DATE: August 16, 2007

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

INTRODUCTION

Naloxone, the standard treatment for heroin overdose, is a safe and effective prescription drug typically administered by emergency room personnel or first responders acting under standing orders of physicians. High numbers of overdose deaths and evidence that witnesses to heroin overdose are often unwilling or unable to call for help has motivated some public health professionals to institute programs that distribute naloxone directly to opiate drug users (ODUs). In such programs, drug users, their partners, or others are instructed in resuscitation techniques and provided a “take-home” dose of naloxone for administration in cases when medical help is not immediately available.

Evidence from US and abroad indicates that naloxone distribution helps reduce opiate overdose deaths and results in cost-savings to society.\(^1\) Despite the high and rising incidence of overdose events in many US locales, however, both the number and the scope of overdose programs remain inadequate. Legal concerns about provider and program liability act as one of the most important limiting factors, often complicating or derailing authorization, expansion, funding and implementation of these programs.

We were funded by the Drug Policy Alliance to analyze the legal issues for naloxone distribution programs in the fifty United States. Our analysis finds that:

1. Naloxone is not a controlled substance as defined by federal or state law, but is a prescription drug subject to the general laws and regulations that govern all prescriptions in regular medical practice.

2. Prescribing naloxone to ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.

3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.

4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODUs who are not patients.

5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensation?
4. How may naloxone be dispensed?
5. Is it legal to prescribe or dispense naloxone for recipients to give or administer to third parties who have not been prescribed the drug by a licensed professional?
6. What is the risk of disciplinary action by a professional board arising from naloxone prescription or distribution, and how can the risk be minimized?
7. What kind of malpractice liability may arise from naloxone prescription or distribution, and how can the risk of liability be minimized?
Executive Summary

From a legal standpoint, naloxone is no different than any other prescription drug. Authorized medical professionals can prescribe and dispense naloxone in the same way they would any other drug. Naloxone is indicated for patients who, upon examination, are at risk of opiate overdose and who are judged by the professional to be capable of benefiting from naloxone administration. The amount of naloxone prescribed or dispensed depends upon the prescriber’s assessment of need. (See Parts I & II describing who may prescribe naloxone.)

As part of the process of prescribing, the patient should be given information about when and how to use the drug, as well as other steps that are advisable in responding to an overdose. Because a person suffering an overdose may not be able to administer the drug him or herself, it is also appropriate to (1) teach groups of patients how to administer the drug so that they can assist each other in an overdose emergency; and (2) instruct—in person, or through written materials—friends, family members and others who may witness an overdose how to administer the drug to a patient. It is not uncommon for third parties to assist patients in administering their drugs, for all sorts of reasons. The key legal requirement is that the recipient have a valid prescription for the drug. (See Parts III & IV.)

Because a legal prescription requires some examination and a specific medical indication, naloxone may not be prescribed or dispensed to patients or program participants to hand out or administer to other ODUs who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws, and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (See Part V.)

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

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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 Michigan is governed by the Medical Practices Act, with regulations found in the Michigan Administrative Code. The Board of Medicine (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. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but 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.

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.

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11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

State law offers no explicit standards for prescribing a prescription drug, but presumably the generic standards applicable to controlled substances provide a basic framework. This requires that for a prescription to be filled, it must have been issued by a licensed practitioner acting in good faith in the regular course of professional treatment, and the prescription must be written for a patient under the treatment of the practitioner.\(^\text{12}\) In normal usage, “good faith” entails a genuine concern for the well-being of the patient, and conduct devoid of malice or deception.\(^\text{13}\) In determining whether a prescription arises within the “regular course of professional treatment,” courts generally consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient’s risk factors, efforts to provide other harm reducing services, follow up and so on.\(^\text{14}\) The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\(^\text{15}\)

B. Analysis

While not explicitly required by Michigan statutes, 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, 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 ODU patient is consistent with the standard for a valid prescription under Michigan 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?

