DATE: August 22, 2007

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

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 ODUs who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws; the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

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

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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 Mississippi is governed by the State Board of Medical Licensure, with regulations in the Mississippi 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 fall beneath the standards of good faith and regular practice of medicine. The statutory and administrative codes of Mississippi do not explicitly define the basis or scope of the physician's general authority to prescribe. However, the Board is authorized to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug.

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is

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10 Miss. Code Ann. § 41-29-105 (West 2007) ("Controlled substance' means a drug, substance or immediate precursor in Schedules I through V of Sections 41-29-113 through 41-29-121"); Miss. Code Ann. §41-29-105(A)(a)(1) (Naloxone is excluded from Schedule II of the Uniform Controlled Substances Law, so it is treated as a prescription drug).
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. In the absence of specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances: "[n]o physician shall prescribe, administer or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore."  The Board is

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

12 Code Miss. Rules 50-031-001(XXIII)(D)(6)(Comment):

A determination as to whether a 'good faith prior examination and medical indication therefore' exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he may recommend a course of treatment to relieve the symptoms and cure the patient of his ailment or maintain him in an apparent state of good health. In order for a physician to achieve a proper diagnosis and treatment plan, a history and physical examination consistent with the nature and complaint are necessary. The importance of these aspects of proper medical practice cannot be over emphasized. The paramount Importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician must take three steps: (a) take and record an appropriate medical history, (b) carry out an appropriate physical examination, and (c) record the results. The observance of these principles as a function of the 'course of legitimate professional practice' is particularly of importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the physician to dispense, prescribe or administer such drugs with proper regard for the actual and potential dangers. This fact has been established in a number of closely related administrative and criminal cases, United States v. Bartee, 479 F.2d 484 (10th Cir. 1973) (No physical examination prior to issuance of prescriptions for controlled substances); United States v. Greene, 511 F.2d 1062 (7th Cir. 1975); Arthurs v. Board of Registration of Medicine, 418 N.E. 2d 1236 (MA 1981) (failure to record in patient file prescriptions for controlled substances issued or failure to record patient visit); Bralnard v. State Board of Medical Examiners, 157 P2d 7 (Ca. 1945); Dannerberg v. Board of Regents, 430 N.Y.2d 700 (1980) (issuance of three prescriptions for sleepingpills to an undercover agent without a physical examination; Widiltz v. Board of Regents of New York, 429 N.Y. 2d 794 (1980) (issuance of Desoxyn to patients whom physician knew were drug addicts without conducting physical examination); United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975) (no physical examination, evidences that prescriptions were not in course of professional practice); and United States v. Hooker, 541 F.2d 300 (1st Cir. 1976), (little more than cursory physical examination, frequent neglect to inquire as to past medical history, little or no exploration of the type of problem the patient allegedly had ‘indicates that the minimal professional procedures followed were designed only to give an appearance of propriety to appellant's unlawful distributions’).

See e.g. United States v. Moore, 423 U.S. 122 (U.S. 1975).

authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{14}

\textbf{B. Analysis}

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

\textbf{Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Mississippi 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{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 prescribe prescription drugs without the direct supervision of a physician, in accordance with a Board of Nursing approved protocol.\textsuperscript{15} Physician

\textsuperscript{14} \textit{Infra} fn 27.
\textsuperscript{15} Code Miss. Rules 50-015-001(IV)(2.1)(b) (Only NPs with temporary permits to practice or within 90 days of graduation of a nurse practitioner program are required to practice under the direct supervision of a physician); Code Miss Rules 50-015-001(IV)(2.3)(c):

\begin{itemize}
  \item (2) Nurse practitioners practicing in other specialty areas must practice according to a Board-approved protocol which has been mutually agreed upon by the nurse practitioner and a Mississippi licensed physician whose practice or prescriptive authority is not limited as a result of voluntary surrender or legal/regulatory order. The protocol must outline diagnostic and therapeutic procedures and categories of pharmacologic agents which may be ordered, administered, dispensed and/or prescribed for patients with diagnoses identified by the nurse practitioner.
  \item (3) Each collaborative/consultative relationship shall include and implement a formal quality assurance/quality improvement program which shall be maintained on site and shall be available for inspection by representatives of the Mississippi Board of Nursing. This quality assurance/quality improvement
assistants (PAs) can prescribe prescription drugs, if included in the Board-approved protocol with the physician and physician assistant.\textsuperscript{16}

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I and II, is valid under Mississippi 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. In accordance with their written protocol, NPs can independently prescribe naloxone. PAs can prescribe, as per the written protocol established between them and the supervising physician, which would permit a PA to staff a naloxone program without the on-site supervision of a physician.

