Temple University Beasley School of Law

Project on Harm Reduction in the Health Care System

MEMORANDUM

DATE: December 24, 2007

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

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 the U.S. 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 U.S. 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 ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensation?
4. How may naloxone be dispensed?
5. Is it legal to prescribe or dispense naloxone for recipients to give or administer to third parties who have not been prescribed the drug by a licensed professional?
6. What is the risk of disciplinary action by a professional board arising from naloxone prescription or distribution, and how can the risk be minimized?
7. What kind of malpractice liability may arise from naloxone prescription or distribution, and how can the risk of liability be minimized?
Executive Summary

From a legal standpoint, naloxone is no different than any other prescription drug. Authorized medical professionals can prescribe and dispense naloxone in the same way they would any other drug. Naloxone is indicated for patients who, upon examination, are at risk of opiate overdose and who are judged by the professional to be capable of benefiting from naloxone administration. The amount of naloxone prescribed or dispensed depends upon the prescriber’s assessment of need. (See Parts I & II describing who may prescribe naloxone.)

As part of the process of prescribing, the patient should be given information about when and how to use the drug, as well as other steps that are advisable in responding to an overdose. Because a person suffering an overdose may not be able to administer the drug him or herself, it is also appropriate to (1) teach groups of patients how to administer the drug so that they can assist each other in an overdose emergency; and (2) instruct—in person, or through written materials—friends, family members and others who may witness an overdose how to administer the drug to a patient. It is not uncommon for third parties to assist patients in administering their drugs, for all sorts of reasons. The key legal requirement is that the recipient have a valid prescription for the drug. (See Parts III & IV.)

Because a legal prescription requires some examination and a specific medical indication, naloxone may not be prescribed or dispensed to patients or program participants to hand out or administer to other ODUs who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws; the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

Assuming the provider does not violate regulations that generally apply to drug prescription in this state, acts competently, and follows the additional guidelines we set out, criminal or civil liability is very unlikely to arise out of naloxone prescription activities. (See Parts VI and VII.) Presumably, few prosecutors would be hard-hearted enough to punish a person for saving a life, but an ODU who uses his or her own naloxone to save the life of a person who has not been prescribed the drug does, technically, break the law. A few states have taken positive action to clearly legalize emergency administration of naloxone by

---

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 Wisconsin is governed by the Medical Examining Board (the "Board"), with regulations in the Wisconsin Administrative Code. The Board has the authority to license physicians and to punish licensed physicians who behave in ways that violate the law or fall beneath the standards of good faith and regular practice of medicine. The statutory and administrative codes of Wisconsin do not explicitly define the basis or scope of the physician's general authority to prescribe. However, Wisconsin 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

---

4 Wis. Stat. Ann. § 448.01 (West 2007), et seq.
5 Wis. Admin. Code Med 1.01 (2007), et seq.
8 State v. Willstead, 248 Wis. 240 (1946).
10 Wis. Stat. Ann. §961.01(4) (West 2007) ("Controlled substance' means a drug, substance or immediate precursor included in schedules I to V of subch. II"); Wis. Stat. Ann. § 961.16(2)(a) (West 2007) (Naxolone is excluded from Schedule II of the Uniform Controlled Substances Act; therefore, it is a prescription or legend drug).
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the U.S.
agents such as naloxone in this state and elsewhere in the U.S. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances:

Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. … An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of §§ 450.01 (21) and 961.38, Stats. \(^{12}\)

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. \(^{13}\) The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. \(^{14}\)

B. Analysis

While not explicitly required by Wisconsin law, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination if necessary, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription.

