



New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT

Supersedes/Updates: 07-02

No. 09 - 09

Date: August 5, 2009

**Re: Fentanyl for
Prehospital EMS
Services**

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This Policy updates Policy Statement 07-02 regarding fentanyl for prehospital Emergency Medical Services agencies. The significant updates are as follows:

- § Item number 6 allows for the use of **vials or ampules** when sub-stocking fentanyl. However, the amount of fentanyl authorized to be carried in each sub-stock remains 200mcg.
- § Item number 9 changes the medical director reporting date from December 31st to January 31st of each year.
- § Item number 12 reminds agencies that they must submit Controlled Substance Operations Plan changes or amendments to the Department **prior** to implementation.

Please take the time to read and understand this Policy Statement. Each individual EMS agency, its controlled substances agent and the medical director are responsible for adhering to all applicable laws, regulations and policies.

History:

At the request of the State Emergency Medical Advisory Committee (SEMAC) and a number of air medical service physician medical directors, the Department was approached requesting that fentanyl be added to the formulary authorized by the Class 3C controlled substance 3C license. This request was reviewed by the Department's Division of Legal Affairs and the Bureau of Narcotics Enforcement (BNE).

Based on the potency of fentanyl and the serious issues of diversion and abuse, the Department initially approved its use by New York States air medical service providers under specific conditions. At the May 2007 meeting of the SEMAC, the use of fentanyl was approved for all advanced life support (ALS) EMS agencies possessing a current Department of Health EMS Agency Certification and Prehospital Controlled Substance License, under the specific conditions indicated below.

Conditions for Approval:

In order for the Department to approve the addition of fentanyl to an EMS agency with a current Class 3C controlled substance license, the following conditions must be met and the Department must review and issue written approvals.

1. The Regional Medical Advisory Committee (REMAC) must develop protocols for the administration of fentanyl and a periodic evaluation of its use on the regional level.
2. The protocols must also be approved by the SEMAC.
3. The service medical director must approve, in writing, fentanyl for use by the EMS service.

4. Only those individuals certified at the critical care or paramedic level may utilize a controlled substance medication.
5. The EMS agency must submit an amendment to their Controlled Substance Operations Plan to include, but not be limited to the following:
 - < A detailed description of the procurement; inventory process and security of fentanyl.
 - < A program for 100% quality assurance by the service medical director for instances where fentanyl has been administered.
 - < The training program used to in-service all appropriate staff on the inventory, security and administration of fentanyl.
 - < A separate Quarterly Report (attached) for fentanyl stock and administrations. This must be received by the Department within 30 days of the end each quarter.
6. Only **two (2)** 2ml vials or ampules containing 50mcg/ml - totaling 200 mcg may be carried in each sub-stock.
7. The program must insure that the formulary includes an appropriate antagonist necessary to reverse the effects of a fentanyl administration.
8. **FENTANYL MAY ONLY BE ADMINISTERED UNDER DIRECT ON-LINE MEDICAL CONTROL.**
9. As a part of the reporting process, the agency medical director is required to provide a written report of the service's use of fentanyl in the prior year no later than **January 31st of each year**. The report should include, but not be limited to the following items:
 - < The total number of administrations, amount of medication used and dose.
 - < The amount of fentanyl wasted.
 - < A summary of the patient presenting problems.
 - < A narrative summary highlighting the Quality Assurance reviews conducted for each fentanyl administration.
10. All instances where a theft, loss or diversion, are suspected **MUST BE REPORTED TO THE DEPARTMENT IMMEDIATELY**. This report must be made to the BEMS Central Office using the *Loss of Controlled Substances Report* form (DOH-2094). This form is available on line at <http://www.nyhealth.gov/forms/doh-2094.pdf>
11. **Prior** to including fentanyl in the EMS agency's formulary, the medical director and the agent must receive written approval from the Department.
12. If the agency makes any changes or updates to the Controlled Substance Operations Plan, it must provide the specific changes to the Department in writing **prior** to implementation.

The Department continues to closely monitor the EMS agencies that maintain a Class 3C controlled substance license to insure that there is the strictest compliance with all of the applicable sections of Public Health Law, the Codes, Rules and Regulations – Part 800 and Section 80.136 of the Part 80 Rules and Regulations on Controlled Substances in New York State, as well as the EMS service's approved Controlled Substance Operations Plan.

Approved by Edward Wronski, Director

This report must be submitted pursuant to PHL Article 33 within 30 days of the end of each Quarter. Reports must be submitted regardless of usage. Retain a copy of this Quarterly Report for a period of 5 years from the date of filing.

Quarterly Reporting Period: _____

Agency Name	NYS-EMS ID No.	NYS-BNE License No.		
Address	City	State	Zip	Business Phone
Name of DEA Registrant	DEA License No.	Day Phone		

	FENTANYL		RESPONSE/ TRANSPORT HISTORY
Total Quantity at Start of Quarter	Stock: _____ Substock: _____ TOTAL of above: _____	Total Number of EMS Response/Transports this Quarter	
Total Quantity Received from DEA Registrant		Total Number of Patients Receiving Fentanyl this Quarter	
Total Quantity Administered		Number of Fentanyl Administrations pursuant to Direct Medical Control	
Total Quantity Wasted		Number of Quality Assurance reviews conducted by the service medical director	
Total Quantity Lost (Attach copy of DOH Form 2094)		Number of Adverse Reactions to Fentanyl Administration	
Total Quantity Remaining at End of Quarter		Number of EMS Personnel Authorized to Administer Fentanyl	Flight Nurses _____ EMT-P _____ EMT-CC _____

I certify that on _____ I conducted an actual physical inventory of the controlled substance listed above. Losses have been reported on a "Loss of Controlled Substances Report" DOH Form 2094 and have been submitted to BNE and a copy of the form has been enclosed. Overages are explained on a separate attached report.

I affirm that this is a true and accurate record of the controlled substance utilization by the above named agency.

Name of Agent (print)

Signature of Agent

Date

Name of CEO (print)

Signature of CEO

Date

Sent completed report by due date to:

New York State Department of Health, Bureau of Emergency Medical Services
 433 River Street 6th Fl., Troy, NY 12180
 Telephone 518-402-0996 x2