DATE: October 15, 2007

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

INTRODUCTION

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

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

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

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

---

2. Prescribing naloxone to ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.
3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.
4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODUs who are not patients.
5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensal?
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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in New Jersey is governed by N.J.S.A. § 45:9-1 et seq., with regulations found in chapter 35 of title 13 of the New Jersey Administrative Code. The Board of Medical Examiners has the authority to license physicians, N.J.S.A. § 45:9-6, and to punish licensed physicians who behave in ways that violate the law or beneath the standards of good faith and regular practice of medicine. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the New Jersey Board of Medical Examiners 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) … a practitioner shall not dispense drugs or issue prescriptions to an individual, pursuant to the requirements of this subchapter, without first having conducted an examination, which shall be appropriately documented in the patient record. As part of the patient examination, the practitioner shall: 1. Perform an appropriate history and physical examination; 2. Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care; 3. Formulate a therapeutic plan and discuss such plan,

---

4 See N.J.S.A. § 45:9-16.
7 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Dangerous Substances Act, N.J.S.A. § 24:21-5 to 24:21-8.1, recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is a “legend drug,” which requires a prescription. N.J.S.A. 2C:35-2.
along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and 4. Ensure the availability of the physician or coverage for the patient for appropriate follow-up care.8

A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may issue a written prescription for a drug to a patient, guardian or authorized representative in the form authorized by this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.9

The required medical examination may be omitted under specified circumstances:

(b) Notwithstanding (a) above, an examination of the patient's condition shall not be required prior to the dispensing of drugs or the issuance of a prescription under the following circumstances:

....

4. For an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription;
5. For a patient examined by a healthcare professional who is in collaborative practice with the practitioner…10

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

The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. Disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances. These cases apply the familiar standard under which a prescription is valid if it is written for a legitimate medical purpose, in the normal course of professional practice.12

B. Analysis

Physicians are required 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. The law does not further specify the length or intensity of these interactions, leaving the precise

8 N.J.A.C 13:35-7.1A.
10 N.J.A.C 13:35-7.1B.
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
contours of the examination and discussion to the judgment of the physician. 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 New Jersey laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone. Some of the prescription tasks can be delegated to allied health professionals.

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

**A. Professional Licensure Law**

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. For specific requirement of physician involvement with prescription by allied health professionals, see the statutes and New Jersey Board of Medical Examiners regulations on advanced practice nurses,¹³ clinical nurse specialists,¹⁴ and

---

¹³ N.J.A.C. 13:37-7.7:

(a) Every nurse practitioner/clinical nurse specialist issuing prescriptions and orders or dispensing medications in any setting other than in a licensed acute care or long-term care facility shall provide the following on all said prescriptions and orders:

1. The prescriber's full name, address, telephone number, license number, certification number and academic degree. This information shall be printed on all prescriptions/orders;
2. The full name, age and address of the patient;
3. The date of issuance of prescription/order;
4. The signature of prescriber, hand-written as "R.N., N.P., C." or "R.N., C.N.S., C."; and
5. The full name and academic degree of the collaborating physician. For prescriptions only, the address and telephone number of the collaborating physician shall be printed.

(b) Every nurse practitioner/clinical nurse specialist who prescribes/orders medications shall, in addition to the information set forth in (a) above, provide the following on all prescriptions:

1. The name, strength, route and quantity of drug or drugs to be dispensed;
2. Adequate instructions for the patient; a direction of "prn" or "as directed" alone shall be deemed an insufficient direction;
3. The number of refills permitted or time limit for refills, or both;
4. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the nurse practitioner/clinical nurse specialist's initials next to the chosen option, in addition to the space required for the signature in (a)4 above;

5. Every nurse practitioner/clinical nurse specialist shall assure that each container of medication dispensed directly to a patient is labeled in a legible manner with at least the following information:
   i. The full name(s) of the nurse practitioner/clinical specialist and the collaborating physician;
   ii. The full name of patient;
   iii. The date medication is dispensed;
   iv. The expiration date of medication;
   v. The name, strength and quantity of medication dispensed; and
   vi. Adequate instructions for the patient regarding the frequency of administration of the medication;