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

A. Professional Licensure Law

\(^{14}\) Willstead, 248 Wis. 240.
Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice nurses (APNs) can write prescriptions, either by obtaining a license from the Board of Nursing or if delegated to prescribe by a physician.15 Physician assistants (PAs) can prescribe prescription drugs, in accordance with the

---


(2) The board shall grant a certificate to issue prescription orders to an advanced practice nurse who meets the education, training and examination requirements established by the board for a certificate to issue prescription orders, and who pays the fee specified under s. 440.05(1).
(3) The board shall promulgate rules necessary to administer this section, including rules for all of the following:

(4) Establishing procedures for maintaining a certificate to issue prescription orders, including requirements for continuing education.
(5) An advanced practice nurse who is certified to issue prescription orders may not delegate the act of issuing a prescription order to any nurse who is not certified to issue prescription orders.
(6) Nothing in this section prohibits a nurse from issuing a prescription order as an act delegated by a physician.


The advanced practice nurse prescriber:

1) May issue only those prescription orders appropriate to the advanced practice nurse prescriber's areas of competence, as established by his or her education, training or experience.

5) Shall, in prescribing or ordering a drug for administration by a registered nurse or licensed practical nurse under s. 441.16 (3) (cm), Stats., present evidence to the nurse and to the administration of the facility where the prescription or order is to be carried out that the advanced practice nurse prescriber is properly certified to issue prescription orders.


1) Prescription orders issued by an advanced practice nurse prescribers shall:

a) Specify the date of issue.

b) Specify the name and address of the patient.

c) Specify the name, address and business telephone number of the advanced practice nurse prescriber.

d) Specify the name and quantity of the drug product or device prescribed, including directions for use.

e) Bear the signature of the advanced practice nurse prescriber.
guidelines established with the supervising physician and under the supervision of a physician.\textsuperscript{16} The physician need not be on-site to supervise the PA.\textsuperscript{17}

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Wisconsin 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. ANPs with prescriptive authority from the Board of Nursing can prescribe medicine without the supervision of a physician.\textsuperscript{18} All nurse practitioners, with independent prescriptive authority or not, can prescribe, if delegated to do so by a physician.\textsuperscript{19}

Physician supervision is required for PAs to prescribe, but provided there were

\textsuperscript{16} Wisdom Statutes Annual, § 448.21(3) (West 2007);
A physician assistant may issue a prescription order for a drug … in accordance with guidelines established by a supervising physician and the physician assistant and with rules promulgated by the board. If any conflict exists between the guidelines and the rules, the rules shall control.

Wisconsin Administrative Code Med 8.08 (2007);
(1) A physician assistant may not prescribe … any drug independently.
(2) A physician assistant may issue a prescription order only if all the following conditions apply:
(a) The physician assistant issues the prescription order only in patient situations specified and described in established written guidelines. The guidelines shall be reviewed at least annually by the physician assistant and his or her supervising physician.
(b) The supervising physician and physician assistant determine by mutual agreement that the physician assistant is qualified through training and experience to issue a prescription order as specified in the established written guidelines.
(c) The supervising physician is available for consultation as specified in s. Med 8.10 (3).
(d) The prescription orders prepared under procedures in this section contain all information required under s. 450.11 (1), Stats.
(e) The supervising physician either:
1. Reviews and countersigns the prescription order prepared by the physician assistant, or
2. Reviews and countersigns within 72 hours the patient record prepared by the physician assistant practicing in the office of the supervising physician or at a facility or a hospital in which the supervising physician has staff privileges, or
3. Reviews by telephone or other means, as soon as practicable but within a 72-hour period, and countersigns within one week, the patient record prepared by the physician assistant who practices in an office facility other than the supervising physician's main office of a facility or hospital in which the supervising physician has staff privileges.

\textsuperscript{17} Wisdom Statutes Annual, § 448.21(3); Wisconsin Administrative Code Med 8.08.

\textsuperscript{18} Wisdom Statutes Annual, § 441.16; Wisconsin Administrative Code N 8.06; Wisconsin Administrative Code N 8.07.

