

Bold blue = new language

~~Red strikethrough~~ = deleted language

Regular text = existing language

Emergency Amendments to 105 CMR 700.000: Implementation of M.G.L. c. 94C

For Optional First Responder Use of Naloxone or Any Other Opioid Antagonist Approved by the Department

EMERGENCY AMENDMENTS TO 105 CMR 700.000 TO ADDRESS THE OPIATE OVERDOSE CRISIS

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700.003: Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)

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(D) Persons specified in 105 CMR 700.003(D) may administer epinephrine, **naloxone or other opioid antagonist approved by the Department**, or atropine, pralidoxime chloride or other designated nerve agent antidotes in a life threatening emergency, where medical professionals are not readily available, in accordance with any applicable Department protocols and the following:

(1) To the extent authorized by 105 CMR 700.003(D), the following persons may administer epinephrine, **naloxone or other opioid antagonist approved by the Department**, or nerve agent antidotes:

(a) a first responder may administer epinephrine **or naloxone or other opioid antagonist approved by the Department** in accordance with 105 CMR 171.000: *Massachusetts First Responder Training* and the Statewide Treatment Protocols;

(b) a public employee of or volunteer to a municipality or an agency, department or authority of the Commonwealth (“agency”), whose function includes emergency preparedness and response and who is designated by a municipality’s or agency’s medical director pursuant to 105 CMR 700.003(6)(b) (“authorized public employee”), may administer epinephrine **or naloxone or other opioid antagonist approved by the Department**, as well as atropine, pralidoxime chloride and other nerve agent antidotes approved by the Department (“nerve agent antidotes”) to another authorized public employee; and

(c) an authorized employee of or volunteer to a facility or program funded, operated or licensed by a municipality or agency may administer epinephrine **or naloxone or other opioid antagonist approved by the Department** to individuals served by such a program or facility (“program”);

(2) A municipality or agency may approve administration of epinephrine, **naloxone or other opioid antagonist approved by the Department**, or nerve agent antidotes by authorized public employees, and a municipality or agency may approve administration of epinephrine by employees or volunteers of a program, provided that the municipality or agency registers with the Department in accordance with 105 CMR 700.004. This registration requirement shall not apply to:

- (a) a municipality or agency registered under 105 CMR 700.004(A)(2)(a) through (t);
 - (b) a school district or non-public school subject to the provisions of 105 CMR 210.000: *The Administration of Prescription Medications in Public and Private Schools*;
- (3) Any administration is pursuant to the order of a practitioner, and, in the case of first responders, ~~and~~ the Statewide Treatment Protocols;
- (4) The epinephrine, **naloxone or other opioid antagonist approved by the Department** or nerve agent antidote is:
- (a) dispensed by a pharmacy pursuant to the order or prescription of a practitioner or other authorized prescriber; or
 - (b) obtained by a municipality or agency in accordance with said entity's registration;
- (5) The epinephrine or ~~other~~ **nerve agent** antidote is packaged in a prefilled, automatic injection device intended for self-administration, **and the naloxone or other opioid antagonist approved by the Department is in the manufacturer's original packaging**;
- (6) A qualified, licensed practitioner shall be designated by the registered municipality or agency as medical director for purposes of 105 CMR 700.003(D). Such person shall:
- (a) be the responsible person named on the registration of the municipality or agency;
 - (b) authorize administration of epinephrine, **naloxone or other opioid antagonist approved by the Department** and nerve agent antidotes, as appropriate, and oversee compliance with 105 CMR 700.003(D);
 - (c) establish and enforce written protocols and procedures to ensure that individuals administering epinephrine, **naloxone or other opioid antagonist approved by the Department** or nerve agent antidotes are properly trained, evaluated for competence, and up to date in their skills and knowledge.
 - Training shall include, but not be limited to:
 1. procedures for risk reduction;
 2. recognition of the symptoms of **an opioid overdose or** a severe allergic or nerve agent reaction;
 3. proper use of an auto-injector **for epinephrine or nerve agent antidote, and other acceptable method of administration for naloxone**;
 4. procedures for notification of emergency medical services and other appropriate persons following administration;
 - (d) establish and enforce written protocols and procedures to ensure:
 1. proper storage, handling and return or disposal of **naloxone or other opioid antagonist approved by the Department**, epinephrine or nerve agent antidote;
 2. review and evaluation of an emergency response;
 3. reporting of adverse events to the medical director;
 4. monitoring of program compliance with 105 CMR 700.003(D); and

(e) establish and enforce written protocols and procedures to ensure that a registered municipality or agency, or a program if authorized to administer epinephrine **or naloxone or other opioid antagonist approved by the Department** by a municipality or agency, maintains current and readily retrievable records of:

1. the authorized public employees or volunteers who may administer epinephrine and nerve agent antidotes or authorized program employees or volunteers who may administer epinephrine;
2. individual trainings and evaluations;
3. receipt and any return or disposal of epinephrine, **naloxone or other opioid antagonist approved by the Department** or nerve agent antidotes; and
4. administration of epinephrine, **naloxone or other opioid antagonist approved by the Department** or nerve agent antidote;

(7) Each program authorized by a registered municipality or agency to administer epinephrine **or naloxone or other opioid antagonist approved by the Department** pursuant to 105 CMR 700.003(D) shall:

- (a) comply with the policies and procedures established pursuant to 105 CMR 700.003(D) by the registered municipality or agency;
- (b) designate a licensed health care practitioner, whenever possible, or the program director or designee, to oversee the program's implementation of said policies and procedures;
- (c) in the case of minors served by the program, obtain prior informed consent whenever possible from the minor's parent or legal guardian for the administration of epinephrine;
- (d) develop individualized medication administration plans that address indications for administration of epinephrine **or naloxone or other opioid antagonist approved by the Department**, any unique issues around storage or handling of the epinephrine **or naloxone or other opioid antagonist approved by the Department** and persons to be notified in the event that epinephrine **or naloxone or other opioid antagonist approved by the Department** is administered; and
- (e) immediately notify emergency medical services and designated contact persons, including those identified in the medication plan, in the event that epinephrine **or naloxone or other opioid antagonist approved by the Department** is administered; and

(8) The registered municipality or agency, and the Department of Public Health, shall have full access to all pertinent records for monitoring purposes.

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700.004: Registration Requirements

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(C) Separate Registrations Required for Separate Activities. Each person shall obtain a separate registration for each group of activities in which he or she engages.

(1) A person engaged in one of the following business or professions shall be deemed to be registered only for the activities appropriate to that business or profession as follows:

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(j) A municipality or agency of the Commonwealth is registered for the purpose of authorizing possession and administration, in accordance with 105 CMR 700.003(D), of ~~auto-injectors containing~~;

1. auto-injectors containing epinephrine for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency; and:

2. auto-injectors containing epinephrine, atropine, pralidoxime chloride and other nerve agent antidotes approved by the Department for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders.

3. A municipality or agency of the Commonwealth is registered for the purpose of authorizing possession and administration, in accordance with 105 CMR 700.003(D), of delivery devices containing:

a. naloxone or other opioid antagonist approved by the Department for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency; or

b. naloxone or other opioid antagonist approved by the Department for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders.