



BUREAU OF HEALTHCARE
SAFETY & QUALITY

FINAL REGULATIONS
RELATED TO THE USE OF NALOXONE



2 Sets of Regulations Relate to First Responders Carrying / Administering Naloxone:

1. Drug Control Program Regulations
2. First Responder Training Regulations



Commonwealth of Massachusetts
Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

FIRST RESPONDER **DCP REGULATIONS** DRUG CONTROL PROGRAM



700.003: REGISTRATION OF PERSONS FOR A SPECIFIC ACTIVITY OR ACTIVITIES IN ACCORDANCE WITH M.G.L. C. 94C, § 7(G)

This change would allow the following persons to administer naloxone or other opioid antagonist:

- A First Responder
- A public employee or volunteer to a municipality...whose function includes emergency preparedness and response to another authorized public employee
- An authorized employee...to a facility or program funded, operated or licensed by a municipality...to individuals served by such program or facility
- A municipality or agency may approve administration...provided that the municipality or agency registers with the Department in accordance with 105 CMR 700.004.

This change states the naloxone or other opioid antagonist must be:

- Dispensed by a pharmacy pursuant to the order or prescription of a practitioner or other authorized prescriber; or
- Obtained by a municipality or agency in accordance with said entity's registration
- Packaged in the manufacturer's original packaging;

This change states a qualified, licensed practitioner must be designated by the registered municipality or agency as medical director that shall:

- Be the responsible person named on the registration of the municipality or agency;
- Authorize administration of naloxone or other opioid antagonist
- Establish and enforce written protocols and procedures

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



700.004: REGISTRATION REQUIREMENTS

This change states a municipality or agency of the Commonwealth is registered for...possession and administration...of delivery devices containing:

- Naloxone or other opioid antagonist...for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency; or
- Naloxone or other opioid antagonist...for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders.



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FIRST RESPONDER TRAINING REGULATIONS

OFFICE OF EMERGENCY MEDICAL SERVICES



- First Responder Law, MGL. c. 111, § 201: Gives DPH the authority to define training requirements. Under the statute, First Responders are police, fire and lifeguards
- 105 CMR 171.000, First Responder Training Regulations, set out these training requirements
- Two proposed amendments to 105 CMR 171.000:
 - **105 CMR 171.165:** Amended to require Department approval for naloxone training for first responder. In order to meet Department approval, the training also needs to:
 - a) meet the minimum requirements set out in the Department's sub-regulatory administrative requirement (A/R)
 - b) be approved by the medical director for the first responder agency's naloxone program



105 CMR 171.227: Amend to require first responder agencies that wish to carry and administer naloxone to maintain a current Memorandum of Agreement with a hospital to provide medical oversight of this program, and the use of naloxone by first responders appropriately trained. The MOA must identify a medical director with responsibility for all aspects of medical oversight of the program. The MOA must address:

- Acquisition and replacement of naloxone
 - Quality assurance
 - Statewide Treatment Protocols
 - Training
 - Record keeping
 - Storage and Disposal
- Updated Statewide Treatment Protocols include protocols for First Responder use of naloxone
 - A/R 2-100, Minimum Standards for First Responder training curriculum, has been updated to include naloxone training



EMERGENCY REGULATION: UPDATE

- Drug Control Program and First Responder Training Regulations
 - The Department held a public hearing on the emergency regulations on April 25, 2014. There were no attendees at the hearing. The Department received written testimony from the Massachusetts College of Emergency Physicians (MACEP) and the AIDS Action Committee. Both organizations expressed full support for the emergency regulations.
 - MACEP stated: “After careful review of the emergency regulations and the Office of Emergency Medical Services ‘Guidance for First Responder Agencies: How to Set Up the Optional Naloxone Program,’ the College is satisfied that appropriate safeguards are in place to ensure that the naloxone is dispensed in accordance with written, standardized procedures and protocols developed by a licensed physician and that rigid quality assurance programs are in place.
 - The referenced “Guidance” document, a 1 ½ page step-by-step guide to implementing a naloxone program in a first responder agency, was distributed April 10, 2014 to all regional EMS offices, regional medical directors, state EMS director, EMS agencies, EMCAB members, accredited EMS training institutions, and police training council and other police organization representatives.
 - Department staff recommends the emergency amendments be adopted as the final amendments.



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QUESTIONS?