NEW YORK STATE'S OPIOID OVERDOSE REGULATIONS
QUESTIONS AND ANSWERS
(MAY 12, 2015)

PROGRAM ELIGIBILITY, STAFFING AND TRAINING

Who is eligible to have a registered opioid overdose prevention program?

The following are eligible to register with the New York State Department of Health and maintain opioid overdose prevention programs: 1) health care facilities, such as hospitals and diagnostic and treatment clinics, that are regulated by the Department of Health under the Public Health Law; 2) individual medical practitioners—which include physicians, nurse practitioners and physician assistants—so long as they are legally authorized in New York State to prescribe medication; 3) drug treatment programs that are licensed under New York's Mental Hygiene Law; 4) not-for-profit community-based organizations incorporated under the Not-for-Profit Corporation Law; 5) local and state government agencies, including local health departments and public safety agencies; 6) institutions of higher education approved by the Regents of the University of the State of New York, which provide a course of study leading to a post-secondary degree or diploma; 7) business, trade, technical and occupational schools approved by the Regents of the University of the State of New York or by a nationally-recognized accrediting agency or association accepted by the Regents; and 8) pharmacies registered under the Education Law.

What personnel are registered programs required to have?

All registered programs must have a program director and a clinical director. The clinical director must be able to prescribe medication in New York State. The same individual may serve as both the program director and the clinical director.

What are the mandated responsibilities of program directors?

Program directors have the overall responsibility for managing their programs and for being the primary liaison with the Department. Their specific roles include: 1) ensuring that a clinical director oversees the clinical aspects of the program; 2) establishing the program's training curriculum consistent with guidance from the Department; 3) identifying other program staff and ensuring that they are properly trained; 4) identifying the trained overdose responders; 5) issuing certificates of completion to responders who have successfully completed the program's training curriculum, however these certificates of completion are not required for public safety or firefighting personnel; 6) establishing and maintaining the program's recordkeeping system; 7) ensuring that all individuals identified as trained overdose responders have successfully completed the training curriculum; 8) being a liaison, where appropriate, with emergency medical services and emergency dispatch agencies; 9) assisting the clinical director in reviewing reports of overdose responses, particularly those involving administration of naloxone; 10) reporting administrations of naloxone as specified by the Department; and 11) reporting on a quarterly basis the number of doses of naloxone provided and the number of overdose responders trained.

What are the mandated responsibilities of clinical directors?

Clinical directors are the primary personnel designated in a program's registration for prescribing naloxone to be administered by individual—or an identifiable pool of—trained overdose responders. In addition to prescribing and/or dispensing naloxone, their specific responsibilities include: 1) providing clinical consultation, expertise and oversight; 2) serving as a clinical advisor and liaison concerning medical issues related to the program; 3) providing consultation to ensure that all trained overdose responders are properly trained; 4) reviewing and approving opioid overdose prevention training curriculum content and protocols; 5) reviewing reports of all administrations of naloxone; and 6) designating individuals in addition to themselves, if any, who are authorized to dispense or furnish naloxone 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. The designation of individuals to dispense or furnish naloxone is sometimes referred to as a "standing order" though in New York State, consistent with Public Health Law Section 3309, it is known as a "non-patient specific prescription." "Shared access" is sometimes referred to as "communal access."

What are affiliated prescribers and what are their responsibilities?

In addition to the clinical director, programs may have other affiliated prescribers. Affiliated prescribers are able to prescribe naloxone to be administered by individual—or an identifiable pool of—trained overdose responders. They are expected to have ongoing communication with the clinical director so the program can document the practitioner responsible for making naloxone available to the trained overdose responders. Each program's policies and procedures should define the parameters of this on-going communication.

What are trained overdose responders?

The following definition appears in the regulations: "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) is 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) is a firefighter who has completed a comparable curriculum approved by the department."
The language in the regulation specifically excludes as trained overdose responders individuals who are otherwise authorized by law to administer an opioid antagonist, such as EMS personnel or health care practitioners who already have the legal authority to administer an opioid antagonist such as naloxone.

