DATE: August 13, 2007

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

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 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 Missouri is governed by the State Board of Registration for the Healing Arts, with regulations in the Missouri Administrative Code. The State Board of Registration for the Healing Arts 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 Missouri do not explicitly define the basis or scope of the physician's general authority to prescribe. However, the State Board of Registration for the Healing Arts is authorized 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 in the state, nor is there case-law challenging the legality of prescription of naloxone specifically. This reflects

---

8 State v. Hathaway, 115 Mo. 36 (Mo. 1893).
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances:

A physician … certified to administer pharmaceutical agents … in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.\(^{12}\)

In determining whether a prescription arises within the usual course of professional practice, courts 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 medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\(^{14}\)

**B. Analysis**

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

**Conclusion:** A prescription for naloxone to an IDU patient is consistent with the standard for a valid prescription under Missouri 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?**


\(^{13}\) State v. Kane, 586 S.W.2d 812 (Mo. App. E. Dist. 1979); see United States v. Moore, 423 U.S. 122 (U.S. 1975).

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 (APNs) are permitted to prescribe prescription drugs, as long as this is included in their collaborative practice arrangement with their supervising physician.\(^{15}\) Registered professional nurses (RPNs) cannot prescribe.\(^{16}\) Physician

(2) Geographic Areas.
(A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating registered professional nurse or advanced practice nurse as to create an impediment to effective collaboration in the delivery of health care services or the adequate review of those services.

\(\ldots\)

(3) Methods of Treatment.
(A) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated in a collaborative practice arrangement between a collaborating physician and collaborating registered professional nurse or advanced practice nurse shall be within the scope of practice of each professional and shall be consistent with each professional's skill, training, education, and competence.
(B) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating registered professional nurse or advanced practice nurse and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.
(C) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall also be consistent with the scope of practice of the collaborating physician.
(D) Guidelines for consultation and referral to the collaborating physician or designated health care facility for services or emergency care that is beyond the education, training, competence, or scope of practice of the collaborating registered professional nurse or advanced practice nurse shall be established in the collaborative practice arrangement.
(E) The methods of treatment and authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall not be further delegated to any other person except that the individuals identified in sections 338.095 and 338.198, \(\ldots\) may communicate prescription drug orders to a pharmacist.
(F) The methods of treatment, including any authority to administer or dispense drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that shall describe a specific sequence of orders, steps, or procedures to be followed in providing patient care in specified clinical situations.
(G) The methods of treatment, including any authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating advanced practice nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that are specific to the clinical conditions treated by the
collaborating physician and collaborating advanced practice nurse.

(H) The collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse or advanced practice nurse shall be signed and dated by the collaborating physician and collaborating registered professional nurse or advanced practice nurse before it is implemented, signifying that both are aware of its content and agree to follow the terms of the collaborative practice arrangement. The collaborative practice arrangement and any subsequent notice of termination of the collaborative practice arrangement shall be in writing and shall be maintained by the collaborating professionals for a minimum of eight (8) years after termination of the collaborative practice arrangement. The collaborative practice arrangement shall be reviewed and revised as needed by the collaborating physician and collaborating registered professional nurse or advanced practice nurse.

(I) Methods of treatment delegated and authority to administer, dispense, or prescribe drugs shall be subject to the following:
1. The physician retains the responsibility for ensuring the appropriate administering, dispensing, prescribing and control of drugs utilized pursuant to a collaborative practice arrangement in accordance with all state and federal statutes, rules, or regulations;
2. All labeling requirements outlined in section 338.059, … shall be followed;
3. Consumer product safety laws and Class B container standards shall be followed when packaging drugs for distribution;
4. All drugs shall be stored according to the United States Pharmacopeia (USP) recommended conditions, which is incorporated by reference;
5. Outdated drugs shall be separated from the active inventory;
6. Retrievable dispensing logs shall be maintained for all prescription drugs dispensed and shall include all information required by state and federal statutes, rules, or regulations;
7. All prescriptions shall conform to all applicable state and federal statutes, rules, or regulations and shall include the name, address, and telephone number of the collaborating physician and collaborating advanced practice nurse;
8. A registered professional nurse shall not, under any circumstances, prescribe drugs;
…
10. An advanced practice nurse or registered professional nurse in a collaborative practice arrangement may only dispense starter doses of medication to cover a period of time for seventy-two (72) hours or less with the exception of Title X family planning providers or publicly funded clinics in community health settings that dispense medications free of charge. The dispensing of drug samples, as defined in 21 U.S.C. section 353 (c)(1), is permitted as appropriate to complete drug therapy; and
11. The medications to be administered, dispensed, or prescribed by a collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating registered professional nurse or advanced practice nurse.

(J) When a collaborative practice arrangement is utilized to provide health care services for conditions other than acute self-limited or well defined problems, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating advanced practice nurse or registered professional nurse.
…
assistants (PAs) can prescribe prescription drugs, but must do so under the on-site supervision of a physician.\textsuperscript{17}

(4) Review of Services.
(A) In order to assure true collaborative practice and to foster effective communication and review of services, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall be immediately available for consultation to the collaborating registered professional nurse or advanced practice nurse at all times, either personally or via telecommunications.
(B) The collaborating physician shall review the work, records, and practice of the health care delivered pursuant to a collaborative practice arrangement at least once every two (2) weeks. This review shall be documented by the collaborating physician. This subsection shall not apply to the situation described in subsection (4)(E) below or during the time the collaborating physician and collaborating advanced practice nurse are practicing together as required in subsection (2)(C) above.

