Name of Agency

Controlled Substances Operations Plan

Date

Agency Address

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I. Definitions

A. Agency – _____
_____

B. Medical Director- _____, MD, _____(Address), a New York State licensed physician who is responsible for authorizing treatment protocols and quality assurance activities for the _____(Agency), an advanced life support system within Mountain Lakes Regional EMS. He will act as the primary prescribing physician for the sub-stocks of controlled substances that are carried by the _____(Agency).

C. Medical Control- Adirondack Health (ADIRONDACK HEALTH), PO Box 471, 2233 State Route 86, Saranac Lake, NY 12983. _____ MD, Emergency Services Director/ Medical Control Director is responsible for the service territory of the ADIRONDACK HEALTH catchments. Dr. _____, or his designee, shall participate in review of each administration of controlled substances via medical control of a field Advanced Emergency Technician-Critical Care or Paramedic (AEMT-CC/P), shall oversee the medical direction offered by the authorized medical control doctors and physician assistants.

D. Agent- This person shall be an AEMT-CC/P that is currently on-line, has maintained continuing education requirements, and is authorized to handle narcotics. This person will be responsible for the Agency's sub-stock of Controlled Substances. The Agent must be registered with the NYS DOH, Bureau of controlled substances, and along with the agency Chief Executive Officer (CEO), accepts legal responsibility for the proper handling of the controlled substances for the agency. In the event there is a change in either the person named as the Agent, or the CEO, the Agent must notify _____Pharmacy and the NYS DOH. A new Agent and/or a new Memorandum of Agreement must be established.

    1) In the absence of the Agent, the Agency may appoint a back up or alternate Agent to act instead of the Agent. This alternate Agent must apply to the NYS DOH, Bureau of Controlled Substances to become an authorized controlled substances agent.

E. Controlled Substance-Schedule 2 and Schedule 3 medications authorized for Pre-Hospital use by the Regional Medical Advisory Committee (REMAC) of the Mountain Lakes Regional EMS Council. Current controlled substances authorized for use by ALS providers are Midazolam, Morphine Sulfate, Fentanyl, and Ketamine.

F. Stock-The sole distribution point for obtaining controlled substances shall be the Pharmacy of _____. Access to the Stock for replenishment of field sub-stocks as outlined in this plan. The Pharmacy Manager will participate in the Quality Assurance/Quality Improvement (QA/QI) process as outlined for controlled substances, and will serve as the primary entity responsible for investigating irregularities and mishandling of controlled substances.

G. Sub-stock – Inventory maintained by the agency in their ambulance, or other emergency response vehicle. Currently these medications, per ambulance, are no more than Midazolam 20mg, Morphine Sulfate 40mg, Fentanyl 400 mcg, and Ketamine 1000 mg.

H. Memorandum of Agreement- a Memorandum of Agreement must exist that is co-signed by the CEO's of both the Agency and _____(Hospital), the appointed Agent, and the Pharmacy Director. This agreement outlines the pharmacy's role as keeper of the stock and the agency's responsibilities as an agency authorized to carry and administer controlled substances.

II. Access to Controlled Substances

A. An Agency's initial sub-stock should be obtained from the Pharmacy Director, by the Agent. The Agent should bring the ALS Drug bag which will store the controlled substances to the pharmacy so the Pharmacy Director and Agent can review locking, reporting, recording, and re-supply procedures.

B. The only persons authorized by Mt. Lakes, Adirondack Health, and the Agency to have access to the controlled substances are those AEMT-CC/P's that are currently online, have maintained continuing education requirements, and have been issued a key for the Gold Lock used to secure the ALS medications container. All Locks are case hardened, security quality padlocks with unique keying systems.
Keys are issued by Mountain Lakes Regional EMS Council to AEMT's upon successful completion of NYS certification and verification of their status with a bona fide ALS Agency. Only AEMT-CC/P's are issued a key that corresponds to the Gold Loc

C. Sub-stocks of controlled substances will be maintained in accordance with the policies and procedures of NYS DOH, Mountain Lakes Regional EMS Council, and this Operations Plan.