Can substance users, their family members and friends be trained overdose responders?

Yes. This program is specifically designed to equip those most at risk of experiencing or witnessing an overdose, including substance users, with the knowledge and tools necessary to reverse overdoses and save lives.

Can nurses be trained overdose responders?

Professional scope of practice dictates what may and may not be done by various health care personnel in their roles within their respective professions. The Department's opioid overdose regulations do not address scope of practice issues. There is no bar to a nurse becoming a trained overdose responder, so long as that trained overdose responder role is distinct from the role of practicing the profession of nursing. When the individual is functioning as a nurse (other than a nurse practitioner), he or she may only administer naloxone following a patient-specific or non-patient specific medical order.

What are the responsibilities of a trained overdose responder?

The trained overdose responder is responsible for: 1) completing an initial training consistent with the program's opioid overdose prevention training curriculum; 2) completing a refresher training at least every two years or otherwise demonstrating competence in opioid overdose recognition and response to the satisfaction of the program director or someone designated by the program director; 3) contacting EMS (dialing 911) when encountering someone who is the victim of a suspected drug overdose and advising EMS personnel if naloxone has been administered; 4) complying with protocols set out in the training curriculum for responding to victims of a suspected drug overdose; and 5) reporting all responses to an opioid overdose to either the program director or someone designated by the program director to receive these reports.

TRAINING

Who trains responders?

In order to implement an opioid overdose program, individuals must be designated by the program director to train the overdose responders. The program director or the clinical director may assume the training role.

What qualifications are necessary for a trainer?

Trainers should have mastery of the overdose curriculum used by the registered program as well as the ability to teach it to others. Programs should consider having staff attend a train-the-trainer session, such as one offered by the Harm Reduction Coalition. Trainers of public safety personnel should either be General Topics Instructors certified by the Division of Criminal Justice Services (DCJS) or Special Topics Instructors specifically certified by DCJS to provide opioid overdose training. The General Topics Instructors must have had their own training in opioid overdose.

What training is required of responders?

The following definition appears in the regulations: "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." A sample curriculum is available online at http://www.health.ny.gov/overdose.

Public safety personnel should be using a curriculum approved by the New York State Division of Criminal Justice Services (DCJS) and following DCJS administrative procedures mandated for these

trainings. Non-EMS firefighters should be using a comparable curriculum, which is under development.

Flexibility is encouraged in the both the content of the curriculum and in its delivery. The training requirement should not be interpreted in a way that would reduce the ability of opioid overdose prevention programs to make naloxone available to those most at risk of witnessing a drug overdose, including drug users themselves. For some trainings, abbreviated training that only covers the core elements of overdose recognition and response may be appropriate.

Must rescue breathing, full CPR or chest-compression-only CPR be part of the curriculum?

Currently most opioid overdose curricula in the United States, including those used in New York, incorporate rescue breathing as a resuscitation technique to be used by responders who are not already trained in full CPR or who do not otherwise have advanced skills or equipment. Although all resuscitation techniques can be valuable and should be given serious consideration for incorporation in a program's curriculum, they are not required elements. Program and clinical directors should assess the capacity and the willingness of individuals contemplated as responders for using the various resuscitation techniques and then decide on their emphasis—if any—in a given curriculum. The New York State Department of Health's Office of the Medical Director has convened a technical working group to look at this issue, and its findings will be shared once the group has concluded its deliberations.

Do prescribers need to be present when responders are trained?

No. There should, however, be policies and procedures in place to ensure that all furnishing or dispensing is pursuant to a patient-specific or non-patient specific prescription and that all responders have been trained in overdose recognition and response.

RECORDKEEPING

What records need to be maintained by opioid overdose prevention programs?

