DATE: August 20, 2007

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

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.**

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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 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 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; 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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in Tennessee is governed by the "Tennessee Medical Practice Act,"\textsuperscript{4} with regulations found in the Rules and Regulations of the State of Tennessee.\textsuperscript{5} The State Board of Medical Examiners (the "Board") has the authority to license physicians\textsuperscript{6} 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.\textsuperscript{7} Tennessee case law authorizes the Board to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.\textsuperscript{8}

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.\textsuperscript{9} Naloxone is not a controlled substance under state or federal law.\textsuperscript{10} Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug, whereby a physician must perform an appropriate history and physical examination, make a diagnosis based on that examination, formulate a therapeutic plan and insure adequate follow-up care before prescribing a prescription drug.\textsuperscript{11}

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\item \textsuperscript{4}Tenn. Code Ann. § 63-6-101 (West 2007), et seq.
\item \textsuperscript{5}Tenn. Comp. R. & Regs. 0880-2-.01 (West 2007), et seq.
\item \textsuperscript{6}Tenn. Code Ann. § 63-6-201 (West 2007).
\item \textsuperscript{7}Tenn. Code Ann. § 63-6-214 (West 2007).
\item \textsuperscript{8}Swafford v. Harris, 967 S.W.2d 319 (Tenn. 1998).
\item \textsuperscript{9}F.D.A. Bulletin, 37 Fed. Reg. 16, 503 (1972).
\item \textsuperscript{10}Tenn. Code Ann. § 39-17-402 (West 2007) ("Controlled substance’ means a drug, substance, or immediate precursor in Schedules I through VI of §§ 39-17-403 -- 39-17-415’); Tenn. Code Ann. § 39-17-408(b)(1) (West 2007) (Naxolone is excluded from Schedule II controlled substances, so it is a legend drug).
\item \textsuperscript{11}Tenn. Comp. R. & Regs 0880-2-.14(7) (2007):
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\item Except as provided in subparagraph (b), it shall be a prima facie violation of T.C.A. § 63-6-214 (b) (1), (4), and (12) for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the Internet or over telephone lines, unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done
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Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically. This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. Disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances. These cases apply the familiar standard under which a prescription is valid if it is written for a legitimate medical purpose, in the normal course of professional practice.

B. Analysis

Physicians are required to follow certain procedures when issuing prescriptions for all prescription drugs, which are stated above. 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).

and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed, all of the following:
1. Performed an appropriate history and physical examination; and
2. Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and
3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatments options, a part of which might be the prescription or dispensed drug, with the patient; and
4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.

(b) A physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, may prescribe or dispense drugs for a person not in compliance with subparagraph (a) consistent with sound medical practice, examples of which are as follows:
1. In admission orders for a newly hospitalized patient; or
2. For a patient of another physician for whom the prescriber is taking calls or for whom the prescriber has verified the appropriateness of the medication; or
3. For continuation medications on a short-term basis for a new patient prior to the patient's first appointment; or
4. For established patients who, based on sound medical practices, the physician feels do not require a new physical examination before issuing new prescriptions.

According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.


Supra fn 11.
Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Tennessee laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone. Some of the prescription tasks can be delegated to allied health professionals.

II. May Anyone Other Than Physician Issue A Prescription For Naloxone?

A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Nurse practitioners (NPs) can write prescriptions, but they must do so under the supervision and control of a physician.15 NPs must also meet advanced educational requirements

(a) The board shall issue a certificate of fitness to nurse practitioners who meet the qualifications, competencies, training, education and experience, pursuant to § 63-7-207(14), sufficient to prepare such persons to write and sign prescriptions and/or issue drugs within the limitations and provisions of § 63-1-132.
(b)(1) A nurse who has been issued a certificate of fitness as a nurse practitioner pursuant to § 63-7-207 and this section shall file a notice with the board, containing the name of the nurse practitioner, the name of the licensed physician having supervision, control and responsibility for prescriptive services rendered by the nurse practitioner, and a copy of the formulary describing the categories of legend drugs to be prescribed and/or issued by the nurse practitioner. The nurse practitioner shall be responsible for updating this information.

…

(3)(A) Any prescription written and signed or drug issued by a nurse practitioner under the supervision and control of a supervising physician shall be deemed to be that of the nurse practitioner. Every prescription issued by a nurse practitioner pursuant to this section shall be entered in the medical records of the patient and shall be written on a preprinted prescription pad bearing the name, address, and telephone number of the supervising physician and of the nurse practitioner, and the nurse practitioner shall sign each prescription so written. Where the preprinted prescription pad contains the names of more than one (1) physician, the nurse practitioner shall indicate on the prescription which of those physicians is the nurse practitioner's primary supervising physician by placing a checkmark beside or a circle around the name of that physician.
(B) Any handwritten prescription order for a drug prepared by a nurse practitioner who is authorized by law to prescribe a drug must be legible so that it is comprehensible by the pharmacist who fills the prescription. The handwritten prescription order must contain the name of the prescribing nurse practitioner; the name and strength of the drug prescribed; the quantity of the drug prescribed, handwritten in both letters and numerals; instructions for the proper use of the drug; and the month and day that the prescription order was issued, recorded in letters or in numerals or a combination thereof. The prescribing nurse practitioner must sign the handwritten prescription order on the day it is issued, unless the prescription order is:

…
and must be recommended for prescriptive authority by the "primary care board at the site where they are practicing."¹⁶ Physician assistants (PAs) also can prescribe, if delegated to do so under the supervision of a physician.¹⁷ PAs must

(ii) Prescribed by a nurse practitioner in the department of health or local health departments, or dispensed by the department of health or a local health department as stipulated in § 63-10-205.

