DATE: January 8, 2008

RE: The legal requirements for operating an Opioid Antagonist Administration Program and potential liability in New York.

INTRODUCTION

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

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

We were funded by the Drug Policy Alliance to analyze the legal issues for naloxone distribution programs in the fifty United States. New York has responded to the overdose problem by authorizing interventions to promote the use of naloxone. The New York Administrative Code regulates how an Opioid Overdose Prevention Training Program (“program”) is to be established and how

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2 10 NY ADC 80.138 (West 2007).
3 10 NY ADC 80.138 (West 2007):

Opioid Overdose Prevention Training Program means a training program offered by an authorized Opioid Overdose Prevention Program which instructs a person to prevent opioid overdoses, including by providing resuscitation, contacting emergency medical services and administering an opioid antagonist.
non-medically licensed people\textsuperscript{4} can become trained overdose responders in order to be prescribed and dispensed naloxone.

This Memorandum addresses the following issues:

1. Operating a naloxone program in New York.
   A. What is required for a training program?
   B. Who is trained?
   C. What is required for the prescription and dispensation of naloxone?

2. Potential Liability
   A. Who has immunity?
   B. Who doesn’t have immunity?

**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\textsuperscript{5} who, upon examination,\textsuperscript{6} 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. Thus there are no legal barriers anywhere in the US to qualified medical personnel prescribing naloxone to patients at risk of overdose.

In most states, however, naloxone distribution programs are limited by the requirement that a clinician may generally only prescribe medications for his or her own patients. Providing naloxone to third parties who are themselves not at risk of overdose, or deputizing third parties (whether or not they are themselves at risk) to treat non-patients, is an effective way to save lives, but violates general prescription rules. Moreover, those third parties who undertake to treat others face at least a theoretical risk of being charged with the illegal practice of medicine. Rules on dispensing drugs to patients may also create uncertainty or inconvenience to naloxone programs, which work best when the drug is provided directly to the patient at the time it is prescribed.

New York has addressed this problem by clearly authorizing naloxone distribution programs involving third parties, and providing liability immunity for

\textsuperscript{4} 10 NY ADC 80.138 (West 2007) (“Person means an individual other than a licensed health care professional, law enforcement personnel, and first responders otherwise permitted by law to administer an opioid antagonist.”).

\textsuperscript{5} We will refer to a person who has received a legal prescription for naloxone as a “patient.”

\textsuperscript{6} 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.
non-medically licensed individuals who respond to drug overdoses. After training by a program, trained overdose responders may be prescribed and dispensed naloxone. As part of the process of dispensation, trained overdose responders should be given information about when and how to use the drug and other steps that are advisable in responding to an overdose.

Assuming the program follows the applicable rules and regulations and acts competently, there is no risk of criminal or civil liability arising out of naloxone prescription and dispensation activities beyond the applicable professional standard of care.

The Legal Analysis in Detail

I. Operating A Naloxone Program In New York.

A. What Is Required For A Training Program?

A program may be established for training individuals to prevent a fatal opioid overdose if a certificate of approval is obtained from the department of health. 7 A program director is to be in charge of managing the program.8 And a

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7 10 NY ADC 80.138 (West 2007).
(b) Registration.
(1) Registered providers may operate an Opioid Overdose Prevention Program if they obtain a certificate of approval from the department authorizing them to operate an Opioid Overdose Prevention Program and otherwise comply with the provisions of this section.
(2) Providers eligible to register to operate an Opioid Overdose Prevention Program that are in good standing may apply to the department to operate an Opioid Overdose Prevention Program on forms prescribed by the department which must include, at a minimum, the following information:
(i) the provider name, address, operating certificate or license number where appropriate, telephone number, fax number, e-mail address, program director and clinical director;
(ii) the name, license type and license number of the affiliated prescriber(s);
(iii) the name and location of the site(s) at which the Opioid Overdose Prevention Program will be conducted;
(iv) a description of the targeted population to be served and recruitment strategies to be employed by the Opioid Overdose Prevention Program; and
(v) the addresses, telephone numbers, fax numbers, e-mail addresses and signatures of the program director and clinical director.