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

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

program must be sufficient to provide a valid evaluation of the practice and be a valid basis for change, if any.

This statute has been interpreted to permit NPs to prescribe prescription drugs within a supervision agreement with a physician. \textit{Survey of Pharmacy Law}, Natl. Assn. Bd. of Pharm. (2007).

\textsuperscript{16} Code Miss. Rules 50-013-001(XXII)(A)(2): ("Physician Assistants may provide any medical service which is delegated by the supervising physician when the service is within the Physician Assistant's training and skills; forms a component of the physician's scope of practice; and is provided with supervision"); Code Miss. Rules 50-013-001(XXII)(D)(1):

Physician Assistants shall practice according to a Board-approved protocol which has been mutually agreed upon by the Physician Assistant and the supervising physician. Each protocol shall be prepared taking into consideration the specialty of the supervising physician, and must outline diagnostic and therapeutic procedures and categories of pharmacologic agents which may be … dispensed and/or prescribed for patients with diagnoses identified by the Physician Assistant. Each protocol shall contain a detailed description of back-up coverage if the supervising physician is away from the primary office. Although licensed, no Physician Assistant shall practice until a duly executed protocol has been approved by the Board.

These statutes have been interpreted to permit PAs to prescribe prescription drugs under the terms of a supervision agreement with a physician. \textit{Survey of Pharmacy Law}, Natl. Assn. Bd. of Pharm. (2007).
As noted in the licensure law described in sections I and II, in general it is recommended that a healthcare provider formulate a therapeutic plan for their patient and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.

**B. Analysis**

The intended use of naloxone is to prevent opiate overdose. Indications for and methods of administration should be explained to patients, along with risks and benefits. Because of the nature of overdose, patients may not always be able to self-administer the necessary dose. Some overdose prevention programs properly instruct pairs or groups of patients in naloxone administration and other emergency measures so that patients can assist each other. Prescribing staff may 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 Mississippi should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

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

**IV. How May Naloxone be Dispensed?**

**A. The Regulatory Scheme**

Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. The practice of pharmacy in Mississippi is governed by the Mississippi Pharmacy Practice Act, with regulations found in

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17 Miss. Code Ann. § 73-21-69 (West 2007), et seq.
the administrative code. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

Physicians in Mississippi can dispense prescription drugs. NPs and PAs cannot dispense prescription drugs. However, PAs and NPs can dispense pre-packaged doses of non-controlled substances, which includes but is not limited to samples provided by a manufacturer. Finally, physicians should

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18 Code Miss. Rules 50-018-001, et seq.
19 Code Miss. Rules 50-031-001(XXIII)(H)(3): A physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" shall mean the physician must actually obtain the medication, prepare, count, place the same into the appropriate container and affix the appropriate label to the container.
22 Code Miss. Rules 50-013-001(XXII)(D)(3)(e) ("A Physician Assistant may receive and distribute pre-packaged medications or samples of non-controlled substances for which the Physician Assistant has prescriptive authority"); Code Miss. Rules 05-015-001(IV)(2.4)(f):
   1) … A nurse practitioner may receive and distribute pre-packaged medications or samples of non-controlled substances for which the nurse practitioner has prescriptive authority.
   2) A nurse practitioner or delegated licensed nurse must distribute the medication. For the purpose of this regulation "distribute" shall mean hand the prepackaged medication to the patient or the patients authorized agent.
   3) All drug products which are maintained/stored in the office of a nurse practitioner, shall be maintained/stored in the manufacturer's or re-packager's original package. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date. Drugs which are pre-counted and pre-packaged for purposes of distributing shall be identifiable as to expiration date and manufacturer's control lot number. The packages in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this Section are in addition to, and not in lieu of, other labeling requirements of the laws of the State of Mississippi, Rules and Regulations of the Mississippi State Board of Nursing, and laws of the United States or Federal Regulations.
   4) A nurse practitioner shall not distribute out-of-date pre-packaged samples or store out-of-date prepackaged samples intermixed with the stock of current pre-packaged samples. Out-of-date pre-packaged samples shall be promptly removed from current stock and stored separately until proper disposal shall be made. When distributing a product in a manufacturer's original package or container, the labeling of which bears an expiration date, a manufacturer's control lot number or other information which may be of value to the patient, the nurse practitioner shall distribute the product with this information intact.
   5) The drug storage area shall be maintained in a sanitary fashion.
   6) A nurse practitioner shall not accept the return for subsequent resale or exchange any drugs after such items have been taken from the premises where sold, distributed and from the control of the nurse practitioner.
   7) All drug products shall be maintained, stored and distributed in such a manner as to maintain the integrity of the product.
follow regulations governing the dispensation of drugs directly from the provider’s office, which are basic standards for storage and record-keeping that must normally accompany such practice.23

