MEMORANDUM

DATE: August 7, 2007

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

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. The legislature in this state has enacted a law that protects health care providers from any civil or criminal liability that may arise from prescribing, administering, or dispensing naloxone. Any additional 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 IDU 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 ODU's who are not patients of the prescriber. 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.) However, this state has provided statutory immunity to healthcare professionals who prescribe, administer, and dispense naloxone to patients (See Parts I and VII).

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. This state has taken

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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.
positive action to clearly legalize prescription, dispensing, and administration of naloxone by medical professionals and protect them from civil and criminal liability. This legislation helps lower legal barriers and increase access to naloxone (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 Connecticut is governed by the chapter entitled “Medicine and Surgery” in the CT statutory code, with regulations found in the Regulations of Connecticut State Agencies. The Board of Medical Examiners 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, but the law has been interpreted to authorize the Connecticut Medical Examining Board 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.

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. Additionally, Connecticut law protects prescribing health care professionals from

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5 CT ADC 19a-9 (2007), et seq; CT ADC 19a-14 (2007), et seq.
8 Pet v. Department of Health Services, 638 A.2d 6 (Conn. 1994).
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
liability for prescribing, dispensing, and administering naloxone. This reflects the broad discretion Connecticut grants to physicians’ in prescribing and dispensing medical agents such as naloxone.

Connecticut 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. State law provides civil and criminal immunity to healthcare professionals who use ‘reasonable care’ in prescribing naloxone to patients. In the absence of any further provisions, we presume a prescription for naloxone would also be governed by the same broad principles that govern prescriptions for controlled substances:

A physician, in good faith and in the course of the physician's professional practice only, may prescribe, administer and dispense controlled substances . . . for demonstrable physical or mental disorders but not for drug dependence except in accordance with state and federal laws and regulations adopted thereunder.

Under these laws, a prescription is valid if it is written (1) in good faith, (2) in the usual course of professional practice, and (3) for a legitimate medical purpose.

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. 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.

B. Analysis

A licensed health care professional who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe, dispense or administer an opioid antagonist to a drug user in need of such intervention without being liable for damages to such person in a civil action or subject to criminal prosecution. For purposes of this section, "opioid antagonist" means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of drug overdose.

Physicians must use reasonable care when prescribing naloxone. While not explicitly required by Connecticut statutes, it is prudent for physicians to also adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

Conclusion: A prescription for naloxone to an IDU patient is consistent with the standard for a valid prescription under Connecticut 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. Advanced practice nurses (APNs) who are working in collaboration with a licensed physician may prescribe drugs, diagnose patients, implement health care regimens, and provide health counseling. Physician Assistants (PAs) may perform functions delegated

In all settings, the advanced practice registered nurse may, in collaboration with a physician licensed to practice medicine in this state, prescribe, dispense and administer medical therapeutics and corrective measures and may request, sign for, receive and dispense drugs in the form of professional samples in accordance with sections 20-14c to 20-14e, inclusive…For purposes of this subsection, “collaboration” means a mutually agreed upon relationship between an advanced practice registered nurse and a physician who is educated, trained or has relevant experience that is related to the work of such advanced practice registered nurse. The collaboration shall address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the advanced practice registered nurse, a method to review patient outcomes and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between an advanced practice registered nurse and a physician shall be in writing…and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, laboratory tests and other diagnostic procedures that the advanced practice registered nurse may prescribe, dispense and administer.
through written orders by a supervising physician. As delegated by the physician, a PA may examine and diagnose patients, and may prescribe legend drugs.\textsuperscript{19}

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Connecticut 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. APNs and PAs may prescribe medication, but must be working with a collaborating physician.

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

According to the licensure law described in sections I and II, a healthcare provider must use reasonable care when prescribing naloxone to a patient.\textsuperscript{20} The physician should also be treating a patient in the ordinary course of professional practice before issuing a prescription.\textsuperscript{21} This means that a prescription for naloxone is subject to general professional standards, which include the requirement that a patient be instructed in the indications, risks and proper administration of the prescribed medication.

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

\begin{itemize}
  \item[(a)] …A physician assistant may, as delegated by the supervising physician within the scope of such physician's license, (A) prescribe and administer drugs…
  \item[(b)] All prescription forms used by physician assistants shall contain the printed name, license number, address and telephone number of the physician under whose supervision the physician assistant is prescribing, in addition to the signature, name, address and license number of the physician assistant.
\end{itemize}

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 Connecticut 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 Practice Act, with regulations found in the Regulations of Connecticut State Agencies, pharmacists are expected to fill a prescription that meets regulatory guidelines.

