



## **Controlled Substance Plan**

**Brighton Volunteer Ambulance**

**Last Update: February 27th 2020**

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## **Purpose**

The controlled substances approved for use by Advanced Life Support Providers are essential elements of pre-hospital care. When administered appropriately, these medications have been proven to improve the outcome and quality of life for many patients. The purpose of this plan is to explain the manner in which Brighton Volunteer Ambulance (BVA) will implement and manage the use of controlled substances by all authorized providers. In order to meet the defined standards for possession and implementation of controlled substances to be administered by ALS technicians, this plan will outline the components of the policy for the management and implementation of all approved controlled substances.

## **Responsibilities**

The following responsibilities will be defined as follows:

### **Controlled Substance Agent**

Brighton Volunteer Ambulance will designate the Clinical Care Manager/ALS Chief defined by regional term as the Primary Controlled Substance Agent or other designee (CSA). The CSA will utilize an experienced, cleared ALS Technician of their choosing as the secondary CSA'(s) with approval from the Chief of EMS Operations and the Vice President of Operations. The secondary CSA'(s) will act in full capacity in the absence of the CSA. Should there be a change in the status of either the primary, secondary CSA or the Agency Medical Director, the supplying pharmacy and the NYS DOH will be promptly notified in writing and submittance of updated CS plan.

The duties of the CSA include, but are not limited to the following:

- 1) Register with the New York State Department of Health.
- 2) Maintain certification as a New York State EMT-Paramedic.
- 3) Renew the Class 3C license, as required.
- 4) Obtain all controlled substances from the designated supply pharmacy to maintain stock for sub stocks.
- 5) Control inventory and restocking of all CS kits and safe stock.
  - Record medication uses with all needed information on electronic log
  - All controlled substances not placed into the sub-stock cases will be secured in the safe, and will remain as the base stock.
  - Complete all NYS DOH required semi and quarterly reports for Morphine, Versed, Fentanyl and Ketamine.

- Maintain appropriate records as defined under the records retention provision.
- 6) Provide appropriate training to all authorized providers for the use, security, and inventory of all controlled substances. This should be done initially as part of the clearing process, and then as needed for Quality Assurance. Assure providers properly adhere to the controlled substance plan and protocols.
- 7) Assign and track all passwords provided to all authorized providers for access to the controlled substance sub-stock lockers through Key Systems®.
- 8) Adjudicate all Pre-Hospital Care Reports that include documentation of the use of controlled substances within one week of the date of administration. This will be done to assure appropriate clinical care through the QA/QI process. Any incidence of inappropriate use, loss, theft, or damage of controlled substances will be promptly reported to the Drug Enforcement Agency (DEA), NYS DOH Bureau of Controlled Substances, local law enforcement, the BVA Chief of EMS Operations, the Agency Medical Director, and the supplying pharmacy.
- 9) Assure that the Agency Medical Director receives an email notification in the form of a special report from emsCharts on every PCR with a controlled substance use.
- 10) Remain knowledgeable of any regulatory changes involving the use, inventory, security, or documentation of controlled substances. Regularly update the Chief of EMS Operations and any other appropriate persons with new or changed information.

### **Agency Medical Director**

The Medical Director for the controlled substance program will be responsible for ensuring adherence to the Controlled Substance plan, and the Quality Assurance plan as it relates to controlled substance and clinical care activities. The Controlled Substance plan shall operate in accordance with the Monroe-Livingston Regional QA guidelines regarding controlled substances. Through the QA process, the Medical Director will assure all controlled substance use meets all applicable standards for clinical care. Therefore, the Medical Director will review all patient care reports involving controlled substance use. Additionally, the Medical Director may review any inventory records or other controlled substance documents as desired.

Antonios Katsetos, DO is the Agency Medical Director. Doctor Katsetos is accessible via phone at: 585-260-2355. His NYS license number is 252846, and his DEA license number is FK0165123. Doctor Katsetos maintains an office at:

Unity Hospital  
1555 Long Pond Road, Box 655  
Rochester, NY 14626

### **Advanced Life Support Provider**

Authorized ALS providers shall be granted limited access to controlled substances for approved clinical care purposes. Administration of controlled substances shall be performed under the

direction of a medical control physician, or in accordance with the protocols approved by the NYS DOH and the REMAC for the Monroe-Livingston Regional EMS.

