DATE: September 30, 2007

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

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.

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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. (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 lay persons, and to protect medical professionals from tort and other liability.

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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.
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 Florida is governed by the Medical Practice Act,4 with regulations found in the Florida Administrative Code.5 The Board of Medicine (the “Board”) has the authority to license physicians6 and to punish licensed physicians who behave in ways that violate the law or fall below the standards of good faith and regular practice of medicine.7 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.8 The Board must show with particularity the reasons why a prescribing practice is improper, and it must offer a standard by which the prescription practice can be evaluated.9

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.10 Naloxone is not a controlled substance under state or federal law.11 Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug.

State law offers no explicit standards for prescribing a prescription drug, but presumably the generic standards applicable to controlled substances provide a basic framework: "[a] practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise

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5 Fla. Admin. Code Ann. 64B8-1.001 (2007), et seq.
8 See generally, Hoover v. Agency for Health Care Admin., 676 So.2d 1380 (Fla. App. 3 Dist. 1996); Van Ore v. Board of Medical Examiners, 489 So.2d 883, 11 Fla. L. Weekly 1321 (Fla. App. 5 Dist. 1986).
9 Id.
11 While naloxone is not specifically excluded from the schedules in the Florida Controlled Substances Act, we have not found any state that considers naloxone a controlled substance. We were unable to contact the Board of Pharmacy, but we assume naloxone is not intended to be a controlled substance in Florida.
prepare a controlled substance.”12 In determining whether a prescription arises within the course of professional practice, courts may 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.13

B. Analysis

While not explicitly required by Florida statutes, it is prudent for physicians as a general matter of law to follow certain procedures when issuing prescriptions to all prescription drugs, including providing a physical examination as appropriate, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. 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 Florida 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. Physician assistants (PAs) may be delegated prescriptive authority by a supervising physician,14 but

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12 Fla. Stat. Ann. §893.05(1) (West 2007); see State v. Weeks, 335 So.2d 274 (Fla. 1976) (The language “in good faith and in course of professional practice only” is not unconstitutionally vague, but conveys a sufficiently definite meaning that a physician who may be liable to penalty of the Act may know if he is within its provisions or not).
(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created
pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that he or she has completed a continuing medical education course of at least 3 classroom hours in prescriptive practice, conducted by an accredited program approved by the boards, which course covers the limitations, responsibilities, and privileges involved in prescribing medicinal drugs, or evidence that he or she has received education comparable to the continuing education course as part of an accredited physician assistant training program.

4. The physician assistant must file with the department, before commencing to prescribe or dispense, evidence that the physician assistant has a minimum of 3 months of clinical experience in the specialty area of the supervising physician.

5. The physician assistant must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

6. The department shall issue a license and a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

7. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

8. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record, and the supervisory physician must review and sign each notation. For dispensing purposes only, the failure of the supervisory physician to comply with these requirements does not affect the validity of the prescription.

9. This paragraph does not prohibit a supervisory physician from delegating to a physician assistant the authority to order medication for a hospitalized patient of the supervisory physician.

(f) 1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant, licensed under this section or s. 459.022, may not prescribe. The formulary must include controlled substances as defined in chapter 893, antipsychotics, general anesthetics and radiographic contrast materials, and all parenteral preparations except insulin and epinephrine.
may not prescribe intravenous drugs. PAs must also receive authorization from the board to prescribe. The supervising physician does not need to be on-site with the PA but must be available for communication with the PA. Advanced registered nurse practitioners (ARNPs) must work with a collaborating physician and may prescribe drugs that are included in their written protocol with the collaborating physician. We did not find any statute that requires the presence

Physician assistants approved to prescribe medicinal drugs under the provisions of section 458.347(4)(e) or 459.022(4)(e), Florida statutes, are not authorized to prescribe the following medicinal drugs, in pure form or combination:

…

(e) Any parenteral preparation except insulin and epinephrine. Parenteral includes: intravenous, subcutaneous, intramuscular, and any route other than the alimentary canal; however, it does not include topical or mucosal application. Nothing in this formulary prohibits a physician assistant from administering a parenteral drug under the direction or supervision of the supervising physician.

16 Supra, fn. 14.

"Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

(1) A supervising physician shall delegate only tasks and procedures to the physician assistant which are within the supervising physician's scope of practice. The physician assistant may work in any setting that is within the scope of practice of the supervising physician's practice. The supervising physician's scope of practice shall be defined for the purpose of this section as "those tasks and procedures which the supervising physician is qualified by training or experience to perform.

(2) The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. Furthermore, the supervising physician must be certain that the physician assistant is knowledgeable and skilled in performing the tasks and procedures assigned.

…

(3) All tasks and procedures performed by the physician assistant must be documented in the appropriate medical record. During the initial six months of supervision of each physician assistant all documentation by the physician assistant in a medical chart must be reviewed, signed and dated by a supervising physician within seven days. Subsequent thereto, a supervising physician must review, sign and date all documentation by a physician assistant in medical charts within 30 days.

