law 2002-2003* (physicians, physician assistants and advanced practice nurses may dispense prescriptions).

¹⁹ 105 MA ADC 140.020 (West 2007):

Clinic means any entity, however organized, whether conducted for profit or not for profit, which is advertised, announced, established, or maintained for the purpose of providing ambulatory medical, surgical ... In addition, clinic shall include any entity, however organized, whether conducted for profit or not for profit, which is advertised, announced, established, or maintained under a name which includes the word clinic, "dispensary", or "institute", and which suggests that ambulatory medical, surgical ... are rendered therein. With respect to any entity which is not advertised, announced, established, or maintained under one of the names in the preceding sentence, clinic shall not include a medical office building, or one or more practitioners engaged in a solo or group practice, whether conducted for profit or not for profit, and however organized, so long as such practice is wholly owned and controlled by one or more of the practitioners so associated, or, in the case of a not for profit organization, its only members are one or more of the practitioners so associated or a clinic established solely to provide service to employees or students of such corporation or institution. No matter how the clinic is named, clinic shall not include a clinic conducted by a hospital ... or by the federal government, or the commonwealth.

²⁰ 105 MA ADC 140.347 (West 2007):

If the clinic does not maintain a clinic pharmacy, but drugs are stored and administered at the clinic directly to patients, the clinic shall comply with the requirements of 105 CMR 140.347. ...

(B) Record System. The clinic professional services director or his designee shall be responsible for ensuring that a record system is kept that is sufficient. ... The record keeping system shall comply with all federal and state laws and regulations.

(C) Storage of Drugs. Drugs shall be stored under proper conditions to ensure product stability and security. Drug storage facilities shall be locked.

(D) Medications for External Use. The clinic shall accurately label each

unable to find any further general dispensation standards but we recommend that healthcare providers dispense according to local custom.

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 from a clinic, it must follow standard dispensation rules. Those rules include the requirement to maintain a dispensation record and proper labeling of the agent, including the patient's name and other essential information. If dispensing otherwise, the healthcare providers should dispense according to local custom.

Conclusion: Dispensing naloxone by valid prescription does not violate Massachusetts 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

medication for external use as such, and shall store such medications separately from medications for internal use.

(E) Outdated Drugs. Outdated drugs shall be eliminated from the clinic's stock in accordance with clinic policies. All drugs shall be destroyed in accordance with applicable state and federal laws.

(G) Labeling. All drugs shall be adequately and distinctly labeled.

(H) Reference Source. The clinic shall provide at least one book or other standard source of information pertaining to current drugs for reference by clinic staff.

fines.²¹ 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.²² 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 making it illegal to possess a prescription drug without a valid 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 may carry license sanctions and punishment.²³ There is no risk of professional censure for participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

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.²⁴ Blatant non-compliance,

²¹ M.G.L.A. 112 § 5 (West 2007) (“A fine not to exceed ten thousand dollars for each classification of violation [for professional misconduct]”).

²² M.G.L.A. 112 § 6 (West 2007):

[W]hoever, not being lawfully authorized to practice medicine ... [or] holds himself out as a practitioner of medicine or practices or attempts to practice medicine in any of its branches, or whoever practices medicine under a false or assumed name or under a name other than that by which he is registered, or whoever personates another practitioner ... shall be punished by a fine of not less than one hundred nor more than one thousand dollars or by imprisonment for not less than one month nor more than one year, or both.

²³ 247 MA ADC 10.06 (West 2007).

²⁴ *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).

cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.²⁵

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."²⁶ 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,²⁷ and, in an actual case, by

²⁵ *Ethridge v. Ariz. State Bd. of Nursing*, 796 P.2d 899 (Ariz. App. 2 Div. 1989), *State v. Hartenbach*, 768 S.W.2d 657 (Mo. App. E. Dist. 1989).

²⁶ *Joudrey v. Nashoba Community Hosp.*, 592 N.E.2d 769 (Mass. App. Ct. 1992); Restatement (Second) of Torts, §282, 1993) Washington, DC: American Law Institute Publishers.

²⁷ See, e.g. John Strang, et al, *Heroin overdose: the case for take-home naloxone*, 312, *BMJ*, 1435-1436 (1996); Karen H. Seal, et al, *Naloxone distribution and cardiopulmonary resuscitation training for injection drug users to prevent heroin overdose death: A pilot intervention study*, 82(2), *J. of Urban Health*, 303-311 (2005); Bigg D. *Opiate Overdose Prevention/Intervention*

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.²⁸ 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.²⁹

“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.³⁰ However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable. A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is arguably too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary

Using Take-Home Naloxone. Paper presented at: 131st Annual Meeting of the American Public Health Association, November 18, 2003; San Francisco, California.

²⁸ MA ST Ch. 231 § 85; Ch. 231B §§ 1-4 (West 2007).

²⁹ *Speer v. U.S.*, 512 F.Supp. 670 (N.D. Tex. 1981); *Hobart v. Shin*, 705 N.E.2d 907 (Ill. 1998); *Walt’s Sheet Metal v. Deblar*, 826 P.2d 333 (Alaska 1992).

³⁰ *Glicklich v. Spievack*, 452 N.E.2d 287 (Mass. App. 1983).

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.³¹ This is effective so long as the agent responsible is a licensed health care provider acting voluntarily and without pay in the scope of his or her license. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. Thus, 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 Massachusetts law we have outlined above:

³¹ 42 U.S.C.A. § 14503 (West 2000).

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, a advanced nurse practitioner, or a licensed medical provider working in collaboration with a physician.
2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.
3. The prescription must be made out to the specific patient and must contain all the information required by law.
4. Each prescription should be accompanied by oral and/or written information on the following:
 - information on how to spot symptoms of an overdose;
 - instruction in basic resuscitation techniques;
 - instruction on proper naloxone administration, and
 - the importance of calling 911 for help.

B. Changes in 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.³²

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.

³² 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.