\(^\text{13}\) See, e.g., In the Matter of DiLeo, 661 So.2d 162, 168 (La. App. 1995) (finding that a physician was acting in good faith when prescribing medications to patients experiencing pain symptoms).
A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Physician assistants (PAs) must work with a supervising physician,\textsuperscript{16} who may delegate prescriptive authority.\textsuperscript{17} The supervising physician does not need to be on-site with the PA or

"Supervision", except as otherwise provided in this article, means the overseeing of or participation in the work of another individual by a health professional licensed under this article in circumstances where at least all of the following conditions exist:
(a) The continuous availability of direct communication in person or by radio, telephone, or telecommunication between the supervised individual and a licensed health professional.
(b) The availability of a licensed health professional on a regularly scheduled basis to review the practice of the supervised individual, to provide consultation to the supervised individual, to review records, and to further educate the supervised individual in the performance of the individual's functions.
(c) The provision by the licensed supervising health professional of predetermined procedures and drug protocol.

\textsuperscript{17} Mich. Comp. Laws Ann. § 333.17049 (2007):
(1) In addition to the other requirements of this section and subject to subsection (5), a physician who supervises a physician's assistant is responsible for all of the following:
(a) Verification of the physician's assistant's credentials.
(b) Evaluation of the physician's assistant's performance.
(c) Monitoring the physician's assistant's practice and provision of medical care services.
(2) Subject to section 17048, a physician who supervises a physician's assistant may delegate to the physician's assistant the performance of medical care services for a patient who is under the case management responsibility of the physician, if the delegation is consistent with the physician's assistant's training.
(3) A physician who supervises a physician's assistant is responsible for the clinical supervision of each physician's assistant to whom the physician delegates the performance of medical care service under subsection (2).
(4) Subject to subsection (5), a physician who supervises a physician's assistant shall keep on file in the physician's office or in the health facility or agency or correctional facility in which the physician supervises the physician's assistant a permanent, written record that includes the physician's name and license number and the name and license number of each physician's assistant supervised by the physician.
(5) A group of physicians practicing other than as sole practitioners may designate 1 or more physicians in the group to fulfill the requirements of subsections (1) and (4).
(6) Notwithstanding any law or rule to the contrary, a physician is not required to countersign orders written in a patient's clinical record by a physician's assistant to whom the physician has delegated the performance of medical care services for a patient.

\textsuperscript{17} Mich. Comp. Laws Ann. § 333.17076(3) (2007):
A physician's assistant may prescribe drugs as a delegated act of a supervising physician, but shall do so only in accordance with procedures and protocol for the prescription established by rule of the appropriate board. Until the rules are promulgated, a physician's assistant may prescribe a drug...as a delegated act of
countersign prescriptions, but must be continuously available by some form of electronic communication. \(^\text{18}\) Advanced registered nurse practitioners (ARNPs) and clinical nurse specialists (CNSs) may be delegated prescriptive authority by a licensed physician. \(^\text{19}\)

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Michigan law. In the same way, a prescription issued by a PA, ARNP, or CNS 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.

**Conclusion:** PAs may replace a physician in specific functions during the prescription process. A program can operate using a PA, ARNP, or CNS who is working in collaboration with a physician and has the physician’s authorization to prescribe. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

### III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

**A. The Regulatory Scheme**

According to the licensure law described in sections I and II, for a healthcare provider to prescribe a drug to a patient the prescription must be in good faith and in the regular course of professional treatment. \(^\text{20}\)

**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

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\(^\text{18}\) *Supra*, fn. 16.
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 Michigan should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

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

IV. How May Naloxone be Dispensed?

A. The Regulatory Scheme

Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. Under the pharmacy laws\(^\text{21}\) and regulations\(^\text{22}\), pharmacists are expected to fill a prescription that meets regulatory guidelines.

A physician may dispense prescription drugs at the point of service if she has applied for and received a drug control license from the Board of Pharmacy.\(^\text{23}\)

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1) Except as otherwise provided in this subsection, a prescriber who wishes to dispense prescription drugs shall obtain from the board a drug control license for each location in which the storage and dispensing of prescription drugs occur. A drug control license is not necessary if the dispensing occurs in the emergency department, emergency room, or trauma center of a hospital licensed under article 17 or if the dispensing involves only the issuance of complimentary starter dose drugs.

2) A dispensing prescriber shall dispense prescription drugs only to his or her own patients.

