Putting the Pieces Together:

A Guide for New York State's Registered Opioid Overdose Prevention Programs

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AIDS Institute
New York State Department of Health
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TABLE OF CONTENTS

GLOSSARY OF ABBREVIATIONS

AOT.....Approved Overdose Trainer
BLS.....Basic Life Support
BOCES.....Board of Cooperative Educational Services
EMS .....Emergency Medical Services
NYC.....New York City
NYCDOHMH.....New York City Department of Health and Mental Hygiene
NYCRR.....New York Codes, Rules and Regulations
NYS .....New York State
NYSDOH.....New York State Department of Health
NYSOOPPS .....New York State Opioid Overdose Prevention Program System
PHL .....New York State Public Health Law
TOR.....Trained Overdose Responder

Overview

This document provides New York State Department of Health (NYSDOH)-approved opioid overdose prevention programs with guidance on delivering services consistent with New York Public Health Law (PHL) Section 3309[1] and 10 NYCRR 80.138[2]. It should be used by registered programs to tailor their policies and procedures and develop training programs.

There are additional statutes, regulations and guidance documents which are relevant for overdose training and naloxone provision in various specialized settings and for specialized responders. Registered opioid overdose prevention programs planning on working with law enforcement, fire fighters, secondary school and BOCES personnel and Basic Life Support EMS agencies should review the Guidance and Legal Framework for Specialized Overdose Responders.[3]

- This guidance document should be reviewed annually. Check www.health.ny.gov/overdose for the most current version.
- Policies and procedures and curricula must be consistent with the laws and regulations, as well as with guidance provided by the NYSDOH. If there any questions about compliance, inquiries should be directed to overdose@health.ny.gov.
- New York State's Drug User Health Center of Excellence may also be consulted for guidance through an email to overdose@health.ny.gov.
- Every registered program's policies and procedures and training protocols should be reviewed annually to ensure they reflect good practice and meet the needs of the persons being served.

Registration

All regulated opioid overdose prevention programs must have an active registration with the NYSDOH.[4]

Registration is limited to the eligible entities specified in the regulations.[5]

Central to each program's registration is the designation of:

- Key staff, including the Program Director and the Clinical Director;
- Addresses where routine program activities will take place; and
- Who the Trained Overdose Responders (TORs) will be.

Registration forms are completed and submitted on the New York State Opioid Overdose Prevention Program System (NYSOOPPS). Once an electronic registration is submitted, a printed version must be signed by the Program Director and the Clinical Director and then mailed to the NYSDOH as instructed in the online registration process.[6]

Once a program registration is approved, the Program Director and the Clinical Director will receive notification that a Certificate of Approval[7] has been issued. The Certificate of Approval remains in effect for two years. A program

[1] Appendix A
[2] Appendix B
[3] Appendix K
[4] 10 NYCRR 80.138(b)
[5] 10 NYCRR 80.138(a)(5)(i-viii)
[6] Further guidance on registration completion is found at www.health.ny.gov/overdose. Assistance may also be sought by sending an email to overdose@health.ny.gov.
[7] Appendix D: Certificate of Approval

may terminate its registration at any time with notification to the NYSDOH through an email to overdose@health.ny.gov. The NYSDOH may also terminate a registration with written notification to the program.[8]

A single registration may cover multiple addresses, all of which should be reflected within the registration. Overdose supplies, including naloxone, may be shipped to these addresses, however the Clinical Director must authorize addresses for naloxone shipments. In special circumstances, an eligible entity may maintain more than one registered program, each of which will be assigned a distinct certificate number. Maintaining multiple registrations should be restricted to instances in which there are administratively distinct or are separately managed units. Merely having multiple program locations is not a good rationale for an organization to have multiple registrations.

The information related to an entities registration should be reviewed quarterly by the Program Director and the Clinical Director to ensure that it is accurate. This quarterly review on the NYSOOPPS is ideally done at the same time as mandated quarterly reporting. Changes to registration information can be made either directly on the NYSOOPPS or through an email to overdose@health.ny.gov.

Because of staff turnover—including perhaps of both the Program Director and the Clinical Director—registered programs should ensure that there are policies and procedures in place so that individuals other than the Program Director and the Clinical Director know to inform the NYSDOH of staff departures and replacements. Those changes in registration information should be conveyed in an email to overdose@health.ny.gov.

Two-year Recertification

Two months prior to the expiration of a two-year Certificate of Approval, the Program Director should access the NYSOOPPS and review all information pertaining to the program's registration including the following:

- Names and contact information for the Program Director and the Clinical Director;
- Current licensure information for the Clinical Director (and Affiliated Prescribers, if any); and
- Names and addresses for all sites at which there is routine program activity.

Confirmation that information in NYOOPS is correct or notification of necessary changes should be communicated in an email from the Program Director to overdose@health.ny.gov. That email should also indicate that the program wants to be recertified for an additional two years.

The NYSDOH recertifies programs every two years at its discretion. If a program is not in good standing, it will not be recertified.[9] At the time of recertification and throughout the course of a registration, the NYSDOH will review the registered program's history of mandated quarterly data reporting and its history of ordering supplies. The quantity of naloxone ordered should be reflected in the quantity of naloxone furnished to trained responders.

Programs should not submit a new registration form for recertification or for changing registration information.

[8] *See* Appendix H: Reasons for Possible Termination of a Registration.
[9] *See* Appendix H: Reasons for Possible Termination of a Registration.

Opioid Overdose Program Staffing

All registered opioid overdose programs are required to have two positions: a Program Director and a Clinical Director. The same individual may serve in both capacities; however, it is recommended that two individuals fill these roles to manage the responsibilities outlined in the regulations and in this guidance document. Some programs may also choose to have Affiliated Prescribers and Approved Overdose Trainers (AOTs). The individuals trained by registered programs are known as Trained Overdose Responders (TORs). Each of the positions is described below.

Program Director

Description and Qualifications

The Program Director has overall responsibility for the Opioid Overdose Prevention Program.[10, 11] Each registered program has only one Program Director. The Program Director must be an employee or a contracted agent of the organization maintaining the registration.

Roles and responsibilities

The Program Director is the registered program's primary contact for the NYSDOH. The Program Director's responsibilities, many of which can be delegated, include the following:

- Identifying a New York State-licensed physician, physician assistant or nurse practitioner to serve as the program's Clinical Director;
- Implementing a curriculum approved by the NYSDOH[12];
- Maintaining appropriate record keeping systems[13] for facilitating compliance with the mandated reporting requirements[14];
- Selecting AOTs in consultation with the Clinical Director and overseeing these AOTs to ensure they are competent in delivering trainings and furnishing naloxone, when naloxone is furnished under a standing order[15];
- Having a validated account on the NYSOOPPS and creating additional accounts for other program staff, if those other accounts are appropriate for helping manage the program;
- Electronically signing the "Terms and Conditions" and the "NYS Release" on the NYSOOPPS if Narcan® nasal spray is to be ordered from the NYSDOH;
- Ensuring that there is a valid "ship to" address on the NYSOOPPS for the delivery of opioid overdose supplies ordered through the NYSDOH;
- Sending an email to overdose@health.ny.gov or using the NYSOOPPS to notify the NYSDOH of impending changes in:
    - Program Director;
    - Clinical Director or licensure;
    - Affiliated Prescribers;
    - Program sites; and
    - Anything that may impede program operations.
- Ordering opioid overdose supplies, or reviewing orders submitted made by other authorized program personnel[16];

[10] 10 NYCRR 80.138(a)(6)
[11] 10 NYCRR 80.138(c)(1)
[12] *See* Core Curriculum for Community Responders and Appendix E: Detailed Outline of Training for TORs.
[13] *See* Mandated Record Keeping
[14] *See* Mandated Reporting
[15] *See* Supervision of Approved Overdose Trainers and Standing Orders.
[16] *See* Ordering Opioid Overdose Supplies

- Maintaining an inventory of opioid overdose supplies and having appropriate inventory controls[17];
- Submitting quarterly reports to the NYSDOH through the NYSOOPPS[18]; and
- Submitting naloxone administrations reports to the NYSDOH through the NYSOOPPS[19].

If the Program Director is also conducting overdose trainings and selectively furnishing naloxone, the Program Director is also responsible for carrying out the duties of an AOT.[20]

Clinical Director

Description and Qualifications

The Clinical Director provides clinical oversight of the program and is the person with primary responsibility for prescribing naloxone for the program's responders.[21, 22] Those prescriptions are either patient-specific prescriptions or non-patient specific standing orders. The Clinical Director must be a physician, physician assistant or nurse practitioner whose scope of practice includes the prescription of medication. The Clinical Director does not need to be an employee of the organization maintaining the overdose program, but there should be documentation supporting the relationship between the Clinical Director and that organization. There is only one Clinical Director for each registered program.

Roles and responsibilities

In addition to providing clinical oversight and prescribing naloxone, the Clinical Director's responsibilities include:

- Working with the Program Director to:
  - Ensure that all overdose responders are properly trained;
  - Develop or adapt—and then implement—an opioid overdose prevention training curriculum[23];
- Reviewing naloxone administration reports[24];
- Having a validated account on the NYSOOPPS and creating, additional accounts, as needed, for other program staff;
- Electronically signing the "ship to" form on the NYSOOPPS, if orders for Narcan® nasal spray will be placed through the NYSDOH;
- Reviewing storage and inventory controls for naloxone;
- Designating and supervising Approved Overdose Trainers (AOTs), if the program model uses them[25, 26]; and
- Designating Affiliated Prescribers, if any, and maintaining routine and ongoing contact with them to ensure appropriate oversight.

If the Clinical Director is also conducting overdose trainings and selectively furnishing naloxone, the Clinical Director is also responsible for carrying out the responsibilities of an AOT.

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[17] *See* Inventory Controls and Supply Management
[18] See Quarterly Reporting
[19] *See* Naloxone Administration Reporting
[20] *See* Approved Overdose Trainer/Roles and Responsibilities
[21] 10 NYCRR 80.138(a)(7)
[22] 10 NYCRR 80.138(c)(2)
[23] *See* Appendix E: Detailed Outline of Training for Trained Overdose Responders (TORs)
[24] 10 NYCRR 80.138(c)(2)(v)
[25] 10 NYCRR 80.138(c)(2)(vi)
[26] This may be coordinated with the Program Director.

Affiliated Prescribers

Description and Qualifications

Affiliated Prescribers are individuals who, in addition to the Clinical Director, may prescribe naloxone for a registered program's TORs.[27] Each Affiliated Prescriber must be licensed in New York State as a physician, a nurse practitioner or a physician assistant and have prescribing medication in their scope of practice. Affiliated Prescribers do not need to be employees of the organization maintaining the overdose program. There may be multiple Affiliated Prescribers.

The Clinical Director in consultation with the Program Director selects Affiliated Prescribers who are designated either in a program's initial registration or in a subsequent notification to the NYSDOH through the NYSOOPPS or through an email to overdose@health.ny.gov.

