DATE: August 13, 2007

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

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 IDU 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 IDU Patient?

A. Professional Licensure Law

The practice of medicine in Delaware is governed by the Medical Practice Act, with regulations found in the Delaware Administrative Code. The Board of Medical Practice (the “Board”) has the authority to license physicians 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. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe.

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

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically. This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.

Delaware law does not define the extent or basis of physicians’ general authority to write prescriptions; however this authority is assumed, as an aspect of the professional practice of medicine. In the absence of any further provisions,

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5 Code Del. R. § 10-517-001 (2007), et seq.
9 While naloxone is not specifically excluded from the schedules in the Delaware 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 Delaware.
10 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
we presume a prescription for naloxone would also be governed by the same
broad principles that govern prescriptions for controlled substances.\textsuperscript{11} Under this
standard, a prescription is valid if it is written (1) for a legitimate medical purpose
by an individual practitioner (2) acting in the usual course of his professional
practice.\textsuperscript{12} In determining whether a prescription arises within the usual 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.\textsuperscript{13}

\textbf{B. Analysis}

While not explicitly required by Delaware statutes, it is prudent for
physicians to adhere to the standards applicable to the prescription of controlled
substances. These common-sense rules require providing a physical examination
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 IDU patient is consistent with
the standard for a valid prescription under Delaware laws governing the
physician's authority to prescribe. The same rules that apply to any
prescription drug in this state apply to naloxone.

\section*{II. May Anyone Other Than Physician Issue A Prescription For Naloxone?}

\textbf{A. Professional Licensure Law}

Allied health professionals in this state are authorized to replace
physicians in some or all aspects of a prescription program. Advanced practice
nurses (APNs) may prescribe drugs if they are working in collaboration with a
physician\textsuperscript{14} and receive authorization from the Joint Practice Committee.\textsuperscript{15}

\textsuperscript{12} Id.
\textsuperscript{13} See e.g., \textit{United States v. Moore}, 423 U.S. 122, 142-43 (1975).
Advanced practice nurses shall operate in collaboration with a licensed physician...or licensed Delaware health care delivery system to cooperate, coordinate, and consult with each other as appropriate pursuant to a collaborative agreement defined in the rules and regulations promulgated by the Board of Nursing, in the provision of health care to their patients. Advanced practice nurses desiring to practice independently or to prescribe independently must do so pursuant to § 1906(20) of Title 24.

Collaborative Agreement - Includes
1. A true collegial agreement between two parties where mutual goal setting, access, authority, and responsibility for actions belong to individual parties and there is a conviction to the belief that this collaborative agreement will continue to enhance patient outcomes and
2. A written document that outlines the process for consultation and referral between an Advanced Practice Nurse (APN) and a licensed physician...or licensed Delaware health care delivery system. This document can include, but not be limited to, written verification of health care facility approved clinical privileges or a health care facility approved job description of the APN. If the agreement is with a licensed Delaware health care delivery system, the individual will have to show that the system will supply appropriate medical back-up for purposes of consultation and referral.

Those individuals who wish to engage in independent practice without written guidelines or protocols and/or wish to have independent prescriptive authority shall apply for such privilege or privileges to the Joint Practice Committee and do so only in collaboration with a licensed physician...This does not include those individuals who have protocols and/or waivers approved by the Board of Medical Practice.

The "Joint Practice Committee" with the approval of the Board of Medical Practice shall have the authority to grant, restrict, suspend or revoke practice or independent prescriptive authority and the Joint Practice Committee with the approval of the Board of Medical Practice shall be responsible for promulgating rules and regulations to implement the provisions of this chapter regarding "advanced practice nurses" who have been granted authority for independent practice and/or independent prescriptive authority...

An APN...who is applying for independent practice and/or independent prescriptive authority shall:
1. Be an Advanced Practice Nurse (APN) holding a current permanent license issued by the Board of Nursing (BON). If the individual does not hold national certification, eligibility will be determined on a case by case basis.
2. Have completed a post basic advanced practice nursing program that meets the criteria as established in Section 4.7 of Article VIII of the Rules and Regulations of the Delaware Board of Nursing with documentation of academic courses in advanced health assessment, diagnosis and management of problems within the clinical specialty, advanced patho-physiology and advanced pharmacology/pharmacotherapeutics. In the absence of transcript verification of the aforementioned courses, applicants shall show evidence of content integration through course descriptions, course syllabi, or correspondence from school officials. If the applicant cannot produce the required documentation, such applicant may petition the Joint Practice Committee for consideration of documented equivalent independent prescriptive authority experience.
3. Submit a copy of the current collaborative agreement to the Joint Practice Committee (JPC). The collaborative agreement(s) shall include arrangements for
Physician assistants (PAs) may prescribe legend drugs according to standing orders approved of by their supervising physician. The supervising physician consultation, referral and/or hospitalization complementary to the area of the nurse’s independent practice.