8 10 NY ADC 80.138 (West 2007).
(1) Each Opioid Overdose Prevention Program shall have a program director who is responsible for managing the Opioid Overdose Prevention Program and shall, at a minimum:
(i) identify a clinical director to oversee the clinical aspects of the Opioid Overdose Prevention Program;
(ii) establish the content of the training program, which meets the approval of the department;
(iii) identify and train other program staff;
clinical director who is a physician, physician assistant or nurse practitioner\(^9\) must be appointed by the program director.\(^9\) Registered providers who may establish a program and prescribe and dispense naloxone include health care facilities; a physician, physician assistant, or nurse practitioner authorized to prescribe the use of an opioid antagonist; a drug treatment program licensed under the Mental Hygiene Law; a not-for-profit community-based organization having the services of a clinical director; and a local health department.\(^11\) The program must provide overdose response supplies and maintain a recordkeeping system.\(^12\)

(iv) select and identify persons as trained overdose responders;
(v) issue certificates of completion to trained overdose responders who have completed the prescribed program;
(vi) maintain Opioid Overdose Prevention Program records including trained overdose responder training records, Opioid Overdose Prevention Program usage records and inventories of Opioid Overdose Prevention Program supplies and materials;
(vii) ensure that all trained overdose responders successfully complete all components of Opioid Overdose Prevention Training Program;
(viii) provide liaison with local emergency medical services and emergency dispatch agencies, where appropriate;
(ix) assist the clinical director with review of reports of all overdose responses, particularly those including opioid antagonist administration; and
(x) report all administrations of an opioid antagonist on forms prescribed by the department.

\(^9\) 10 NY ADC 80.138 (West 2007).

(1) **Clinical director** means a physician, physician assistant or nurse practitioner who provides oversight of the clinical aspects of the Opioid Overdose Prevention Program. This oversight includes serving as a clinical advisor and liaison concerning medical issues related to the Opioid Overdose Prevention Program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

\(^10\) 10 NY ADC 80.138 (West 2007).

(2) Each Opioid Overdose Prevention Program shall have a clinical director who is responsible for clinical oversight and liaison concerning medical issues related to the Opioid Overdose Prevention Program and, at a minimum, shall:
(i) provide clinical consultation, expertise, and oversight;
(ii) serve as a clinical advisor and liaison concerning medical issues related to the Opioid Overdose Prevention Program;
(iii) provide consultation to ensure that all trained overdose responders are properly trained;
(iv) adapt and approve training program content and protocols; and
(v) review reports of all administrations of an opioid antagonist.

\(^11\) 10 NY ADC 80.138 (West 2007).

\(^12\) 10 NY ADC 80.138 (West 2007).

(5) The Opioid Overdose Prevention Program will maintain and provide response supplies including: latex gloves, mask or other barrier for use during rescue breathing, and agent to prepare skin before injection.

(6) The Opioid Overdose Prevention Program will establish and maintain a recordkeeping system that will include, at a minimum, the following information:
(i) list of trained overdose responders, including dates of completion of training;
(ii) a log of opioid overdose prevention trainings which have been conducted;
(iii) copies of program policies and procedures;
(iv) copy of the contract/agreement with the clinical director, if appropriate;
B. Who Is Trained?

Any adult may be trained to work as a targeted responder. ODUs and their families, friends and domestic partners are the primary target of this policy. Other targets are non-medical personnel who might encounter an overdose victim while performing their duties, like police officers. Trained overdose responders are those people that have been trained by a program.13

C. What Is Required For The Prescription And Dispensation Of Naloxone?

Naloxone is a prescription drug but is not a controlled substance.14 It may be prescribed by any clinician with the appropriate licensure. Physician assistants may prescribe naloxone when they work in collaboration with physicians, who do not have to be on site.15 Nurse practitioners may prescribe drugs in accordance with a physician practice agreement and the physician does not have to be on site.16

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13 10 NY ADC 80.138 (West 2007)