The duties of the authorized ALS provider include, but are not limited to the following:

- 1) Maintain certification as an EMT-P and notify the CSA of any changes in certification or regional clearance status.
- 2) Complete any mandatory State, Regional, or Agency controlled substance training. Ample time for questions regarding use, inventory, and security of controlled substances will be provided during training. All questions after training should be directed to the CSA, or the Secondary CSA as appropriate.
- 3) Understand the indications, contraindications, dosing, route, and administration procedures for all controlled substances for which the authorized provider has access to.
- 4) Notify the CSA of the loss, theft, or diversion of controlled substances immediately. This should be done via phone to ensure the possibility of an immediate response.
- 5) Comply with all approved protocols, regulations, and documentation requirements for the use of controlled substances.
- 6) All required documentation for the administration, destruction, security, and inventory of controlled substances shall be correctly completed in a timely fashion.
- 7) In the event that controlled substances are administered, a special report must be attached to the chart to alert the CSA, Secondary CSA, and the Medical Director of the use.
- 8) In the event that a provider has a concern with a case (ie: the seal is broken, it needs a replacement key or paperwork sleeve) the provider must write a special report utilizing the “controlled substance concern” report which will notify the CSA and Secondary CSA.

When reporting for a shift, the provider shall enter the ALS supply room for access to all controlled substances. Access to all available sub-stock will be regulated through the Key System®. Use of the Key System® will grant authorized providers access to the **eight** sub-stock safes in the ALS supply room. The provider will assure that the safe which they select contains one sub-stock case, and all associated keys to the safe and the case. The provider will then verify that their sub-stock is sealed in the designated case using a tamper-evident numeric seal, and will verify that the number on the seal matches the last recorded number on the Sub-Stock Seal Tracking Log provided in the C/S sign out log book. The provider will then unseal the sub stock case and verify that the sub-stock log indicates the controlled substances contained within the case are the correct medications and levels with expiration dates unexpired. If there is a discrepancy, the provider will contact the on duty Captain or a CSA immediately. The provider will remain on BVA property and in possession of the sub-stock until relieved by an ALS officer of BVA or an CSA. It is the provider’s responsibility to maintain control of and appropriately secure all controlled substances in their possession. If controlled substances are used, destroyed, or lost; appropriate measures will be taken by the provider as outlined in this plan.

At the completion of a shift, the provider will assign a number seal to their C/S kit. Seals will be colored. Red will always signify the kit is low, less the minimum standard for use. If the kit is less it will be sealed with a red numbered seal. The sealed sub-stock case will be placed back in the correct sub-stock safe, and all keys will also be returned to the safe as well. The provider shall assure that after returning the sub-stock and closing the safe, the safe is fully closed and all controlled substances are fully secured. All authorized providers are responsible to return their controlled substances properly at the end of each shift without exception.

If controlled substances are used during the shift, the provider is to follow the administration procedure outlined in this plan. If more than one Paramedic is involved in the treatment of a patient to whom controlled substances have been administered, only the provider to whom the controlled substances are signed must take responsibility for the controlled substances. The provider can only use controlled substances they have signed out, and may not use controlled substances signed out by another provider.

### **Sponsoring/Supplying Pharmacy**

Brighton Volunteer Ambulance has entered into an agreement with the Pharmacy at Strong Memorial Hospital for supply of controlled substances. Brighton Volunteer Ambulance shall possess and maintain a Class 3C license, separate from the hospital's license. A copy of this license will be provided to the Pharmacy at Strong Memorial Hospital. The Pharmacy at Strong Memorial Hospital shall only supply approved medications, which presently include Morphine Sulfate, Midazolam, Fentanyl, and Ketamine. If the Pharmacy at Strong Memorial Hospital chooses not to continue as a sponsoring or supply agency for Brighton Volunteer Ambulance, the Medical Director, CSA, Chief of EMS Operations, and the NYS DOH will be notified immediately. In accordance with the agreement, thirty days written notice will be provided to the CSA. The DEA registration number for the Pharmacy at Strong Memorial Hospital is AU4158033.