4. Show evidence of the equivalent of at least thirty hours of advanced pharmacology and pharmacotherapeutics related continuing education within the two years prior to application for independent practice and/or independent prescriptive authority. This may be continuing education programs or a three credit, semester long graduate level course. The thirty hours may also occur during the generic APN program as integrated content as long as this can be documented to the JPC. All offerings will be reviewed and approved by the JPC.

5. Demonstrate how submitted continuing education offerings relate to pharmacology and therapeutics within their area of specialty. This can be done by submitting the program titles to show content and dates attended. If the JPC questions the relevance of the offerings, the applicant must have available program descriptions, and/or learner objectives, and/or program outlines for submission to the JPC for their review and approval.


1. APNs [with prescriptive authority] may prescribe, administer, and dispense legend medications…

2. APNs will be assigned a provider identifier number as outlined by the Division of Professional Regulation.

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4. APNs may request and issue professional samples of legend…medications that must be labeled in compliance with 24 Del.C., Section 2536(C).

5. APNs may give verbal prescription orders.


(a) A physician who delegates medical acts to a physician assistant is responsible for the physician assistant’s medical acts and must provide adequate supervision.

(b) A supervising physician may not delegate a medical act to a physician assistant who, by statute or professional regulation, is prohibited from performing the act.

(c) A supervising physician may not be involved in patient care in name only.

(d) A supervising physician may not delegate medical acts to a physician assistant that exceed the physician’s scope of practice.

(e) A supervising physician may not at any given time supervise more than 2 physician assistants, unless a regulation of the Board increases or decreases the number.

(f) A physician who supervises a physician assistant in violation of the provisions of this subchapter or of regulations adopted pursuant to this subchapter is subject to disciplinary action by the Board of Medical Practice for permitting the unauthorized practice of medicine.

(g) A supervising physician who has supervising physician’s patients followed by a physician assistant shall reevaluate within…12 months every patient receiving other prescription medications…

(h) Prescription and nonprescription medications may be initiated by standing orders if these standing orders have been approved by the supervising physician.

(i) Hospitals, clinics, medical groups and other healthcare facilities may employ physician assistants; however, no more than 2 physician assistants may at any given time be employed and supervised for each physician practicing in the same facility unless a regulation of the Board increases or decreases the number.
does not have to be on-site, but must be available by some form of electronic communication and be able to be on-site within thirty minutes if needed.\textsuperscript{17}

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Delaware law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. Given the proper agreements with physicians or necessary regulatory authorization, either an APN or a PA could staff an overdose prevention program including the prescription of naloxone.

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

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

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 the 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

\textsuperscript{17} Del. Code Ann. tit. 24, § 1770A(3) (2007): "Supervision of physician assistants” means the ability of the supervising physician to provide or exercise control and direction over the services, activities, and duties of a physician assistant. The constant physical presence of the supervising physician is not required in the supervision of a physician assistant, provided that the supervising physician is readily accessible by some form of electronic communication and that the supervising physician can be physically present with the physician assistant within 30 minutes. Depending upon the specific clinical activity of the physician assistant, a shorter response time may be required[.]
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 Delaware should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

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

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

**A. The Regulatory Scheme**

Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. Under the pharmacy laws, with regulations found in the administrative code, pharmacists are expected to fill a prescription that meets regulatory guidelines.

Healthcare providers can dispense the agent at the point of service. Physicians may dispense prescription drugs. APNs with prescriptive authority may dispense legend drugs. They may also dispense professional samples of

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19 Code Del. R. § 10-522-001 (Lexis 2007), et seq.
drugs, but must follow basic labeling requirements. Registered nurses may dispense drugs in accordance with standing orders of the prescribing practitioner. PAs may dispense legend drugs under the supervision of a physician. 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.

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22 Code Del. R. § 10-518-8.18(4) (Lexis 2007) (“APNs may request and issue professional samples of legend…medications that must be labeled in compliance with 24 Del.C., Section 2536(C)").

23 Code Del. R. § 10-518-7.6 (Lexis 2007):
(1)3. "Standing order" - An order written by the practitioner which authorizes a designated registered nurse or nurses to dispense prescription drugs to his/her patients(s) according to the standards listed below.

