DATE: August 7, 2007

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

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 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 IDU patient?
2. May an allied health professional other than physician prescribe naloxone to an IDU patient?
3. What instructions should accompany naloxone prescription/dispensal?
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, 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; 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 IDU Patient?

A. Professional Licensure Law

The practice of medicine in Illinois is governed by the Medical Practice Act of 1987, with regulations in the Illinois Administrative Code. The Medical Licensing 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 law has been interpreted to authorize the Illinois Board of Medical Examiners to set limits on allowable practices, either by enacting specific regulations banning certain practices, or through the disciplinary process.  

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and 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.

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4 IL ST CH 225 §§ 60/1 to 60/63 (2007).
6 IL ST CH 225 § 60/8 (2007).
7 IL ST CH 225 § 60/22 (2007).
10 IL ST CH 720 § 570/102(f) (2007) (“Controlled Substance” means a drug, substance, or immediate precursor in the Schedules of Article II of this Act’); Naxolone is excluded from Schedule II of the Illinois Controlled Substances Act, so it is a prescription drug. IL ST CH 720 § 570/206(b)(1) (2007).
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
Illinois law does not define the extent or basis of the physician’s general authority to write prescriptions. This authority is assumed, as an aspect of the professional practice of medicine; however, the laws and regulations governing the prescription of controlled substances set out a standard that covers the principal elements of a valid prescription, which is consistent with the standard used across the nation under the Uniform Controlled Substances Act. Under this law, a prescription is valid if it is written in good faith and for a medical purpose, and in the regular course of professional treatment. 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. The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.

B. Analysis

While not explicitly required by Illinois statutes, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

Conclusion: A prescription for naloxone to an IDU patient is consistent with the standard for a valid prescription under Illinois 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 Physician Issue A Prescription For Naloxone?

13 Id.
A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice nurses and physician assistants may be delegated authority by a licensed physician to prescribe medication.

Advanced practice nurses (APNs) in Illinois must work in collaboration with a licensed physician, and there must be a written collaborative agreement defining the working relationship between the APN and the physician. For an APN to prescribe, the physician must include prescriptive authority within the scope of practice described in their written collaborative agreement.

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   a) A written collaborative agreement shall describe the working relationship of the advanced practice nurse with the collaborating physician and shall authorize the categories of care, treatment, or procedures to be performed by the advanced practice nurse. (Section 15-15(b) of the Act)
   b) The agreement shall be defined to promote the exercise of professional judgment by the advanced practice nurse commensurate with his or her education and experience. The services to be provided by the advanced practice nurse shall be services that the collaborating physician generally provides to his or her patients in the normal course of his or her clinical medical practice. The agreement need not describe the exact steps that an advanced practice nurse must take with respect to each specific condition, disease, or symptom, but must specify which authorized procedures require a physician's presence as the procedures are being performed. The collaborative relationship under an agreement shall not be construed to require the personal presence of a physician at all times at the place where services are rendered. Methods of communication shall be available for consultation with the collaborating physician in person or by telecommunications in accordance with established written guidelines as set forth in the written agreement. (Section 15-15(b) of the Act)
   c) A copy of the signed, written collaborative agreement must be available to the Division upon request from both the advanced practice nurse and the collaborating physician and shall be annually updated. An advanced practice nurse shall inform each collaborating physician of all collaborative agreements he or she has signed and provide a copy of these to any collaborating physician, upon request. (Section 15-15(d) of the Act).

   a) A collaborating physician who delegates limited prescriptive authority to an advanced practice nurse shall include that delegation in the written collaborative agreement. The prescriptive authority may include prescription and dispensing of legend drugs…
   c) The APN may only prescribe and dispense within the scope of practice of the collaborating physician.
   d) All prescriptions written and signed by an advanced practice nurse shall indicate the name of the collaborating physician. The collaborating physician's signature is not required. The advanced practice nurse shall sign his/her own name.
   e) An APN may receive and dispense samples per the collaborative agreement.
Physician does not need to be on-site with the APN each day, but specific conditions govern the communication between the physician and the APN.¹⁹

Physician assistants (PAs) must work with a supervising physician.²⁰ The supervising physician does not need to be on-site with the PA each day, but must be available within a reasonable travel distance to provide supervision if needed, or designate an alternate supervising physician if he or she is unable to provide appropriate supervision.²¹ The physician may delegate through written guidelines

f) Medication orders shall be reviewed periodically by the collaborating physician.

   a) Physician medical direction shall be adequate with respect to collaboration with Certified Nurse Practitioners…:
      1) participates in the joint formulation and joint approval of orders or guidelines with the advanced practice nurse and periodically reviews those orders and the services provided patients under those orders in accordance with accepted standards of medical practice and advanced practice nursing practice;
      2) is on site at least once a month to provide medical direction and consultation. On site is defined in the collaborative agreement; and
      3) is available through telecommunications for consultation on medical problems, complications, or emergencies or patient referral. [225 ILCS 60/54.5(b)]

…

   c) In the absence of the collaborating physician, another physician shall be available for consultation.