The following information must be maintained: 1) the names of trained overdose responders; the dates they were trained, and the dates they were furnished naloxone; 2) the name of the designated program staff who dispensed or furnished the naloxone or who are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders; 3) program policies and procedures; 4) copies of contracts or agreements with the clinical director, if appropriate; 5) naloxone use and overdose reversal reports; 6) documentation of review of these reports; 7) inventory records on overdose response supplies; and 8) documentation of the practitioner responsible for making the naloxone available to a trained overdose responder, including any non-patient specific prescriptions issued by the clinical director or by an affiliated prescriber.

How should the inventory and storage of naloxone be addressed?

Every program needs to have policies and procedures which address these issues. Naloxone should be stored at room temperature, in a secured location consistent with manufacturer guidelines. The naloxone inventory should be maintained so that trained overdose responders receive this medication with at least six months and preferably 12 months prior to its labeled expiration. There should be a policy and procedure for disposing of expired naloxone. Naloxone coming into—and out of—inventory under the program's policies and procedures should be documented with the

quantities specified. The actual inventory of naloxone and other overdose supplies should be routinely assessed, with a recommended frequency of at least once per month, to determine whether there are any discrepancies between documented inventory and actual inventory and to prevent such discrepancies.

REPORTING

What protocols should be in place to ensure that reporting of naloxone administration and overdose reversals are reported?

It is the responsibility of each registered program to ensure that there are policies and procedures in place to collect information on naloxone use and overdose reversal. All training should stress the importance of returning to the registered program for replacement of naloxone and for reporting that naloxone was used, as well as the circumstances of that use. The regulations require the trained overdose responder to: "report all responses to victims of suspected drug overdose to the opioid overdose prevention program director or to someone designated by the program director." Staff at registered programs should be trained to collect this information and to forward it to the program and clinical directors for their review. After this information is reviewed, it should be sent as soon as possible to the Department on the mandated reporting form. Law enforcement agencies have a different protocol for the submission of their reports, consistent with administrative requirements provided by DCJS. Programs should also document any unauthorized use of naloxone by a person who is not a trained overdose responder.

What other reporting requirements are there?

Under the regulations, all registered programs "must 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." These forms are currently being developed and will be provided in the near future. Consistent with the recordkeeping requirements noted above, all registered programs should already have this information readily available.

PRESCRIBING NALOXONE

Must naloxone always be prescribed by a medical provider who is affiliated with a registered program, i.e. a clinical director or an affiliated prescriber?

No. The regulations state: "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." If naloxone is prescribed specifically to someone who is personally at risk for an opioid overdose—and family members or others are trained to do the actual administration of naloxone on that individual—the medical provider does not need to be affiliated with a registered program.

What are non-patient specific prescriptions for naloxone and how are they issued?

A non-patient specific prescription—or standing order—is a signed and dated document issued by a prescriber to direct the dispensing of a prescribed drug to an individual not specifically identified at the time of its issuance. The clinical director of a registered program—or an affiliated prescriber of a registered program with the approval of the clinical director—may issue a non-patient specific prescription for naloxone. Non-patient specific prescriptions—either by name or title—should designate those individuals who are to do the furnishing or dispensing and must identify the pool of trained overdose responders who may have access to the opioid antagonist. No furnishing or dispensing should take place absent the recipient having had a training which includes how to recognize an overdose and how to respond to it appropriately. Those appropriate responses should always include summoning EMS (calling 911), if it has not already taken place, and administering naloxone.

May a non-patient specific prescription for naloxone be issued to an organization rather than to an individual?

Yes, the clinical director of a registered program—or an affiliated prescriber of a registered program with the approval of the clinical director—may issue a non-patient specific prescription for an organization to make naloxone available. The organization which is receiving naloxone pursuant to a non-patient specific prescription must have policies and procedures in place that ensure the appropriate training of its staff; the safe and secure storage of naloxone; and the controlled access to naloxone solely by those who have been trained.

What documentation must be maintained with the naloxone when naloxone is dispensed pursuant to a non-patient specific prescription?

