DATE: August 14, 2007

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

INTRODUCTION

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

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

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

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

---

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

---

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

The Legal Analysis in Detail

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

A. Professional Licensure Law

The practice of medicine in Ohio is governed by the Ohio Medical Board (the "Board"), with regulations in the Ohio Administrative Code. 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 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:

A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. … An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

---

4 Ohio Rev. Code Ann. § 4731.01 (West 2007), et seq.
7 Infra fn 28.
8 Infra fn 28.
10 Ohio Rev. Code Ann. § 3719.01 (West 2007) ("Controlled substance' means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V"). Naxolone is excluded from Schedule II of the Ohio Controlled Substances Act; therefore, it is treated as a prescription drug. Ohio Rev. Code Ann. § 3719.41 (West 2007).
In determining whether a prescription arises within the usual course of professional practice, 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.\textsuperscript{12}

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically.\textsuperscript{13}

This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

B. Analysis

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

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

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

A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Certified nurse practitioners (CNPs) and clinical nurse specialists (CNSs) can apply to the board of nursing for a certificate authorizing the prescribing of medication and must work in collaboration with one or more physicians.\textsuperscript{14} Physician assistants (PAs)

\textsuperscript{13} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
\textsuperscript{14} Ohio Rev. Code Ann. § 4723.43 (West 2007):
(C) A nurse authorized to practice as a certified nurse practitioner, in collaboration with one or more physicians … may provide preventive and primary care services and evaluate and promote patient wellness within the nurse's nursing specialty, consistent with the nurse's education and certification, and in accordance with rules adopted by the board. A certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code may, in collaboration with one or more physicians … prescribe drugs … in accordance with section 4723.481 of the Revised Code.

(D) A nurse authorized to practice as a clinical nurse specialist, in collaboration with one or more physicians … may provide and manage the care of individuals and groups with complex health problems and provide health care services that promote, improve, and manage health care within the nurse's nursing specialty, consistent with the nurse's education and in accordance with rules adopted by the board. A clinical nurse specialist who holds a certificate to prescribe issued under section 4723.48 of the Revised Code may, in collaboration with one or more physicians … prescribe drugs … in accordance with section 4723.481 of the Revised Code.


(A) A clinical nurse specialist … or certified nurse practitioner seeking authority to prescribe drugs … shall file with the board of nursing a written application for a certificate to prescribe. The board of nursing shall issue a certificate to prescribe to each applicant who meets the requirements specified in section 4723.482 or 4723.484 of the Revised Code.

Except as provided in division (B) of this section, the initial certificate to prescribe that the board issues to an applicant shall be issued as an externship certificate. Under an externship certificate, the nurse may obtain experience in prescribing drugs … by participating in an externship that evaluates the nurse's competence, knowledge, and skill in pharmacokinetic principles and their clinical application to the specialty being practiced. During the externship, the nurse may prescribe drugs … only when one or more physicians are providing supervision in accordance with rules adopted under section 4723.50 of the Revised Code.

After completing the externship, the holder of an externship certificate may apply for a new certificate to prescribe. On receipt of the new certificate, the nurse may prescribe drugs … in collaboration with one or more physicians …. 

(B) In the case of an applicant who on May 17, 2000, was approved to prescribe drugs … under section 4723.56 of the Revised Code, as that section existed on that date, the initial certificate to prescribe that the board issues to the applicant under this section shall not be an externship certificate. The applicant shall be issued a certificate to prescribe that permits the recipient to prescribe drugs and therapeutic devices in collaboration with one or more physicians …. 


Under a certificate to prescribe issued under section 4723.48 of the Revised Code, a clinical nurse specialist … or certified nurse practitioner is subject to all of the following:

(A) The nurse shall not prescribe any drug … that is not included in the types of drugs and devices listed on the formulary established in rules adopted under section 4723.50 of the Revised Code.

(B) The nurse's prescriptive authority shall not exceed the prescriptive authority of the collaborating physician …. 

(D) The nurse may personally furnish to a patient a sample of any drug … included in the types of drugs and devices listed on the formulary, subject to all of the following:

(1) The amount of the sample furnished shall not exceed a seventy-two-hour …
can be delegated prescriptive authority by their supervising physician, if certified by the Board and included in their physician supervisory plan. Collaborating/supervising physicians need not be on site.