…
(D) The collaborating physician and collaborating registered professional nurse or advanced practice nurse shall determine an appropriate process of review and management of abnormal test results which shall be documented in the collaborative practice arrangement.

…
(F) The process and documentation of review shall be on file and maintained in the collaborative practice setting.
(G) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Nursing separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee’s participation in a collaborative practice arrangement.

\textsuperscript{16} \textit{Id.}
\textsuperscript{17} \textit{Mo. Rev. Stat. Ann. § 334.735(2) (West 2007):}

1. As used in sections 334.735 to 334.749, the following terms mean:

…
(8) "\textit{Supervision\textquotedblright}, control exercised over a physician assistant working within the same office facility of the supervising physician except a physician assistant may make follow-up patient examinations in hospitals … each such examination being reviewed, approved and signed by the supervising physician. The board shall promulgate rules pursuant to chapter 536 … for the proximity of practice between the physician assistant and the supervising physician and documentation of joint review of the physician assistant activity by the supervising physician and the physician assistant.

2. The scope of practice of a physician assistant shall consist only of the following services and procedures:

…
3. Physician assistants shall not prescribe nor dispense any drug … independent of consultation with the supervising physician … Prescribing and dispensing of drugs … by a physician assistant shall be pursuant to a physician assistant supervision agreement which is specific to the clinical conditions treated by the supervising physician and the physician assistant shall be subject to the following:

…
(2) The types of drugs … prescribed or dispensed by a physician assistant shall be consistent with the scopes of practice of the physician assistant and the supervising physician;
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Missouri 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 can prescribe, as long it is within the scope of the collaborative agreement with their supervising physician. PAs can prescribe under the on-site supervision of a physician.

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

As noted in the licensure law described in sections I and II, 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

(3) All prescriptions shall conform with state and federal laws and regulations and shall include the name, address and telephone number of the physician assistant and the supervising physician;
(4) A physician assistant or advanced practice nurse as defined in section 335.016 … may request, receive and sign for noncontrolled professional samples and may distribute professional samples to patients;
…
(6) A physician assistant may only dispense starter doses of medication to cover a period of time for seventy-two hours or less.
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 Missouri should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

**Conclusion:** Program participants receiving a take-home dose of naloxone should receive verbal and written instructions on how and when to use this drug. Program staff should not instruct patients to administer naloxone to persons who do not have a valid prescription for the drug.

### IV. How May Naloxone be Dispensed?

#### A. The Regulatory Scheme

Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. The practice of pharmacy in Missouri is governed by the Missouri Board of Pharmacy, 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 Missouri can dispense prescription drugs. ANPs and RPNs in collaborative arrangements with supervising physicians can dispense starter doses of medication and professional samples. Like ANPs and RPNs, PAs can dispense starter doses and professional samples, but they must consult with their supervising physician before dispensing. Finally, healthcare providers should follow regulations governing the dispensation of drugs directly

---

21 Starter doses are limited to a seventy-two hour supply. *Supra* fn 15.
22 *Supra* fn 15.
23 *Supra* fn 17.
from the provider’s office, which are basic standards for storage and record-keeping that must normally accompany such practice, unless they are distributing professional samples, which should adhere 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, whether it be a physician, advanced nurse practitioner or physician assistant. If a program decides to dispense naloxone on premises, it should follow standard dispensation rules.

Conclusion: Dispensing naloxone by valid prescription does not violate Missouri 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

1. It shall be the duty of … a physician to affix or have affixed by someone under the … physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:
   (1) The date the prescription is filled;
   (2) The sequential number;
   (3) The patient's name;
   (4) The prescriber's directions for usage;
   (5) The prescriber's name;
   (6) The name and address of the pharmacy;
   (7) The exact name and dosage of the drug dispensed;
   (8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";

2. The label of any drug which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.
A physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to license sanctions. The patient or volunteer who dispensed naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no law that made it a crime to possess a prescription drug without a prescription.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another patient. But a program in this state that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

VI. What Is The Risk Of Disciplinary Action By A Professional Board Arising Kind Of Medical Discipline Or Criminal Liability May Arise From Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules may carry license sanctions or fines. There is no risk of professional censure for participating in a naloxone prescription program. Our analysis above makes clear

---


1. Upon application by the board, and the necessary burden having been met, a court of general jurisdiction may grant an injunction, restraining order or other order as may be appropriate to enjoin a person from:

   …

   (2) Engaging in any practice or business authorized by a certificate of registration or authority, permit or license issued pursuant to this chapter upon a showing that the holder presents a substantial probability of serious danger to the health, safety or welfare of any resident of the state or client or patient of the licensee.

   …

3. Any action brought under this section shall be in addition to and not in lieu of any penalty provided by this chapter and may be brought concurrently with other actions to enforce this chapter.
that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct. Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.

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

A. The Legal Scheme

Any practice of medicine implies a risk that something may go wrong. In the context of a naloxone prescription/dispensing program, a patient may suffer one of the rare side effects from the drug. An error in administration by a 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.

28 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).
B. Analysis

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,\(^{31}\) 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.\(^{32}\)

“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.\(^{33}\) 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 resuscitation procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population. In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent and unless a state expressly rejects the protection offered by the VPA. Missouri law provides similar liability for volunteers of non-profit organizations. 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.

Any volunteer of a nonprofit organization or governmental entity shall be immune from personal liability for any act or omission resulting in damage or injury to any person intended to receive benefit from such volunteer's service if:
(1) The volunteer acted in good faith and within the scope of his official functions and duties with the organization or entity; and
(2) The damage or injury was not caused by the intentional or malicious conduct or by the negligence of such volunteer.
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 Missouri 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.37

   [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.
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.