D. Access to all controlled substances, medications, and IV supplies shall be restricted in accordance with the protocols of Mountain Lakes Regional EMS Council (MLREMSC). The system of storage is outlined as follows:

1) The vehicle in which any medications, controlled substances, or IV supplies are stored must be garaged in a manner that protects them from extreme temperatures.
2) Medications, controlled substances, or IV supplies will be maintained in a locked compartment that either is an integral part of the vehicle's construction or permanently fixed to the vehicle.
3) The lock and key to this compartment will be secured by a Green Lock obtained through MLREMSC.
4) Medications and Controlled Substances must be stored inside the compartment in a container or device, such as an ALS medication Bag. This bag will be locked with a Gold Lock obtained through MLREMSC. The lock will pass through the zippers in such a manner as to prevent unauthorized persons from gaining access to the medications within.
5) All controlled substances will be maintained in the _____(storage device/safe). Each AEMT-CC/P will have an individualized *PIN# code to(specific to each agency device)* access the controlled substances. Inside the safe the Controlled Substances container will be sealed with a numbered, tamper proof seal.
6) At any time the Controlled Substances container is removed from the *Med Vault*, it shall remain in the AEMT-CC/P's possession at all times until re-secured within the vault.

E. Within this compartment, each Agency may possess no more than Midazolam 20mg, Morphine Sulfate 40mg, Fentanyl 400 mcg, and Ketamine 1000mg. One set of controlled substances may be held within each cabinet and is secured according to the policies outlined above.
F. Upon breaking the seal and prior to replacing with a new seal, the date, seal number, name of person accessing, and the reason for accessing the controlled substances will be recorded on the reverse side of the EMS Providers Controlled Substance Tracking Form. These forms are kept in the same sealed compartment as the controlled substances.
G. Access to controlled substances shall be limited to the following:
    1) Medical Administration- Any qualified and credentialed AEMT-CC/P that is authorized to practice in the jurisdiction of the MLREMSC may access the controlled substances for a medical administration as ordered by a medical control physician.
    2) Physical Inspection- The designated Agent and/ or the representative from the QA/QI sub-committee may have access to the medication bag/kit at any time to perform an inspection of the medicines contained within including controlled substances.
    3) Training- the kit may be removed from service and opened by an Agency's AEMT CC/P for training, whenever necessary and appropriate.
    4) Controlled substances may not be carried as part of any AEMT's personal inventory of medications.
    5) Only the specific quantity of controlled substances as detailed in the Operations Plan may be stocked by an Agency.
H. Completion of documentation requirements and restocking of controlled substances should be done as soon as possible after completing a run where controlled substances were administered.

III. Medical Administration

A. Controlled substances may only be administered according to the protocols established by New York State and MLREMSC.
B. Administration of any medication must be documented on the Patient Care Report (PCR) or the accompanying continuation form.
C. Record of administration and wastage, along with all other necessary information must be recorded on the EMS Providers Controlled Substances Tracking Form as a record for the Pharmacy of _____. Completing this form is Necessary to restock used medications and the original must be turned into the Pharmacy of _____. The Agency must also keep a running record of administrations, wastage, and restocks on the Controlled Substances Usage Verification Form [DOH-4004 (mod)]. This form serves as the Agency's record of administration.
D. All witnessing of wastage of controlled substances must be made by either a Pharmacist, Nurse, PA, or MD at the receiving hospital. The EMS Providers Controlled Substances Tracking Form must be signed both by the AEMT-CC/P that received the authorization and by the person who witnessed the wastage of the remainder.

IV. Monthly Inspections

A. The Agency will conduct a monthly physical inspection of all medications, including controlled substances, which are carried on an emergency vehicle. Inspections are designed to:

1) Check expiration dates on all medications.
2) Ensure that no medications are contaminated.
3) Check to ensure medications do not appear to be discolored, or leaking.
4) Verify quantities of medications match the numbers authorized by the MLREMSC, and the Medical Director.
5) Ensure that syringes and medication containers are intact and in a sterile condition.
6) It shall be the responsibility of the agent to insure that all inventories are submitted, complete, and correct. Any irregularities shall be immediately brought to the attention of the Pharmacy Director and the Medical Director (or his designee) for appropriate corrective action.

