



El Dorado County Emergency Services Authority

Policy Subject Matter: **3.5.1 Security of Controlled Substances**
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I.PURPOSE:

The El Dorado County Emergency Services Authority (EDC ESA) and its member agencies including the assigned prehospital care personnel have a responsibility to adhere to all applicable laws and regulations regarding controlled substances including the Controlled Substances Act and California Code of Regulations, Title 22, Div. 9, CH. 4, Art. 7, Subsection 100168 (3) (A, B), and to ensure that security measures and procedures are followed.

This policy and procedure document establishes the requirements for Advanced Life Support (ALS) Ambulance Unit supply, use, replacement, and accountability of controlled substances.

II.POLICY:

- A.** Controlled substances are to be administered in accordance with El Dorado County EMS Agency treatment protocols and shall be stored in a secure manner at all times.
- B.** Any discrepancies shall be reported to the Station Captain, Department/District EMS Officer, and the EDC ESA Office
 - A Report of Occurrence (ROO) shall be completed and submitted to the EDC ESA Office through the chain of command prior to the reporting parties going off duty.
- C.** The EDC ESA issues a unique, personal identification number (PIN) to every user for the purpose of accessing the NarcBox.
 - Users shall not share their PIN with another person, nor shall they open a vault utilizing someone else's PIN.
 - If the security of the PIN becomes compromised, the user shall notify the Station Captain, the EMS Officer, and the EDC ESA Office immediately.
 - In addition, a ROO shall be completed and submitted to the EDC ESA Office through the chain of command no later than the end of the shift in which the incident occurred.
- D.** In the event of a NarcBox failure, a ROO shall be completed and submitted to the EDC ESA Office through the chain of command.
 - The ROO should address in detail the reason why the NarcBox was unable to be opened (e.g. PIN code not working, electrical power supply to NarcBox interrupted, etc.)

- E.** Broken or missing controlled substance vials and/or evidence of tampering with the controlled substances container shall be reported immediately to the Station Captain, the EMS Officer, and the EDC ESA Office.
- The EDC ESA Executive Director will notify the appropriate law enforcement agencies and the County's Medical Director as deemed necessary.
 - In addition, a ROO shall be completed and submitted to the EDC ESA Office through the chain of command no later than the end of the shift in which the incident occurred.
- F.** If a controlled substance is unaccounted for, the investigation will be turned over to the local law enforcement with investigative responsibility.
- Failure to demonstrate proper security and accounting procedures can have legal ramifications for both the Department/District's personnel, the EDC ESA and the El Dorado County EMS Agency.
- G.** Failure to comply with this policy and the procedures described herein will result in progressive discipline up to and including termination of employment. If employed by a JPA Member Agency, discipline will be in line with individual Department/District policy and procedure.

III.PROCEDURE:

A. CENTRAL SUPPLY: INITIAL ORDERING OF CONTROLLED SUBSTANCE

- EDC ESA Office shall be the Central Supply hub for all controlled substances.
- Staff will maintain an available inventory consistent with El Dorado County EMS Agency Field Policy "ALS Unit Minimum Equipment Inventories" for each medic unit in the system.
- EDC ESA staff will work with the Medical Director to ensure that all required DEA paperwork, including DEA Form 222 is completed and maintained in a fashion that is consistent with federal regulations.
- EDC ESA staff shall order controlled substances from one of the approved medical supply accounts.

B. CENTRAL SUPPLY: INITIAL RECEIPT OF CONTROLLED SUBSTANCE

- The Medical Director, EDC ESA Executive Director or EDC ESA Deputy Director shall order controlled substances using the DEA 222 form for initial stock or restock.
- Controlled substance orders shall be inventoried and secured in the presence of two designated EDC ESA representatives.
- Once controlled substance orders are inventoried, EDC ESA Staff will attach the appropriate RFID Tag to each individual vial. RFID tags are color coded as follows:
 - **White RFID Tags= Midazolam**
 - **Red RFID Tags= Fentanyl Citrate**
 - **Blue RFID Tags= Ketamine**
 - **Green RFID Tags= Morphine**
 - **Yellow RFD Tags= Unassigned**
- EDC ESA Staff will "**Add New Tagged Medications**" into the NarcBox Tracking System via the HQ Panel.

1. Select "**Manage Inventory**"
2. Enter User(s) Credentials – PIN/RFID/BIO
3. Choose "**Add New Med**"
4. Do you want to add RFID Tagged Items?, Select "**Yes**"
5. Select Medication Name
6. Enter Lot Number
7. Enter Form 222 Number
8. Enter Expiration Date
9. Proceed to Scan Medication RFID Tags
 - a. To add additional medications, repeat the same process by selecting "Medication"
10. When finished, Press "**Done**"
11. Review Action, Press "**Confirm**"

Tagged medications are now added into the HQ Panel.