(C) Any typed or computer-generated prescription order for a drug issued by a nurse practitioner who is authorized by law to prescribe a drug must be legible so that it is comprehensible by the pharmacist who fills the prescription order. The typed or computer-generated prescription order must contain the name of the prescribing nurse practitioner; the name and strength of the drug prescribed; the quantity of the drug prescribed, recorded in letters or in numerals; instructions for the proper use of the drug; and the month and day that the typed or computer-generated prescription order was issued, recorded in letters or in numerals or a combination thereof. The prescribing nurse practitioner must sign the typed or computer-generated prescription order on the day it is issued, unless the prescription order is:

(ii) Prescribed by a nurse practitioner in the department of health or local health departments, or dispensed by the department of health or a local health department as stipulated in § 63-10-205.

(D) Nothing in this section shall be construed to prevent a nurse practitioner from issuing a verbal prescription order.

(4) The nurse practitioner shall maintain a copy of the protocol the nurse practitioner is using at the nurse practitioner's practice location and shall make the protocol available upon request by the board of nursing, the board of medical examiners or authorized agents of either board.

(c)(1) The board may issue a temporary certificate of fitness to a registered nurse who:

(A) Is licensed to practice in Tennessee;

(B) Has a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills that includes three (3) quarter hours of pharmacology instruction or its equivalent; and

(C) Has applied for examination and/or is awaiting examination results for national certification as a first-time examinee in an appropriate nursing specialty area.

(2) Such temporary certificate shall remain valid until the examination results are obtained. The holder of a temporary certificate issued under the provisions of this subsection (c), who has not received the results of the examination, shall work only under the supervision and control of a certified nurse practitioner or physician.

(d) Any rules that purport to regulate the supervision of nurse practitioners by physicians shall be jointly adopted by the board of medical examiners and the board of nursing (emphasis added).

We were unable to find any definition of "supervision and control." We recommend that NPs adhere to local custom.


(A) In accordance with rules adopted by the board and the committee, a supervising physician may delegate to a physician assistant working under the physician's supervision the authority to prescribe and/or issue legend drugs …

(B) A physician assistant to whom the authority to prescribe legend drugs … has been delegated by the supervising physician shall file a notice with the
notify the Board of Medical Examiners' Committee on Physician Assistants (the "Committee") when the supervising physician grants them prescriptive privileges.\footnote{id}

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Tennessee 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. NPs can prescribe under the "supervision and control of a supervising physician;" however, the Tennessee statutory code does not define "supervision and control." Likewise, PAs can dispense when delegated to so by under the "supervision" of a physician. In the absence of a definition of "control" or "supervision," we recommend that NPs and PAs follow local custom with respect to physician involvement when prescribing prescriptions for naloxone in an overdose prevention program. 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.

\footnote{id}
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 must 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.\textsuperscript{19}

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 Tennessee 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

\textsuperscript{19} Supra fn 11.
Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. The practice of pharmacy in Tennessee is governed by the Tennessee Pharmacy Act of 1996,\textsuperscript{20} with regulations found in the Tennessee Rules and Regulations.\textsuperscript{21} 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 can dispense prescription drugs and professional samples.\textsuperscript{22} NPs can dispense prescription drugs, but they must do so under the supervision and control of a physician.\textsuperscript{23} PAs can also dispense prescription drugs, but they also must do so under the supervision of a physician.\textsuperscript{24} Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage, labeling and record-keeping must to accompany such practice.\textsuperscript{25} Physicians dispensing professional samples\textsuperscript{26} are not required to adhere to these labeling requirement.\textsuperscript{27}

### B. Analysis

\textsuperscript{20}Tenn. Code Ann. § 63-10-201 (West 2007).
\textsuperscript{21}Tenn. Comp. R. & Regs. 1140-1-.01 et seq. (West 2007).
\textsuperscript{22}Tenn. Comp. R. & Regs. 0880-2-.14 (West 2007):
Physicians who elect to dispense medication for remuneration must comply with the following:

\textsuperscript{24}Tenn. Code Ann. § 63-19-107(F) (West 2007) ("No drugs shall be dispensed by a physician assistant except under the supervision, control, and responsibility of the supervising physician").
\textsuperscript{25}Supra fn 21.
\textsuperscript{26}While there is no definition for a "professional sample," Tennessee statutory and case law define a "sample" as a drug distributed for free by a physician to his or her patients. Tenn. Comp. R. & Regs. title 1320, Ch. 5-1-.47. \textit{American Cyanamid Co. v. Huddleston}, 908 S.W.2d 396, rehearing denied, appeal denied (Tenn. App. 1995).
\textsuperscript{27}Supra fn 21.
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, which include the requirements for record keeping and proper labeling of the agent, including the patient’s name and other essential information.\textsuperscript{28}

**Conclusion:** Dispensing naloxone by valid prescription does not violate Tennessee law and may be done on premises of the distribution program.