(1) An Advanced Registered Nurse Practitioner shall only perform medical acts of diagnosis, treatment, and operation pursuant to a protocol between the ARNP and a Florida-licensed medical doctor… The degree and method of supervision, determined by the ARNP and the physician … shall be specifically identified in the written protocol and shall be appropriate for prudent health care providers
of the physician on-site with the prescribing ARNP, but the degree and methods of supervision must be included in the written collaborative protocol.\textsuperscript{19}

\textbf{B. Analysis}

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Florida law. In the

under similar circumstances. General supervision by the physician...is required unless these rules set a different level of supervision for a particular act. The number of persons to be supervised shall be limited to insure that an acceptable standard of medical care is rendered in consideration of the following factors:
(a) Risk to patient;
(b) Educational preparation, speciality, and experience of the parties to the protocol;
(c) Complexity and risk of the procedures;
(d) Practice setting; and
(e) Availability of the physician...
(2) A written protocol signed by all parties, representing the mutual agreement of the physician...and the ARNP, shall include the following, at a minimum:
(a) General Data.
1. Signatures of individual parties to the protocol,
a. Name, address, ARNP certificate number,
b. Name, address, license number, and DEA number of the physician...,  
2. Nature of practice, practice location, including primary and satellite sites, and
3. Date developed and dates amended with signatures of all parties.
(b) Collaborative Practice Agreement.
1. A description of the duties of the ARNP.
2. A description of the duties of the physician... (which shall include consultant and supervisory arrangements in case the physician...is unavailable).
3. The management areas for which the ARNP is responsible, including
   a. The conditions for which therapies may be initiated,
   b. The treatments that may be initiated by the ARNP, depending on patient condition and judgment of the ARNP,
   c. The drug therapies that the ARNP may prescribe, initiate, monitor, alter, or order.
4. A provision for annual review by the parties.
5. Specific conditions, and a procedure for identifying conditions, that require direct evaluation or specific consultation by the physician...
The parties to the protocol, to insure an acceptable standard of supervision and medical care, will decide the detail and scope needed in the description of conditions and treatments, and in doing so will consider the factors listed in subparagraphs (1)(a) through (e) above.
(3) The original of the protocol and the original of the notice shall be filed with the Department yearly, and a copy of the protocol and a copy of the notice required by Section 458.348(1), F.S., shall be kept at the site of practice of each party to the protocol. Any alterations to the protocol or amendments should be signed by the ARNP and a Florida-licensed medical doctor, osteopathic physician, or dentist and filed with the Department within 30 days of the alteration to be kept in the Department for filing purposes only.
After the termination of the relationship between the ARNP and the supervising professional, each party is responsible for insuring that a copy of the protocol is maintained for future reference for a period of four years.

\textsuperscript{19} \textit{Id.}
same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A consultation with a non-physician healthcare provider may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued. PAs may receive authorization from the Board to prescribe drugs as delegated by a supervising physician. PAs can prescribe naloxone as a nasal spray, but cannot prescribe naloxone as an injectable drug. ARNPs may prescribe drugs if working with a collaborating physician. The supervising or collaborating physician may allow a PA or ARNP to prescribe drugs without his or her presence on-site.

**Conclusion:** Allied health professionals may replace a physician in specific functions during the prescription process. PAs and ARNPs may prescribe drugs to patients, but only with a collaborating physician’s authorization. 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**

While there is no explicit regulatory scheme for prescribing, 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 Florida 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 Florida Pharmacy Act, with regulations in the Florida Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines.

The prescribing physician or ARNP may also dispense the agent at the point of service, but if they dispense anything other than complimentary prepackaged samples of medicinal drugs they must register as a dispensing practitioner with the licensing board. The dispensing practitioner must comply

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1) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:
   (a) Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed $100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.
   (b) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.
   (c) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

3) The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the
with the standard dispensation rules that apply to pharmacists, which include recordkeeping and the proper labeling of the agent.\textsuperscript{23} PAs who are authorized to prescribe drugs may only dispense complimentary sample drugs.\textsuperscript{24}

B. Analysis

same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

(4) The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(5) A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

(a) Practitioner's name;
(b) Patient's name;
(c) Date dispensed;
(d) Name and strength of drug; and
(e) Directions for use.


(1) Those ARNPs whose protocols permit them to dispense medications for a fee as contemplated by Section 465.0276, F.S., must register with the Board of Nursing.

(2) The ARNP dispensing practitioner must comply with all state and federal laws and regulations applicable to all dispensing practitioners under Section 465.0276, F.S.

\textsuperscript{23} Id.