\textsuperscript{19} Wisdom Statutes Annual, § 441.16; Wisconsin Administrative Code N 8.06; Wisconsin Administrative Code N 8.07.
written guidelines, a PA could staff a naloxone program without the on-site supervision of a physician.\textsuperscript{20}

**Conclusion:** Allied health professionals may replace a physician in specific functions during the prescription process. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

III. **What Instructions Should Accompany Naloxone Prescription or Dispensing?**

**A. The Regulatory Scheme**

In general it is recommended that a healthcare provider 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 Wisconsin 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

\textsuperscript{20} \textit{Wis. Stat. Ann.} § 448.21(3); \textit{Wis. Admin. Code Med} 8.08.
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 Wisconsin is governed by the Pharmacy Examining Board, with regulations found in the administrative code. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing healthcare provider may also dispense the agent at the point of service. Physicians in Wisconsin can dispense prescription drugs, with few restrictions. ANPs are limited to dispensing complimentary samples in their original containers or packaging, unless "the treatment facility at which the patient is treated is located at least 30 miles from the nearest pharmacy," in which case the ANP may dispense prescription drugs. Although complimentary samples are not defined in the statute, they could be interpreted to include pre-packaged doses of naloxone purchased from the manufacturer and delivered free to patients. PAs cannot dispense prescription drugs. 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.

---

21 WIS. STAT. ANN. § 450.01 (West 2007), et seq.
22 WIS. ADMIN. CODE PHAR 1.01 (2007), et seq.
23 NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW (2007); cf. WIS. STAT. ANN. § 961.38(4g) (West 2007) (Physicians' ability to dispense controlled substances).
24 Physicians dispensing a prescription drugs in the course of professional treatment is exempt from the requirements of the Pharmacy Examining Board. 41 Op.Atty.Gen. 23 (1952); WIS. ADMIN. CODE MED. 17.01-17.06 (2007).
   (1) Except as provided in sub. (2), advanced practice nurse prescribers shall restrict their dispensing of prescription drugs to complimentary samples dispensed in original containers or packaging supplied by a pharmaceutical manufacturer or distributor.
   (2) An advanced practice nurse prescriber may dispense drugs to a patient if the treatment facility at which the patient is treated is located at least 30 miles from the nearest pharmacy.
27 WIS. STAT. ANN. §450.11(1) (West 2007):
B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. A physician may dispense naloxone to participants, and an ANP may also do so provided the doses qualify as “samples” and are given away free of charge. PAs may not independently dispense naloxone. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirements for record keeping, packaging and proper labeling of the agent, including the patient’s name and other essential information. 28

Conclusion: Dispensing naloxone by valid prescription does not violate Wisconsin law and may be done by a physician and in some cases an ANP on the premises of the distribution program.

All prescription orders shall specify the date of issue, the name and address of the patient, the name and address of the practitioner, the name and quantity of the drug product or device prescribed, directions for the use of the drug product or device, the symptom or purpose for which the drug is being prescribed if required under sub. (4)(a)8., and, if the order is written by the practitioner, the signature of the practitioner.


(1) A prescription drug dispensed by a practitioner shall contain a legible label affixed to the immediate container disclosing:

(a) The name and address of the facility from which the prescribed drug is dispensed;
(b) The date on which the prescription is dispensed;
(c) The name of the practitioner who prescribed the drug or device;
(d) The full name of the patient;
(e) The generic name and strength of the prescription drug dispensed unless the prescribing practitioner requests omission of the name and strength of the drug dispensed; and,
(f) Directions for use of the prescribed drug and cautionary statements, if any, contained in the prescription or required by law.

(2) Nonapplication of labeling requirements. The labeling requirement specified in sub. (1) does not apply to complimentary samples dispensed by a practitioner in original containers or packaging supplied to the practitioner by a pharmaceutical manufacturer or distributor.

WIS. ADMIN. CODE MED 17.05(1) (2007):

(a) A practitioner shall maintain complete and accurate records of each prescription drug received, dispensed or disposed of in any other manner.
(b) All prescription drugs dispensed by a practitioner shall be recorded in the patient record.

WIS. ADMIN. CODE MED 17.06 (2007):

Prescription orders prepared by professional nurses and ancillary health care personnel, as delegated and supervised by a practitioner under s. 448.03 (2) (e), Stats., shall contain in addition to other information required by this chapter, the name, address and telephone number of the delegating practitioner and the name, address and signature of the person preparing the prescription order.
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. The patient or volunteer who dispensed naloxone to recipients who were not prescribed this agent could be charged with illegally dispensing prescription drugs and/or practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal.