(A) Under a physician supervisory plan approved under section 4730.17 of the Revised Code, a physician assistant may provide any or all of the following services without approval by the state medical board as special services:

(7) Exercising physician-delegated prescriptive authority pursuant to a certificate to prescribe issued under this chapter;

(A) A physician assistant seeking a certificate to prescribe shall submit to the state medical board a written application on a form prescribed and supplied by the board. The application shall include all of the following information:

(1) The applicant’s name, residential address, business address, if any, and social security number;

(2) Evidence of holding a valid certificate to practice as a physician assistant issued under this chapter;

(A) A provisional certificate to prescribe issued under section 4730.44 of the Revised Code authorizes the physician assistant holding the certificate to participate in a provisional period of physician-delegated prescriptive authority or satisfactory proof of successful completion of the provisional period, evidenced by a letter or copy of a letter attesting to the successful completion written by a supervising physician of the physician assistant at the time of completion;
condition of receiving a new certificate to prescribe.

(B) The provisional period shall be conducted by one or more supervising physicians in accordance with rules adopted under section 4730.39 of the Revised Code. When supervising a physician assistant who is completing the first five hundred hours of a provisional period, the supervising physician shall provide on-site supervision of the physician assistant's exercise of physician-delegated prescriptive authority.

The provisional period shall last not longer than one year, unless it is extended for not longer than one additional year at the direction of a supervising physician. The physician assistant shall not be required to participate in the provisional period for more than one-thousand-eight-hundred hours, except when a supervising physician has extended the physician assistant's provisional period.

(C) If a physician assistant does not successfully complete the provisional period, each supervising physician shall cease granting physician-delegated prescriptive authority to the physician assistant. The supervising physician with primary responsibility for conducting the provisional period shall promptly notify the state medical board that the physician assistant did not successfully complete the provisional period and the board shall revoke the certificate.

(D) A physician assistant who successfully completes a provisional period shall not be required to complete another provisional period as a condition of being eligible to be granted physician-delegated prescriptive authority by a supervising physician who was not involved in the conduct of the provisional period.


(A) After a physician assistant successfully completes the provisional period of physician-delegated prescriptive authority required under section 4730.45 of the Revised Code, the physician assistant may apply for a new certificate to prescribe.

(B) A supervising physician participating in the provisional period may continue to grant physician-delegated prescriptive authority to the physician assistant pursuant to the provisional certificate to prescribe until one of the following occurs:

(1) The supervision agreement between the supervising physician and the physician assistant expires;
(2) The supervision agreement is terminated;
(3) A decision is made by the state medical board regarding an application submitted by the physician assistant for a new certificate to prescribe.


(A) The supervising physician of a physician assistant exercises supervision, control, and direction of the physician assistant. In supervising a physician assistant, all of the following apply:

(1) Except when the on-site supervision requirements specified in section 4730.45 of the Revised Code are applicable, the supervising physician shall be continuously available for direct communication with the physician assistant by either of the following means:

(a) Being physically present at the location where the physician assistant is practicing;
(b) Being readily available to the physician assistant through some means of telecommunication and being in a location that under normal conditions is not more than sixty minutes travel time away from the location where the physician assistant is practicing.

(2) The supervising physician shall personally and actively review the physician assistant's professional activities.

(3) The supervising physician shall regularly review the condition of the patients
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 Ohio law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A properly credentialed CNP, CNS or PA could staff a naloxone prescription program without a physician in attendance.

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

(4) The supervising physician shall ensure that the quality assurance system established pursuant to division (F) of this section is implemented and maintained.

(5) The supervising physician shall regularly perform any other reviews of the physician assistant that the supervising physician considers necessary.

(B) A physician may enter into supervision agreements with any number of physician assistants, but the physician may not supervise more than two physician assistants at any one time. A physician assistant may enter into supervision agreements with any number of supervising physicians, but when practicing under the supervision of a particular physician, the physician assistant's scope of practice is subject to the limitations of the physician supervisory plan that has been approved under section 4730.17 of the Revised Code for that physician or the policies of the health care facility in which the physician and physician assistant are practicing.

(C) A supervising physician may authorize a physician assistant to perform a service only if the service is authorized under the physician supervisory plan approved for that physician or the policies of the health care facility in which the physician and physician assistant are practicing. A supervising physician may authorize a physician assistant to perform a service only if the physician is satisfied that the physician assistant is capable of competently performing the service. A supervising physician shall not authorize a physician assistant to perform any service that is beyond the physician's or the physician assistant's normal course of practice and expertise.