I. Whenever an Authorized AEMT-CC/P opens the medication cabinet, it will be the responsibility of that technician to assure that the seal and the integrity of the compartment holding the controlled substances is intact. Evidence of tampering should be reported immediately to the Controlled Substances Agent or their credentialed alternate.

J. When a container of controlled substance is found, out-dated, damaged, contaminated, or otherwise unsuitable for use, the controlled substance must be taken out of inventory and replaced at the earliest appropriate time. The transaction between the technician and the pharmacy must be recorded on the **EMS Providers Controlled Substance Tracking Form** and the **Controlled Substances Usage Verification Form** [DOH-4004(mod)].

II. Record Keeping

A. Appendix A of this plan contains copies of the forms utilized in this QA plan.

1) **EMS Providers Controlled Substances Tracking Form**
2) **Controlled Substances Usage Verification Form** [DOH-4004 (mod)].
3) **Controlled Substances Semi-annual Report for Pre-Hospital ALS Agencies** [DOH-3848 (mod)]
4) **Loss of Controlled Substances Report** [DOH-2094]
5) **Affirmation of Controlled Substances In-service Training & Receipt of Policies**

B. **EMS Providers Controlled Substance Tracking Form.** Within the sealed compartment that holds the controlled Substances there shall be a record to detail the administration, wastage, out-dated drug replacement, theft/loss, and restock of these medications. This form is the tracking mechanism for the pharmacy of _____. One record shall be kept for each medication: Midazolam, Morphine Sulfate, Fentanyl, and Ketamine. There will be a unique set of these forms in each sub-stock compartment maintained by the Agency. This record shall be filled out each time there is an alteration in the Agency's controlled substance sub-stock. The form will be used to record multiple changes in sub-stock. Once the form is filled, a new form will be used and a summary of transactions will be logged on the top of the form in the block allocated for it. Every effort should be made to replace the controlled substance after each administration or

change of stock. Using the form to record multiple changes in sub-stock should be discouraged.

C. **Controlled Substances Usage Verification Form** [DOH-4004]. This form is the Agency's record of use and replacement of controlled substances. A copy of this form, for each medication, should be maintained with the sub-stock. At the end of the preset six (6) month period, this form should be collected and data for each controlled substance summarized and transferred to the **Controlled Substances Report for Pre-Hospital ALS Agencies** [DOH-4352].
D. **Controlled Substances Report for Pre-Hospital ALS Agencies** [DOH-4352]. This state form must be completed and submitted to the Pharmacy of _____ semi-annually for all controlled substances and quarterly for Fentanyl and Ketamine. This provides a summary of the changes in inventory. Note, there is no need to report any changes in inventory due to replacement of out-dated, contaminated, or damaged medications, as these do not constitute a loss or use of controlled substances. This form must be signed by both the Agency's licensed Agent, the Agency CEO, and the Agency Medical Director.
E. **Loss of Controlled Substances Report** [DOH-2094]. This form must be completely filled out in the event of theft, loss, or diversion of controlled substances. Diversion is defined as, "the manufacture, possession, delivery, or use of a controlled substance by a person, or in a manner not specifically authorized by law". Once completed, it should be submitted to the Pharmacy Director of _____. A copy should be maintained by the Agency for their files.
F. **Affirmation of Controlled Substances In-service Training & Receipt of Policies.** This form affirms that the technician has received the items mentioned above and agrees to the policies designated therein.

III. Continuing Education

A. Each AEMT-CC/P that is authorized to administer controlled substances shall receive in-service training for handling controlled substances that governs record keeping and handling, Controlled Substances Operations Plan, MLREMSC protocols, and Article 80 of the NYCRR. In-service training must:
    1) Include all AEMT-CC/P's authorized to administer controlled substances.
    2) Include all policies and procedures and the legal requirements that govern the handling of controlled substances.
    3) Periodic in-services must be held to assure that 100% of the authorized AEMT-CC/P's have received this training.
    4) Upon completion of training, all AEMT-CC/P's will sign an **Affirmation of Controlled Substances In-service Training & Receipt of Policies** affirming that they have received in-service training, copies of all policies and procedures, and stating that they will follow the policies detailed within.
    5) AEMT-CC/P's who fail to follow these procedures and policies within six months of adopting this plan are subject to review and/or suspension of his/her privileges to administer controlled substances.

