



**Department
of Health**

**Bureau of Emergency Medical Services
And Trauma Systems**

POLICY STATEMENT

Supersedes/Updates: 07-02, 09-09, 11-04

No. 17 - 04

Date: March 31, 2017

**Re: Fentanyl for
Prehospital EMS Services**

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This policy is an update 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.

At present, the SEMAC and the Department approve regional ALS protocols that allow for the administration of fentanyl on standing orders for specific prehospital conditions in both adult and pediatric patients. 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. Each substock may have a maximum of 400mcg of fentanyl.

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 31st 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.health.ny.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. Fentanyl may only be stocked in 2ml vials or ampules containing 50mcg/ml.
2. The Department must approve the sub-stock inventory that exceeds 400mcg of fentanyl.
3. 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.
4. 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.

Issued and authorized by Bureau of EMS Office of the Director