A prescribing physician, PA, or APN may dispense the agent at the point of service. Dispensing must be done by the prescribing practitioner, within the

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23 CT ADC 20-576-1 (2007), et seq.
"Prescribing practitioner" means a physician…physician assistant, [or] advanced practice registered nurse…licensed by the state of Connecticut and authorized to prescribe medication within the scope of such person's practice.
These statutes have been interpreted to allow physicians, PAs, and APNs to dispense prescription drugs. Survey, Survey of Pharmacy Law, Natl. Assn. Bd. of Pharm. (2002).
scope of his or her prescriptive practice (See Part II). Regulations governing the dispensation of drugs directly from the provider’s office set basic standards packaging record-keeping that must accompany such practice. These regulations include the proper labeling of the agent, including the patient’s name and other essential information.25

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 Connecticut 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


…

(b) A patient's medical record shall include a complete record of any drug dispensed by the prescribing practitioner.
(c) A prescribing practitioner dispensing a drug shall package the drug in containers approved by the federal Consumer Product Safety Commission, unless requested otherwise by the patient, and shall label the container with the following information: (1) The full name of the patient; (2) the prescribing practitioner's full name and address; (3) the date of dispensing; (4) instructions for use; and (5) any cautionary statements as may be required by law.
(d) Professional samples dispensed by a prescribing practitioner shall be exempt from the requirements of subsection (c) of this section.
fines.\textsuperscript{26} 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{27} We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We could not locate any Connecticut law making it a crime to possess or distribute prescription drugs without a prescription.

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

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

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\textsuperscript{28} 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. The law in this state also protects healthcare providers providing naloxone to patients from criminal charges (See Part VII).\textsuperscript{29}

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.

  The board is authorized to restrict, suspend or revoke the license or limit the right to practice of a physician or take any other action in accordance with section 19a-17, for any of the following reasons:
  ...
  (4) illegal, incompetent or negligent conduct in the practice of medicine;
  (5) possession, use, prescription for use, or distribution of controlled substances or legend drugs, except for therapeutic or other medically proper purposes …
  ...
  (11) violation of any provision of this chapter or any regulation established hereunder.
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.30 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.31

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. There is little risk of being liable for any of these possibilities, because Connecticut state law provides immunity to health care providers who prescribe naloxone:

A licensed health care professional who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe, dispense or administer an opioid antagonist to a drug user in need of such intervention without being liable for damages to such person in a civil action or subject to criminal prosecution. For purposes of this section, "opioid antagonist" means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of drug overdose.32

Thus, it seems that a health care professional participating in a naloxone distribution program or prescribing and dispensing naloxone in her office would not be held liable for any misuse of or side effects from the drug, provided the health care professional acted non-negligently.

Generally, every tort claimant must establish that he or she suffered an injury that was actually caused by the defendant healthcare provider’s failure to exercise reasonable care. 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

30 Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist.); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
of care.”33 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 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,34 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. The existence of a state statute providing immunity to healthcare providers working with naloxone suggests that the state recognizes that naloxone is an appropriate drug to prescribe to ODUs at risk of overdose.

“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 “proximate cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.\textsuperscript{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.\textsuperscript{36} 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.\textsuperscript{37} However, the imposition of liability under this doctrine would be unusual if programs explicitly instruct patients not to rely wholly on the effects of naloxone, but rather to use it as an emergency 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 of their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent and unless a state expressly rejects the protection offered by the VPA.\textsuperscript{38}

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

\textsuperscript{38} 42 U.S.C.A. § 14503 (West 2000).
laws that apply specifically to volunteer providers may provide additional protection.

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state, and healthcare professionals are provided immunity under state law from civil or criminal liability charges for prescribing, administering, or dispensing naloxone. 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 Connecticut 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. 39

C. Cooperation with First Responders

Programs should also work with police and EMTs to inform them about program goals and practices. Alerting first responders to the presence of take-home naloxone can help inform their work and alleviate resistance or roadblocks to program implementation. By building their programs according to the regulatory schemes we have referenced above, programs can successfully navigate the legal questions around dispensation of this life-saving agent to IDUs.

39 N.Y. Pub. Health Law §3309 (McKinney 2006): [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.