Roles and responsibilities

In addition to prescribing naloxone, they are responsible for:

- Coordinating their program-related activities closely with the Clinical Director;
- Ensuring that any training or naloxone dispensing done by the Affiliated Prescriber becomes part of the registered program's records in a timely way;
- Reporting program-related activities to the Clinical Director; and
- Supervising Approved Overdose Trainers (AOTs) if that role is delegated to them by the Clinical Director.

If Affiliated Prescribers are also conducting overdose trainings and selectively furnishing naloxone, they are also responsible for carrying out the responsibilities of an AOT.

When are Affiliated Prescribers Advisable?

Affiliated Prescribers are optional. They may not be necessary if a program's naloxone furnishing is done solely under a standing order from the Clinical Director. Affiliated Prescribers may be helpful to some programs in the following situations:

- If the program chooses only to issue patient-specific prescriptions for naloxone;
- If there are multiple clinical settings in which local clinical oversight of the overdose program sites is deemed appropriate by the program;
- If there is a large and changing set of AOTs, and having Affiliated Prescribers provides helpful capacity for overseeing their work; or
- If the clinical environment of the program is that such that multiple prescribers are helpful in supporting the program's operations.

Approved Overdose Trainers (AOTs)

Description

AOTs train TORs. These are individuals designated by the Clinical Director in consultation with the Program Director to provide opioid overdose training and to selectively furnish naloxone pursuant to a non-patient specific prescription (standing order) issued by the Clinical Director. A registered program may designate its AOTs by another name such as "Approved Dispensers".

[27] 10 NYCRR 80.138(a)(8)

Qualifications

AOTs are encouraged to complete a train-the-trainer session delivered by the New York State Drug User Health Center of Excellence, the Program Director, the Clinical Director or by someone else with strong, broad competency in opioid overdose recognition and response. They do not need to be staff of the registered program.

Roles and responsibilities

An AOT has the following responsibilities:

- Delivering the core curriculum for community responders[28];
- Having sufficient knowledge to respond to frequently asked questions raised by trained responders;
- Tailoring the training session so it is responsive to the setting and the audience;
- Demonstrating naloxone device preparation, if any, and administration;
- Verifying that trained responders understand core curriculum content, including overdose recognition and naloxone administration;
- Handling the logistics for conducting a training including having the following available:
    - Training materials;
    - Certificates of Completion;
    - Naloxone:
        - For demonstration; and
        - For furnishing, if naloxone is being provided to TORS as part of the training.
- Directing trained individuals to pharmacies for naloxone, or furnishing naloxone to trained responders consistent with the Clinical Director's standing order, with the program's policies and procedures and with the NYSDOH guidance on use of pharmacies[29];
- Providing a Certificate of Completion to each trained responder, whether they receive naloxone or not;
- Creating a record for all trained individuals [30]; and
- Ensuring that all training records are returned to the overdose Program Director or Clinical Director consistent with the program's policies and procedures.

Benefits to Having AOTs

Approved Overdose Trainers (AOTs) are not required by law or regulation. AOTs, when combined with standing orders help provide naloxone to trained responders without the presence of the Clinical Director or of an Affiliated Prescriber. They also act as "extenders" for both the Program Director and the Clinical Director.

Supervision of Approved Overdose Trainers

The supervision of AOTs should occur at least 4 times a year and may be conducted in-person or by telephone. This supervision may also be done in coordination with the Program Director. The supervision should cover:

- Creating a record for training responders and the provision of naloxone;
- Storage and inventory maintenance of overdose supplies; and
- Questions arising in overdose trainings where the AOT can benefit from additional clinical or programmatic information.

Records on AOTs

There should be a roster of AOTs signed by the Clinical Director with the date on which the AOT was approved.

[28] See Core Curriculum for Community Responders
[29] *See* Appendix I: Maximizing use of Pharmacies as a Source of Naloxone for TORs
[30] *See* Records Pertaining to Trained Overdose Responders

Trained Overdose Responders (TORs)

Description and Qualifications

Trained Overdose Responders are the individuals trained by an AOT, a Program Director, a Clinical Director, an Affiliated Prescriber, a pharmacist or by a clinician as part of patient care to respond to an opioid overdose. Through that training, they should have the knowledge and skills to 1) recognize an opioid overdose; 2) call 911; 3) administer naloxone; 4) provide post-naloxone administration support; 5) report their naloxone administrations; and 6) seek replacement naloxone.[31] [32]

Virtually anyone in New York State can be a trained overdose responder. This includes individuals who use opioids; their family members and friends; persons affiliated with healthcare or social service agencies serving persons at risk for an overdose; public safety personnel (law enforcement officers and fire fighters); school and library staff; university staff and students; supportive housing and shelter personnel and residents; and anyone else who may witness or encounter an overdose. If some prospective TORs appear to be unable to understand adequately training instructions, they should be given an opportunity to return for training on another day.

Minors as Trained Overdose Responders

An adolescent minor may become a trained overdose responder if, in the opinion of the program staff, there are reasonably foreseeable circumstances in which this minor will be positioned to save a life by administering naloxone. This minor must be deemed to be sufficiently mature with respect to intellect and emotions to carry out all the responsibilities of a trained overdose responder. The program's records should document this maturity in its records on this responder. The Program Director, the Clinical Director, an Affiliated Prescriber or an Approved Overdose Trainer may make this assessment and should document this in a way consistent with the program's policies and procedures.

If the required maturity appears to be lacking, an effort should be made to make the minor a trained overdose responder in all ways other than furnishing that minor with naloxone, i.e. training the minor in recognizing an opioid overdose; in calling 911 and in waiting with the overdosed individual until EMS arrives.

Roles and responsibilities

TORs are responsible for:

- Completing an initial training consistent with the program's opioid overdose prevention training curriculum;
- Maintaining the knowledge and skills to respond to an opioid overdose by periodically reviewing the training materials accompanying the rescue kit; and
- Returning to the registered program, pharmacy or medical provider which furnished the kit to:
    - Receive a replacement kit or direction on how to obtain one; and
    - Provide information on the administration of naloxone, so that this information may then be communicated to NYS DOH in a "usage report."

Standing Orders

Clinical Directors may issue standing orders (non-patient specific prescriptions) authorizing persons to furnish naloxone on their behalf to TORs.[33]

The Clinical Director must issue a standing order for naloxone if a program intends to have personnel other than the Clinical Director or an Affiliated Prescriber furnish naloxone to TORs.

[31] 10 NYCRR 80.138(a)(9)
[32] 10 NYCRR 80.138(c)(3)
[33] Public Health Law Section 3309(3)(b)(i)

Standing orders should include the following:

- Conditions of dispensing;
- Formulation(s) being furnished;
- Protocols for the naloxone administration;
- Dated signature of the Clinical Director;
- Address of the Clinical Director; and
- Clinical Director's NYS License Number.

The program is required to retain a copy of the standing order in its files.[34]

When naloxone is furnished under a standing order, it must be accompanied by an indication that it is done pursuant to a non-patient specific prescription[35].

Training

Core Curriculum for Community Responders

The program must maintain an up-to-date training curriculum, which is consistent with guidance provided by the NYSDOH.[36] Appendix E contains a detailed outline of training for TORs. Programs are encouraged to include all elements of the training; however, this is not always feasible, particularly when there are time constraints.

From that curriculum, the TOR should know:

- How to recognize an opioid overdose;
- How to respond to an opioid overdose by:
  - Verifying non-responsiveness of the overdosed individual through doing a sternal rub or similar stimulus;
  - Administering at least one formulation of naloxone;
  - Calling 911;
  - Providing rescue breathing or CPR if these techniques are taught or otherwise known;
  - Administering a second dose of naloxone 2-3 minutes after the first dose if the individual has not become responsive;
  - Placing the non-responsive individual in the recovery position after naloxone administration if;
    - Rescue breathing or CPR is not being performed; or if
    - The non-responsive person is being left alone.
  - Providing appropriate aftercare, which includes:
    - Informing—or having someone else inform--EMS of the situation, including that naloxone has been administered, specifying the quantity and formulation;
    - Discouraging the revived individual from using more opioids to treat withdrawal symptoms brought on by the naloxone;

[34] Where a standing order is covering personnel of an external organization such as a police department or an agency serving persons at risk for an overdose, it is good practice for a copy of the standing order to also be on file with that agency or organization.
[35] This requirement in 10 NYCRR 80.138(c)(12)(i) can be met through a Certificate of Completion, so long as it indicates that a non-patient specific prescription is in place.

[36] 10 NYCRR 80.138(a)(4)

- Assuring the revived person that these symptoms will go away as the naloxone wears off;
- Having someone stay with the individual for 3 hours if the revived individual does not go to the hospital;
- Obtaining replacement naloxone, either from the program which provided the training or from a pharmacy; and
- Reporting the administration of naloxone to the program that did the training.[37]

For training of law enforcement personnel; firefighters; school personnel, or Basic Life Support EMS personnel, please *see* Appendix K: Guidance and Legal Framework for Specialized Overdose Responders.

Tailoring Training to the Audience

Delivering the Detailed Curriculum in Appendix E is not required for every training. If someone is already familiar with the material, the training can be abbreviated. Similarly, if the window of opportunity for engaging someone who needs to be trained is short, then a less detailed training is also appropriate, as long as it addresses the core curriculum items summarized above. To communicate the material effectively, it should be done:

- In a manner that does not stigmatize individuals who use drugs;
- With language and a style that is appropriate for those being trained;
- Avoiding unnecessarily technical or distracting language; and
- Allowing time for questions.

Although there are advantages to a face-to-face training, all or part of a training may be done online or via telephone. Written training materials alone, while permissible, are ideally augmented by opportunities for interactive engagement.

Refresher Trainings for TORs

TORs should have a refresher training to retain their status if more than 2 years have passed since their most recent training.[38] This refresher training can be a brief assessment that the TOR still understands how to recognize an opioid overdose; how to respond to it appropriately by calling 911 and administering naloxone; providing appropriate follow-up care for the revived person; and understanding how to obtain naloxone and report administrations. As new naloxone formulations are introduced, information on them should be included in refresher trainings. Program records should reflect dates for training encounters. Any encounter that includes the basic elements for a refresher training is adequate to re-start the two-year certification period.

Training Approved Overdose Trainers (AOTs) to Train Responders and Furnish Naloxone

Staff at registered programs who will be training responders or interacting with them are strongly encouraged to attend an in-person or web-hosted Training-of-Trainer (TOT). For information on these trainings, please send an email to overdose@health.ny.gov. AOTs in NYC are required by the New York City Department of Health and Mental Hygiene (NYCDOHMH) to attend a NYCDOHMH Training-of-Dispenser (TOD) course.