6. When a nurse practitioner/clinical nurse specialist dispenses a pharmaceutical sample which has been packaged and labeled by the manufacturer and such sample package contains the information required by (b)5ii, v and vi above, the information listed in (b)5i and iii, inclusive, above need not be added;

7. When a nurse practitioner/clinical nurse specialist dispenses a medication other than a sample exempted pursuant to (b)6 above in a container without sufficient space for the information required by this subsection, the container shall be placed in a large container or envelope and the larger container or envelope shall be labeled as indicated in this subsection; and

8. Each container of medication dispensed shall contain only one type of medication.

(c) In no instance shall a nurse practitioner/clinical nurse specialist dispense drugs or sign a blank prescription form without complying with the standards in (b) above.

(d) In licensed acute care and long term care facilities where routine identifying information is maintained on file in a central repository or in the patients' record, it shall not be required for the nurse practitioner/clinical nurse specialist to include the identifying information contained in (a)1, 2 and 5 above on each prescription or order.

N.J.S.A. §45:11-49 as interpreted by N.J.A.C. 13:35-6.6:

a) "Collaboration" [with a physician] means the ongoing process by which an advanced practice nurse and a physician engage in practice, consistent with agreed upon parameters of their respective practices. ... "Joint protocol" means an agreement or contract between an advanced practice nurse and a collaborating physician which conforms to the standards established by the Director of the Division of Consumer Affairs pursuant to this rule.

b) Physician(s) with whom they are in collaboration shall develop a joint protocol, which shall be:
   1. In writing; 2. Signed by both the advanced practice nurse and the physician, with an acknowledgment that any inappropriate professional behavior or violation of the protocol on the part of either the physician or the advanced practice nurse will be reported to his or her respective licensing board; 3. Maintained on the premises of every office in which the advanced practice nurse practices; 4. Updated on an ongoing basis to reflect changes in the practice, office personnel, skills of the advanced practice nurse, frequency of record review, and reference materials containing practice guidelines or accepted standards of practice; and 5. Reviewed at least on an annual basis.

c) The content of a joint protocol under (b) above shall address:
   1. The nature of the practice, the patient population (for example, pediatric patients) and settings (for example, inpatient, nursing home, patient residences
physician assistants.\textsuperscript{15} Physician assistants must be under the supervision of a physician, which, in an outpatient setting, is satisfied by telephone availability and chart review.

or other alternative care environments); 2. Any particular circumstances for which, prior to prescribing, a specific examination is to be performed or a definitive diagnosis made; 3. The recordkeeping methodology to be used in the practice (for example, the protocol might indicate that records should contain subjective complaints, objective findings, an assessment and a plan of treatment); 4. A list of categories of medications appropriate to the practice; 5. A delineation of specific medications and the specific number of refills, to be prescribed pursuant to the direction of the physician; 6. Specific requirements with respect to the recordation, in the patient record and/or in separate logs, of medications prescribed or \textit{dispensed}, dosages, frequency, duration, instructions for use and authorizations for refills (emphasis added); 7. Any medical conditions or findings within the nature of the practice which should require direct consultation prior to the prescribing or ordering of medications or devices; 8. The frequency and methodology to be employed to ensure periodic review of patient records; 9. Identification of the means by which the advanced practice nurse and collaborating physician can be in direct communication, as well as a description of arrangements which will assure that the collaborating physician or peer coverage is accessible and available; 10. Procedures for the use of medications in emergency situations; and 11. Identification of reference materials containing practice guidelines or accepted standards of practice.

(d) Failure to establish and implement joint protocols consistent with the standards set forth in this section and any violation of the joint protocol by an advanced practice nurse or physician may be deemed professional misconduct or other grounds for disciplinary sanction within the meaning of N.J.S.A. 45:1-21 by his or her respective licensing board.

\textsuperscript{14} \textit{Id.} \\
\textsuperscript{15} N.J.S.A. §45:9-27.16 with regulations found in N.J.C.A. 13:35-2B.12:

(a) A physician assistant may issue prescriptions only in accordance with the following conditions:

\[ \ldots \]

2. A physician assistant shall provide the following on all prescription blanks:

i. The physician assistant's full name, professional identification ("PA-C"), license number, address and telephone number. This information shall be printed or stamped on all prescription blanks;

ii. The supervising physician's full name, printed or stamped;

iii. A statement indicating whether the prescription is written pursuant to protocol or specific physician direction. Acceptable abbreviations are "prt" for protocol and "spd" for specific physician direction;

iv. The full name, age and address of the patient;

v. The date of issuance of prescription;

vi. The name, strength and quantity of drug or drugs to be dispensed and route of administration;

vii. Adequate instruction for the patient. A direction of "p.r.n." or "as directed" alone shall be deemed an insufficient direction;

viii. The number of refills permitted or time limit for refills, or both;

ix. The signature of the prescriber, hand-written; and

x. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician assistant's initials next to the chosen option, in addition to the space required for the signature in (a)3ix above.
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under New Jersey law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A consultation with a non-physician healthcare provider may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued. However, specific and detailed conditions govern the communication between the “collaborating physician,” a licensed non-physician provider, and the patient. These rules must be met for the prescription to be valid.

Conclusion: Advanced practice nurses, clinical nurse specialists and physician assistants may independently staff a naloxone prescription program, provided the appropriate collaboration or supervision agreement with a physician is in place. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

N.J.S.A. §45:9-27.18:

a. A physician assistant and a temporary licensed physician assistant shall be under the direct supervision of a physician at all times during which the physician assistant or temporary licensed physician assistant is working in his official capacity.

b. In an inpatient setting, direct supervision of a physician assistant shall include, but not be limited to:
   (1) continuing or intermittent presence with constant availability through electronic communications;
   (2) regularly scheduled review of the practice of the physician assistant; and
   (3) personal review by a physician of all charts and records of patients and countersignature by a physician of all medical orders, including prescribing and administering medication, within 24 hours of their entry by the physician assistant.

c. In an outpatient setting, direct supervision of a physician assistant shall include, but not be limited to:
   (1) constant availability through electronic communications;
   (2) regularly scheduled review of the practice of the physician assistant; and
   (3) personal review by a physician of the charts and records of patients and countersignature by a physician of all medical orders, including prescribing and administering medication, within seven days of their entry by the physician assistant, except that in the case of any medical order prescribing or administering medication, a physician shall review and countersign the order within 48 hours of its entry by the physician assistant.

d. In any setting, direct supervision of a temporary licensed physician assistant shall include, but not be limited to:
   (1) continuing physical presence of a physician or a licensed physician assistant;
   (2) regularly scheduled review by a physician of the practice of the temporary licensed physician assistant; and
   (3) personal review by a physician of all charts and records of patients within 24 hours of an entry by the temporary licensed physician assistant.
III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

According to the licensure law described in sections I and II, a healthcare provider must “formulate a therapeutic plan 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.16

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 New Jersey 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 N.J.S.A. § 45:14-1 et seq., with regulations found in chapter 39 of title 13 of the New Jersey Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines, barring personal objections.

Physicians and physician assistants may dispense the agent at the point of service. The Code states, in part:

A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may dispense a drug directly to a patient, guardian or authorized representative under the circumstances and limitations set forth in this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.\(^\text{17}\)

Advanced practice nurses and clinical nurse specialists working in collaboration with a physician may also dispense legend drugs.\(^\text{18}\) Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that have to accompany such practice.\(^\text{19}\)

\(^{17}\) N.J.A.C. 13:35-7.5(a); N.J.A.C. 13:35-7.1 (“‘Practitioner’ means any licensee subject to the regulatory authority of the Board authorized to prescribe or dispense drugs, including physicians… and, to the extent permitted by law and rule, registered residents, resident permit holders, [and] physician assistants”).