The following elements should be included: (i) indication that the naloxone was dispensed pursuant to a non-patient specific prescription; (ii) the name of the prescriber; (iii) the opioid antagonist being prescribed, including the route of administration and dosing; (iv) the date of the dispensing or furnishing; and (v) identification of the group of trained overdose responders who may have access to the naloxone under the prescription, where applicable.

What guidance is available to clinical directors and affiliated prescribers in implementing use of non-patient specific prescriptions?

Model non-patient specific prescriptions and policies and procedures for their implementation are being developed for and by various agencies. These will be posted on the Department's website and may be adapted for use by registered programs for their specific purposes.

FURNISHING AND DISPENSING

Who can dispense or furnish naloxone?

Naloxone may be dispensed or furnished in the following ways: 1) by a registered pharmacist pursuant to a patient-specific or non-patient specific prescription; 2) by a licensed prescriber under that prescriber's patient-specific or non-patient specific prescription; and 3) by individuals specifically authorized by a prescriber affiliated with a registered opioid overdose prevention program to furnish naloxone under a non-patient specific prescription (standing order).

Do prescribers always need to be present when naloxone is furnished to trained overdose responders?

No. Under the regulations, the clinical director may "designate individuals 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."

What should be provided at the time naloxone is furnished or dispensed?

The regulations state the following: "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."

SHARING OF NALOXONE/COMMUNUAL ACCESS

Does everyone have to have his or her own personal rescue kit with naloxone or can it be shared?

Shared access to—and use of—naloxone is permitted in certain circumstances specified in the regulations: "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." The permissible sharing of naloxone can occur under a non-patient specific prescription issued to an organization. It is also permissible under the regulations for naloxone that has already been dispensed or furnished pursuant to a patient-specific prescription to be shared so long as the conditions noted above are met. Where sharing of naloxone is anticipated, it is preferable that a non-patient specific prescription be in place.

What does the "common organizational or workforce bond" requirement for the sharing of naloxone mean?

If a group of individuals are trained overdose responders for the same program or agency or in the same location, they will be considered as meeting this requirement. Examples include law enforcement personnel working for the same police department; staff and volunteers in a social service agency; and personnel in a homeless shelter, who may or may not have the same employer.

How are decisions made whether or not sharing should be permitted?

This should be a collaborative decision between the prescriber and the organization or workforce.

LIABILITY

Does the law address liability?

Yes. The statute contains this provision: "A recipient or opioid overdose prevention program 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." 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." This broad liability coverage is inclusive of trained overdose responders and registered organizations.

Do prescribers have liability coverage?

The Department of Health interprets the liability protection provided by Public Health Law § 3309 (4) as being inclusive of clinical directors and affiliated prescribers of registered opioid overdose prevention programs, so long as they are acting reasonably and in good faith.

Are trained overdose responders engaged in the unlawful practice of medicine when they administer naloxone?

No. Under Public Health Law Section 3309: "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." In addition: "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."

PHARMACIES

What are the roles of pharmacies and pharmacists under the regulations?

1) A pharmacy may register as an opioid overdose prevention program. Like every other registered program, it would need to identify a prescriber to act as its clinical director. This clinical director could then issue a non-patient specific prescription covering potential witnesses to an overdose as well as persons who may be at risk of experiencing an opioid overdose. This is one collaborative practice model.
2) Pharmacists may dispense naloxone pursuant to a non-patient specific prescription issued by a prescriber affiliated with a registered program other than the pharmacy. This is another collaborative practice model.
3) Pharmacists may dispense naloxone pursuant to a patient-specific prescription in the same manner as any other prescription medication. The New York State Department of Health is working with community pharmacies to ensure that naloxone in its various formulations is more routinely stocked.

What are the training requirements for pharmacists and their patients?

Everyone being furnished or dispensed naloxone should have training in opioid overdose recognition and response. Mechanisms for pharmacist and patient training are still being explored.