After successfully completing a TOT or TOD, participants will understand:

- National and statewide impact of opioid overdose, including current trends and emergent issues;
- Nature of an opioid overdose;
- Factors which place an individual at risk for an opioid overdose and for an opioid overdose fatality;

[37] There will soon be an option for individuals to report their use of naloxone online.
[38] 10 NYCRR 80.138(c)(3)(ii)

- How to reduce the risks associated with those factors;
- How to recognize an opioid overdose;
- How naloxone works;
- How to administer naloxone, ideally with multiple formulations;
- Recommended aftercare for the person who overdoses; and
- How to conduct a training for others by tailoring the training for the audience.
- NYC-based programs will also understand how to complete the Naloxone Recipient Form (NRF) and learn about ordering and reporting requirements specific to NYC.

After a TOT/TOD, a trainee should demonstrate sufficient mastery of the comprehensive curriculum for TORs through the completion of a multiple-choice test or other assessment, such as conducting a short training.

Materials Provided to Trained Overdose Responders (Rescue Kit Contents)

Certificate of Completion

A Certificate of Completion, sometimes referred to as the *blue card*, must be issued to all TORs who have successfully completed the opioid overdose prevention training curriculum. This requirement does not apply to law enforcement or firefighting personnel.[39]

There are examples of the Certificate of Completion in Appendix F.

A Certificate of Completion should be issued whether naloxone is furnished to the TOR or not.

TORs are not required to carry their Certificates of Completion. The Certificate of Completion, however, may be helpful in explaining to others, including to pharmacy personnel, that training has already occurred. The Certificate of Completion is also a useful tool for reminding TORs where to return for reporting naloxone use and how to obtain additional naloxone.

Naloxone

Programs should reserve naloxone from the NYSDOH for TORs who are at high risk of having or witnessing an overdose and who are unlikely or unable to use a pharmacy to obtain naloxone. All other TORs should be directed to obtain their naloxone from pharmacies that have naloxone standing orders in place. All TORs should also be informed of the Naloxone Co-payment Assistance Program (N-CAP). Through N-CAP, individuals with prescription drug coverage can have naloxone co-payments of up to $40 covered, without any need for individuals to be enrolled in any program other than their primary health insurance. Through N-CAP, there will be no or lower out-of-pocket expenses.

Programs are encouraged to develop relationships with local pharmacies. All programs are required to refer trained overdose responders to pharmacies for their naloxone unless there are compelling reasons for not doing so. This is addressed below in Appendix I: Maximizing Use of Pharmacies as a Source of Naloxone for TORs.

Two doses of naloxone should be included in every kit when naloxone is furnished to Trained Overdose Responders.

The NYSDOH provides two formulations of naloxone to registered opioid overdose prevention programs:

[39] 10 NYCRR 80.138 (c)(1)(v)

- Narcan® nasal spray (4 mg/dose)
  Each carton sent to the program, contains 2 doses, which is the appropriate quantity for a single kit.
- Intramuscular naloxone (0.4mg/mL in 1 mL single-dose vials).
  Each carton sent to the program contains 10 doses, i.e. enough to equip 5 kits.

Intramuscular syringes

Two intramuscular syringes must be provided to each TOR getting intramuscular naloxone. The NYSDOH provides safety syringes that incorporate a lockable shield that should be deployed after use. Used syringes should be disposed of in a container that minimizes the likelihood of someone subsequently being exposed to the needle. Syringes should not be re-used.

Face Shield for Rescue Breathing

Programs are required to provide "a mask or other barrier where rescue breathing is part of the curriculum."[40] If a program is not instructing its TORs in rescue breathing, the face shield does not need to be included in the kit.

Alcohol wipes

Programs are required under the regulation to provide "an agent to prepare skin before injection where an injectable form of an opioid antagonist is used."[41] Alcohol wipes are not required if a nasal formulation is being furnished.

Instructions on Opioid Overdose Recognition and Response

When naloxone is provided to TORs, it must always include information on: (a) how to recognize symptoms of an opioid overdose; (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders; (c) the number for the toll free Office of Alcoholism and Substance Abuse Services (OASAS) HOPEline; (d) how to access the OASAS website."[42] The OASAS HOPEline and web site requirements may be met through the issuance of a Certificate of Completion that contains this information. Instructions from any of the following sources are appropriate for inclusion in an overdose kit: the manufacturer; the NYSDOH; the NYCDOHMH; and New York State's Drug User Health Center of Excellence.

Zippered Nylon Bag for Holding Kit Contents

A nylon zippered bag is a convenient way to hold the contents of an overdose kit, but it is not required. Where a bag is desired and a nylon zippered bag is unavailable, a program should consider providing TORs with re-sealable plastic bags which may be ordered through the NYSOOPPS or purchased from a grocery store.

[40] 10 NYCRR 80.138(c)(5)(i)
[41] 10 NYCRR 80.138(c)(5)(ii)
[42] PHL Section 3309(3-a)(a-d); 10 NYCRR 80.138(c)(5)(iii)

Mandated Reporting

Quarterly Reporting

All opioid overdose prevention programs are required to "report the number of trained overdose responders and the number of doses of an opioid antagonist provided on a quarterly basis on forms prescribed by the department."[43]

- The reporting requirements apply to all registered programs regardless of how they are funded or the source of their naloxone.
- Failure to comply with this reporting requirement places a program at risk of losing its certification and jeopardizes its ability to order opioid overdose supplies, including naloxone.
- All quarterly reporting should be done through the New York State Opioid Overdose Prevention Program System. NYCDOHMH may have additional reporting requirements, but these do not replace the mandated reporting for the NYSDOH.
- The quarters are calendar quarters, January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.
- Quarterly reporting data includes the following for each reporting period:
    - Number of TORs trained by the following categories: law enforcement; fire fighters; EMS; school personnel; library personnel; and all others.
    - Quantity of naloxone in kits (not doses) furnished to TORs by formulation type (intramuscular or nasal spray).
    - Number of TORs referred to pharmacies for obtaining their naloxone.
    - Names of specific law enforcement agencies; fire departments; EMS agencies; schools and libraries that were given support with supplies.
- A quarterly report should be submitted, even if no program activity occurred during the quarter.
- Quarterly reports are due no later than 4 weeks after the end of a quarter.

Naloxone Administration Reporting

Registered programs are required to "report all administrations of an opioid antagonist on forms prescribed by the department; however, public safety and firefighting personnel are required to report administrations of an opioid antagonist directly, or through their department or agency, to the department."[44]

- This reporting requirement applies to **all registered programs**
- There are distinct forms used for naloxone administrations by "civilian" responders[45] and by public safety personnel[46]. Programs must ensure they are using the correct form. If there is any question regarding which form to use, an inquiry should be directed to overdose@health.ny.gov.
- Reporting of "civilian" naloxone administrations should be done online using the NYSOOPPS.
- The Program Director must ensure that administration reports are reviewed by the Clinical Director.

    Note: This review may occur after a report has been submitted through the NYSOOPPS. When a report is submitted, an email summarizing the administration is automatically sent to program and clinical directors. If there are details of that report that need to be changed, an email specifying those changes should be sent to overdose@health.ny.gov.

[43] 10 NYCRR 80.138(c)(1)(xi)
[44] 10 NYCRR 80.138(c)(1)(x)
[45] Appendix L: Community (Non-Public Safety Naloxone Administration Reporting Form
[46] Appendix M: Public Safety Naloxone Administration Reporting Form

- The Program Director must ensure that program staff, including AOTs, are familiar with—and using—the appropriate naloxone administration forms to collect information from TORs returning to the program to report their use of naloxone.
- To the extent practicable, a protocol should be established to engage TORs returning to the program, ascertaining whether naloxone was used, and summarizing the details of those administrations on the reporting form.
- Training must always stress the importance of reporting naloxone administrations.

Mandated Record Keeping

Inventory Controls and Supply Management

Registered programs have a record keeping system that addresses the inventory of overdose response supplies.[47] The following are required:

- Confirming receipt of opioid overdose supplies on the NYSOOPPS. No more than 5 business days should pass between receipt of product and confirmation of receipt.
- Logging the date and quantity for each item received, as well as the lot numbers and expiration dates for all naloxone.
- Using a first-in-first-out system for optimal deployment of supplies.
- Noting the date and quantity of products taken out of inventory by AOTs for a training, as well as the date and quantity of product returned into inventory after a training.
- Segregating and then disposing of all expired naloxone.
- Ensuring that all ordering of naloxone is consistent with realistic, near-term need.
- Segregating all supplies that get recalled and following guidance offered by the manufacturer or the NYSDOH with respect to the handling of that product.
- Following the manufacturer's guidelines for storage and handling of naloxone.

Record-Keeping to Support Mandated Reporting

The Program Director is responsible for establishing and maintaining a record keeping system to ensure compliance with the Quarterly Reporting and Naloxone Administration Reporting requirements described above.

Records Pertaining to Trained Overdose Responders

Programs have options to maintain records on their TORs. They may use:

- A basic enrollment form that collects the date of a training, name of the individual trained, their birth date and zip code of residence, as well as additional information on naloxone that may have been provided, including its lot number and expiration date. It may also include a means of contacting the individual and other information that a program may find helpful;
- An electronic medical record, for facility-based programs; or
- Forms that may be promulgated by the NYSDOH or by the NYCDOHMH.[48]

[47] 10 NYCRR 80.138(c)(6)(vi)

[48] A generic enrollment form appears in Appendix N. This particular form is not mandated. NYCDOHMH has promulgated a Narcan/Naloxone Recipient Form (NRF) specific to SEPs within the 5 boroughs and a different NRF for non-SEPs.

Records Pertaining to Approved Overdose Trainers

The Program Director and the Clinical Director are responsible for establishing and maintaining a record keeping system to ensure that there is a log of all AOTs that includes, at a minimum:

- Names.
- Dates on which they were approved for training TORs and furnishing them with naloxone under a standing order from the Clinical Director.
- Dates on which AOT status is withdrawn, if applicable.
- Periodic assessment of AOT performance.

Records Pertaining to Ordering Naloxone

Program Directors are responsible for maintaining retrievable records on overdose supplies that the program has ordered and ensuring that there are appropriate controls in place for the ordering process.

Ordering Opioid Overdose Supplies

- Programs in the 57 counties of New York State outside of New York City (NYC) should order all overdose supplies through the NYSOOPPS.
- Programs within the 5 boroughs of NYC should order nasal naloxone, intramuscular naloxone, intramuscular syringes, zippered nylon blue bags and Certificate of Completion cards from the NYCDOHMH in a manner prescribed by the NYCDOHMH. All other supplies for NYC-based programs are ordered from the NYSDOH through the NYSOOPPS.
- An order should be limited to what is realistically needed to cover the provision of naloxone for the next 2-3 months.
- Barring unforeseen circumstances, ordering should be done no more frequently than every 2 months.
- Ordering may be delegated by the Program Director to other staff. Those other staff must have accounts created for them by the Program Director on the NYSOOPPS.
- The Program Director receives an automatic notification of all orders placed through the NYSOOPPS. The underlying order should be immediately reviewed. If the order was not internally approved, the NYSDOH must immediately be notified through an email to overdose@health.ny.gov.
- The Program Director or delegated staff must make a timely confirmation on the NYSOOPPS that orders have been received. No more than 5 business days should pass between receipt of product and confirmation of receipt.