IV. Run Review and Quality Assurance

A. The _____(Agency) belongs to the QA/QI Sub-committee of the Tri-Lakes EMS Committee. 100% of all ALS runs where controlled substances are administered, shall undergo review. These runs will be first reviewed by the agency, and if there are any unresolved issues, it will be brought forth to the committee as a whole. These runs shall also be subject to review by the _____ Director of Pharmacy. This review will verify:

1) Proper documentation of medical control authorization to administer controlled substances.
2) Accurate completion of all forms necessary to document the administration, such as:
   a) The Patient Care Record
   b) Continuation Form
   c) EMS Providers Controlled Substance Tracking Form
3) That procedure was followed to the satisfaction of the Pharmacy Director at _____.
4) All controlled substances are stored in an appropriate manner and will undergo stocking and inspection in accordance with the _____(Agency) Service's Controlled Substances Operations Plan, and Article 80 of the NYCRR.

B. Medical Control Director, or his designee shall evaluate the performance of the on-line AEMT-CC/P for field administrations of a controlled substance. He will verify that field administrations were done in accordance with the protocols of MLREMSC and that all paperwork was correctly completed. The Medical Director must review all field administrations of Ketamine. The Pharmacy Director shall likewise verify that all documentation of administration and replenishment of sub-stock are done completely and accurately. All irregularities shall be investigated immediately. The results of this QA/QI process shall be reported to the QA/QI Sub-committee on a Semi-annual basis.

C. Semi-annual reports will be made to the QA/QI Sub-committee by the _____ Pharmacy Director and the sub-committee chairman on compliance of ALS Agencies with policies and procedures as mandated by Article 80 of the NYCRR and the Controlled Substances Operations Plan.

D. Theft/Loss/Diversion of Controlled Substances. In the event controlled substances are stolen, lost, or otherwise diverted from their authorized use, the following procedure should be followed:

1) The _____ Pharmacy Director must be notified immediately, or on the next business day.
2) An incident report must be filed with the _____ Pharmacy describing the incident.
3) A **Loss of Controlled Substances Report** [DOH-2094] must be filled out and submitted to the _____ Pharmacy Director.
4) A copy of all paperwork should be retained by the Agency for a minimum of five (5) years.
5) The **Loss of Controlled Substances Report** [DOH-2094] will be forwarded to the NYS DOH thereby notifying them of any theft, loss, or diversion of a controlled substance.

E. In the event that an irregularity or violation of procedures is identified, the Pharmacy Director and the Agency Agent will be notified of the problem. The Pharmacy Director will take the lead in resolving any irregularities or inconsistency associated with the administration of controlled substances. The Medical Director shall also be notified of any problems as they are identified.

V. Remediation & Corrective Action

A. Corrective action may include any or all of the following, depending on the severity of the violation and the decision of the Medical Director, Pharmacy Director, and/or the QA/QI Sub-committee.
    1) Remediation must occur, in the form of in-service training through the QA/QI Sub-committee.
    2) A six (6) month probationary period for the AEMT(s) involved.
    3) Suspension of privileges to administer controlled substances.
    4) Revocation of his/her privileges to practice as an AEMT in the Mountain Lakes Region.
    5) Forfeiture of the Agency's permission to carry controlled substances.
    6) Criminal investigation by an appropriate law enforcement agency.
B. At no time will this plan act to supercede, or contradict the authority or decisions of: the laws of the State of New York, Rules and regulations of NYS DOH, the Mountain Lakes Regional EMS Council, or the Medical Director.

_____

_____

_____

Agency name, Address, Phone #

Date:_____

Name:_____ NYS EMT#_____

Address:_____ Mt Lakes Tek#_____

_____

_____

I acknowledge that I have received the following:

- ☐ _____(Agency) Controlled Substances Operations Plan
- ☐ Mountain Lakes Policies and Protocols for controlled substances
- ☐ Part 80 of the NYCRR
- ☐ In service training on policies, procedures, and record keeping

Furthermore, I understand the information outlined by these documents and agree to follow the policies and procedures contained therein.

_____

Name (Please Print)

_____

Signature