\textsuperscript{24} Although practitioners, which by definition include PAs, who are licensed to prescribe drugs may dispense drugs, we interpret the legal scheme as limiting the PAs to the dispensing of samples. See, e.g., Survey, Survey of Pharmacy Law, Natl. Assn. Bd. of Pharm.(2007) (PAs may only dispense samples); Fla. Stat. Ann. § 459.022 (West 2007) (“Unless it is a drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465”); Fla. Admin. Code Ann. 64B8-30.006 (2007):

Only those physician assistants authorized by law and rule to prescribe shall be permitted to dispense sample drugs to patients. Dispensing of sample drugs to patients shall be permitted only when no charge is made to the patient or a third party for the service or the drugs and if the sample being dispensed could otherwise have been legally prescribed by the physician assistant. This rule shall not be construed to prohibit a physician assistant employed in a county health department from ordering and providing patients with prepackaged and prelabeled drugs in accordance with Section 154.04(1)(c), F.S.
Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized (see part II) can dispense the drug directly to the clients. Physicians, ARNPs, and PAs may dispense naloxone as a complimentary drug sample to patients. Physicians and ARNPs may also register with the appropriate board to dispense prescription drugs. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules that apply to pharmacists.

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

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

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

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI) and be subject to 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 illegally distributing a legend drug. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. Finally, the unauthorized recipient of the drug could be charged with illegal possession of a prescription (legend) drug, subject to fines. Even a minor crime

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25 Only drugs that the practitioner is legally able to prescribe may be dispensed as a sample. PAs may not prescribe naloxone as an injectable drug but may prescribe it as a nasal spray, so they are likewise limited to dispensing naloxone samples in the form of a nasal spray (See Part II).
28 Infra fn. 29.
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.

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

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

It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

... (4) The sale, distribution, purchase, trade, holding, or offering of any drug ... in violation of § 499.001-499.081.
... (12) The possession of any drug in violation of § 499.001-499.081.
... (14) The purchase or receipt of a legend drug from a person that is not authorized under this chapter to distribute legend drugs to that purchaser or recipient.
(15) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess legend drugs from the person selling or transferring the legend drug.
... (17) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.
... (24) The distribution of a legend device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.
... (27) Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
...
participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct.31 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.32

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

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(f) Aiding, assisting, procuring, or advising any unlicensed person to practice medicine contrary to this chapter or to a rule of the department or the board.

... (g) Failing to perform any statutory or legal obligation placed upon a licensed physician.

... (q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

31 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).

provider is required to practice his or her profession in a reasonably competent manner. Particular conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the ‘‘standard of care.’’ The essence of the inquiry is whether the provider’s treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances.

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

B. Analysis

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

“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.


35 Schuette v. State, 822 So.2d 1275 (Fla. 2002).
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.36

“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.37 However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable. A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is arguably too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary resuscitation procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population.

In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent.38 Florida state law provides similar liability protections from damages caused by volunteers at nonprofit organizations for acts or omissions if the volunteer was acting in good faith and within the scope of his or her official duties.39 It appears that under Florida 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

(1) Any person who volunteers to perform any service for any nonprofit organization, including an officer or director of such organization, without compensation, except reimbursement for actual expenses, shall be considered an agent of such nonprofit organization when acting within the scope of any official duties performed under such volunteer services. Such person shall incur no civil liability for any act or omission by such person which results in personal injury or property damage if:
(a) Such person was acting in good faith within the scope of any official duties performed under such volunteer service and such person was acting as an ordinary reasonably prudent person would have acted under the same or similar circumstances; and
(b) The injury or damage was not caused by any wanton or willful misconduct on the part of such person in the performance of such duties.
1. For purposes of this act, the term "nonprofit organization" means any organization which is exempt from taxation pursuant to 26 U.S.C. s. 501, or any federal, state, or local governmental entity.
2. For purposes of this act, the term "compensation" does not include a stipend as provided by the Domestic Service Volunteer Act of 1973, as amended (Pub. L. No. 93-113), or other financial assistance, valued at less than two-thirds of the federal hourly minimum wage standard, paid to a person who would otherwise be financially unable to provide the volunteer service.

(2) Except as otherwise provided by law, if a volunteer is determined to be not liable pursuant to subsection (1), the nonprofit organization for which the volunteer was performing services when the damages were caused shall be liable for such damages to the same extent as the nonprofit organization would have been liable if the liability limitation pursuant to subsection (1) had not been provided.

(3) Members of elected or appointed boards, councils, and commissions of the state, counties, municipalities, authorities, and special districts shall incur no civil liability and shall have immunity from suit as provided in s. 768.28 for acts or omissions by members relating to members' conduct of their official duties. It is the intent of the Legislature to encourage our best and brightest people to serve on elected and appointed boards, councils, and commissions.
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 Florida law we have outlined above:

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

B. Changes in State Law

Under the current law of this state, dispensing or administering naloxone to third parties who have not been prescribed the drug is illegal. Passing legislation to allow these practices would help reduce overdose deaths and ease the concerns of providers and clients about possible legal penalties. New York’s legislature recently passed a law to provide clear authorization of medical providers to “prescribe” or “dispense” naloxone to unknown ODUs via trained patients or volunteers (“Trained Overdose Responders” under NYS law); establish immunity for providers participating in such programs; and establish immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.40

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

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[The 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.]
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 ODU's.