DATE: August 8, 2007

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

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. 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.**

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2. Prescribing naloxone to ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.
3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.
4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODUs who are not patients.
5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an IDU patient?
2. May an allied health professional other than physician prescribe naloxone to an IDU patient?
3. What instructions should accompany naloxone prescription/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 ODU’s who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws, and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

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

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2 We will refer to a person who has received a legal prescription for naloxone as a “patient.”
3 We will define examination, generally, as an interaction sufficient to allow the physician to determine the patient's diagnosis and treatment needs in the context of the service being sought or medical issues being raised.
lay persons, and to protect medical professionals from tort and other liability. Such legislation can help lower legal barriers and increase access to naloxone here. (See “Conclusion.”)

The Legal Analysis in Detail

I. May a Physician Legally Prescribe Naloxone to an IDU Patient?

A. Professional Licensure Law

The practice of medicine in Indiana is governed by the Medical Practice Act of 1975, with regulations found in the Indiana Administrative Code. The Medical Licensing Board (the "Board") has the authority to license physicians and to punish licensed physicians who behave in ways that violate the law or fall below 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] prescription or drug order for a legend drug is not valid unless the prescription or drug order is issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's business.”

No Indiana cases have explicitly defined "usual course of the practitioner’s business,” but courts have relied on reasoning from other states that consider such indicia 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

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5 844 Ind. Admin. Code 1-1-1 (West 2007), et seq.
7 Bd. of Medical Registration and Examination v. Moore, 70 N.E.2d 354 (Ind. 1947).
9 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Substances Act, Ind. Code Ann. § 35-48-1-2 to 35-48-7-14 (West 2007), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. Ind. Code Ann. § 16-18-2-199 (West 2007).
individualized assessment of the patient's risk factors, efforts to provide other harm reducing services, follow up and so on.\(^\text{11}\)

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.\(^\text{12}\) This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\(^\text{13}\)

**B. Analysis**

While not explicitly required by Indiana statutes, it is prudent for physicians as a general matter of law to follow certain procedures indicative of good faith and legitimate professional practice when issuing prescriptions to all prescription drugs. These include providing a physical examination if appropriate, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

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

Allied health professionals in Indiana are authorized to replace physicians in some or all aspects of a prescription program. Advanced nurse practitioners (ANPs) may assess clients by gathering patient histories and conducting


\(^{12}\) According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.

examinations, diagnose conditions, and develop and monitor treatment plans.\textsuperscript{14} ANPs may prescribe medication, but only if they apply to the Board of Nursing for such authority and if approved may only prescribe what is within the scope of a collaborating physician’s practice.\textsuperscript{15} The collaborating physician does not need...

\textsuperscript{14} 848 Ind. Admin. Code 4-2-1 (West 2007).
\textsuperscript{15} 848 Ind. Admin. Code 5-1-1 (West 2007):