²⁰ IL ST CH 225 § 95/4 (2007), with specific provisions in IL ST CH 225 § 95/7 (2007):
   No more than 2 physician assistants shall be supervised by the supervising physician, although a physician assistant shall be able to hold more than one professional position. Each supervising physician shall file a notice of supervision of such physician assistant according to the rules of the Department. However, the alternate supervising physician may supervise more than 2 physician assistants when the supervising physician is unable to provide such supervision consistent with the definition of alternate physician in Section 4. Physician assistants shall be supervised only by physicians as defined in this Act who are engaged in clinical practice, or in clinical practice in public health or other community health facilities…Nothing in this Act shall be construed to prohibit the employment of physician assistants by a hospital…or other health care facility where such physician assistants function under the supervision of a supervising physician.
   …A physician assistant may be employed by a practice group or other entity employing multiple physicians at one or more locations. In that case, one of the physicians practicing at a location shall be designated the supervising physician. The other physicians with that practice group or other entity who practice in the same general type of practice or specialty as the supervising physician may supervise the physician assistant with respect to their patients without being deemed alternate supervising physicians for the purpose of this Act.

   …

   d) Any time the supervising physician is unable to provide the appropriate supervision to the physician assistant, he/she shall designate an alternate supervising physician to provide such supervision. The name(s) of the alternate supervising physician(s) shall be identified in the guidelines established by the supervising physician. If the supervising physician will be unable to supervise
prescriptive authority to a physician’s assistant. The supervising physician must review medication orders periodically, and his or her name must appear on the prescription order.

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Illinois 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. APNs with delegated prescriptive authority from a physician may prescribe drugs without the presence of the physician. PAs may be delegated prescriptive authority by a supervising physician. The PA’s supervising physician does not need to be on-site, but must be reasonably available.

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(a) A supervising physician may delegate limited prescriptive authority to a physician assistant. This authority may, but is not required to, include prescription and dispensing of legend drugs…Medication orders issued by a physician assistant shall be reviewed periodically by the supervising physician. The supervising physician shall file with the Department notice of delegation of prescriptive authority to a physician assistant and termination of delegation, specifying the authority delegated or terminated…Nothing in this Act shall be construed to limit the delegation of tasks or duties by the supervising physician to a nurse or other appropriately trained personnel. (Section 7.5 of the Act)

b) Written Guidelines.

1) If the supervising physician has delegated prescriptive authority to the physician assistant, the written guidelines shall include a statement indicating that the supervising physician has delegated prescriptive authority for legend drugs…The delegation must be appropriate to the physician's practice and within the scope of the physician assistant's training.

2) The written guidelines shall be signed by both the physician and the physician assistant and a copy maintained at each location where the physician assistant practices…

(c) A physician assistant may only prescribe or dispense prescriptions or orders for drugs and medical supplies within the scope of practice of the supervising physician or alternate supervising physician.

(d) The name of the supervising physician shall appear on any prescription written by the physician assistant.

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23 Id.
Conclusion: Allied health professionals may replace a physician in specific functions during the prescription process. APNs and PAs may be authorized by a supervising physician to prescribe medication. 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 patient a prescription for a diagnosed medical purpose for a patient in good faith and in the regular course of professional treatment. 24

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 Illinois 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.

24 IL ST CH 720 § 570/312 (2007).
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 Illinois is governed by the Pharmacy Practice Act of 1987, with regulations in the Illinois Administrative Code. Under these laws and regulations pharmacists are expected to fill a prescription that meets regulatory guidelines.

Physicians may dispense prescription drugs directly to patients at the point of service. APNs and PAs may be delegated the authority to dispense medication if the physician includes such authority in their written collaborative agreement. Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that must accompany such practice. These regulations include the requirement to maintain a dispensation record, and proper labeling of the agent, including the patient’s name and other essential information.

