MEMORANDUM

DATE: August 20, 2007

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

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 have 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 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, 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

---

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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in Kentucky is governed by the Medical Practice Act, with regulations found in the Kentucky Administrative Code. The State Board of Medical Licensure (the "Board") has the authority to license physicians, and to punish licensed physicians who behave in ways that violate the law or beneath the standards of good faith and regular practice of medicine. The law has been interpreted to authorize the Board to set limits on allowable practices, either by enacting specific regulations banning certain practices, or through the disciplinary process.

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: “[a] practitioner may…[a]dminister, dispense, or prescribe a legend drug for a legitimate medical purpose and in the course of professional practice.”

In determining whether a prescription arises within the “course of professional practice,” courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether

---

5 Ky. Admin. Regs. 9:005 (2007), et seq.
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.\textsuperscript{12} The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{13}

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.\textsuperscript{14} This reflects physicians' broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

\textbf{B. Analysis}

Physicians are required to follow certain procedures when issuing prescriptions, including conducting a physical examination as appropriate, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

\textit{Conclusion}: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Kentucky laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

\textbf{II. May Anyone Other Than Physician Issue A Prescription For Naloxone?}

\textbf{A. Professional Licensure Law}

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Physician assistants (PAs) may be delegated authority from a supervising physician to prescribe.

\textsuperscript{13} \textit{Commonwealth v. Sears}, 206 S.W.3d 309 (Ky. 2006).
\textsuperscript{14} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
legend drugs to patients.\textsuperscript{15} Advanced registered nurse practitioners (ARNPs) may also prescribe legend drugs, if it is encompassed within a written collaborative agreement with a licensed physician that defines the scope of their prescriptive authority.\textsuperscript{16}


(1) A physician shall not supervise a physician assistant without approval of the board. Failure to obtain board approval as a supervising physician or failure to comply with the requirements of KRS 311.840 to 311.862 or related administrative regulations shall be considered unprofessional conduct and shall be subject to disciplinary action by the board that may include revocation, suspension, restriction, or placing on probation the supervising physician's right to supervise a physician assistant.

(2) To be approved by the board as a supervising physician, a physician shall:

(a) Be currently licensed and in good standing with the board;
(b) Maintain a practice primarily within this Commonwealth. The board in its discretion may modify or waive this requirement;
(c) Submit a completed application and the required fee to the board. The application shall include but is not limited to:
1. A description of the nature of the physician's practice;
2. A statement of assurance by the supervising physician that the scope of medical services and procedures described in the application or in any supplemental information shall not exceed the normal scope of practice of the supervising physician;
3. A description of the means by which the physician shall maintain communication with the physician assistant when they are not in the same physical location;
4. The name, address, and area of practice of one (1) or more physicians who agree in writing to accept responsibility for supervising the physician assistant in the absence of the supervising physician; and
5. A description of the scope of medical services and procedures to be performed by the physician assistant for which the physician assistant has been trained in an approved program.


Advanced registered nurse practitioners...shall be authorized to issue prescriptions for and dispense nonscheduled legend drugs as defined in KRS 217.905...under the conditions set forth in KRS 314.042 and regulations promulgated by the Kentucky Board of Nursing on or before August 15, 2006.


Before an advanced registered nurse practitioner engages in the prescribing or dispensing of nonscheduled legend drugs as authorized by KRS 314.011(8), the advanced registered nurse practitioner shall enter into a written "Collaborative Agreement for the Advanced Registered Nurse Practitioner's Prescriptive Authority for Nonscheduled Legend Drugs" (CAPA-NS) with a physician that defines the scope of the prescriptive authority for nonscheduled legend drugs.
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Kentucky law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. An ARNP or a PA could staff an overdose prevention program including the prescription of naloxone, provided that the activities carried out were consistent with their collaboration or supervision agreements with 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

According to the licensure law described in sections I and II, a healthcare provider may prescribe drugs for a medical purpose and in the course of professional practice. This means that a prescription for naloxone is subject to professional standards, which would include the requirements that proper records are kept and that the patient is instructed in the indications, risks and proper administration of the prescribed medication.

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:

I. 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 Kentucky 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. Under the pharmacy laws and regulations, pharmacists are expected to fill a prescription that meets regulatory guidelines. Physicians and ARNPs may also dispense legend drugs at the point of service. PAs may distribute professional samples of drugs to patients. We did not find any provisions regulating the storage or labeling of drugs dispensed from the provider’s office, but we recommend that drugs be dispensed according to local custom.

**B. Analysis**

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Physicians and ARNPs can dispense the drug directly to the clients. PAs may dispense samples only.

---

21 Id; Supra fn. 16.
22 Ky. Rev. Stat. Ann. § 311.858(4) (2007) (“A physician assistant who is delegated prescribing authority may request, receive, and distribute professional sample drugs to patients’’); Ky. Admin. Regs. 2:105 (2007)(3) (“‘Drug sample’ means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug’’).
Conclusion: Dispensing naloxone by valid prescription does not violate Kentucky law and may be done on premises of the distribution program by physicians or ARNPs.

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 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 (legend) drug, subject to fines. 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 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.

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.


1. Prescrib[ing] or dispens[ing] any medication:
   (a) With the intent or knowledge that a medication will be used or is likely to be used other than medicinally or for an accepted therapeutic purpose....
   (b) With the intent to evade any law with respect to sale, use, or disposition of the medication;
   (d) In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that said amounts so prescribed or dispensed are excessive under accepted and prevailing medical practice standards; or
   (e) In response to any communication transmitted or received by computer or other electronic means, when the licensee fails to take the following actions to establish and maintain a proper physician-patient relationship:
      1. Verification that the person requesting medication is in fact who the patient claims to be;
      2. Establishment of a documented diagnosis through the use of accepted medical practices; and
      3. Maintenance of a current medical record.
2. Conduct which is calculated or has the effect of bringing the medical profession into disrepute, including, but not limited to, any departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky, and any departure from, or failure to conform to the principles of medical ethics of the American Medical Association.
with the rules and regulations of professional conduct.\textsuperscript{27} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{28}

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

\subsection*{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.”\textsuperscript{29} 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.

\subsection*{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

\begin{itemize}
  \item \textsuperscript{27} \textit{Williams v Ohio Bd. of Nursing}, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); \textit{Sermchief v. Gonzales}, 660 S.W.2d 683 (Mo. banc 1983).
  \item \textsuperscript{29} \textit{Knopp v. Thornton}, 250 S.W. 853 (Ky. App. 1923); Restatement (Second) of Torts, §282, 1993)
\end{itemize}
clinical literature discussing take-home naloxone,\textsuperscript{30} 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.\textsuperscript{31} 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.\textsuperscript{32}

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


\textsuperscript{31} \textit{Gerberich v. Gaillard}, 338 S.W.2d 216 (Ky. App. 1960).

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.\textsuperscript{33} It appears that volunteers working with naloxone distribution programs would be immune from any liability.

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 Kentucky law we have outlined above:

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

B. Changes in State Law

\textsuperscript{33} 42 U.S.C.A. § 14503 (West 2000).
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.34

C. Cooperation with First Responders

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


[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.