If the physician is only dispensing complimentary starter dose drugs, A this license is not required. A A supervising physician may delegate the authority to order and dispense complimentary starter doses of drugs to a PA or a registered professional nurse.

(1) A drug control license shall contain the name and address of the dispensing prescriber and each location in which the storage and dispensing of drugs occur and other information the board requires.

(2) A drug control license is valid until the date on which the dispensing prescriber's professional license must be renewed, at which time the drug control license shall be renewed. The drug control license shall be renewed automatically, if both of the following conditions are met:

(a) The dispensing prescriber indicates that he or she dispenses drugs and desires to continue to do so.

(b) The dispensing prescriber renews his or her professional license.

(3) A dispensing prescriber whose drug control license is renewed pursuant to subsection (2) is subject to section 16226 and the other requirements of this article and article 7.

(4) A drug control license is automatically void if a board suspends or revokes the licensee's health professional license.

As used in this section, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients.

25 Id.

A physician's assistant may order, receive, and dispense complimentary starter dose drugs...as a delegated act of a supervising physician. When the delegated ordering, receipt, or dispensing of complimentary starter dose drugs occurs, the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each order, receipt, or dispensing so that the individual who processes the order or delivers the complimentary starter dose drugs or to whom the complimentary starter dose drugs are dispensed knows under whose delegated authority the physician's assistant is ordering, receiving, or dispensing.

As used in this subsection, "complimentary starter dose" means that term as defined in section 17745. It is the intent of the legislature in enacting this subsection to allow a pharmaceutical manufacturer or wholesale distributor, as those terms are defined in part 177, to distribute complimentary starter dose drugs to a physician's assistant, as described in this subsection, in compliance with section 503(d) of the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1051, 21 U.S.C. 353.

[A] supervising physician may delegate in writing to a registered professional nurse the ordering, receipt, and dispensing of complimentary starter dose drugs other than controlled substances as defined by article 7 or federal law. When the delegated ordering, receipt, or dispensing of complimentary starter dose drugs occurs, both the registered professional nurse's name and the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each order, receipt, or dispensing. As used in this subsection, "complimentary starter dose" means that term as defined in section 17745.

Finally, regulations governing the dispensation of prescription drugs and complimentary starter dose drugs directly from the provider’s office set basic standards for storage and record-keeping that must accompany such practice. These include the requirement to maintain a dispensation record, and proper labeling of the agent, including the patient’s name and other essential information.  

B. Analysis


(3) A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber or indirectly under his or her delegatory authority. If prescription drugs are dispensed under the prescriber's delegatory authority, the delegatee who dispenses the prescription drugs shall initial the patient's chart, clinical record, or log of prescription drugs dispensed. In a patient's chart or clinical record, a dispensing prescriber shall distinguish between prescription drugs dispensed to the patient and prescription drugs prescribed for the patient. A dispensing prescriber shall retain information required under this subsection for not less than 5 years after the information is entered in the patient's chart or clinical record.

(4) A dispensing prescriber shall store prescription drugs under conditions that will maintain their stability, integrity, and effectiveness and will assure that the prescription drugs are free of contamination, deterioration, and adulteration.

(5) A dispensing prescriber shall store prescription drugs in a substantially constructed, securely lockable cabinet. Access to the cabinet shall be limited to individuals authorized to dispense prescription drugs in compliance with this part and article 7.

(6) Unless otherwise requested by a patient, a dispensing prescriber shall dispense a prescription drug in a safety closure container that complies with the poison prevention packaging act of 1970, Public Law 91-601, 84 Stat. 1670.

(7) A dispensing prescriber shall dispense a drug in a container that bears a label containing all of the following information:

(a) The name and address of the location from which the prescription drug is dispensed.
(b) The patient's name and record number.
(c) The date the prescription drug was dispensed.
(d) The prescriber's name.
(e) The directions for use.
(f) The name and strength of the prescription drug.
(g) The quantity dispensed.
(h) The expiration date of the prescription drug or the statement required under section 17756.