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has followed the prescription guidelines, and does not require payment for the drug or the associated medical services, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients.24 If a program decides to dispense naloxone on premises, it should follow standard dispensation rules, unless dispensing pre-packaged samples of controlled substances, which should adhere to local custom.

There is no specific authorization or prohibition of RNs or LPNs dispensing pre-packaged samples of non-controlled substances. However, RNs or LPNs cannot sell or trade any pre-packaged samples of legend drugs. Code Miss. Rules 50-015-001(2.4)(d)(3). This regulation can be read to imply that RNs and LPNs can dispense, or give away, pre-packaged samples. With that said, we recommend that programs follow local custom.


Health care professionals licensed by an agency of this state and whose practice encompasses the prescribing and dispensing of drugs or medical devices shall automatically provide the patient with a prescription containing all of the necessary information to allow any prescription provider to dispense the drug … to the consumer. Upon the request of another health care professional or prescription provider to confirm prescription information for a specified individual, the prescribing health care professional shall immediately confirm all necessary information to enable the person requesting verification to accurately dispense the drug …. Confirmation may be requested or confirmed in any form, including electronically. If confirmation of the verification request for the drug … is not received within one (1) hour following the request, all information contained in the request, including the fact that the prescription has not expired, shall be presumed accurate, and the provider shall be authorized to dispense pursuant to the prescription. If no expiration date is included on the prescription, the prescription shall expire two (2) years after the date of issue.

24 For the rules governing services and drugs provided for a fee, see Code Miss. Rules 50-031-001 (XXIII)(H):

1. For the purposes of this rule, a “dispensing physician” shall mean any physician who shall dispense to a patient for the patient’s use any … legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.
2. Every dispensing physician, as defined above, who shall dispense a … legend drug or any other medication shall insure that all such substances dispensed be labeled containing the following information:
   a. the name of the patient to whom the medication was dispensed;
   b. the date that the medication was dispensed;
   c. the name, strength and quantity of the medication;
   d. direction for taking or administering the medication;
   e. the name and address of the physician dispensing the medication.
The label required by this subsection shall be written in legible handwriting or typed and shall be permanently affixed to the package or container in which the medication is dispensed. This labeling requirement shall not apply to prepackaged samples or starter packs in their original packages or containers.
Conclusion: Dispensing naloxone by valid prescription does not violate Mississippi 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 license sanctions. The patient or volunteer who dispensed naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license and/or illegally dispensing a prescription drug. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no law that made it a crime to possess a prescription without a prescription.

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

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

25 Infra fn 27.
Non-compliance with prescription and other professional practice rules may carry license sanctions or fines. There is no risk of professional censure for participating in a naloxone prescription program. Our analysis above makes clear 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

The board shall have authority to deny an application for licensure or other authorization to practice medicine in this state and to discipline a physician licensed or otherwise lawfully practicing within this state who, after a hearing, has been adjudged by the board as unqualified due to one … of the following reasons:
(a) Unprofessional conduct as defined in the physician licensure and disciplinary laws, pursuant to Section 73-25-29.