Appendices

Appendix A: New York State Public Health Law Section 3309

PHL Section 3309: Opioid overdose prevention.

1. The NYS Health Commissioner is authorized to establish standards for approval of any opioid overdose prevention program, and opioid antagonist prescribing, dispensing, distribution, possession and administration pursuant to this section which may include, but not be limited to, standards for program directors, appropriate clinical oversight, training, record keeping and reporting.

2. Notwithstanding any inconsistent provisions of section sixty-five hundred twelve of the education law or any other law, the purchase, acquisition, possession or use of an opioid antagonist pursuant to this section shall not constitute the unlawful practice of a profession or other violation under title eight of the education law or this article.

3. (a) As used in this section:

(i) "Opioid antagonist" means a drug approved by the Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. "Opioid antagonist" shall be limited to naloxone and other medications approved by the department for such purpose.

(ii) "Health care professional" means a person licensed, registered or authorized pursuant to title eight of the education law to prescribe prescription drugs.

(iii) "Pharmacist" means a person licensed or authorized to practice pharmacy pursuant to article one hundred thirty-seven of the education law.

(iv) "Opioid antagonist recipient" or "recipient" means a person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioid-related overdose, or an organization registered as an opioid overdose prevention program pursuant to this section or a school district, public library, board of cooperative educational services, county vocational education and extension board, charter school, non-public elementary and/or secondary school in this state or any person employed by such district, library board or school.

(b)(i) A health care professional may prescribe by a patient-specific or non-patient-specific prescription, dispense or distribute, directly or indirectly, an opioid antagonist to an opioid antagonist recipient.

(ii) A pharmacist may dispense an opioid antagonist, through a patient-specific or non-patient-specific prescription pursuant to this paragraph, to an opioid antagonist recipient.

(iii) An opioid antagonist recipient may possess an opioid antagonist obtained pursuant to this paragraph, may distribute such opioid antagonist to a recipient, and may administer such opioid antagonist to a person the recipient reasonably believes is experiencing an opioid overdose.

(iv) The provisions of this paragraph shall not be deemed to require a prescription for any opioid antagonist that does not otherwise require a prescription; nor shall it be deemed to limit the authority of a health care professional to prescribe, dispense or distribute, or of a pharmacist to dispense, an opioid antagonist under any other provision of law.
(v) Any pharmacy with twenty or more locations in the state, shall either: (1) pursue or maintain a non-patient-specific prescription with an authorized health care professional to dispense an opioid antagonist to a consumer upon request, as authorized by this section; or (2) register with the department as an opioid overdose prevention program.

3-a. Any distribution of opioid antagonists through this program shall include an informational card or sheet. The informational card or sheet shall include, at a minimum, information on: (a) how to recognize symptoms of an opioid overdose; (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders; (c) the number for the toll-free office of alcoholism and substance abuse services HOPE line; (d) how to access the office of alcoholism and substance abuse services' website; and (e) any other information deemed relevant by the commissioner. The educational card shall be provided in languages other than English as deemed appropriate by the commissioner. The department shall make such informational cards available to the opioid overdose prevention programs.

4. Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.
A recipient, opioid overdose prevention program, school district, public library, board of cooperative educational services, county vocational education and extension board, charter school, non-public elementary school and/or secondary school in the state, or any person employed by such district, public library, board or school under this section, acting reasonably and in good faith in compliance with this section, shall not be subject to criminal, civil or administrative liability solely by reason of such action.

5. The Commissioner shall publish findings on statewide opioid overdose data that reviews overdose death rates and other information to ascertain changes in the cause and rates of opioid overdoses, including fatal opioid overdoses. The report shall be submitted annually, on or before October first, to the governor, the temporary president of the senate, the speaker of the assembly and the chairs of the senate and assembly health committees, and shall be made public on the department's internet website. The report shall include, at a minimum, the following information on a county basis: (a) information on opioid overdoses and opioid overdose deaths, including age, gender, ethnicity, and geographic location; (b) data on emergency room utilization for the treatment of opioid overdose; (c) data on utilization of pre-hospital services; (d) data on the dispensing and utilization of opioid antagonists; and (e) any other information necessary to ascertain the success of the program, areas of the state which are experiencing particularly high rates of overdoses, ways to determine if services, resources and responses in particular areas of the state are having a positive impact on reducing overdoses, and ways to further reduce overdoses.

* 6. The Commissioner shall provide the current information and data specified in subdivision five of this section to each county every three months. Such information and data may be utilized by a county or any combination thereof as it works to address the opioid epidemic. * NB Repealed March 31, 2021

Appendix B: New York Codes, Rules and Regulations, Title 10 Section 80.138

80.138 Opioid overdose prevention programs.

(a) Definitions.

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

(2) *Opioid antagonist* means a drug approved by the Food and Drug Administration, 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.

(3) *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.

(4) *Opioid overdose prevention training curriculum* refers to any set of instructions, consistent with guidance from the department, which provides a person encountering a suspected opioid overdose with the steps to take for preventing a fatality, including contacting emergency medical services, administering an opioid antagonist and, where appropriate, providing resuscitation.

(5) *Registered provider* for the purposes of this section shall mean any of the following that have the services of both a program director and a clinical director and 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;

(v) a local health department, public safety agency, or other local or State government agency;

(vi) an institution of higher education, recognized and approved by the regents of the university of the State of New York, which provides a course of study leading to the granting of a post-secondary degree or diploma;

(vii) a business, trade, technical or other occupational school approved as such by the regents of the university of the State of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the regents of the State of New York; and

(viii) a pharmacy registered in accordance with the article 137 of the Education Law.

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

(7) *Clinical director* means a physician, physician assistant or nurse practitioner who is designated in an Opioid Overdose Prevention Program's registration for prescribing an opioid antagonist to individual or an identifiable pool of trained overdose responders and 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.

(8) *Affiliated prescriber* means a physician, physician assistant or nurse practitioner, who, in addition to the clinical director, is designated in an Opioid Overdose Prevention Program's registration for prescribing an opioid antagonist to individual or an identifiable pool of trained overdose responders.

(9) *Trained overdose responder* means any individual not otherwise permitted by law to administer an opioid antagonist, who is either:

(i) an opioid antagonist recipient as defined in PHL section 3309 who has successfully completed an opioid overdose prevention training curriculum offered by an authorized opioid overdose prevention program and has been authorized by a registered provider to possess the opioid antagonist;

(ii) a public safety officer who has completed a curriculum approved by the division of criminal justice services for purposes of intervening in opioid overdoses prior to the arrival of emergency medical services; or

(iii) a firefighter who has completed a comparable curriculum approved by the department.

(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 and operating certificate or license number where appropriate;

(ii) the name, address, telephone number, fax number, e-mail address and signature of the program director;

(iii) the name, address, telephone number, fax number, e-mail address, license type, license number and signature of the clinical director;

(iv) the name, license type and license number of the affiliated prescribers, if any;

(v) the name and address of the sites at which the Opioid Overdose Prevention Program will be conducted; and

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

(c) Program operation.

(1) Each Opioid Overdose Prevention Program shall have a program director who is responsible for managing the Opioid Overdose Prevention Program and shall, either directly or through a designee, 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 program's opioid overdose prevention training curriculum consistent with guidance from 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 successfully completed the program's opioid overdose prevention training curriculum however, certificates of completion of curriculum under subparagraphs (a)(9)(ii) and (iii) of this section are not required for public safety or firefighting personnel;

(vi) establish and maintain the Opioid Overdose Prevention Program's mandated recordkeeping system;

(vii) ensure that all trained overdose responders successfully complete the program's opioid overdose prevention training curriculum;

(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 involving administration of an opioid antagonist;

(x) report all administrations of an opioid antagonist on forms prescribed by the department; however, public safety and firefighting personnel are required to report administrations of an opioid antagonist directly, or through their department or agency, to the department; and

(xi) report the number of trained overdose responders and the number of doses of an opioid antagonist provided on a quarterly basis 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 opioid overdose prevention training curriculum content and protocols;

(v) review reports of all administrations of an opioid antagonist; and

(vi) designate individuals, either by name or by description, who are authorized to dispense or furnish an opioid antagonist to trained overdose responders and/or individuals who are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders pursuant to a non-patient specific prescription.

(3) The trained overdose responders shall:

(i) complete an initial training consistent with the program's opioid overdose prevention training curriculum;

(ii) complete a refresher training consistent with the opioid overdose prevention training curriculum at least every two years or otherwise demonstrate competence in opioid overdose recognition and response to the satisfaction of the opioid overdose prevention program director or to someone designated by the program director;

(iii) ensure that emergency medical service has been contacted when encountering a victim of a suspected drug overdose and advise responding emergency medical services personnel if an opioid antagonist has been used;

(iv) comply with protocols for response to victims of suspected drug overdose consistent with the program's opioid overdose prevention training curriculum, or, in the case of responders who are public safety or firefighting personnel, comply with policies developed by their local public safety agency or fire department; and

(v) report all responses to victims of suspected drug overdose to the Opioid Overdose Prevention Program director or to someone designated by the program director.

(4) The opioid antagonist shall be provided or furnished 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 consistent with its policies and procedures; however, these supplies must include:

(i) a mask or other barrier where rescue breathing is part of the curriculum;

(ii) an agent to prepare skin before injection where an injectable form of an opioid antagonist is used; and

(iii) instructional material required by the department, including information on how to recognize symptoms of an opioid overdose; the steps to be taken in responding to an overdose; and how to access the Office of Alcoholism and Substance Abuse Services through both a toll free number and its website.

(6) The Opioid Overdose Prevention Program's recordkeeping system must include, at a minimum, the following elements:

(i) the names of trained overdose responders, the dates they were trained, and the dates they were furnished naloxone; however, where an opioid antagonist is furnished or dispensed by an opioid overdose prevention program pursuant to a non-patient specific prescription, the program must also maintain records on who has issued the non-patient specific prescription and which designated program staff have dispensed or furnished the opioid antagonist and/or are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders;

(ii) program policies and procedures;

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

(iv) opioid antagonist administration usage reports and forms;

(v) documentation of review of administration of an opioid antagonist; and

(vi) an inventory of overdose response supplies.

(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.

(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 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.

(10) Trained overdose responders may have shared access to, and use of, an opioid antagonist so long as the following conditions are met:

(i) they are trained in accordance with these regulations;

(ii) they have a common organizational or workforce bond; and

(iii) there are policies and procedures in place within that organization or workforce that ensure orderly, controlled access to an opioid antagonist by an identifiable pool of trained overdose responders.

(11) Clinical directors and affiliated prescribers of registered providers are authorized to direct the furnishing or dispensing of an opioid antagonist to trained overdose responders pursuant to a patient-specific prescription or a non-patient specific prescription.

