January 17, 2013

Dear Emergency Medical Services (EMS) – Controlled Substance Agent and Medical Director,

Based on recent inquiries made to the US Food and Drug Administration (FDA) and the current manufacturers of injectable lorazepam (Ativan®), the Department of Health (DOH) has serious concerns about storing injectable lorazepam outside of refrigeration. DOH’s research found there is no consensus among manufacturers for the proper period of time that injectable lorazepam can be kept outside of refrigeration. Moreover, the FDA indicated there was no scientifically accepted data to support storage of all forms of injectable lorazepam outside of refrigeration, defined as storage between 2 and 8 degrees Celsius (or approximately 35 to 46 degrees Fahrenheit).

Therefore, the Bureaus of Narcotic Enforcement and Emergency Medical Services advise that if your EMS agency is utilizing injectable lorazepam (Ativan®), effective February 15, 2013, any and all stock and sub-stock maintained under your EMS controlled substance license must be kept in a refrigerated environment of 2-8 degrees Celsius (approximately 35 to 46 degrees Fahrenheit) until it is administered to a patient. Refrigerated storage of injectable lorazepam should be safeguarded and secure, consistent with Title 10 NYCRR Part 80.136.

If your EMS agency is unable to maintain injectable lorazepam (Ativan®) in a refrigerated environment, in consultation with the agency Medical Director, a change must be made to your formulary to allow for another appropriate benzodiazepine that does not require refrigeration. Any change in the formulary will require the EMS agency to submit an update to its Controlled Substance Operations Plan to the Department of Health. If your EMS agency includes lorazepam in its formulary, please verify that the medication is included in your Controlled Substance Operations Plan and complete the enclosed form. It must be returned to the Bureau of EMS no later than March 1, 2013.

Sincerely,

Terence O’Leary
Director
Bureau of Narcotic Enforcement

Lee Burns
Director
Bureau of Emergency Medical Services
Name of EMS Agency:

_____________________________________________________________

EMS Controlled Substance License Number:

03C________________

Name of Controlled Substance Agent:

_____________________________________________________________

Name of EMS Service Medical Director:

_____________________________________________________________

Is lorazepam on your formulary?

Yes [ ] Our EMS agency’s Operation Plan reflects this.

No [ ] If no and you plan on maintaining this drug under refrigeration, please submit a revised Operations Plan no later than February 15, 2013.

Is all lorazepam maintained in secure refrigeration on the EMS response vehicle and (sub stock) in quarters (restock)?

Yes [ ]

No [ ] If No, arrangements will be made to refrigerate lorazepam and an amendment to the agency’s Operations Plan will be made no later than February 15, 2013.

or

Lorazepam will be removed from the formulary no later than February 15, 2013.

Please return this form, no later than March 1, 2013, to the Bureau of EMS at:

875 Central Avenue, Albany, NY 12206