(2) Standards
1. Only registered nurses may assume the responsibility of dispensing as defined in the Nurse Practice Act and delineated below.
2. The medication must be prepackaged by a pharmaceutical company or prepared by a registered pharmacist.
3. The nurse shall be responsible for proper drug storage of the medication prior to dispensing.
4. The practitioner who originated the prescription or drug order must be on the premises or he/she or their designated coverage shall be available by telephone during the act of dispensing.
5. Once a drug has been dispensed it shall not be returned for reuse by another or the same patient in an institutional setting.
6. The nurse may not designate any part of the dispensing function to any other individual who is not licensed to dispense.
7. The dispensing nurse must assure compliance to the state generic substitution laws when selecting the product to be dispensed.
8. The nurse-dispensed prescription may not be refillable; it requires the authority of the prescriber with each dispensing.
9. A usage review process must be established for the medicines dispensed to assure proper patient usage.
10. All dispensed drugs must be labeled as defined above and dispensed in proper safety closure containers that meet the standards established by the United States Pharmacopoeia for stability.
11. Record keeping must include the maintenance of the original written prescription of drug order for at least three years, allow retrospective review of accountability, and provide an audit trail. All dispensing records must be maintained on site, and available for inspection by authorized agents of the Board of Health, Pharmacy, and Nursing.
12. The dispensing nurse shall assume the responsibility of patient counseling of drug effects, side-effects, desired outcome, precautions, proper storage, unique dosing criteria, drug interactions, and other pertinent data, and record evidence of patient education.


Practitioners who dispense drugs directly to patients shall label all drugs or provide a document including the following information:
B. Analysis

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. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

Conclusion: Dispensing naloxone by valid prescription does not violate Delaware 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. 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 can have serious repercussions for a person with a record of drug convictions or who is on probation or parole.

(1) The patient's full name;
(2) The date the drugs were dispensed to the patient;
(3) The practitioner's name;
(4) The practitioner's directions.

27 Del. Stat. Ann. tit. 24, § 1702(9)(c) (2007) (The “practice of medicine” includes “[o]ffering or undertaking to...give, or administer any drug or medicine for the use of another person”).
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

(a) It is unlawful for any person knowingly or intentionally to possess any drug for which a prescription is required…
(b) Possession of a drug…in violation of this section, is a class B misdemeanor.
(c) In any prosecution for "unlawful possession of a noncontrolled prescription drug," it is an affirmative defense that the drug was possessed or consumed within the residence of the defendant, that a member of the defendant's household possessed a valid prescription for said drug, that the possession or consumption by the defendant was for the purpose of treating an illness and that the drug in question was approved for use for the specific illness.

Class B misdemeanors are punishable by up to six months in jail and a fine up to $1,150. Del. Code Ann. tit. 11, § 4206(b) (2007).


(a) A person to whom a certificate to practice medicine in this State has been issued may be disciplined by the Board for unprofessional conduct, as defined in subsection (b) of this section, by means of levying a fine, or by the restriction, suspension, or revocation, either permanent or temporary, of that person's certificate to practice medicine, or by other appropriate action, which may include a requirement that a person who is disciplined must complete specified continuing education courses.
(b) "Unprofessional conduct" includes but is not limited to any of the following acts or omissions:

(1) …[T]he use of any fraudulent, deceitful, dishonest, or unethical practice in connection with a certification, registration, or licensing requirement of this chapter, or in connection with the practice of medicine or other profession or occupation regulated under this chapter;

(3) Any dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the public;

(6) The use, distribution, or issuance of a prescription for a dangerous…drug, other than for therapeutic or diagnostic purposes;

(11) Misconduct, incompetence, or gross negligence in the practice of medicine or other profession or occupation regulated under this chapter;
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. 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.

(17) The violation of a provision of this chapter or the violation of an order or regulation of the Board related to medical procedures or to the procedures of other professions or occupations regulated under this chapter, the violation of which more probably than not will harm or injure the public or an individual...

30 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).
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 IDU 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.34 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.35

“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.\(^3\) 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.\(^4\)

**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

\(^3\) U.S. v. Anderson, 669 A.2d 73 (Del. 1995).  
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 Delaware law we have outlined above:

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

**B. Changes in State Law**

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

**C. Cooperation with First Responders**

Programs should also work with police and EMTs to inform them about program goals and practices. Alerting first responders to the presence of take-home naloxone can help inform their work and alleviate resistance or roadblocks.

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