   a) An advanced practice nurse may be authorized to prescribe legend drugs...if the advanced practice nurse does the following:
      (1) Submits an application on a form prescribed by the board with the required fee, including, but not limited to, the following information:
          (A) Complete name, residence and office addresses with zip codes, and residence and business telephone numbers with area codes.
          (B) All names used by the applicant, explaining the reasons for any name change or use.
          (C) Date and place of birth.
          (D) Citizenship and visa status, if applicable.
          (E) A complete statement of all nursing education received, providing the following:
              (i) Names and locations of all colleges, schools, or universities attended.
              (ii) Dates of attendance.
              (iii) Degrees obtained or received.
          (F) Whether the applicant has ever had any disciplinary action taken against the applicant's nursing license by the board or by the licensing agency of any other state or jurisdiction and the details and dates thereof.
          (G) A complete list of all places of employment...
          (H) Whether the applicant is, or has been, addicted to any narcotic drug, alcohol, or other drugs and, if so, the details thereof.
          (I) Whether the applicant has been convicted of any violation of law relating to drug abuse, controlled substances, narcotic drugs, or any other drugs.
          (J) Whether the applicant has previously been licensed to practice nursing in any other state or jurisdiction...
          (K) Whether the applicant has been denied a license to practice nursing by any state or jurisdiction and, if so, the details thereof...
          (L) A certified statement that the applicant has not been convicted of a criminal offense (excluding minor traffic violations) or a certified statement listing all criminal offenses of which the applicant has been convicted.
          (M) All information in the application shall be submitted under oath or affirmation, subject to the penalties for perjury.
      (2) Submits proof of holding an active, unrestricted:
          (A) Indiana registered nurse license; or
          (B) registered nurse license in another compact state and having filed a Multi-state Privilege Notification Form with the health professions bureau.
      (3) Submits proof of having met the requirements of all applicable laws for practice as an advanced practice nurse in the state of Indiana.
      (4) Submits proof of a baccalaureate or higher degree in nursing.
      (5) If the applicant holds a baccalaureate degree only, submits proof of certification as a nurse practitioner or certified nurse-midwife by a national organization recognized by the board and which requires a national certifying examination.
      (6) Submits proof of having successfully completed a graduate level pharmacology course consisting of at least two (2) semester hours of academic credit from a college or university accredited by the Commission on Recognition of Postsecondary Accreditation:
          (A) within five (5) years of the date of application; or
to be physically present with the ANP, but the ANP must submit documentation of his or her prescribing practices to the collaborating physician at least every seven days. Physician assistants (PAs) may be delegated the authority to prescribe legend drugs by their supervising physician, but they must follow the

(B) if the pharmacology course was completed more than five (5) years immediately preceding the date of filing the application, the applicant must submit proof of the following:
(i) Completing at least thirty (30) actual contact hours of continuing education during the two (2) years immediately preceding the date of the application, including a minimum of at least eight (8) actual contact hours of pharmacology, all of which must be approved by a nationally approved sponsor of continuing education for nurses.
(ii) Prescriptive experience in another jurisdiction within the five (5) years immediately preceding the date of the application.
(7) Submits proof of collaboration with a licensed practitioner in the form of a written practice agreement that sets forth the manner in which the advanced practice nurse and licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to patients. Practice agreements shall be in writing and shall also set forth provisions for the type of collaboration between the advanced practice nurse and the licensed practitioner and the reasonable and timely review by the licensed practitioner of the prescribing practices of the advanced practice nurse. Specifically, the written practice agreement shall contain at least the following information:
(A) Complete names, home and business addresses, zip codes, and telephone numbers of the licensed practitioner and the advanced practice nurse.
(B) A list of all other offices or locations besides those listed in clause (A) where the licensed practitioner authorized the advanced practice nurse to prescribe.
(C) All specialty or board certifications of the licensed practitioner and the advanced practice nurse.
(D) The specific manner of collaboration between the licensed practitioner and the advanced practice nurse, including how the licensed practitioner and the advanced practice nurse will:
(i) work together;
(ii) share practice trends and responsibilities;
(iii) maintain geographic proximity; and
(iv) provide coverage during absence, incapacity, infirmity, or emergency by the licensed practitioner.
(E) A description of what limitation, if any, the licensed practitioner has placed on the advanced practice nurse's prescriptive authority.
(F) A description of the time and manner of the licensed practitioner's review of the advanced practice nurse's prescribing practices. The description shall include provisions that the advanced practice nurse must submit documentation of the advanced practice nurse's prescribing practices to the licensed practitioner within seven (7) days. Documentation of prescribing practices shall include, but not be limited to, at least a five percent (5%) random sampling of the charts and medications prescribed for patients.
(G) A list of all other written practice agreements of the licensed practitioner and the advanced practice nurse.
(H) The duration of the written practice agreement between the licensed practitioner and the advanced practice nurse.

16 Id.
supervising physician’s written protocol for prescriptive procedure. The supervising physician must review the PA’s patient encounters within 24 hours,

(a) Except as provided in this section, a physician assistant may prescribe, dispense, and administer drugs…to the extent delegated by the supervising physician.