15 10 NY ADC 94.2 (West 2007):

A registered physician's assistant or a registered specialist's assistant may perform medical services but only when under the supervision of a physician. Such supervision shall be continuous but shall not necessarily require the physical presence of the supervising physician at the time and place where the services are performed. …

Prescriptions and medical orders may be written by a registered physician's assistant as provided in this subdivision when assigned by the supervising physician. (1) A registered physician's assistant may write prescriptions for a patient who is under the care of the physician responsible for the supervision of the registered physician's assistant. The prescription shall be written on the form of the supervising physician and shall include the name, address and telephone number of the physician. The prescription shall also bear the name, the address, the age of the patient and the date on which the prescription was written.

16 McKinney's Education Law § 6902 (West 2007)

Prescriptions for drugs, devices and immunizing agents may be issued by a nurse practitioner … in accordance with the practice agreement and practice protocols. … Each practice agreement shall provide for patient records review by the collaborating physician in a timely fashion but in no event less often than every three months.

National Association of Boards of Pharmacy, Survey of Pharmacy Law 2002-2003 (nurse practitioners have independent prescribing authority within a practice agreement or protocol).
New York’s requirement to receive a prescription of naloxone is completion of a program. The program teaches trained overdose responders how to respond to an overdose, the importance of calling emergency services and the importance of reporting all administrations of naloxone to the program director.\textsuperscript{17}

Physicians, physician assistants and nurse practitioners may dispense naloxone from a program.\textsuperscript{18} Of course, patients wishing to buy naloxone themselves may take a valid prescription to a pharmacy.\textsuperscript{19}

**Conclusion**: New York law and regulations explicitly authorize naloxone distribution programs that include prescribing and dispensing naloxone to trained responders who may not themselves be ODUs. In the normal course of practice, physicians, APNs and PAs may also prescribe and dispense naloxone to patients at risk of overdose.

**II. Potential Liability**

**A. Who has immunity?**

New York’s legislature passed a law to provide clear authorization for medical providers to prescribe and dispense naloxone to unknown ODUs via trained overdose responders. The law provides immunity for program

\textsuperscript{17} 10 NY ADC 80.138 (West 2007)

The trained overdose responders shall:

(i) complete an initial Opioid Overdose Prevention Training Program;
(ii) complete a refresher Opioid Overdose Prevention Training Program at least every two years;
(iii) contact the emergency medical system during any response to a victim of suspected drug overdose and advise if an opioid antagonist is being used;
(iv) comply with protocols for response to victims of suspected drug overdose; and
(v) report all responses to victims of suspected drug overdose to the Opioid Overdose Prevention Program director.

\textsuperscript{18} McKinney’s Education Law § 6807 (West 2007):

1. This article shall not be construed to affect or prevent: …

b. Any physician … or other licensed health care provider legally authorized to prescribe drugs under this title who is not the owner of a pharmacy or who is not in the employ of such owner, from supplying his patients with such drugs as the … licensed health care provider legally authorized to prescribe drugs under this title deems proper in connection with his practice, provided, however, that all such drugs shall be dispensed in a container labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.


\textsuperscript{19} Even if a pharmacist does not agree with the program they are legally expected to fill a prescription that meets regulatory guidelines. McKinney's Education Law § 6810 (West 2007).
participants; and establishes immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.\(^{20}\)

New York has a good Samaritan law protecting non-medically licensed people who voluntarily render first aid or emergency treatment to a person who is “unconscious, ill, or injured.” The liability protection exists as long as the first aid is given without expectation of monetary compensation and such emergency treatment is not given in a manner that is grossly negligent.\(^{21}\)

**B. Who doesn’t have immunity?**

The immunity provided for program participants does not apply to professional medical practice. 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.”\(^{22}\) The essence of the inquiry is whether the provider’s treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances. Blatant non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\(^{23}\)

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.\(^{24}\) New York state law provides similar liability protections from damages caused by health care providers acting voluntarily and without pay in the scope of his or her license.\(^{25}\) It appears that under New York 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:** Trained overdose responders are safe from civil or criminal liability when administering naloxone to an ODU as long as the administration is not conducted in a grossly negligent manner. Licensed

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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.

