

Pursuant to the authority vested in the Commissioner by Public Health Law Section 3309(1), Part 80 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended by adding a new section 80.138 to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The Table of Contents for Part 80 of Title 10 NYCRR is amended to read as follows:

PART 80

RULES AND REGULATIONS ON CONTROLLED SUBSTANCES

(Statutory authority: Public Health Law, Sections 338, 3300, 3305, 3307, 3308, 3309, 3381, 3701(1), (6), art. 33)

Sec.

GENERAL PROVISIONS

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80.138. Opioid Overdose Prevention Programs

A new Section 80.138 is added as follows:

Section 80.138. Opioid Overdose Prevention Programs.

(a) Definitions.

(1) “Clinical Director” means a physician, physician assistant or nurse practitioner who provides oversight of the clinical aspects of the Opioid Overdose Prevention Program. This oversight includes serving as a clinical advisor and liaison concerning

medical issues related to the Opioid Overdose Prevention Program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

(2) “Opioid” means an opiate as defined in section 3302 of the public health law.

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

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

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

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

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

(8) “Registered provider” for the purposes of this section shall mean any of the following that have registered with the Department pursuant to subsection (b):

(i) a health care facility licensed under the public health law;

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

(iii) a drug treatment program licensed under the mental hygiene law;

(iv) a not-for-profit community-based organization incorporated under the not-for-profit corporation law and having the services of a Clinical Director;

(v) a local health department.

(9) “Trained Overdose Responder” means a person who has successfully completed an authorized Opioid Overdose Prevention Training Program offered by an authorized Opioid Overdose Prevention Program within the past two years and has been authorized by a Registered Provider to possess the opioid antagonist.

(b) Registration.

(1) Registered providers may operate an Opioid Overdose Prevention Program if they obtain a certificate of approval from the Department authorizing them to operate an Opioid Overdose Prevention Program and otherwise comply with the provisions of this section.

(2) Providers eligible to register to operate an Opioid Overdose Prevention Program that are in good standing may apply to the Department to operate an Opioid Overdose Prevention Program on forms prescribed by the Department which must include, at a minimum, the following information:

(i) the provider name, address, operating certificate or license number where appropriate, telephone number, fax number, e-mail address, Program Director and Clinical Director;

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

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

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

(v) the addresses, telephone numbers, fax numbers, e-mail addresses and signatures of the Program Director and Clinical Director.

(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, at a minimum:

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

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

(iii) identify and train other program staff;

(iv) select and identify persons as Trained Overdose Responders;

(v) issue certificates of completion to Trained Overdose Responders who have completed the prescribed program;

(vi) maintain Opioid Overdose Prevention Program records including Trained Overdose Responder training records, Opioid Overdose Prevention Program usage records and inventories of Opioid Overdose Prevention Program supplies and materials;

(vii) ensure that all Trained Overdose Responders successfully complete all components of Opioid Overdose Prevention Training Program;

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

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

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

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

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

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

(iii) provide consultation to ensure that all Trained Overdose Responders are properly trained;

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

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

(3) The Trained Overdose Responders shall:

(i) complete an initial Opioid Overdose Prevention Training Program;

(ii) complete a refresher Opioid Overdose Prevention Training program at least every two (2) years;

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

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

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

(4) The opioid antagonist shall be dispensed to the Trained Overdose Responder in accordance with all applicable laws, rules and regulations.

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

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

- (i) list of Trained Overdose Responders, including dates of completion of training;
- (ii) a log of Opioid Overdose Prevention Trainings which have been conducted;
- (iii) copies of program policies and procedures;
- (iv) copy of the contract/agreement with the Clinical Director, if appropriate;
- (v) opioid antagonist administration usage reports and forms; and
- (vi) documentation of review of administration of an opioid antagonist.

(7) The Opioid Overdose Prevention Program will establish a procedure by which any administration of Opioid Antagonist to another individual by a Trained Overdose Responder affiliated with an Opioid Overdose Prevention Program, shall be reported on forms prescribed by the Department.

(8) Approval obtained pursuant to this section shall consist of a certificate of approval provided by the Department that shall remain in effect for two years or until

receipt by the authorized provider of a written notice of termination of the program from the Department, whichever shall first occur. The Department may renew a certificate of approval for a subsequent two-year period if the registered provider is in good standing with all applicable state and federal licensing agencies and such provider is found to have complied with the requirements of this section and has submitted a request for renewal.

(9) Pursuant to Public Health Law Section 3309(2) the purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.