(E) Each time a physician assistant writes a medical order, including prescriptions written in the exercise of physician-delegated prescriptive authority, the physician assistant shall sign the form on which the order is written and record on the form the time and date that the order is written. When writing a medical order, the physician assistant shall clearly identify the physician under whose supervision the physician assistant is authorized to write the order (emphasis added).
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 Ohio 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 Ohio is governed by the Ohio State Board of Pharmacy, with regulations found in the administrative code. Pharmacists are expected to fill a prescription that meets

---

16 Ohio Rev. Code Ann. § 4729.01 (West 2007), et seq.
regulatory guidelines. Only physicians may dispense the agent at the point of service.\textsuperscript{18} Physicians should follow regulations governing the dispensation of drugs directly from the provider’s office, which are basic standards for labeling and record-keeping that must normally accompany such practice.\textsuperscript{19} CNPs, CNSs\textsuperscript{20} and PAs,\textsuperscript{21} who hold certificates to prescribe and who are granted physician-delegated prescriptive authority, can dispense seventy-two hour doses of sample drugs\textsuperscript{22} free of charge. CNPs, CNSs, and PAs can dispense greater than

\textsuperscript{18} Survey, \textit{Survey of Pharmacy Law}, Natl. Assn. Bd. of Pharm. (2007) (physician can dispense to his or her own patients). We found no provision directly authorizing physicians to dispense at the point of service in Ohio, but a physician engaging in the practice of medicine includes dispensing drugs. \textsuperscript{19} Ohio Rev. Code Ann. § 4731.34(A) (West 2007):

\begin{quote}
A person shall be regarded as practicing medicine … within the meaning of this chapter, who does any of the following:
\begin{itemize}
  \item[(3)] In person or, regardless of the person's location, through the use of any communication, including oral, written, or electronic communication, does any of the following:
  \begin{itemize}
    \item[(b)] Prescribes, advises, recommends, administers, or dispenses for compensation of any kind, direct or indirect, a drug or medicine … for the cure or relief of a … bodily injury, infirmity, or disease (emphasis added).
  \end{itemize}
\end{itemize}
\end{quote}

\textsuperscript{20} \textit{Supra} fn 15.

\textsuperscript{21} Ohio Rev. Code Ann. § 4730.43(A) (West 2007):

\begin{quote}
(A) A physician assistant who holds a certificate to prescribe issued under this chapter and has been granted physician-delegated prescriptive authority by a supervising physician may personally furnish to a patient samples of drugs … that are included in the physician assistant's physician-delegated prescriptive authority, subject to all of the following:
\begin{itemize}
  \item[(1)] The amount of the sample furnished shall not exceed a seventy-two hour supply, except when the minimum available quantity of the sample is packaged in an amount that is greater than a seventy-two hour supply, in which case the physician assistant may furnish the sample in the package amount.
  \item[(2)] No charge may be imposed for the sample or for furnishing it.
\end{itemize}
\end{quote}

\textsuperscript{22} Ohio Rev. Code Ann. § 2925.01 (West 2007):
a seventy-two hour dose when it is the minimum quantity the sample is packaged in, within the same parameters listed previously. Unlike physicians, there are no additional dispensing requirements for samples dispensed by CNPs, CNSs and PAs, since drug samples are already prepackaged by the drug manufacturer.  

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the physician has followed the prescription guidelines, he or she can dispense the drug directly to the clients. CNPs, CNSs and PAs can all dispense seventy-two hour doses of naloxone samples without charge to clients. The definition of sample includes the stipulation that the dose be marked as a sample by the manufacturer, which likely makes the use of the sample route infeasible for a naloxone prescription program. If a program decides to dispense naloxone on premises, it should follow standard dispensation rules.

Conclusion: Dispensing naloxone by valid prescription does not violate Ohio law and may be done by a physician on the premises of the distribution program. Allied health professionals will not generally be able to dispense naloxone to program participants.

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

"Sample drug" means a drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

23 Supra fn 22; supra fn 15.
24 Id.; supra fn 23.
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. 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?