- Controlled substances shall be stored in a locked safe in the EDC ESA Office. Access to the safe is strictly limited to designated personnel of the EDC ESA.
- EDC ESA Staff will conduct an Inventory Audit once a month.
 - Select "**Inventory Audit**"
 - Enter User(s) Credentials-PIN/RFID/BIO
 - Select "**Visual Confirm**"
 - Quick Audit Selected?, Press "**Yes**"
 - Enter Number of Vials for Each Medication, Press "**Next**"
 - Confirm Count Matches Number of Vials, Press "**Done**"
 - Save Report, Press "**Save**"
 - Match RFID Tags, Press each tag number you have confirm you have in inventory. *The RFID Number will turn from red to green, Press "**Save**"
 - Save Report, Press "**Save**"

C. MEDIC UNIT SUPPLY: TRANSFER/RESTOCK OF INVENTORY

- Restock supply shall be maintained only in designated secured NarcBoxes located in the EDC ESA Office.
- Controlled substances will be distributed from EDC ESA Central Supply to Medic Unit Supply.
- If the amount of controlled substances in stock on the transport unit drops to the minimum inventory outlined in County Policy ALS Unit Minimum Inventories, the medic unit shall go out-of-service and contact EDC ESA Central Supply immediately for restock.
- EDC ESA Staff will "**Transfer Out**" Inventory from the NarcBox Tracking System HQ Panel:
 1. Select "**Manage Inventory**"
 2. Enter User(s) Credentials-PIN/RFID/BIO
 3. Choose "**Transfer Out**"
 4. Select "**Yes**" Transferring RFID Tagged Items
 5. Proceed to Scan Medication RFID Med Tag(s),
 6. When finished choose "**Done**" and "**Confirm**"
 7. Tagged medications are now transferred out of Central Supply inventory.
- Medic Unit Staff will "**Transfer In**" Inventory to the Medic Unit NarcBox:
 1. Select "**Inventory**"
 2. Enter User(s) Credentials-PIN/RFID/BIO
 3. Choose "**Transfer In**"
 4. Proceed to Scan Medication RFID Med Tag(s),

5. When finished scanning all meds choose “**Done**” and “**Save Report**”
 6. RFID Tagged Medication(s) are now transferred into the Medic Unit Supply NarcBox
- If EDC ESA Central Supply is unavailable, the Medic Unit may restock from available inventory on the assigned Reserve Medic Unit NarcBox.
 - Medic Unit Staff will “**Transfer Out**” Inventory from the Reserve Medic Unit NarcBox:
 1. Select “**Inventory**” and enter credentials
 2. Choose “**Transfer Out**”
 3. Proceed to Scan Medication RFID Med Tag(s),
 4. When finished scanning all meds choose “**Done**” and “**Save Report**”
 5. Tagged medications are now transferred out of Reserve Medic Unit inventory.
 - Medic Unit Staff will “**Transfer In**” Inventory to the Medic Unit NarcBox:
 1. Select “**Inventory**”
 2. Enter User(s) Credentials-PIN/RFID/BIO
 3. Choose “**Transfer In**”
 4. Proceed to Scan Medication RFID Med Tag(s),
 5. When finished scanning all meds choose “**Done**” and “**Save Report**”
 6. RFID Tagged Medication(s) are now transferred into the Medic Unit Supply NarcBox
 - Expired and used vials of controlled substance shall be exchanged on a one-for-one basis with EDC ESA Central Supply.
 - For restocking of controlled substances while out of County see El Dorado County EMSA Fireline Medic Policy.

D. APPARATUS SECURITY

- The controlled substances are stored in a double secure system.
- The medic unit apparatus is the first level of security.
- The locked NarcBox within the apparatus is the second level of security.
- Controlled substance are to be secured inside the NarcBox at all times.
- Controlled substances must be stored in an environmentally controlled environment.
- Should the medic unit be taken out of service and sent off site for repair, controlled substances must be “Transferred Out” of the NarcBox and “Transferred In” to the replacement Medic Unit as identified in Section III. C. of this policy.
- Should the assigned Reserve Medic Unit be stored at an un-staffed station location, controlled substances may be stored in an alternate NarcBox kept at the primary station location of the Medic Unit. All restock procedures will follow those identified in Section III.C. of this policy.
- Nitronox:
 - It is permissible to keep a single cylinder of Nitronox in the rapid deployment bag to expedite its use.
 - All additional cylinders of Nitronox must be kept in a locked cabinet or box.