### **Controlled Substance Stock**

All on premises controlled substance stock will be maintained, secured, and inventoried at Brighton Volunteer Ambulance Headquarters; 1551 Winton Road South, Rochester, NY 14618. The on premises stock will be maintained in a double locked safe, which will be kept in the ALS supply room. The supply room door will be locked at all times, and limited access will be granted to this room. The safe will be permanently affixed to the wall of the ALS supply room, and access to the safe will only be granted to the CSA's. The safe must be made of steel, and will be sufficient in size to securely contain all controlled substance stock and required records.

### **Controlled Substance Sub-Stock**

A defined amount of sub-stock will be placed in designated cases. One case will be placed in each of the 8 Key Systems® safes located in the ALS supply room and an sealed, double lock

box on the designated duty operations vehicle or fly car. These locker(s) will be labeled 1 through 8, 8 will be the duty operations kit. Each locker will contain one sealed sub-stock case, two keys to the safe from which the sub-stock is being removed, and a key to the sub-stock case. Each sub-stock case will contain **at maximum** 20mg Morphine Sulfate, 20mg Midazolam, 400mcg Fentanyl, and 1,000mg Ketamine. Every case will be sealed with a tamper evident numeric seal.

Every authorized provider will be assigned a secure password by the CSA, which will be used to access sub-stock for approved clinical use. The provider will be assigned responsibility for sub-stock using this password for accountability purposes. The Key System® will only allow an authorized provider to access one sub-stock safe at a time. This system, in conjunction with the sub-stock inventory and seal tracking sheets as well as the master logs, will track the flow of controlled substances, including signing CS in and out, as well as usage (medication administration). If a discrepancy is discovered in obtaining or returning controlled substances, the CSA will be called or paged immediately. If controlled substances are administered, or if a security question arises regarding controlled substances, the procedures described in this plan will be followed, and the CSA can be contacted for further direction.

The provider will carry the controlled substances on their person at all times during their shift. The only exception to this is when ALS operations persons are using the fly car in idemedelet response circumstances.

### **Provider Injury or Incapacitation**

If an authorized provider is injured or incapacitated while in possession of controlled substances, the following procedure will be observed:

- 1) If the provider is able to sign, the provider will sign possession of their sub-stock over to a BVA cleared Paramedic or law enforcement officer to be returned to the proper locker. The agency CSA will ensure the kit has correct counts should it be completed by another Non CSA of BVA. If the meds are surrendered to law enforcement in absence of another BVA ALS provider an BVA CSA must respond to the location with official vehicle and secure the control substances.
- 2) If the provider is incapacitated, unconscious, or unable to sign over their sub-stock:
  - Their BLS partner will ensure the controlled substances are secured by law enforcement and they will notify BVA ALS operations or CSA staff.

### **Transportation of Controlled Substances**

All controlled substances will be transported officially and or vehicles certified by the NYS DOH.

## **Administration of Controlled Substances**

When a provider administers controlled substances, they shall follow NYS DOH and MLREMS protocols at all times. To document controlled substances administration on a PCR/emsChart, include the following data points:

- 1) Name of CS administered
- 2) Dosage and route of administration
- 3) Concentration of medication (CS)
- 4) Reason for CS administration (pain management, sedation, seizure, etc.)
- 5) Date/time of administration
- 6) Patient weight (Adult and Pediatric patients)
- 7) On what authority CS was administered (standing order, on-line direction)
- 8) Receiving facility

If a provider administers controlled substances on standing order, the provider must follow the above listed steps. If controlled substances are administered with on-line medical direction, the following data points must be documented:

- 1) Ordering hospital and physician name
- 2) Specifically what the order received was
- 3) Name of CS administered
- 4) Dosage and route of administration
- 5) Concentration of medication (CS)
- 6) Reason for CS administration (pain management, sedation, seizure, etc.)
- 7) Patient weight (Adult and Pediatric patients)
- 8) Date/time of administration
- 9) Receiving facility

If controlled substances must be wasted after an administration, the provider must document the following data points for accountability and integrity of CS security:

- 1) Name and concentration of medication to be wasted
- 2) Amount of medication to be wasted
- 3) Reason for medication waste (administration)
- 4) Name and title of witness to controlled substances waste (must be an EMT, AEMT, Nurse, or Physician and preferably a provider that was not on the listed crew if possible)
- 5) Signature of witness to waste on the BVA CS Administration Form

For a provider to be 'in-service,' (Non RSI) the provider must have at least 10mg of Midazolam, 500mg of Ketamine, and 100mcg Fentanyl in their sub-stock.  
RSI providers must have full completed kits.