\(^{18}\) Supra, fn. 15.

\(^{19}\) N.J.A.C. 13:35-7.5:

\(\ldots\)

(b) A practitioner who dispenses drugs in the office shall maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. A practitioner shall be responsible for the disposal of such drugs in a manner which will not pose a health hazard and in accordance with all local, State and Federal requirements.

(c) All drugs dispensed shall be recorded in the applicable patient record.

(d) All drugs dispensed, with the exception of samples of drugs which are not controlled substances and which are packaged and labeled by the manufacturer, shall be recorded in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1. The full name of the patient;
2. The complete name of each drug dispensed;
3. The strength and quantity of the drug dispensed;
4. Instructions as to the frequency of use;
5. The date of dispensing; and
6. The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.
B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that she has followed the prescription guidelines, a physician, physician assistant or advanced practice nurse may dispense the drug directly to the clients. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirement to maintain a dispensation log, and proper labeling of the agent, including the patient’s name and other essential information.

Conclusion: Dispensing naloxone by valid prescription does not violate New Jersey 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.

(e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

(f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:
1. The complete name of the drug dispensed;
2. The strength and quantity of the drug dispensed;
3. Instructions as to the frequency of use;
4. Special precautions, as appropriate; and
5. The expiration date of the drug.

(g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:
1. The full name of the patient;
2. A list of the ingredients if the drug was compounded, not manufactured;
3. The date of dispensing; and
4. The identity of the dispensing practitioner.

N.J.A.C. 13:35-7.5 (d) and (e).
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.\textsuperscript{21} 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.\textsuperscript{22} 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.\textsuperscript{23} While this is not a serious crime—and the possession of less than six doses of the drug received within the previous 24 hours from the person for whom the drug was prescribed may be exempt from prosecution\textsuperscript{24}—even a minor crime can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

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

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

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\textsuperscript{25} There is no risk of professional censure for participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

\textsuperscript{21} Distribution of prescription drugs without a valid prescription is punishable by fines and other penalties, depending on the number of doses and other circumstances. Distribution of up to 4 doses may carry a fine of up to $1,000 (N.J.S.A. 2C:35-10.5 (A)(1)); up to 100 doses, may carry a fine of $200,000 (N.J.S.A. 2C:35-10.5 (A)(3)); and 100 or more units may carry a fine of $300,000 (N.J.S.A. 2C:35-10.5 (A)(4)).

\textsuperscript{22} N.J.S.A. 45:9-22, which makes the practice of medicine without a license punishable by a fine of $200 for the first offense, with penalties to be determined by the Medical Board for the subsequent offences.

\textsuperscript{23} N.J.S.A. 2C:35-10.5(e)(1).

\textsuperscript{24} N.J.S.A. 2C:35-10.5 (A).

\textsuperscript{25} N.J.S.A. 45:9-22.
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.

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.’’ 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

26 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).
28 Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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 primarily caused by a patient’s decision to inject heroin; courts have usually applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.

“Loss of chance” doctrine in tort law establishes liability when negligent or otherwise harmful behavior substantially contributes to an injury, even if the injury may have also occurred from other causes. A plaintiff could also allege that the provision of naloxone led to delay or failure to summon medical help, leading to the “loss of a chance” to receive medical care. However, the imposition of liability under this doctrine would be highly problematic if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as a stop-loss measure before medical help can be summoned.

Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the

program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable. 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. New Jersey law provides similar liability protections from damages caused by “employees… of non-profit corporations, servants or volunteers” for negligent acts affecting anyone within the scope of the organization’s benefactions “to whatever degree.” This is effective so long as the agent responsible is not a “compensated health provider” employee practicing within the scope of their profession. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. Thus, it appears that under New Jersey law, volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

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

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state. However, as with any healthcare practice, institutions and professionals providing this service should follow the relevant rules and regulations that govern their practice to avoid professional, civil, and criminal liability.

The following is a summary of the program guidelines dictated by New Jersey 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.

C. Cooperation with First Responders

[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.]
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 ODU's.