(12) All dispensing or furnishing of an opioid antagonist pursuant to a non-patient-specific prescription shall be to individuals who have been trained in opioid overdose recognition and response and be accompanied by documentation indicating:

(i) that the opioid antagonist has been furnished pursuant to a non-patient specific prescription;

(ii) the name of the prescriber;

(iii) the opioid antagonist being prescribed;

(iv) the date of the dispensing or furnishing; and

(v) the name of the person (or identification of the pool under subparagraph [10][iii] of this subdivision) receiving the opioid antagonist.

(d) Nothing in this section shall prevent a health care practitioner from issuing a patient-specific prescription for an opioid antagonist as otherwise permitted by law.

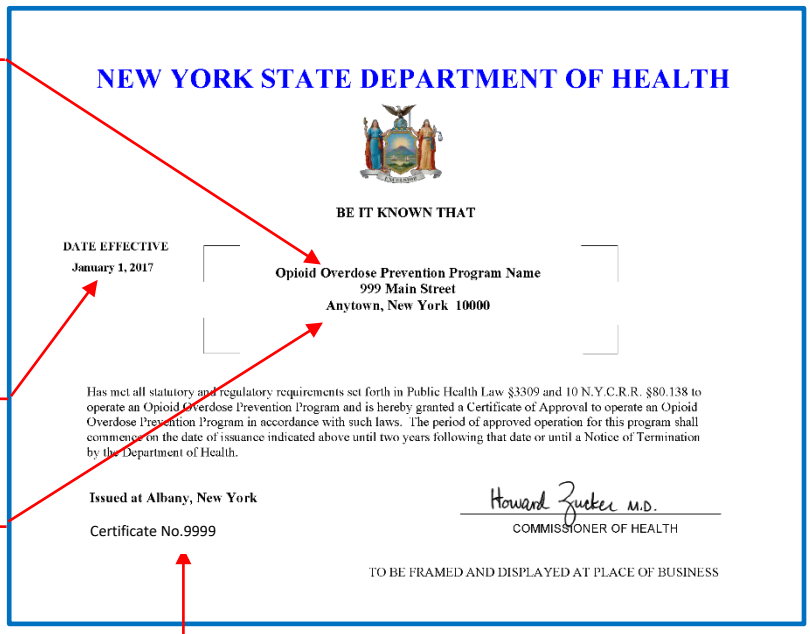
Appendix C: New York State Education Law Section 6509-D

6509-D Limited exemption from professional misconduct.

§ 6509-d. Limited exemption from professional misconduct. Notwithstanding any other provision of law to the contrary, it shall not be considered professional misconduct pursuant to this sub-article for any person who is licensed under title eight of this chapter and who would otherwise be prohibited from prescribing or administering drugs pursuant to the article that licenses such individual, to administer an opioid antagonist in the event of an emergency.

Appendix D: Certificate of Approval

Every opioid overdose program authorized to operate in New York State is issued a Certificate of Approval by the NYSDOH. A Certificate of Approval is generally issued within two weeks of registration submission, unless there are problems with the registration. Certificates are issued for a period of two years and may be renewed at the discretion of the NYSDOH upon request from the program. A sample Certificate of Approval with a description of its elements appears below.



NEW YORK STATE DEPARTMENT OF HEALTH

BE IT KNOWN THAT

DATE EFFECTIVE
January 1, 2017

Opioid Overdose Prevention Program Name
999 Main Street
Anytown, New York 10000

Has met all statutory and regulatory requirements set forth in Public Health Law §3309 and 10 N.Y.C.R.R. §80.138 to operate an Opioid Overdose Prevention Program and is hereby granted a Certificate of Approval to operate an Opioid Overdose Prevention Program in accordance with such laws. The period of approved operation for this program shall commence on the date of issuance indicated above until two years following that date or until a Notice of Termination by the Department of Health.

Issued at Albany, New York

Certificate No.9999

Howard Zucker M.D.
COMMISSIONER OF HEALTH

TO BE FRAMED AND DISPLAYED AT PLACE OF BUSINESS

Program name

This is the official name of the registered program. It should reflect the entity which registered with the NYSDOH. A program name may be changed if there is a change in the identity of the underlying organization or if doing so more clearly distinguishes the registered entity. The program must notify the NYSDOH of any proposed changes through an email to overdose@health.ny.gov.

Date effective

The registration is valid for two years from this date.

Primary address

The address on the Certificate of Approval is the primary address associated with the program. This is generally the address of an agency's administrative office or of the Program Director. All changes in this address should be communicated to overdose@health.ny.gov or through the Opioid Overdose Prevention Program System.

Certificate number

Each registered program has a unique certificate number, which is represented by the digits on this section of the Certificate.

Both Public Health Law Section 3309 and 10 NYCRR 80.138 address the Certificate of Approval and maintaining a registered program with the same language:

> *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.*

- Program Directors and Clinical Directors should be familiar with their Certificate Number(s). The Certificate Number should be referenced every time there is an inquiry to the NYSDOH for an issue pertaining to a registered program. This identifier is also integral to mandated quarterly reporting and to the ordering of supplies.
- A copy of the Certificate of Approval should be displayed at all sites at which overdose program activities are routinely conducted.
- Both the Program Director and the Clinical Director have access to—and may print—their program's Certificate of Approval through the New York State Opioid Overdose Prevention Program System

(NYSOOPPS), so long as they have validated accounts on the System. Any questions regarding access to the System should be directed to overdose@health.ny.gov.

- Although only one address appears on the Certificate of Approval, program activities are NOT restricted to this this address. Additional sites where there is ongoing overdose program activity, should be part of a program's registration information and reflected in the NYSOOPPS.

Appendix E: Detailed Outline of Training for Trained Overdose Responders (TORs)

1. Describe what opioids are and how they contribute to an overdose.
    a) Provide examples of pharmaceutical and street opioids.
    b) Note that opioids slow down respiration (breathing), in addition to relieving pain and providing a good feeling for many people.
    c) Itemize risk factors for opioid overdose.
        - Loss of tolerance.
            - Use after a period of not using (abstinence) poses a particularly high risk.
            - Individuals coming out of correctional settings, abstinence-based programs and detox are at a very high risk, though anyone having not used for as few as 24-48 hours may be at risk with return to use.
        - History of previous overdose.
        - Mixing drugs.
            - Note that non-opioid classes of drugs (depressants, including alcohol; benzodiazepines; and cocaine) can contribute to an opioid overdose.
        - Using alone is a risk for death, because there is nobody available to help.
        - Injection as route of administration.
        - Unpredictable strength of street drugs.
    d) Highlight presence and consequences of fentanyl.
        - Fentanyl is prevalent throughout New York State.
        - Strong opioids such as fentanyl increase risk of an overdose.
        - Fentanyl may be mixed with a wide variety of illicitly manufactured drugs, including heroin, cocaine and pills.
        - Any powdered drug may contain fentanyl.
        - Merely being in the presence of fentanyl or being in contact with someone who has used a substance that includes fentanyl does not place a responder at risk.[49] It is safe to provide care to someone who is overdosing, even with fentanyl as part of the overdose.
        - Trainees may need reassurance that naloxone works for fentanyl and it is uncommon for more than 2 doses to be required.

2. Explain what naloxone does.
    a) Blocks temporarily the effects of opioids.

        Note: Trainers may choose to describe opioid receptors and how naloxone replaces opioids on these receptors.
    b) Reverses overdoses due to opioids allowing breathing to return to normal.
    c) May bring on withdrawal symptoms in opioid-dependent individuals, with this withdrawal subsiding as the naloxone wears off.
    d) Does not cause harm if it is administered on someone not experiencing an opioid overdose.
    e) Does not reverse overdoses from other drugs.

3. Explain how to recognize an overdose.
    a) Person is unconscious/unresponsive.

[49] The American College of Medical Toxicology and the American Academy of Clinical Toxicology have jointly issued a Position Statement on Preventing Occupational Fentanyl and Fentanyl Analog Exposure to Emergency Responders. That guidance includes the following statement: *For opioid toxicity to occur, the drug must enter the blood and brain from the environment. Toxicity cannot occur from simply being in proximity to the drug.*

b) There is shallow or no breathing. Breathing may be accompanied by snoring or gurgling sound.
c) Person may have blue lips or blue color to base of the finger nails.
d) There may be signs of drug use visible, such as needles, packets of drugs or pills.

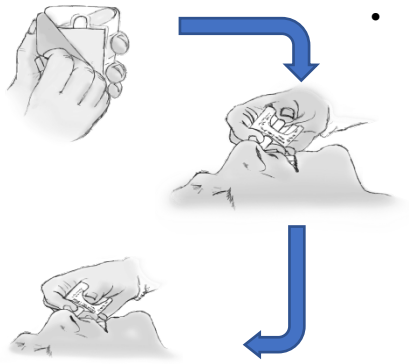
4. Describe additional assessment steps to take:
   a) Shake the unresponsive person and shout at them.
   b) If this is unsuccessful, use sternal rub (hard up and down rubbing of the knuckles in the middle of the chest).

      Note: The sternal rub is not only used for assessing whether an opioid overdose has taken place, but it also may bring about a sufficient response so that no further treatment is necessary.
   c) If sternal rub does not bring the person to a responsive state, it is an emergency which may be an opioid overdose.

5. Explain how to respond to an opioid overdose:
   a) Call 911
      - Either do this or administer naloxone first, depending on the circumstances.
      - If more than one person is present with the overdosed individual, one person can call 911 and the other may administer the naloxone. Do first whichever is quickest.
      - Stay calm and state clearly to the 911 dispatcher: Someone has overdosed and is not breathing.
      - Give precise location.
      - Follow the directions of the dispatcher.

      Explain New York's 911/Good Samaritan law and engage responders on concerns they may have regarding potential interactions with law enforcement personnel.[50]

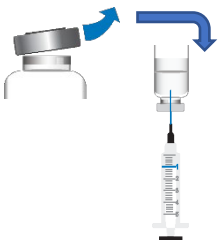
   b) Administer naloxone



- Narcan® nasal spray:
  - Follow directions in the package insert and/or other guidance provided by the NYSDOH or the NYCDOHMH, including
    a. Peel: *Peel* back the package (blister pack) to remove the device.
    b. Place: With the person on his/her back and the head tilted back, hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle. Then *place* the tip of the nozzle in either nostril until your fingers touch the bottom of the person's nose.
    c. Press: Once the tip is in the nostril, *press* the plunger firmly to release the dose into the person's nose.

Do not test the device or press down on the plunger prior to use as that will waste the dose. There is only one dose in each device.

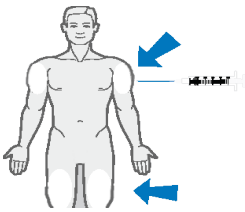
OR



- Intramuscular injection:
  - Remove cap from single-dose naloxone vial to expose the rubber plug and remove the syringe from its packaging.
  - Insert needle through the vial's rubber plug.
  - Pull back on the syringe plunger to draw all the naloxone from the single dose vial into the syringe.