## **Controlled Substance Diversion Policy**



This plan has been designed to assist in preventing the diversion of controlled substances. However, upon the discovery of the theft or loss of controlled substances, the following steps shall be taken:

- 1) The lead CSA shall be notified immediately.
- 2) The authorized provider will promptly write an incident report.
- 3) The CSA will notify the following:
  - a) Chief of EMS Operations
  - b) Medical Director
  - c) Supplying Pharmacy
  - d) NYS DOH
  - e) Local Law Enforcement in case of theft
- 4) The CSA will perform the following tasks:
  - a) Complete a full investigation, including hand-written statements from the provider and any witnesses
  - b) Submit a written report of the incident and investigation to be kept in CS safe
  - c) Complete NYS DOH loss of controlled substances for (DOH-2094)

All policies pertaining to the safeguard and security of controlled substances defined in this document shall be continually adhered to. Discovery of any diversion or violation of stated policies shall result in appropriate disciplinary action, which may include civil or criminal penalties as dictated by law. Disciplinary action will follow the established progressive disciplinary policy, up to and including termination.

### **Controlled Substance Disciplinary Policy**

All disciplinary action taken with regard to controlled substances will follow the established progressive disciplinary plan. However, due to the level of security and integrity required for BVA to maintain a controlled substances program, it may become necessary to initiate the disciplinary process at a high level within the progressive plan. The following incidents will result in immediate high-level disciplinary action:

- 1) Any discrepancy in paperwork completed by an authorized provider relative to controlled substances could result in immediate suspension of clinical care privileges at BVA based on circumstances found. This suspension will remain in effect until an investigation can be completed by the CSA. All suspensions of this nature will be made by the CSA handling the investigation, on recommendation of the Clinical Care Manager and agency Medical Director.
- 2) Any act which constitutes a willful or grossly negligent violation of regional protocols or acceptable clinical care standards will result in immediate suspension of the authorized provider and all associated clinical care privileges at BVA. This

suspension will remain in effect until an investigation can be completed by the CSA. All suspensions of this nature will be made by the CSA handling the investigation, on recommendation of the Clinical Care Manager and Agency Medical Director.

Any suspension of clinical care privileges or suspension of a provider will be performed by the CSA handling the investigation, on recommendation of the Clinical Care Manager and Agency Medical Director. The duration of the suspension will be determined by the Clinical Care Manager, Medical Director, and the Chief of EMS Operations. If remedial training is required, the CSA and the Medical Director will work with the Training Manager to determine the type and process for remediation. Any incident may also be brought to the NYS DOH Bureau of EMS, or local Law Enforcement as deemed necessary. Any actions taken shall become part of the provider's permanent personnel file.

### **Controlled Substance Quality Assurance Policy**

In order to assure appropriate clinical care and use of controlled substances, the following plan will be used:

- 1) The provider will complete the PCR as required, and will check 'CS Administered' while completing the electronic PCR activity audit. In checking this designator, the Medical Director, Chief of EMS Operations, Clinical Care Manager/CSA, and the Secondary CSA will receive notice of the CS administration.
- 2) The CSA will thoroughly check all CS administration PCRs within one week for QA/QI. The PCR will then be forwarded through the intrinsic electronic PCR QA program to the Medical Director for review. The Medical Director will also review the PCR within one week of receipt for QA/QI.
- 3) Should any issues with quality clinical care regarding the administration of CS be found during the QA/QI process, the Medical Director and the CSA will follow the BVA QA/QI policy and the Controlled Substance Disciplinary Policy as applicable to resolve any identified issues.
- 4) An electronic copy of all controlled substance PCRs, along with all QA/QI correspondence and associated disciplinary and remediation plans will be maintained on file for a minimum of 5 years. As appropriate, a paper copy may be kept in the personnel file for the specific provider.