\(^{21}\) McKinney’s Public Health Law § 3000-a (West 2007).


\(^{23}\) McKinney’s Education Law § 6511 (West 2007).


health care professionals participating in overdose prevention programs are safe from liability as long as they possess and apply the knowledge and use the skill and care ordinarily used by similarly qualified professionals.

CONCLUSION

A Program requires a program director who must appoint a clinical director. The clinical director must be a physician, physician assistant or nurse practitioner. However, a physician can be assisted by physician assistants and nurse practitioners for the prescription and dispensation of naloxone.

Each prescription should be accompanied by oral and/or written information on the following:

- information on how to spot symptoms of an overdose,
- the importance of calling 911 for help,
- instruction on proper naloxone administration,
- instruction in basic resuscitation techniques,
- instruction on how the opioid antagonist drugs and other supplies are to be maintained, and
- the number of the program to report administrations of naloxone.

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 ODUs.
Appendix

New York’s Overdose Program Regulations

N.Y. Comp. Codes R. & Regs. tit. 10, § 80.138

OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS OF THE STATE OF NEW YORK
TITLE 10. DEPARTMENT OF HEALTH
CHAPTER II. ADMINISTRATIVE RULES AND REGULATIONS
SUBCHAPTER K. CONTROLLED SUBSTANCES
PART 80. RULES AND REGULATIONS ON CONTROLLED SUBSTANCES
TOXIC VAPORS, HYPODERMIC SYRINGES AND NEEDLES
Text is current through October 15, 2007.

Section 80.138 Opioid overdose prevention programs.

(a) Definitions.

(1) Clinical director means a physician, physician assistant or nurse practitioner who provides oversight of the clinical aspects of the Opioid Overdose Prevention Program. This oversight includes serving as a clinical advisor and liaison concerning medical issues related to the Opioid Overdose Prevention Program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

(2) Opioid means an opiate as defined in section 3302 of the Public Health Law.

(3) Opioid antagonist means an FDA-approved drug that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. The opioid antagonist is limited to naloxone or other medications approved by the department for this purpose.

(4) Opioid Overdose Prevention Program means a program the purpose of which is to train individuals to prevent a fatal opioid overdose in accordance with these regulations.

(5) Opioid Overdose Prevention Training Program means a training program offered by an authorized Opioid Overdose Prevention Program
which instructs a person to prevent opioid overdoses, including by providing resuscitation, contacting emergency medical services and administering an opioid antagonist.

(6) Person means an individual other than a licensed health care professional, law enforcement personnel, and first responders otherwise permitted by law to administer an opioid antagonist.

(7) Program director means an individual who is identified to manage and have overall responsibility for the Opioid Overdose Prevention Program.

(8) Registered provider for the purposes of this section shall mean any of the following that have registered with the department pursuant to subdivision (b) of this section:

(i) a health care facility licensed under the Public Health Law;

(ii) a physician, physician assistant, or nurse practitioner who is authorized to prescribe the use of an opioid antagonist;

(iii) a drug treatment program licensed under the Mental Hygiene Law;

(iv) a not-for-profit community-based organization incorporated under the Not-for-Profit Corporation Law and having the services of a clinical director;

(v) a local health department.

(9) Trained overdose responder means a person who has successfully completed an authorized Opioid Overdose Prevention Training Program offered by an authorized Opioid Overdose Prevention Program within the past two years and has been authorized by a registered provider to possess the opioid antagonist.

(b) Registration.