    Note: The tip of the syringe must be in the naloxone.

[50] *See* Explaining New York State's 911/Good Samaritan Law *below*.

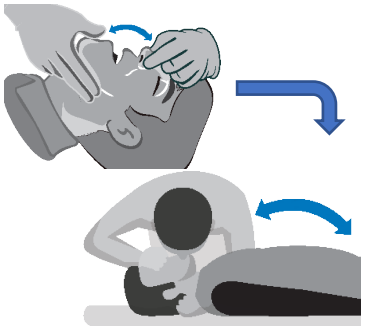


- Inject the entire dose into muscle of upper arm or thigh.
- Alcohol wipes for sterilizing skin are included in overdose kits, however the most critical element is administering the naloxone without delay. If undue time will be spent in finding and using an alcohol wipe, naloxone should be injected without skin preparation.

c) Resuscitation support

- TOR may provide rescue breathing or CPR, if either of these techniques are taught or otherwise known by the TOR.
- Steps for rescue breathing
  - Tilt head back, pinch nose, and form mouth-to-mouth seal, using breathing mask if one is available.
  - Give with 2 quick breaths
  - If chest doesn't rise, reposition head to confirm that airway is clear; confirm that nose is pinched; and that a good mouth-to-mouth seal is maintained.
  - Give one normal-sized breath every 5 seconds.

    Note: You don't want the rescue breath to be so extreme that the TOR becomes exhausted. When there are multiple TORs present, they may choose to take turns. Normal sized breaths are less likely to fill the stomach with air.
- It is optional for programs to teach a resuscitation technique, however either rescue breathing or CPR may be beneficial pending the arrival of EMS.
- When rescue breathing is taught, a face shield should be provided and there should be a demonstration on its use.



d) Place individual in the Recovery Position (lying them on their side) if rescue breathing or CPR is not being provided or if the overdosed person is being left alone, even for a brief time. This is intended to keep someone from choking on vomit.

e) Administer a second dose of naloxone in 2-3 minutes if the person is not breathing normally or remains unresponsive.

Note: The goal is to have the overdosed individual once again breathing normally and not necessarily being fully alert. A vigorous sternal rub may be used to assess return to a responsive state.

f) If 911 has not already been called, that the call should be made now without delay.

Note: There are important benefits in individuals going to the emergency room. These include more extensive follow-up care as well as opportunities for linkage to services.

g) Provide aftercare for revived individuals.

- For fully revived individuals, explain what happened and advise against using any more drugs now to treat withdrawal symptoms as these symptoms will subside as the naloxone wears off.
- When EMS arrives, inform them that naloxone was administered.
- If EMS was not called or has not arrived, stay with the person at least 3 hours to watch for return of overdose.
- If the person isn't fully awake, walking and talking, call 911 or take them to the ER.

6. Demonstrating or describing in detail how naloxone is used, including whatever assembly or preparation is necessary.

- A "hands-on" component to the training will give the TOR some "muscle memory" and may elicit further questions regarding administration technique. This may be particularly helpful for intramuscular naloxone.
- Cross-training on both the Narcan® nasal spray and intramuscular naloxone can be beneficial, as TORs may encounter a different formulation in the field.

7. Directing all TORs to return to the program to report their use of naloxone as soon after that use as possible.

   Note: This is important so that administration of naloxone can be reported by the program to the NYSDOH and so that naloxone replacement can be addressed. Soon, there will be an option for TORs to report their naloxone use through an online portal.

8. Providing direction to TORs on how to obtain initial and replacement naloxone.
   - Pharmacy is the default option for most TORs.[51] [52]
   - TORs who are furnished naloxone as part of their training should always be given information on availability of naloxone in pharmacies for replacing what they have used.

9. Explaining New York State's 911/Good Samaritan Law.

   New York State's 911/Good Samaritan Law offers substantial protections which apply both to the person who has overdosed as well as to those who have summoned assistance. The presence of drugs on the scene of an overdose is not unusual.

   The laws protections apply to individuals
   - Possessing controlled substances up to and including A2 felony offenses (anything under 8 ounces);
   - Possessing alcohol, where underage drinking is involved;
   - Possessing marijuana (any quantity);
   - Possessing drug paraphernalia; and
   - Sharing drugs.

   The law does not provide protection for
   - A1 felony possession of a controlled substance (8 ounces or more);
   - Sale or intent to sell controlled substances;
   - Open warrants for your arrest; or
   - Violation of probation or parole.

     Note: The New York State Department of Corrections and Community Supervision is actively supporting the training of incarcerated individuals and parolees. a

[51] *See* Appendix I: Maximizing use of Pharmacies as a Source of Naloxone for TORs.
[52] NYCDOHMH may provide different guidance on this for programs in NYC for which it furnishes naloxone.

Appendix F: Certificate of Completion

After a training, each person who has demonstrated an adequate understanding of the course material should be given a Certificate of Completion, whether naloxone is furnished or not. The Certificate of Completion is sometimes referred to as the "blue card."

- This requirement does not apply to law enforcement personnel and firefighters.
- It is a good practice to issue a new Certificate of Completion whenever a TOR has a Refresher Training, even if two years since the initial training have not yet passed.
- When naloxone is furnished, the formulation must always be indicated

There are two versions of the Certificate of Completion, both of which may be ordered online using the New York State Opioid Overdose Prevention Program System. One of these is for TORs who are being furnished naloxone when they are trained, and the other is for TORs when they are directed to a pharmacy for their naloxone.

When naloxone is provided:

FRONT

Certificate of Completion

Date _____

This certifies that _____
has been trained in opioid overdose prevention including the use of naloxone for the purpose of preventing death from an opioid overdose. This practice is legal under New York State Public Health Law Section 3309 and under 10 N.Y.C.R.R. Section 80.138.

Prescribed by (name):

_____
Under a non-patient specific order

Check formulation(s), if any
- ☐ NARCAN® Nasal Spray (naloxone HCl) 4 mg units, 2 units. Administer IN prn as directed
- ☐ Naloxone 2mg/2mL 2 prefilled syringes with atomizers. Administer IN prn as directed
- ☐ Naloxone 0.4mg/mL 2 vials and 2 3cc syringes. Administer IM prn as directed
- ☐ Other, specify: _____

BACK

NYSDOH Registered Opioid Overdose Program
Get a kit at your pharmacy or program.

[ ]

New York State Department of Health Opioid Overdose Initiative
1-800-692-8528 | www.health.ny.gov/overdose
Syringe Access, Drug & Syringe Disposal Resources
www.health.ny.gov/syringes | www.thepointny.org
OASAS HOPEline
1-877-846-7369 | www.oasas.ny.gov

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When naloxone is not provided:

FRONT

CERTIFICATE OF COMPLETION

Date _____

This certifies that _____
has been trained in opioid overdose prevention including the use of naloxone for the purpose of preventing death from an opioid overdose. This practice is legal under New York State Public Health Law Section 3309 and under 10 N.Y.C.R.R. Section 80.138.

Name of registered opioid overdose prevention program.

_____

BACK

N-CAP NALOXONE CO-PAYMENT ASSISTANCE PROGRAM

Go to this participating pharmacy to get naloxone.

[ ]

Questions about participating pharmacies or claim processing call 800-542-2437.
NEW YORK STATE DEPARTMENT OF HEALTH OPIOID OVERDOSE INITIATIVE
1-800-692-8528 | www.health.ny.gov/overdose
SYRINGE ACCESS, DRUG & SYRINGE DISPOSAL RESOURCES
www.health.ny.gov/syringes | www.thepointny.org
OASAS HOPELINE
1-877-846-7369 | www.oasas.ny.gov

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Appendix G: Naloxone Formulations

The NYSDOH provides two naloxone formulations, both of which may be ordered through the Opioid Overdose Prevention Program System:

- Narcan® nasal spray, which delivers 4 mg/0.1mL naloxone in a single-step (no assembly) device.
- Intramuscular (IM) naloxone in 0.4mg/1mL single-use vials, which is delivered with an IM syringe.

NYCDOHMH provides these same formulations for programs within NYC.

Administration techniques for both products are described in the Narcan administration section of Appendix E: Detailed Outline of Training for TORs.

Some opioid overdose programs may still have in their inventory the multi-step intranasal product whose naloxone is manufactured by Amphastar. That product should continue to be furnished to TORs so long as it is 6 months or more from its expiration date.

A third product, the Evzio® 2mg auto-injector is another option, however it is not furnished by the NYSDOH or the NYCDOHMH.

Appendix H: Reasons for Possible Termination of a Registration

With written notification, the NYSDOH may terminate a program's registration as an opioid overdose prevention program. Reasons for terminating a registration may include:

- Failure of the program to inform the NYSDOH of changes in the overdose program which are relevant to the registration. This critical information includes the names and contact information for the Program Director and the Clinical Director; correct and current licensure information for the Clinical Director; and names and addresses for all sites at which there is routine program activity.
- Failure to submit mandated quarterly reports.
- Program activities in the absence of a Program Director.
- Program activities in the absence of a Clinical Director or loss or lapse of licensure of that individual.
- Failure to implement inventory controls of product furnished by the NYSDOH.
- Failure to log information pertaining to responders trained and to naloxone furnished consistent with the regulations in 10 NYCRR 80.138 and with other guidance provided by the NYSDOH.
- Persistent failure to respond to communications from the NYSDOH regarding the registration.

Appendix I: Maximizing use of Pharmacies as a Source of Naloxone for TORs

Registered opioid overdose prevention programs are required to make best efforts to maximize the use of pharmacies as a source of naloxone for their trained responders and to incorporate this emphasis in their policies and procedures.

More than 2,200 pharmacies throughout the State have standing orders for naloxone in place. At those pharmacies, one does not need to bring in a prescription, so these venues are an ideal place to refer many trained responders. There is an online directory of these pharmacies at https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/directories.htm.

That web page also has information on the Naloxone Co-payment Assistance Program (N-CAP). Through N-CAP individuals with prescription drug coverage can have naloxone co-payments up to $40 covered, without any need for individuals to be enrolled in any other program other than their primary health insurance. Through N-CAP, there will be no or lower out-of-pocket expenses. N-CAP does not cover deductibles, and some primary health plans may limit the amount of naloxone that will be dispensed in a given time frame. Pharmacies enrolled in the New York AIDS Drug Assistance Plan (ADAP) are able to bill for N-CAP.

The Program Director must ensure that AOTs and other relevant staff understand the policy of maximizing use of pharmacies and incorporate it in their trainings and in interactions with TORs. This requirement pertains most directly to trained responders who have prescription drug coverage and for whom pharmacy acquisition of naloxone is a reasonable expectation. It does NOT apply to public safety personnel, staff at agencies whose access to naloxone is associated with work-related responsibilities; persons transitioning from correctional settings; persons who have just experienced an overdose; and others for whom pharmacy is not a realistic option and for whom the need for naloxone is tangible. This latter category may include syringe exchange program participants and individuals leaving detox.