E. SHIFT CHANGE/AUDIT-VISUAL

- At the beginning of every shift and/or any time a crew change occurs of any duration, a “**Shift Change Audit**” shall occur.
 1. Wake the NarcBox and choose “**Shift Change**”
 2. Enter incoming medic credentials-PIN/RFID/BIO

3. Enter offgoing medic credentials-PIN/RFID/BIO
 4. Select “**Visual Confirm**” and “**Yes**” to proceed
 5. Enter quantity of medication vials and select “**Next**”
 6. Continue entering all medication quantities
 7. Confirm quantity summary and select “**Done**”
 8. “**Save**” Report
 9. Proceed to matching RFID Med tags
 10. Confirm by selecting RFID (green=present/red=missing)
 11. Select “**Save**” and Save Report
 12. Close NarcBox door-Shift Change/Audit-Visual Confirm Complete.
- Inspection of the controlled substances shall include:
 - RFID Med tag intact without evidence of tampering
 - Contents intact and no visible leaks
 - Presence of correct quantity of medications and verification that there is an appropriate amount of fluid
 - The on-coming paramedic takes full responsibility for the inventory and security of controlled substances on the unit for the new period of responsibility.
 - Any evidence of tampering, e.g. loose/missing cap on a vial, or numbers different from the “**Shift Change Audit**” are indicative of potential unauthorized tampering with the controlled substances.
 - Report this immediately to the Station Captain, Department/District EMS Officer and the EDC ESA Executive Director or Deputy Director. Both the on-coming and off-going paramedic shall send a written Report of Occurrence to the EDC ESA Office through the chain of command.
 - If, at the change of shift, the apparatus is dispatched to an incident and verification would delay response, as soon as practical upon returning to quarters, the on-coming crew will conduct the “**Shift Change Audit**”.
 - Paramedic interns and ride-alongs are not authorized to sign for, manage, or perform “**Shift Change Audits**” of Controlled Substances.

F. ADMINISTRATION OF CONTROLLED SUBSTANCE

- The administration and use of a controlled substance shall be in accordance with the El Dorado County scope of practice for paramedics and treatment protocols.
- Administration of Controlled Substances will be logged into the NarcBox.
- Log Med Usage:
 1. Select “**Log Med Usage**”
 2. Enter User(s) Credentials-PIN/RFID/BIO
 3. Scan Med RFID tag
 4. Select and Enter “**Admin Qty**”, Press “**Done**”
 5. Select “**Waste Qty**”
 6. Enter 2nd Credential (witness)-PIN/RFID/BIO
 7. Confirm or re-enter Waste qty, Press “**Done**”
 8. Double check qty is correct,
 - a. Need to enter another Med?, Press “**Next**” and go back to step 3
 - b. Done with Med entry, Press “**Done**”
 9. Enter Incident #, press “**Done**”
 10. Confirm Meds and Admin/Waste Qty, press “**Done**”
 11. Save Report, press “**Save**”

- When controlled substances are administered to a patient, the amounts used and wasted shall be documented on the ePCR with the time, amount & the paramedic license number of the responsible paramedic.
- The ePCR shall contain signatures from both the responsible paramedic and the person who witnessed any wastage of the unused controlled substances.
- In the event a paramedic draws up a controlled substance but does not use it on the incident, all of the medication shall be wasted in front of a witness. The wasting of controlled substances shall be completed utilizing the EDC ESA approved controlled substance disposal system. If the vial seal is broken and the medication not drawn up, the unused medication must be wasted utilizing the EDC ESA approved controlled substance disposal system. The empty vial must then be exchanged in accordance with the one-for-one vial exchange as documented in Section C of this policy. For both circumstances, indicate zero (0) milligrams administered and the amount wasted with the reason the medication was not used (e.g. failed to establish IV, seizure activity stopped, patient refused, B/P dropped, etc.).
- After medication wasting, unused vials with a broken seal shall be placed back inside the controlled substance container with each vial labeled with the date of use, patient name, and the incident number.
- To Transfer the un-used medication back in to the NarcBox:
 1. Select “**Inventory**”
 2. Enter User(s) Credentials-PIN/RFID/BIO
 3. Choose “**Transfer In**”
 4. Proceed to Scan Medication RFID Med Tag(s),
 5. When finished scanning all meds choose “**Done**” and “**Save Report**”
RFID Tagged Medication(s) are now transferred into the Medic Unit Supply NarcBox.
- At no time shall empty, partially used or expired vials of controlled substance be stored outside of the NarcBox.
- Out of County-Response
 - When on Out of County Response follow standard EDC ESA and EDC EMSA Policies and Procedures.
- For situations where there is some controlled medication left over after administration to a patient the medication must be wasted in front of a witness utilizing the EDC ESA approved controlled substance disposal system. This witness should be another healthcare provider (i.e. a registered nurse, physician, or another paramedic) whenever possible.
- Used vials shall be exchanged on a one-for-one basis with the EDC ESA Central Supply.
- NITRONOX:
A single cylinder of Nitronox may be used for more than one patient. A minimum of at least one (1) completely full cylinder of Nitronox shall be maintained at all times on transporting medic units.
*Nitronox information:
 - The tracking/usage log shall be updated anytime Nitronox is used. A note of how many minutes used shall be documented in the amount used column. Names and signatures are required when Nitronox is administered. Nitronox cylinders should be used until they are completely empty before restocking. If in doubt about whether a cylinder is empty, simply open the valve and allow a small amount of product to escape.