…

(e) A physician assistant may not prescribe drugs unless the physician assistant has successfully completed at least thirty (30) contact hours in pharmacology from an educational program that is approved by the committee.

…

(g) Before a physician assistant may prescribe drugs, the physician assistant must have been continuously employed as a physician assistant for not less than one (1) year after graduating from a physician assistant program approved by the committee. To be considered to have been continuously employed as a physician assistant for a year for purposes of this subsection, a person must have worked as a physician assistant more than one thousand eight hundred (1,800) hours during the year.

Ind. Code Ann. § 25-27.5-5-6 (West 2007):

a) Except as provided in section 4(d) of this chapter, a supervising physician may delegate authority to a physician assistant to prescribe:
(1) legend drugs, except as provided in section 4(c) of this chapter; and

…

(b) Any prescribing authority delegated to a physician assistant must be expressly delegated in writing by the physician assistant's supervising physician, including:
(1) the name of the drug or drug classification being delegated by the supervising physician; and
(2) the protocols the physician assistant shall use when prescribing the drug.

(c) A physician assistant who is delegated the authority to prescribe legend drugs or medical devices must do the following:
(1) Enter the following on each prescription form that the physician assistant uses to prescribe a legend drug or medical device:
(A) The signature of the physician assistant.
(B) The initials indicating the credentials awarded to the physician assistant by the NCCPA.
(C) The physician assistant's state license number.
(2) Comply with all applicable state and federal laws concerning prescriptions for legend drugs and medical devices.
(d) A supervising physician may delegate to a physician assistant the authority to prescribe only legend drugs and medical devices that are within the scope of practice of the licensed supervising physician or the physician designee.


(a) A physician assistant must engage in a dependent practice with physician supervision. A physician assistant may perform, under the supervision of the supervising physician, the duties and responsibilities that are delegated by the supervising physician and that are within the supervising physician's scope of practice, including prescribing and dispensing drugs and medical devices. A patient may elect to be seen, examined, and treated by the supervising physician.
(b) If a physician assistant determines that a patient needs to be examined by a physician, the physician assistant shall immediately notify the supervising physician or physician designee.

(f) A physician assistant's supervisory agreement with a supervising physician must:
but does not need to be physically present when the PA is providing medical services.\textsuperscript{19}

\textbf{B. Analysis}

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Indiana law. In the same way, a prescription issued by allied health professionals in accordance with the relevant regulations is valid. A consultation with an allied health professional may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued. ANPs and PAs can be authorized in Indiana to prescribe medicine when working in collaboration with a physician. Specific and detailed conditions govern the communication between the “collaborating physician,” an allied health professional, and the patient. These rules must be met for the prescription to be valid.

\textbf{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.

\section*{III. What Instructions Should Accompany Naloxone Prescription or Dispensing?}

\textbf{A. The Regulatory Scheme}

(1) be in writing;

(2) include all the tasks delegated to the physician assistant by the supervising physician;

(3) set forth the supervisory plans for the physician assistant, including the emergency procedures that the physician assistant must follow; and

(4) specify the name of the drug or drug classification being delegated to the physician assistant and the protocol the physician assistant shall follow in prescribing a drug.

(g) The physician shall submit the supervisory agreement to the board for approval. The physician assistant may not prescribe a drug under the supervisory agreement until the board approves the supervisory agreement. Any amendment to the supervisory agreement must be resubmitted to the board for approval, and the physician assistant may not operate under any new prescriptive authority under the amended supervisory agreement until the agreement has been approved by the board.