Non-compliance with prescription and other professional practice rules may carry license sanctions or fines. There is no risk of professional censure for

25 Infra fn 28.
26 Ohio Rev. Code Ann. § 4731.99 (A person who dispenses drugs without a license to practice medicine is "guilty of a felony of the fifth degree on a first offense and a felony of the fourth degree on each subsequent offense").
(B) The board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend an individual's certificate to practice, refuse to register an individual, refuse to reinstate a certificate, or reprimand or place on probation the holder of a certificate for one or more of the following reasons:

... (3) Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug;

... (6) A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established;

... (14) Commission of an act involving moral turpitude that constitutes a misdemeanor in this state, regardless of the jurisdiction in which the act was committed;
(15) Violation of the conditions of limitation placed by the board upon a certificate to practice;
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.

(20) Except when civil penalties are imposed under section 4731.225 or 4731.281 of the Revised Code, and subject to section 4731.226 of the Revised Code, violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board.

(22) Any of the following actions taken by the agency responsible for regulating the practice of medicine and surgery ... for any reason other than the nonpayment of fees: the limitation, revocation, or suspension of an individual's license to practice; acceptance of an individual's license surrender; denial of a license; refusal to renew or reinstate a license; imposition of probation; or issuance of an order of censure or other reprimand;

(C) Disciplinary actions taken by the board under divisions (A) and (B) of this section shall be taken pursuant to an adjudication under Chapter 119. of the Revised Code, except that in lieu of an adjudication, the board may enter into a consent agreement with an individual to resolve an allegation of a violation of this chapter or any rule adopted under it. A consent agreement, when ratified by an affirmative vote of not fewer than six members of the board, shall constitute the findings and order of the board with respect to the matter addressed in the agreement. If the board refuses to ratify a consent agreement, the admissions and findings contained in the consent agreement shall be of no force or effect. If the board takes disciplinary action against an individual under division (B) of this section for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the disciplinary action shall consist of a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice. Any consent agreement entered into under this division with an individual that pertains to a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of that section shall provide for a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice.

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).
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 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,31 and, in an actual case, by expert testimony from clinicians and public health experts. If the prescription of

30 Ramage v. C. Ohio Emerg. Serv., Inc., 64 Ohio St.3d 97 (Ohio 1992); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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.\(^{32}\)

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable.\(^{33}\) 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.\(^{34}\) Ohio law provides similar liability for volunteer healthcare professionals who act in good faith for acts or omissions that do no

---


\(^{33}\) Hall v. Watson, 2002 WL 1396763 (Ohio App. 7th Dist. June 18, 2002).

\(^{34}\) 42 U.S.C.A. § 14503 (West 2000).
Constitute willful or wanton misconduct. 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.

CONCLUSION

35 Ohio Rev. Code Ann. § 2305.234(B) (West 2007):
   (1) Subject to divisions (F) and (G)(3) of this section, a health care professional who is a volunteer and complies with division (B)(2) of this section is not liable in damages to any person or government entity in a tort or other civil action, including an action on a medical, dental, chiropractic, optometric, or other health-related claim, for injury, death, or loss to person or property that allegedly arises from an action or omission of the volunteer in the provision to an indigent and uninsured person of medical, dental, or other health-related diagnosis, care, or treatment, including the provision of samples of medicine and other medical products, unless the action or omission constitutes willful or wanton misconduct.
   (2) To qualify for the immunity described in division (B)(1) of this section, a health care professional shall do all of the following prior to providing diagnosis, care, or treatment:
      (a) Determine, in good faith, that the indigent and uninsured person is mentally capable of giving informed consent to the provision of the diagnosis, care, or treatment and is not subject to duress or under undue influence;
      (b) Inform the person of the provisions of this section, including notifying the person that, by giving informed consent to the provision of the diagnosis, care, or treatment, the person cannot hold the health care professional liable for damages in a tort or other civil action, including an action on a medical, dental, chiropractic, optometric, or other health-related claim, unless the action or omission of the health care professional constitutes willful or wanton misconduct;
      (c) Obtain the informed consent of the person and a written waiver, signed by the person or by another individual on behalf of and in the presence of the person, that states that the person is mentally competent to give informed consent and, without being subject to duress or under undue influence, gives informed consent to the provision of the diagnosis, care, or treatment subject to the provisions of this section. A written waiver under division (B)(2)(c) of this section shall state clearly and in conspicuous type that the person or other individual who signs the waiver is signing it with full knowledge that, by giving informed consent to the provision of the diagnosis, care, or treatment, the person cannot bring a tort or other civil action, including an action on a medical, dental, chiropractic, optometric, or other health-related claim, against the health care professional unless the action or omission of the health care professional constitutes willful or wanton misconduct.
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 Ohio 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.36

C. Cooperation with First Responders

[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.
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.