### **Records Keeping and Retention**

The CSA will keep an accurate record of all controlled substances purchased from the supplying pharmacy, delivered to individual sub-stocks, and administered to patients. Purchase records will include date, quantity obtained, and the source from which they were obtained. The CSA will also keep a record of the following:

- 1) Name of controlled substance
- 2) Concentration of the controlled substance
- 3) Total amount of controlled substances received

- 4) Name, address, and DEA registration number of authorized supplier for controlled substances
- 5) Date when controlled substances was received
- 6) Signature of the authorized person receiving the controlled substance stock
- 7) Date and amount of controlled substance delivered to sub-stock
- 8) Signature of the agent who delivered the controlled substance sub-stock
- 9) Signature of the authorized person receiving the controlled substance sub-stock
- 10) The Key Systems® locker/kit number where the sub-stock is placed
- 11) The remaining amount of controlled substance stock on the premises
- 12) A separate record will be kept of all non-administered losses from any stock or sub-stock, with a brief statement describing the diversion. The diversion statement must be signed by the individual provider and the agent.

All records will be kept for a minimum of five years, and will be available for inspection by properly authorized officers, agents, and representatives of the Drug Enforcement Administration, Brighton Volunteer Ambulance, Controlled Substance Agent, NYS DOH Bureau of Controlled Substances, Supplying Pharmacy, and Local Law Enforcement.

## **Definitions**

**Administer:** The direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient.

**Advanced Life Support Provider:** EMT-Paramedic

**On Duty Officer:** Any Brighton Volunteer Ambulance Chief, Major, Captain, or Lieutenant,

**Authorized Provider:** A person who is specifically approved in writing by the CSA to handle controlled substances. In all cases this person will be the CSA, Deputy CSA, or any BVA cleared advanced life support provider.

**Case:** A portable steel container used to secure individual controlled substances of a sub-stock. Cases will be locked using a specialized key. Cases will be secured in a locker when not signed out to a provider.

**Controlled Substance:** A substance or substances listed in section 3306 of the Public Health Law (Morphine Sulfate, Midazolam, Fentanyl, Ketamine)

**Controlled Substance Agent (CSA):** The Clinical Care Manager will serve as the CSA. The CSA shall enforce the policies and procedures outlined in this plan.

**Secondary Controlled Substance Agent:** The back-up CSA will serve as alternate to the CSA. See also; CSA.

**Dispense:** To deliver a controlled substance to an ultimate user by lawful means, including: packaging, labeling, and compounding as necessary to prepare the substance for such delivery.

**Distribute:** To deliver a controlled substance other than by administering or dispensing. This is performed only by the CSA or backup CSA.

**Diversion:** The manufacture, possession, delivery, or use of a controlled substance by a person in a manner not specifically authorized by law.

**Locker:** Individual locked container affixed to the structure used to secure sub-stock cases and case keys. Lockers will be numbered 1-6.

**Master Controlled Substance Log:** The record of all controlled substance activities. This will include all stock, sub-stock, diversion, administration, purchasing, dispensing, and distribution of controlled substances.

**Prescribe:** Direction or authorization permitting the CSA to obtain controlled substances from any person authorized by law to dispense such substances. This should be limited to the Supplying Pharmacy.

**Stock:** The residual amount of controlled substances that is secured on the Brighton Volunteer Ambulance premises. This is used to replenish the sub-stock as needed.

**Sub-Stock:** The controlled substances designated for secure portable use by authorized providers. There are six sub-stocks, each contained in separate lockers.

**Sub-Stock Log:** The daily record of controlled substance activity (in/out/administered).

## **References**

### **Accessibility to Controlled Substances for Pre-Hospital settings:**

Chapter VI Title 10 of the Official Compilation of Codes, Rules and Regulations; Part 80  
Controlled Substances-August 1993.

### **Possessing and Administering Controlled Substances for Pre-Hospital EMS Services:**

New York State DOH.

### **Advisory 10-04; Ketamine for Prehospital Services:**

New York State DOH.

### **Monroe-Livingston Regional Emergency Medical Services Protocols:**

2014 Edition

### **Brighton Volunteer Ambulance Controlled Substance Plan:**

February 2019 Edition.

### **Brighton Volunteer Ambulance QA/QI Plan**

### **Brighton Volunteer Ambulance Discipline Policy**

Policy 3.12 in the Employee/Member Handbook