\textsuperscript{19} \textit{Ind. Code Ann.} \textsection 25-27.5-6-1 (West 2007):

\begin{itemize}
  \item a) Supervision by the supervising physician or the physician designee must be continuous but does not require the physical presence of the supervising physician at the time and the place that the services are rendered.
  \item b) A supervising physician or physician designee shall review all patient encounters not later than twenty-four (24) hours after the physician assistant has seen the patient.
\end{itemize}
According to the licensure law described in sections I and II, a healthcare provider may prescribe medication for legitimate medical purposes within the usual course of the physician’s business, which is understood to mean the physician must evaluate a patient sufficiently to support a diagnosis for a need for the treatment plan and monitor the patient’s condition.\textsuperscript{20}

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 Indiana 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 Act,\textsuperscript{21} with regulations found in title 856 of the Indiana Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines. The prescribing physician,

\textsuperscript{20} Ind. Code Ann. § 16-42-19-20(a) (West 2007)
ANP, or PA may also dispense the agent at the point of service, as long as the drug is labeled with directions for use, the name of the patient, and the name and address of the dispensing practitioner.\textsuperscript{22} They may also dispense professional samples of drugs at the point of service, if oral instructions for proper use of the drug are given.\textsuperscript{23}

\textbf{B. Analysis}

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

\textbf{Conclusion: Dispensing naloxone by valid prescription does not violate Indiana law and may be done on premises of the distribution program.}

\section*{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

\textsuperscript{22} \textit{Ind. Code Ann. § 16-42-19-5 (West 2007)}:

\textit{As used in this chapter, "practitioner" means any of the following:}

\begin{itemize}
  \item [1)] A licensed physician.
  \item [2)] An advanced practice nurse who meets the requirements of IC 25-23-1- 19.5 [requirements for APNs to be authorized to prescribe legend drugs].
  \item [3)] A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.
\end{itemize}

\textsuperscript{23} \textit{Id.}
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
license sanctions. 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.

24 Ind. Admin. Code 5-4-1(b) (West 2007):
Except in institutional settings, on-call situations, cross-coverage situations, and
situations involving advanced practice nurses with prescriptive authority
practicing in accordance with the requirements of IC 25-23-1-19.4 and 848 IAC
5, as described in subsection (d), a physician shall not prescribe, dispense, or
otherwise provide, or cause to be provided, any legend drug that is not a
controlled substance to a person who the physician has never personally
physically examined and diagnosed unless the physician is providing care in
consultation with another physician who has an ongoing professional
relationship with the patient, and who has agreed to supervise the patient’s use of
the drug or drugs to be provided.

25 Ind. Code Ann. § 25-22.5-8-1 (West 2007) (“It is unlawful for any person to practice
medicine…in this state without holding a license or permit to do so”). Ind. Code Ann. § 25-22.5-
8-2 makes this offense a Class C felony, punishable under Ind. Code Ann. § 35-50-2-6 by
imprisonment between 2 and 8 years and/or a fine up to $10,000.

26 Ind. Code Ann. § 16-42-19-13 (West 2007) (“A person may not possess or use a legend drug or
a precursor unless the person obtains the drug…on the prescription or drug order of a
practitioner”). Ind. Code Ann. § 16-42-19-27 makes this offense a Class D felony, punishable
under § 35-50-2-7 by imprisonment between 6 months and 3 years and/or a fine of up to $10,000.
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.\textsuperscript{27} 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 with the rules and regulations of professional conduct.\textsuperscript{28} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{29}

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

\textsuperscript{27} Ind. Code Ann. § 25-22.5-2-7 (West 2007).
\textsuperscript{28} Williams \textit{v} Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); Sermchief \textit{v.} Gonzales, 660 S.W.2d 683 (Mo. banc 1983).

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

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

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applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.33

“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.34 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.35 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.36 It appears that volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

**Conclusion:** The risk of tort liability in a naloxone program is low. Conceptually, this risk is no different from any other healthcare context. By

following state rules and general standards of practice, providers can protect themselves from the imposition of tort liability. Malpractice insurance and laws that apply specifically to volunteer providers may provide additional protection.

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state. However, as with any healthcare practice, institutions and professionals providing this service should follow the relevant rules and regulations that govern their practice to avoid professional, civil, and criminal liability.

The following is a summary of the program guidelines dictated by Indiana 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

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 IDUs.

[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.