25 IL ST CH 225 § 85/1 (2007), et seq.
27 IL ST CH 225 s 60/33 (2007):
Any person licensed under this Act to practice medicine in all of its branches shall be authorized to purchase legend drugs requiring an order of a person authorized to prescribe drugs, and to dispense such legend drugs in the regular course of practicing medicine. The dispensing of such legend drugs shall be the personal act of the person licensed under this Act and may not be delegated to any other person not licensed under this Act or the Pharmacy Practice Act of 1987 unless such delegated dispensing functions are under the direct supervision of the physician authorized to dispense legend drugs…Prior to dispensing a prescription to a patient, the physician shall offer a written prescription to the patient which the patient may elect to have filled by the physician or any licensed pharmacy…A violation of any provision of this Section shall constitute a violation of this Act and shall be grounds for disciplinary action provided for in this Act.
28 Supra fn. 18. 68.
29 Supra fn. 22.
30 IL ST CH 225 § 60/33 (2007):
Except when dispensing manufacturers’ samples or other legend drugs in a maximum 72 hour supply, persons licensed under this Act shall maintain a book or file of prescriptions as required in the Pharmacy Practice Act of 1987. Any person licensed under this Act who dispenses any drug or medicine shall dispense such drug or medicine in good faith and shall affix to the box, bottle, vessel or package containing the same a label indicating (a) the date on which such drug or medicine is dispensed; (b) the name of the patient; (c) the last name of the person dispensing such drug or medicine; (d) the directions for use thereof; and (e) the proprietary name or names or, if there are none, the established name or names of the drug or medicine, the dosage and quantity,
B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

Conclusion: Dispensing naloxone by valid prescription does not violate Illinois 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 fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this

31 Infra fn 33.
32 IL ST CH 225 § 60/3.5(a) (2007):
Any person who practices, offers to practice, attempts to practice, or holds oneself out to practice as a physician without being licensed under this Act shall, in addition to any other penalty provided by law, pay a civil penalty to the Department in an amount not to exceed $5,000 for each offense as determined by the Department. The civil penalty shall be assessed by the Department after a

except as otherwise authorized by regulation of the Department of Professional Regulation. The foregoing labeling requirements shall not apply to drugs or medicines in a package which bears a label of the manufacturer containing information describing its contents which is in compliance with requirements of the Federal Food, Drug, and Cosmetic Act and the Illinois Food, Drug, and Cosmetic Act. "Drug" and "medicine" have the meaning ascribed to them in the Pharmacy Practice Act of 1987, as now or hereafter amended; "good faith" has the meaning ascribed to it in subsection (v) of Section 102 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended.
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, 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 fines. There no risk of professional censure for
participating in a naloxone prescription program run as described here. Our
analysis above makes clear that prescribing naloxone to ODU patients is well
within the normal parameters of medical practice.

33 IL ST CH 225 § 60/22 (2007): the Board has the power to take disciplinary action against a
physician and limit, revoke, or suspend a license upon any of the following grounds:
(3) The conviction of a felony in this or any other jurisdiction, except as
otherwise provided in subsection B of this Section, whether or not related to
practice under this Act, or the entry of a guilty or nolo contendere plea to a
felony charge.
(4) Gross negligence in practice under this Act.
(5) Engaging in dishonorable, unethical or unprofessional conduct of a character
likely to deceive, defraud or harm the public.
...
(13) Violation of any provision of this Act ... or violation of the rules, or a final
administrative action of the Director, after consideration of the recommendation
of the Disciplinary Board.
...
(17) Prescribing, selling, administering, distributing, giving or self-
administering any drug classified as a controlled substance (designated product)
or narcotic for other than medically accepted therapeutic purposes.
...

The Department may promulgate rules for the imposition of fines in disciplinary
cases, not to exceed $5,000 for each violation of this Act. Fines may be imposed
in conjunction with other forms of disciplinary action, but shall not be the
exclusive disposition of any disciplinary action arising out of conduct resulting
in death or injury to a patient. Any funds collected from such fines shall be
deposited in the Medical Disciplinary Fund.
Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct. Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.

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

A. The Legal Scheme

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

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

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

B. Analysis

34 *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).
Naloxone is the drug of choice for overdose. Assuming that the patient is an IDU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone, and, in an actual case, by expert testimony from clinicians and public health experts. If the prescription of naloxone is reasonable, there can be no tort liability even if the other elements of the case are established.

“But for” causation will be extremely difficult to establish where the injury results from overdose, because at the moment naloxone was administered serious injury was already likely to happen. Where the injury is caused by the rare occurrence of side effects of naloxone, the causal connection is still tenuous: the behavior of the injured party, in overdosing on heroin, is the key causal factor that necessitated treatment with the agent. Injury was likely to be as severe, if not more so, had naloxone not been administered. It is not considered malpractice to prescribe a drug that carries a low risk of side effects to avert death or severe impairment, particularly if the patient is adequately informed of the risks. Even in the unlikely cases in which “but for” factual causation may be established, the provider’s actions must represent a major contributing factor to the injury 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.

“Loss of chance” doctrine in tort law establishes liability when negligent or otherwise harmful behavior substantially contributes to an injury, even if the injury may have also occurred from other causes. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the “loss of a chance” to receive medical care. However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the

program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable.\footnote{Hobart v. Shin, 705 N.E.2d 907 (Ill. 1998).} 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 for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. 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 Illinois law we have outlined above:

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

B. Changes in 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.\(^{42}\)

C. Cooperation with First Responders

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

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\(^{42}\) 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.