The grounds for the nonissuance, suspension, revocation or restriction of a license or the denial of reinstatement or renewal of a license are:
…
(8) Unprofessional conduct, which includes, but is not limited to:
…
(b) Knowingly performing any act which in any way assists an unlicensed person to practice medicine.

…
(d) Being guilty of any dishonorable or unethical conduct likely to deceive, defraud or harm the public.
…
(13) Violation of any provision(s) of the Medical Practice Act or the rules and regulations of the board or of any order, stipulation or agreement with the board. In addition to the grounds specified above, the board shall be authorized to suspend the license of any licensee for being out of compliance with an order for support, as defined in Section 93-11-153. The procedure for suspension of a license for being out of compliance with an order for support, and the procedure for the reissuance or reinstatement of a license suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license suspended for that purpose, shall be governed by Section 93-11-157 or 93-11-163, as the case may be. If there is any conflict between any provision of Section 93-11-157 or 93-11-163 and any provision of this chapter, the provisions of Section 93-11-157 or 93-11-163, as the case may be, shall control.

The Mississippi State Board of Medical Licensure, in exercising its authority under the provisions of Section 73-25-29, shall have the power to discipline the holder of a license who has been found by the board in violation of that statute after notice and a hearing as provided by law, and the licensee shall be disciplined as follows:
(a) By placing him upon probation, the terms of which may be set by the board, or
(b) By suspending his right to practice for a time deemed proper by the board, or
(c) By revoking his license, or
(d) By taking any other action in relation to his license as the board may deem proper under the circumstances.
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.\(^{28}\) Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\(^{29}\)

**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 circumstances, which is said to establish the “standard of care.”\(^{30}\) 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

\(^{28}\) Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).


\(^{30}\) Partin v. N. Miss. Med. Ctr., Inc., 929 So.2d 924 (Miss. App. 2005); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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 applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.

“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. 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.\textsuperscript{34} 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.\textsuperscript{35} Mississippi law provides similar liability for licensed physicians and nurse practitioners that volunteer their medical services.\textsuperscript{36} Thus, it appears that volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

Conclusion: The risk of tort liability in a naloxone program is low. Conceptually, this risk is no different from any other healthcare context. By following state rules and general standards of practice, providers can protect themselves from the imposition of tort liability. Malpractice insurance and laws that apply specifically to volunteer providers may provide additional protection.

\textsuperscript{34} Green v. Dalewood Prop. Owners' Assn, Inc., 919 So.2d 1000 (Miss. App. 2005).
\textsuperscript{35} 42 U.S.C.A. § 14503 (West 2000).
\textsuperscript{36} Miss. Code Ann. § 73-25-28(1) (West 2007):
Any licensed physician or certified nurse practitioner who voluntarily provides needed medical or health services to any person without the expectation of payment due to the inability of such person to pay for said services shall be immune from liability for any civil action arising out of the provision of such medical or health services provided in good faith on a charitable basis. This section shall not extend immunity to acts of willful or gross negligence. Except in cases of rendering emergency care wherein the provisions of Section 73-25-37 apply, immunity under this section shall be extended only if the physician or certified nurse practitioner and patient execute a written waiver in advance of the rendering of such medical services specifying that such services are provided without the expectation of payment and that the licensed physician or certified nurse practitioner shall be immune as provided in this subsection. The immunity from liability granted by this subsection also shall extend to actions arising from a church operated outpatient medical clinic that exists solely for the purpose of providing charitable medical services to persons who are unable to pay for such services, provided that the outpatient clinic receives less than Forty Thousand Dollars ($40,000.00) annually in patient payments.
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 Mississippi law we have outlined above:

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

B. Changes in State Law

Under the current law of this state, dispensing or administering naloxone to third parties who have not been prescribed the drug is illegal. Passing legislation to allow these practices would help reduce overdose deaths and ease the concerns of providers and clients about possible legal penalties. New York’s legislature recently passed a law to provide clear authorization of medical providers to “prescribe” or “dispense” naloxone to unknown ODUs via trained patients or volunteers (“Trained Overdose Responders” under NYS law); establish immunity for providers participating in such programs; and establish immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.37

[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a
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.