(8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient shall give the patient at least all of the following information, either by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the information or by giving the patient a written document which may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug, that contains the information:

(a) The name and strength of the complimentary starter dose drug.
(b) Directions for the patient's use of the complimentary starter dose drug.
Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided she has the necessary license, a physician may dispense naloxone to the patient at the point of service. Physicians, PAs, and registered professional nurses may dispense complimentary starter doses of naloxone, but to meet the statutory definition, such a dose must not only be free to the patient but provided to the practitioner by the manufacturer without charge. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

Conclusion: Dispensing naloxone by valid prescription does not violate Michigan law and may be done on premises of the distribution program. A physician may dispense naloxone to patients at the point of service only if she has obtained the necessary drug control license or is distributing without cost starter doses provided at no charge by the manufacturer.

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

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

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license or the illegal dispensation of a prescription drug.

(c) The expiration date of the complimentary starter dose drug or the statement required under section 17756.
(9) The information required under subsection (8) is in addition to, and does not supersede or modify, other state or federal law regulating the labeling of prescription drugs.

29 Mich. Comp. Laws Ann. § 333.17011 (2007) (An individual shall not engage in the practice of medicine or practice as a physician's assistant unless licensed or otherwise authorized); Mich. Comp. Laws Ann § 333.17766 (2007) (“Except as provided in sections 17766d and 17780, a person who does any of the following is guilty of a misdemeanor: …dispenses, or gives away, a
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.\textsuperscript{30} 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.

\textbf{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{31} 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, drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the control of a pharmacist\textsuperscript{\textendash}).

Except as provided in sections 17766d and 17780, a person who does any of the following is guilty of a misdemeanor:
\begin{itemize}
  \item [(d)] Knowingly possesses a false, forged, or altered prescription.
  \item [(e)] Knowingly attempts to obtain, obtains, or possesses a drug by means of a prescription for other than a legitimate therapeutic purpose, or as a result of a false, forged, or altered prescription.
  \item [(f)] Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the control of a pharmacist.
\end{itemize}

so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct.\textsuperscript{32} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{33}

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."\textsuperscript{34} 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

\textsuperscript{32} 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).


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

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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. 39 Michigan state law provides similar liability protections for health care professionals providing non-emergency care, so long as the agent responsible is a licensed health care provider acting voluntarily and without pay. 40 It appears

(1) A licensee or registrant who provides to a patient nonemergency health care that the licensee or registrant is licensed or registered under this article to provide, and who receives no compensation for providing the nonemergency health care, is not liable in a civil action for damages for acts or omissions in providing the nonemergency health care, unless the acts or omissions were the result of gross negligence or willful and wanton misconduct or were intended to injure the patient.
(2) The limitation on liability provided under subsection (1) applies only if the nonemergency health care is provided inside the premises of or as a result of a referral from either of the following:
(a) A health facility organized and operated for the sole purpose of delivering nonemergency health care without receiving compensation.
(b) An entity that is not a health facility and that provides nonemergency health care to uninsured or underinsured individuals through the voluntary services of licensees or registrants who receive no compensation for providing the nonemergency health care.
(3) In addition to the restrictions under subsection (1), the limitation on liability provided in subsection (1) does not apply in regard to the nonemergency health care of a patient unless, before the licensee or registrant provides that health care, both of the following occur:
(a) The licensee or registrant provides the patient with a written disclosure describing the limitation on liability and stating that the health care is free and compensation for the health care will not be requested from any source.
(b) The patient signs an acknowledgment of receipt of the written disclosure.
(4) A health facility, other than a health facility described in subsection (2), that provides financial, in-kind, or other support, not including health care services, to a health facility or other entity described in subsection (2) is not liable in a civil action for damages based on nonemergency health care provided by the health facility or entity described in subsection (2).
that under Michigan law, 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 Michigan 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;

(5) This section does not affect the liability of a health facility or entity described in subsection (2) as that liability existed before the effective date of this section.

(7) As used in this section:
   (a) "Compensation" means receipt of payment or expected receipt of payment from any source, including, but not limited to, receipt of payment or expected receipt of payment directly from a patient, from a patient's parent, guardian, or spouse, or from a public or private health care payment or benefits plan on behalf of the patient, or indirectly in the form of wages, salary, or other valuable consideration under an employment or service agreement.
   (b) "Health facility" means a health facility or agency licensed under article 17.
• 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 ODUs.

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