



**DOH**  
New York State  
Department of Health  
**Bureau of Emergency Medical Services**

**POLICY STATEMENT**

*Supersedes/Updates: 07-02, 09-09*

**No. 11 - 04**

**Date: April 5, 2011**

**Re: Fentanyl for  
Prehospital EMS  
Services**

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This Policy updates Policy Statement 07-02 and 09-09 regarding fentanyl for prehospital Emergency Medical Services agencies. 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 license. This request was reviewed by the Department's Division of Legal Affairs and the Bureau of Narcotic 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.

In 2011, the SEMAC and the Department approved regional ALS protocols that allow for the administration of fentanyl on standing orders for specific prehospital conditions in **adult patients only**. In order for an ALS level EMS agency to possess and administer fentanyl, all of the following conditions must be met and the agency must receive Department approval.

This policy addresses the following:

- **Approval Process**
- **Reporting Process**
- **Required Conditions**

**Approval Process:**

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 approval.

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

4. Only those individuals certified at the EMT - Critical Care or Paramedic level may participate in the Operational Plan and administer a controlled substance medication to a prehospital patient.
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 routine 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.
  - ▶ Policies for submitting the Quarterly Report (attached) for fentanyl stock and administrations. This must be received by the Department within 30 days of the end each quarter.
6. **Prior** to including fentanyl in the EMS agency's controlled substance formulary, the medical director and the agent must receive written approval from the Department.
7. The agency medical director must make a written request to the Department to carry more than a total of 200mcg of fentanyl in each substock. The letter must describe the specific necessity for the increase in substock above 200mcg. This will be reviewed, and if approved, the Department will notify the EMS agency in writing.

### **Reporting Requirements:**

1. A separate Quarterly Report for fentanyl stock and administrations. This form is available on line at <http://www.health.state.ny.us/forms/doh-4352.pdf>. This must be received by the Department within 30 days of the end each quarter.
2. 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 31<sup>st</sup> of each year**. The report should include, but not be limited to the following items:
  - ▶ The total number of administrations, amount or 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.

Please note that failure to submit the quarterly and/or the annual reports may result in the suspension of the agency's authority to possess and administer controlled substance medications.

3. 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>.
4. **Prior** to including fentanyl in the EMS agency's formulary, the medical director and the agent must receive written approval from the Department.
5. 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.

**Required Conditions:**

1. The amount of fentanyl carried in each sub-stock must be determined and approved by the agency medical director. This determination should be made considering historical usage, transport times and average call volumes. The Department must approve the sub-stock inventory that exceeds 200mcg of fentanyl
2. Fentanyl may only be stocked in 2ml vials or ampules containing 50mcg/ml.
3. The Department must approve the sub-stock inventory that exceeds 200mcg of fentanyl.
4. The agency operation plan and the medical director must insure that the formulary includes an appropriate antagonist in an amount proportional to the amount of fentanyl carried, necessary to reverse the effects of a fentanyl administration.
5. Fentanyl may only be administered on standing orders for adult patients as delineated in the approved regional ALS protocols. **Other administrations will require direct medical control consultation.**

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 Lee Burns, Acting Director**