V. Is It Legal To Prescribe Or Dispense Naloxone For Recipients To Give Or Administer To Third Parties Who Have Not Been Prescribed The Drug By A Licensed Professional?

A legal prescription requires a specific patient who has been examined and found to have a medical indication for the drug. Before the drug can properly be dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to heavy fines.\textsuperscript{29} The patient or volunteer who distributed or administered naloxone

\textsuperscript{28} *Supra* fn 21.

\textsuperscript{29} Tenn. Comp. R. & Regs. 0880-2-.12(4) (2007):

(a) Purpose - The purpose of this is to set out a schedule designating the minimum and maximum civil penalties which may be assessed pursuant to T.C.A. §63-1-134.

(b) Schedule of Civil Penalties

1. A Type A civil penalty may be imposed whenever the Board finds the person who is required to be licensed or certified, permitted or authorized by the Board guilty of a willful and knowing violation of the Practice Act, or regulations promulgated pursuant thereto, to such an extent that there is, or is likely to be an imminent, substantial threat to the health, safety and welfare of an individual client or the public. For purposes of this section, willfully and knowingly practicing medicine without a license, certification or other authorization from the Board is one of the violations of the Medical Practice Act for which a Type A civil penalty is assessable.

2. A Type B civil penalty may be imposed whenever the Board finds the person who is required to be licensed or certified, permitted or authorized by the Board is guilty of a violation of the Medical Practice Act, or regulations promulgated
to recipients who were not prescribed this agent could be charged with practicing medicine without a license.\footnote{Tenn. Ann. Code § 63-6-203(a) (West 2007): (1) Any person who practices medicine or surgery in this state without having first complied with the provisions of this chapter commits a Class B misdemeanor for each instance of such practice. (2) Each time any person practices medicine or surgery without first obtaining a valid certificate or renewing a certificate constitutes a separate offense.}

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,\footnote{Tenn. Code Ann. § 53-10-104(a) (West 2007): It is unlawful for any person … to possess, sell, barter or give away any drug known as a legend drug, as defined in § 53-10-101, except upon the written prescription of a duly licensed physician; certified physician assistant; nurse authorized pursuant to § 63-6-204 or § 63-9-113, who is rendering service under the supervision, control and responsibility of a licensed physician, and who meets the requirements pursuant to § 63-7-123.} subject imprisonment and possibly a fine.\footnote{Tenn. Code Ann. § 53-10-108 (West 2007) (Any person … possessing … any drug in violation of this part or violating any other provision of this part commits a Class C misdemeanor’); Tenn. Code Ann. § 40-35-111(3) (West 2007) (“Class C felony, not less than three (3) years nor more than fifteen (15) years. In addition, the jury may assess a fine not to exceed ten thousand dollars ($10,000), unless otherwise provided by statute”).} While this is not a serious crime, even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another

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\item \textbf{pursuant thereto}, in such a manner as to impact directly on the care of patients or the public.
\item 3. A Type C civil penalty may be imposed whenever the Board finds the person who is required to be licensed by the Board or certified, permitted or authorized by the Board is guilty of a violation of the Medical Practice Act, or regulations promulgated pursuant thereto, which are neither directly detrimental to the patients or public, nor directly impact their care, but have only indirect relationship to patient care or the public.
\item \textbf{(c) Amount of Civil Penalties}
\begin{enumerate}
\item Type A Civil Penalties shall be assessed in the amount of not less than $500 or more than $1,000.
\item Type B Civil Penalties may be assessed in the amount of not less than $100 and not more than $500.
\item Type C Civil Penalties may be assessed in the amount of not less than $50 and not more than $100.
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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 is no risk of professional censure for participating in a naloxone prescription program. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

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

33 Tenn. Code Ann. § 63-6-214:
(b) The grounds upon which the board shall exercise such power include, but are not limited to:
(1) Unprofessional, dishonorable or unethical conduct;
(2) Violation or attempted violation, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter or any lawful order of the board issued pursuant thereto, or any criminal statute of the state of Tennessee;
...
(12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.


35 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).

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

A. The Legal Scheme

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

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

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

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an ODU at risk of a fatal overdose and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone, and, in an actual case, by 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.

37 Godbee v. Dimick, 213 S.W.3d 865 (Tenn. App. 2006); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
“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.\(^{39}\)

“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.\(^{40}\) 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.\(^{41}\) 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. \(^{42}\) Tennessee law provides similar liability for volunteer
medical professionals. \(^{43}\) Volunteer medical professional must provide "services
within the limits of the person's license, certification or authorization, voluntarily
and without compensation" and immunity exists so long as the "act or omission
was [not] the result of such person's gross negligence or willful misconduct." \(^{44}\)
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 context 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
Tennessee 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.

\(^{44}\) Tenn. Code Ann. § 63-6-708 (West 2007).
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.45

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.

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[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.