(1) Registered providers may operate an Opioid Overdose Prevention Program if they obtain a certificate of approval from the department authorizing them to operate an Opioid Overdose Prevention Program and otherwise comply with the provisions of this section.
Providers eligible to register to operate and Opioid Overdose Prevention Program that are in good standing may apply to the department to operate an Opioid Overdose Prevention Program on forms prescribed by the department which must include, at a minimum, the following information:

(i) the provider name, address, operating certificate or license number where appropriate, telephone number, fax number, e-mail address, program director and clinical director;

(ii) the name, license type and license number of the affiliated prescriber(s);

(iii) the name and location of the site(s) at which the Opioid Overdose Prevention Program will be conducted;

(iv) a description of the targeted population to be served and recruitment strategies to be employed by the Opioid Overdose Prevention Program; and

(v) the addresses, telephone numbers, fax numbers, e-mail addresses and signatures of the program director and clinical director.

Program operation.

Each Opioid Overdose Prevention Program shall have a program director who is responsible for managing the Opioid Overdose Prevention Program and shall, at a minimum:

(i) identify a clinical director to oversee the clinical aspects of the Opioid Overdose Prevention Program;

(ii) establish the content of the training program, which meets the approval of the department;

(iii) identify and train other program staff;

(iv) select and identify persons as trained overdose responders;

(v) issue certificates of completion to trained overdose responders who have completed the prescribed program;
(vi) maintain Opioid Overdose Prevention Program records including trained overdose responder training records, Opioid Overdose Prevention Program usage records and inventories of Opioid Overdose Prevention Program supplies and materials;

(vii) ensure that all trained overdose responders successfully complete all components of Opioid Overdose Prevention Training Program;

(viii) provide liaison with local emergency medical services and emergency dispatch agencies, where appropriate;

(ix) assist the clinical director with review of reports of all overdose responses, particularly those including opioid antagonist administration; and

(x) report all administrations of an opioid antagonist on forms prescribed by the department.

(2) Each Opioid Overdose Prevention Program shall have a clinical director who is responsible for clinical oversight and liaison concerning medical issues related to the Opioid Overdose Prevention Program and, at a minimum, shall:

(i) provide clinical consultation, expertise, and oversight;

(ii) serve as a clinical advisor and liaison concerning medical issues related to the Opioid Overdose Prevention Program;

(iii) provide consultation to ensure that all trained overdose responders are properly trained;

(iv) adapt and approve training program content and protocols; and

(v) review reports of all administrations of an opioid antagonist.

(3) The trained overdose responders shall:
(i) complete an initial Opioid Overdose Prevention Training Program;

(ii) complete a refresher Opioid Overdose Prevention Training Program at least every two years;

(iii) contact the emergency medical system during any response to a victim of suspected drug overdose and advise if an opioid antagonist is being used;

(iv) comply with protocols for response to victims of suspected drug overdose; and

(v) report all responses to victims of suspected drug overdose to the Opioid Overdose Prevention Program director.

(4) The opioid antagonist shall be dispensed to the trained overdose responder in accordance with all applicable laws, rules and regulations.

(5) The Opioid Overdose Prevention Program will maintain and provide response supplies including: latex gloves, mask or other barrier for use during rescue breathing, and agent to prepare skin before injection.

(6) The Opioid Overdose Prevention Program will establish and maintain a recordkeeping system that will include, at a minimum, the following information:

(i) list of trained overdose responders, including dates of completion of training;

(ii) a log of opioid overdose prevention trainings which have been conducted;

(iii) copies of program policies and procedures;

(iv) copy of the contract/agreement with the clinical director, if appropriate;

(v) opioid antagonist administration usage reports and forms; and

(vi) documentation of review of administration of an opioid antagonist.
(7) The Opioid Overdose Prevention Program will establish a procedure by which any administration of opioid antagonist to another individual by a trained overdose responder affiliated with an Opioid Overdose Prevention Program, shall be reported on forms prescribed by the department.

(8) Approval obtained pursuant to this section shall consist of a certificate of approval provided by the department that shall remain in effect for two years or until receipt by the authorized provider of a written notice of termination of the program from the department, whichever shall first occur. The department may renew a certificate of approval for a subsequent two-year period if the registered provider is in good standing with all applicable State and Federal licensing agencies and such provider is found to have complied with the requirements of this section and has submitted a request for renewal.

(9) Pursuant to Public Health Law, section 3309(2) 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 8 of the Education Law or article 33 of the Public Health Law.