Note: If during administration to a patient it becomes apparent that the Nitronox is not working, check the cylinder (using the above method) to make certain it is not empty.

G. RECORD KEEPING & RETENTION

- All records concerning controlled substances must be maintained for at least three years for inspection and copying by duly authorized DEA officials. The records that must be maintained are:
 - Official Order Forms (DEA Form-222)
 - Power of Attorney authorization to sign Order Forms
 - All inventory records of controlled substances
 - Records of controlled substances distributed or dispensed
 - Report of Theft or Loss (DEA Form -106)
 - Inventory of Drugs Surrendered for Disposal (DEA Form-41)
 - DEA registration certificate
- All records concerning controlled substances will be maintained by the EDC ESA Office.

H. REVERSE DISTRIBUTION

- All open controlled substance vials not administered to a patient or expired controlled substance vials shall be properly reverse distributed of as per the Controlled Substances Act and California Code of Regulations Title 22, Div. 9, Chapter 4, Article 7 with all documentation retained in the EDC ESA Office for a minimum of three years.
- For purposes of this Policy, an open controlled substance vial is one in which the RFID tag is broken, torn or ripped.
- Open controlled substance vials and expired controlled substance vials shall be wasted using the EDC ESA approved controlled substance disposal device.
- Empty vials of controlled substances, including used, wasted and expired vials shall be exchanged with the EDC ESA Central Supply on a one-for-one basis.
- The Reverse Distribution process involves collecting and removing either damaged, expired, unused, or recalled controlled substance inventory. Reverse distributors are defined as “a person who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.”
- EDC ESA Staff are responsible for the reverse distribution process including establishing and maintaining an active account with a Reverse Distributor.
- Once reverse distribution shipping container arrives to the EDC ESA Office, EDC ESA Staff will complete the “**Retire Out RFID Tagged Medication**” Process:
 1. Select “**Manage Inventory**” and enter your credentials.
 2. Choose “**Retire Items**”
 3. Select “**Yes**” retiring RFID tagged items
 4. Proceed to scan medication RFID Tag and select “**Next**”
 5. Select reason for retiring medication (Broken Vial, Expired, Recall, Damaged Tag, Other) and “**Finish**”.
 6. Medication is now retired from your Inventory.

References

- Addendum A Rx Destroyer
- EDC ESA Policy Controlled Substance Distribution for Strike Team and Fireline Medic Response
- United States Code, Title 21, Controlled Substances Act
- California Code of Regulations, Title 22, Div. 9, Ch. 4, Art. 7, Section 100168 (3) (A, B)
- El Dorado County EMS Agency Field Policy: Controlled Substances
- El Dorado County EMS Agency Field Policy: Fireline Paramedic
- https://www.youtube.com/channel/UCfjO7iTX3_GbfaX_lytNaow

Addendum A.

Controlled Substance Disposal System

The EDC ESA utilizes the Rx Destroyer product to facilitate disposal of controlled substances. Each medic unit has a mounted Lockbox equipped with a key and Rx Destroyer liquid bottle.



Once the Rx Destroyer bottle contents reach 2" from the top, contact the EDC ESA Business Office to schedule the exchange of the full bottle for a new empty bottle. Staff at the EDC ESA Business Office will complete the disposal process.

EDC ESA Business Office Staff Mail-In Drug Disposal Process

Rx Destroyer's national Mail Back Disposal Program provides a simple and cost effective alternative for the safe disposal of used Rx Destroyer bottles. The mail back system is ideal for facilities located in states that prohibit the disposal of Rx Destroyer in the common trash or those that do not have a contracted pharmaceutical waste provider. When ready, simply seal the prepaid shipping box and get it picked up by UPS.



DRUG DISPOSAL EASY



**Safety Data Sheets for the Rx Destroyer Hardener substance are available at the EDC ESA Business Office.*