Finally, the unauthorized recipient of the drug could be charged with illegal possession of a prescription drug, subject imprisonment and possibly a fine. While this is not a serious crime, even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

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

29 Wis. Stat. Ann. §448.09 (West 2007) (A physician who violates any provision of this subchapter, except s. 448.08 (3), or any rule promulgated under this subchapter may be fined not more than $25,000 or imprisoned not more than 9 months or both).
30 Wis. Stat. Ann §450.11(1) (“No person may dispense any prescribed drug or device except upon the prescription order of a practitioner”).
31 Wis. Stat. Ann. § 448.03(1) (Unlawful for someone to practice medicine without a license); Wis. Stat. Ann. § 448.09 (A person practicing medicine without a license shall be no more than $10,000 and/or imprisoned for no more than nine months).
32 Wis. Stat. Ann. §450.11(7)(h) (West 2007) (“No person may possess a prescription drug unless the prescription drug is obtained in compliance with this section”).
33 Wis. Stat. Ann. §450.11(9)(a) (West 2007) (“Except as provided in par. (b), any person who violates this section may be fined not more than $500 or imprisoned not more than 6 months or both”).
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 34 may carry fines or imprisonment.35 There is no risk of professional censure for participating in a naloxone prescription program. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply

34 WIS. ADMIN. CODE MED 10.02(2) (2007):
   The term "unprofessional conduct" is defined to mean and include but not be
   limited to the following, or aiding or abetting the same:
   (a) Violating or attempting to violate any provision or term of ch. 448, Stats., or
       of any valid rule of the board.
   (b) Violating or attempting to violate any term, provision, or condition of any
       order of the board.
   ...
   (g) Engaging or attempting to engage in the unlawful practice of medicine and
       surgery or treating the sick.
   (h) Any practice or conduct which tends to constitute a danger to the health,
       welfare, or safety of patient or public.
   (i) Practicing or attempting to practice under any license when unable to do so
       with reasonable skill and safety to patients.
   (j) Practicing or attempting to practice under any license beyond the scope of
       that license.
   ...
   (t) Aiding or abetting the unlicensed practice of medicine or representing that
       unlicensed persons practicing under supervision, including unlicensed M.D.'s
       and D.O's, are licensed, by failing to identify the individuals clearly as
       unlicensed physicians or delegates.
   ...
   (z) Violating or aiding and abetting the violation of any law or administrative
       rule or regulation the circumstances of which substantially relate to the
       circumstances of the practice of medicine.

35 WIS. STAT. ANN. §448.09 (West 2007) (A physician who violates any provision of this subchapter, except s. 448.08 (3), or any rule promulgated under this subchapter may be fined not more than $25,000 or imprisoned not more than 9 months or both).
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

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

36 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).
38 Manke v. Physicians Ins. Co. of Wis., Inc., 289 Wis.2d 750 (Wis. App. 2006); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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.40

“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.41 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.42 A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-

---

42 Schneider Fuel & Supply Co. v. Thomas H. Bentley & Son, Inc., 26 Wis.2d 549 (1965).
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.43

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 Wisconsin law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician or licensed medical provider working in collaboration with a physician.
2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.
3. The prescription must be made out to the specific patient and must contain all the information required by law.
4. Each prescription should be accompanied by oral and/or written information on the following:

information on how to spot symptoms of an overdose;
instruction in basic resuscitation techniques;
instruction on proper naloxone administration, and
the importance of calling 911 for help.

B. Changes in State Law

Under the current law of this state, dispensing or administering naloxone to third parties who have not been prescribed the drug is illegal. Passing legislation to allow these practices would help reduce overdose deaths and ease the concerns of providers and clients about possible legal penalties. New York’s legislature recently passed a law to provide clear authorization of medical providers to “prescribe” or “dispense” naloxone to unknown 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.  

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.

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.