Every order of naloxone through the NYSOOPPS requires certification that the naloxone being ordered is intended for individuals who cannot reasonably be expected to obtain naloxone from a pharmacy. Each of these orders must also be accompanied by a projected percentage of kits that will go to the following designated populations:

- Syringe exchange program participants;
- Individuals being released from prison/jail;
- Uninsured who are not in the categories above;
- Public safety personnel;
- Agency staff;
- School or library personnel;
- Patients/clients with insurance;
- Family members with insurance;
- General public; and
- Other.

The percentages, which must add up to 100, should be low for persons with insurance and for the general public. The naloxone needs of these responders are most appropriately addressed by making referrals to pharmacies.

Programs should continue to train all types of TORs. Training does not imply provision of naloxone. This is particularly true for persons with prescription drug coverage and for the general public.

Individuals for whom direct provision of naloxone by the registered program is most appropriate (i.e. uninsured individuals; individuals transitioning from correctional settings; syringe exchange program participants; public safety personnel; staff at agencies where there are individuals at risk for an overdose; and others at high risk for experiencing or witnessing an overdose but who are unlikely to access a pharmacy), should be provided with information on obtaining naloxone at pharmacies and the role of N-CAP in reducing or eliminating their out-of-pocket expenses. All TORs should be encouraged to obtain naloxone at a pharmacy if they use or lose their naloxone.

Best practice: Where feasible, the registered program should establish collaborative relationships with local pharmacies to minimize barriers to trained responders obtaining naloxone from those pharmacies.

Appendix J: Guidance for Opioid Overdose Prevention Programs in Specialized Settings

Syringe Exchange Programs

All Syringe Exchange Program (SEP) participants and persons in their social networks should be prioritized for having naloxone.

Certain considerations are particularly important for SEP participants as TORs:

- Trainings should not be unduly long. It can take 5 minutes or less to convey the basic information on how to recognize an overdose and respond to it.
- SEP participants should be routinely engaged regarding their risk for an opioid overdose and be provided with naloxone if they do not already have it.
- Ensure that engagement with SEP participants includes strategies to reduce the likelihood of an overdose, including
    - Understanding risks associated with:
        - Lost tolerance;
        - Potency of the drug supply
    - Access to Medication for Addiction Treatment (MAT), i.e. buprenorphine and methadone;
    - Referrals, where appropriate, for other treatment;
    - Access to mental health services; and
    - Housing stability.
- Promoting Safety Plans: Engagement with participants should also include discussions regarding a personal overdose safety plan. Elements of this safety plan may include:
    - Always having naloxone available and easily accessible for oneself and others.
    - Letting others know you have naloxone and making sure they know how to use it.
    - Encouraging others to obtain their own naloxone, either from the SEP or from a pharmacy.
    - Avoiding using drugs alone, or minimizing the extent to which this happens.
    - If using alone, having an arrangement with someone to check in so see how things are going.
    - Being aware of the prevalence of fentanyl and the increased risk for overdose it presents.
    - Being particularly careful about mixing drugs as this increases the risk for an overdose, particularly if opioids are combined with depressants (including alcohol), benzodiazepines or cocaine.
    - Using a test shot or smaller quantity:
        - If using alone.
        - After a period of abstinence.
          Note: Tolerance decreases and the risk for overdose increases after not using drugs for as little as 24-48 hours.
        - If a substance looks different.
        - If the source for drugs has changed.
        - If the presence of fentanyl is suspected.
        - If drugs are being mixed.
    - Consider initially snorting to assess strength.
    - Planning where drugs are consumed so that you will have:
        - A clean environment.
        - Sterile water.
        - Sufficient lighting.
        - An adequate quantity of new injection equipment.
        - Time to consume drugs without being rushed.
        - Access to the space by others who may be able to help.
          Note: Locking a door or leaning against it may prevent someone from coming in to help.
    - If not already injecting, avoiding that as a route of administration.
    - Managing one's use of drugs by

- Considering alternatives such as methadone or buprenorphine, which can address cravings and reduce the risk of an overdose.

When SEP participants are engaged around overdose, there should be an inquiry whether they have recently used naloxone, so that information can be submitted to the NYSDOH on that administration.

Every SEP site should have a protocol for responding to an on-site overdose.

Emergency Room, Primary Care and Opioid Treatment Settings

All settings where care or treatment is provided to individuals at risk for experiencing or witnessing an opioid overdose are ideal for engagement regarding overdose and bridging access to naloxone.

Programs in these settings may consider use of an Electronic Health Record or an assessment tool to ascertain whether patients fit into one of the following categories, each of which warrants serious consideration for ensuring access to naloxone with a patient-specific prescription:

- Patients presenting with an opioid overdose or who have an opioid overdose history.
  Note: Patients do not always characterize past overdoses as such, but may instead acknowledge having had a "bad reaction" to—or an "accident" with—their opioids that required naloxone or a trip to the Emergency Room. Other opioid-experienced individuals may only be able to articulate symptoms consistent with withdrawal such as sweating, vomiting, diarrhea, yawing, and tremors after a hiatus from opioid use.
- Patients in acute opioid withdrawal.
- Patients who have recently undergone managed withdrawal/stabilization ("detox").
- Patients with diagnosed or undiagnosed opioid use disorder.
- Patients with a history of opioid use who have recently been released from a correctional or treatment setting.
- Patients being treated with, or otherwise using, methadone, buprenorphine or naltrexone.
- Patients being discharged with prescribed opioids.
- Patients being discharged with a prescription for an opioid and having other underlying diagnoses that may contribute to an opioid overdose, including respiratory illness such as asthma, COPD or a respiratory infection; renal dysfunction; hepatic disease; cardiac illness; or depression.
- Patients being discharged with a prescription for an opioid with concurrent use of a benzodiazepine or other sedative; suspected excessive alcohol use or dependency.
- Patients who have been prescribed long-term opioids.
- Patients presenting with an injury associated with their opioid use.
- Patients with "active" use of licit or illicit opioids, other than those with limited-dose prescriptions.
- Patients who may be unnecessarily requesting opioids.
- Patients resuming opioid use after a period of abstinence.

Best practices:

Build relationships with pharmacies

Care and treatment providers should consider establishing relationships with local pharmacies to ensure seamless access to naloxone for their patients. The outcomes may include:

- Improved likelihood that naloxone will be in stock for patients directed to those pharmacies.
- Wider understanding and use of the Naloxone Co-payment Assistance (N-CAP) program, resulting in no or lower co-payments by insured patients.
- Delivery of naloxone to the patient location.

In instances where patients are unlikely to access a pharmacy for their naloxone (*see* Maximizing Use of Pharmacies as a Source of Naloxone for TORs), furnishing naloxone provided by the NYSDOH directly to

them is permitted. Naloxone provided by the NYSDOH or by the NYCDOHMH cannot under any circumstances be billed to a patient's insurance

Promote safety plans

Where feasible, patients should be engaged around developing a personal safety plan such as the one described above for syringe exchange program participants.

Integrate buprenorphine into patient care

Consider prescribing and providing buprenorphine for treating withdrawal symptoms and as part of ongoing care. Methadone is also a MAT option for many individuals.

Appendix K: Guidance and Legal Framework for Specialized Overdose Responders

There are additional statutes, regulations and guidance documents which are relevant to overdose training and naloxone provision in various specific settings.

All registered programs contemplating training any of the sets of responders listed below, should be aware of the unique protocols that pertain to them and tailor their practices accordingly. The curricula for these sets of responders are all specialized. A registered opioid overdose prevention program must be involved in the provision of naloxone to all the responders enumerated above, except for EMS personnel.

Law Enforcement Personnel

The Division of Criminal Justice Services (DCJS), the NYSDOH, the Harm Reduction Coalition and Albany Medical Center collaborated in the development of a curriculum and policies and procedures pertaining to public safety agencies. Programs working with personnel in these agencies should review DCJS materials available at https://www.criminaljustice.ny.gov/ops/training/trainingnews.htm.

Policies and procedures

Police Departments and Sheriff's Offices in developing their agencies' policies and procedures should consult the Municipal Police Training Council Model Policy for the Administration and Maintenance of Intranasal Naloxone.

Training

A slide-based curriculum and instructor manual, both available at https://drive.google.com/drive/u/0/folders/0B-tIyJeL0-5ER2JGcjEzVFViUVU, are intended for use by:

- Approved DCJS General Topics Instructors who have completed the Opioid Overdose and Intranasal Naloxone Training for Law Enforcement;
- Health care practitioners authorized by either the NYSDOH or DCJS to deliver the training; or
- Qualified individuals from NYS-registered opioid overdose prevention programs.

If a public safety agency wants to add the successful completion of the course to a police or peace officer's training record in the state registry, that public safety agency should contact OPS.CourseApproval@dcjs.ny.gov prior to the training.

Registering as an opioid overdose prevention program

Law enforcement agencies may either become the NYSDOH-registered opioid overdose prevention programs or work with "external" registered programs (e.g. local health departments or other law enforcement agencies which have registered programs) for purposes of getting their naloxone.

Reporting naloxone use

When naloxone is administered by public safety personnel, those administrations should be reported to the NYSDOH on a form specifically designed for law enforcement personnel and for fire fighters: the New York State Public Safety Naloxone Quality Improvement Usage Report. This is NOT the same reporting form used for civilian administration of naloxone.

Fire Fighters

The New York State Office of Fire Prevention and Control (OFPC) in collaboration with the New York State Department of Health has developed guidance for non-EMS firefighters. That guidance may be accessed www.dhses.ny.gov/ofpc/resources/naloxone/index.cfm.

Training

There is a specialized slide-based curriculum and accompanying, student manual and training manual that should be used for these responders.

NYS Fire Instructors should be delivering the course content, with scheduling for training done through the County Fire Coordinator.

If a fire fighting agency is working with an "external" registered opioid overdose prevention program for purposes of obtaining naloxone (e.g. Regional EMS Council or local health department), it should coordinate the proposed scheduling of trainings with the registered program to ensure that naloxone is ordered and received prior to the training.

Reporting naloxone use

When naloxone is administered by fire fighters, it should be reported to the NYSDOH on a form specifically designed for fire fighters and law enforcement personnel: the New York State Public Safety Naloxone Quality Improvement Usage Report. This is NOT the same reporting form used for civilian administration of naloxone.

Secondary School and Board of Cooperative Educational Services (BOCES) Personnel

The New York State Education Department, in collaboration with NYSDOH, the Harm Reduction Coalition and the New York State Center for School Health, has developed a curriculum and other resources for school personnel. These are available at https://www.schoolhealthny.com/OpioidOverdose. The guidance is reflective of provisions in the Public Health Law Section 3309, as well as Education Law Section 922 and in regulations.

Registering as an opioid overdose prevention program

Response capacity for opioid overdoses with naloxone is voluntary for schools, school districts and BOCES.

Consent to have opioid overdose response capacity on secondary school campuses must come from the School Board or the School Superintendent. The Board or Superintendent is also responsible for choosing which model to implement for this capacity. A school district contemplating having its staff furnished with naloxone should consult SED's Guidance for Implementing Opioid Overdose Prevention Measures in Schools. The three options for school districts choosing to have naloxone on its campuses are:

- Option One: Becoming a NYSDOH-registered opioid overdose prevention program.
- Option Two: Having school nurses able to administer naloxone pursuant to a non-patient-specific order and protocols.
  - **Note**: The non-patient specific order must come from either a physician or a nurse practitioner.
- Option Three: Collaborating with a NYSDOH-registered opioid overdose prevention program operated by another organization ("external" programs).

Reporting naloxone use

Naloxone administration reporting should be done on the "civilian" NYS DOH Opioid Overdose Reporting Form that is integrated into the New York State Opioid Overdose Prevention Program System.

Licensed Professionals as Trained Overdose Responders

The administration of medication on another person and the provision of medication to another person are highly regulated activities which are generally restricted to professionally trained, licensed individuals. Opioid overdose prevention programs and their trained responders, however, are not violating laws governing the practice of a profession by acquiring, furnishing or administering naloxone.[53]

Emergency Medical Services (EMS) personnel

EMS personnel are NOT trained responders under Public Health Law Section 3309. EMS in New York State is governed under Articles 30, 30-A, 30-B and 30-C of the Public Health Law. The permissible scope of practice for Basic Life Support (BLS) EMS personnel was expanded in 2013 to be inclusive of the intranasal administration of naloxone. Guidance on the protocols to follow as well as on the training to use for those BLS personnel is found here: https://www.health.ny.gov/professionals/ems/policy/13-10.htm.

[53] PHL Section 3309(2); Educ Law Section 6509-D

Appendix L: Community (Non-Public Safety) Naloxone Administration Reporting Form

NOTE: This hardcopy form may be used internally by registered programs only for data collection. Naloxone administration reporting must be done online through the New York State Opioid Overdose Prevention Program System.

NYSDOH Opioid Overdose Prevention Initiative

Community Naloxone Usage Form

Purpose: Program staff may use this form as a data collection instrument. All community naloxone usage reports must be entered electronically into the New York State Opioid Overdose Prevention Program System.

On what day was the naloxone used?
If naloxone was used on more than one day, please submit a separate report for each use. If you don't know the precise date, choose one that you think is close.

Date naloxone used:

Do you know the zip code where the overdose happened?

Yes: Zip Code:

No: County/Borough & Town

Did the person who overdosed survive? (choose one) Yes No Don't know

(Check all that apply.) Select the type of naloxone used and the number of doses given.

☐ **Narcan™ Nasal spray, Doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Intramuscular injection generic Doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Nasal spray generic Doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Evzio Autoinjector Doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

Did anyone else also give naloxone for this same overdose? (choose one) Yes No Don't know

(check all that apply) Were they
- ☐ Police
- ☐ EMS
- ☐ Fire Fighter
- ☐ Another civilian witness or bystander
- ☐ Other

Do you know what type of naloxone they used? Yes No

(Check all that apply) What did they use (formulation & doses)?

☐ **Narcan™ Nasal spray doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Intramuscular injection generic doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Nasal spray generic doses:**
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Evzio Autoinjector doses:**
- ☐ 1
- ☐ 2 3
- ☐ 4
- ☐ More than 4
- ☐ Don't Recall

☐ **Other**

Was 911 called? (choose one) Yes No Don't know

Was rescue breathing performed before EMS, police or fire fighters arrived? (choose one)	Yes	No	Don't know
Were chest compressions performed before EMS, police or fire fighters arrived? (choose one)	Yes	No	Don't know
How old were they? (best guess)	Age:		
Were they	☐ Male ☐ Female	☐ Transgendered or gender non-conforming ☐ Unknown Sex ☐ Other	
Were they (more than one may be selected)	☐ African-American/Black ☐ Asian/Pacific Islander ☐ Hispanic/Latino(a)	☐ Native American ☐ White ☐ Unknown race/ethnicity ☐ Other	
(Indicate all that apply) Select which drugs the overdoser is likely to have used.	☐ Heroin ☐ Pain pills ☐ Cocaine ☐ Fentanyl ☐ Benzos	☐ Alcohol ☐ Amphetamine/methamphetamine ☐ Methadone ☐ Other	

In what kind of place did the overdose happen?

- ☐ Someone's home or apartment
- ☐ Shelter or in a supportive housing setting
- ☐ Agency or facility that provides services, such as a syringe exchange, drug treatment program or social services agency or government office
- ☐ Public place outside (e.g. park; sidewalk, yard)
- ☐ Public place inside, other than a library, secondary school, or college/university/trade school camp us (e.g. restroom, business, train, car)
- ☐ Library
- ☐ Secondary school (e.g. high school, middle school)
- ☐ On a college/university/trade school campus
- ☐ Other

What is the relationship to the person who overdosed?	☐ Friend or acquaintance ☐ Family ☐ Stranger	☐ Patient or client Prefer not to answer ☐ Other (specify)	
Has this person experienced an opioid overdose in the past? (choose one)	Yes	No	Don't know
Was a replacement kit given? (choose one)	Yes	No	Don't know
Was information provided about getting naloxone from a pharmacy? (choose one)	Yes	No	Don't know

Please add any additional comments about this naloxone administration.

Comments:

For Registered Program Internal Use (optional):
If your program collects additional information about the administration of naloxone, you may enter that here.

Additional agency-specific information::

DO NOT **provide any patient- or client-identifying information on this form.**

Appendix M: Public Safety Naloxone Administration Form

New York State Public Safety Naloxone Quality Improvement Usage Report

Print Form

Version: 3/10/2015

Date of Overdose: ☐☐/☐☐/☐☐ **Arrival Time of Responder:** ☐☐:☐☐ ◯ AM ◯ PM **Arrival Time of EMS:** ☐☐:☐☐ ◯ AM ◯ PM

Agency Case #: _____ Gender of the Person Who Overdosed: ◯ Female ◯ Male ◯ Unknown Age: ☐☐

ZIP Code Where Overdose Occurred: _____ County Where Overdose Occurred: _____

Aided Status Prior to Administering Naloxone: (*Check one in each section.*)

Responsiveness: ◯ Unresponsive ◯ Responsive but Sedated ◯ Alert and Responsive ◯ Other (specify): _____

Breathing: ◯ Breathing Fast ◯ Breathing Slow ◯ Breathing Normally ◯ Not Breathing

Pulse: ◯ Fast Pulse ◯ Slow Pulse ◯ Normal Pulse ◯ No Pulse ◯ Did not Check Pulse

Aided Overdosed on What Drugs: (*Check all that apply.*)

☐ Heroin ☐ Benzos/Barbiturates ☐ Cocaine/Crack ☐ Buprenorphine/Suboxone ☐ Pain Pills ☐ Unknown Pills

☐ Unknown Injection ☐ Alcohol ☐ Methadone ☐ Don't Know ☐ Other (specify): _____

Administration of Naloxone **Number of naloxone vials used:** ◯ 1 vial ◯ 2 vials ◯ 3 vials ◯ 4 vials ◯ > 4 vials

How long did 1st dose of naloxone take to work: ◯ < 1 minute ◯ 1-3 minutes ◯ 4-5 minutes ◯ >5 minutes ◯ Don't Know ◯ Didn't Work

Aided's response: ◯ Combative ◯ Responsive & Angry ◯ Responsive & Alert ◯ Responsive but Sedated ◯ Unresponsive but Breathing ◯ No Response

If 2nd dose given, was it: ◯ IN (instranasal) ◯ IM (intramuscular) ◯ IV (intravenous)

How long after 1st dose was 2nd dose administered: ◯ < 1 minute ◯ 1-3 minutes ◯ 4-5 minutes ◯ >5 minutes ◯ Don't Know

Aided's response: ◯ Combative ◯ Responsive & Angry ◯ Responsive & Alert ◯ Responsive but Sedated ◯ Unresponsive but Breathing ◯ No Response

Post-naloxone symptoms: (*Check all that apply.*)

☐ None ☐ Dope Sick (e.g. nauseated, muscle aches, runny nose and/or watery eyes) ☐ Respiratory Distress

☐ Seizure ☐ Vomiting ☐ Other (specify): _____

What Else was Done by the Responder: (*Check all that apply.*)

☐ Yelled ☐ Shook Them ☐ Sternal Rub ☐ Recovery Position ☐ Bag Valve Mask ☐ Mouth to Mask ☐ Mouth to Mouth

☐ Defibrillator (if checked, indicate status of shock): ◯ Defibrillator - no shock ◯ Defibrillator - shock administered

☐ Chest Compressions ☐ Oxygen ☐ Other (specify): _____

Was Naloxone Administered by Anyone Else at the Scene: (*Check all that apply.*)

☐ EMS ☐ Bystander ☐ Other (specify): _____

Disposition: (*Check one.*) ◯ Transported by EMS ◯ EMS Transport Refused ◯ Other (specify): _____

Did the Person Live: ◯ Yes ◯ No ◯ Don't Know

Hospital Destination: _____ **Transporting Ambulance:** _____

Comments: _____

Administering Responder's Information: Agency: _____ ◯ Police ◯ Fire ◯ EMS Badge #: _____

Last Name: _____ First Name: _____

Please send the completed form to the NYS Department of Health using any one of the three following methods:

E-mail: oper@health.ny.gov

Fax: (518) 402-6813

Mail: Shu-Yin John Leung
OPER, AIDS Institute, NYSDOH
Empire State Plaza CR342
Albany, New York 12237

Appendix N: Sample Generic Enrollment Form

Naloxone Trained Overdose Responder Enrollment Form

Date of training:
Agency and location of training:
Zip code of training:

Trained Overdose Responder

Name: _____ **Birth date:** ___ ___ / ___ ___ / ___ ___
month day year

Race/Ethnicity:

☐ White ☐ Black ☐ Hispanic ☐ Asian and Pacific Islander ☐ Native American ☐ Mixed race ☐ Unknown ☐ Other (specify):_____

Gender ☐M ☐F ☐T(FTM) ☐T(MTF) ☐ Other: _____

Residence zip code:_____

To be filled out by trainer:

☐ Response education provided

☐ Demonstration of assembly

Naloxone and related equipment provided:

☐ Two NARCAN® Nasal Spray -- 4 mg/0.1 ml. intranasal naloxone
Expiration Date -- month _____ year _____

☐ Two vials -- 0.4 mg/ ml. naloxone for injection and 2 syringes
Expiration Date -- month _____ year _____

☐ No kit provided; Blue Certificate of Completion only

Trainer: _____ **Trainer Signature**: _____