

Drug Security Policy

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OVERVIEW

This policy establishes Boston Emergency Medical Services' procedures for the administration, documentation, storage and inventory levels of Schedule II, Schedule III, Schedule IV, and Schedule VI drugs, and for the control of keys required for the security of these drugs. Boston EMS personnel are authorized to administer approved medications or assist in the administration of medications in accordance with standing orders as listed in the Commonwealth of Massachusetts Statewide Treatment protocols, and / or under the direction of a Boston Medical Center (BMC) Emergency Department medical control physician as part of an affiliate hospital agreement. Except for medications prescribed to a department member or patient, no other drugs or pharmaceutical equipment or supplies are permitted in an ALS ambulance or at a district station. A list of all approved medications is included in the appendix of this policy.

DRUG BOX KEYS

1. Each ALS unit is issued two sets of drug keys. Drug keys are keyed to each drug box, are not interchangeable, and cannot be duplicated without authorization. These keys shall remain in the custody and control of the on-duty paramedic until passed on to the paramedic of the oncoming shift, or properly secured at the end of shift. Each set will include a key for the designated storage compartment for the drug box, and the locked compartment located within the drug box itself. Any loss of keys will immediately be reported to the on-duty shift commander.

MEDICATION STORAGE / EXPIRATION

1. All drug boxes containing controlled substances will be stored inside a locked compartment of the EMS Unit. ALS level drugs will be carried in a Department-issued drug box inside of which shall be an additional locked compartment rocuronium and Schedule II, Schedule III, & Schedule IV medications. A separate Department issued drug box will be designated for nerve agent response; these boxes contain diazepam as well as pralidoxime and atropine and are accessed by a key lock as well as the removal of a pharmacy tag.
2. Stock levels of Schedule VI drugs shall be stored inside a compartment of the ALS unit. Stock supplies of Schedule II, III, and IV drugs shall be stored at the Boston Medical Center Emergency Department and accessed via the Pyxis System terminal. Rocuronium and Etomidate are stored in the secure ALS equipment room at Materials Management, with Rocuronium restocked from the refrigerator.
3. Additional authorized Schedule VI drugs shall be stored in the designated locked area at each ALS Station. Only personnel authorized by Boston EMS to administer controlled substances shall have unsupervised access to these locked areas. The quantities of Schedule VI drugs shall be within the parameters outlined for each ALS Station (see appendix) and within the parameters outlined for the drug box and for the ambulance.

4. BLS units shall store albuterol unit doses and the EpiPen Auto Injector inside the metal BLS medication box within their portable oxygen bag. BLS units will also be issued a pelican case with DuoDote autoinjectors (see next section).
5. All controlled medications shall have a specific expiration date (MM/DD/YY) noted on the Controlled Substance Record accompanying the plastic kit containing the medications. The expiration date will be determined by the pharmacy prior to distribution. When removing Rocuronium from the refrigerator at Materials Management, a notation "Out of Fridge" and the date shall be clearly marked on the vial. Once procured from Materials Management, Rocuronium shall be stored in the ALS drug box and will be considered expired 60 days after removal from refrigeration.
6. For the purpose of inventory control of other medications, intravenous fluids, or supplies that do not list a specific expiration date, these items shall be considered as expired on the last day of the month immediately preceding the expiration date written on the package. For example, a medication or intravenous bag with an expiration date of 04/18 shall be considered expired on 03/31/18.

DuoDOTE™ AUTO-INJECTOR ("BLACK BOX")

Each BLS and Supervisory response unit shall carry a locked black Pelican case containing thirty (30) DuoDOTE auto injectors. The box will be stored in the dedicated, front wall interior cabinet of the Ford ambulances and under the bench seat in the rear compartment of non-Ford ambulances. Two keys will be provided for each District truck so that both crewmembers will have a key to maintain security of the black pelican case. At the beginning of each shift, the oncoming crew shall be responsible for inspecting the box and confirming that the padlock is secure, and the inventory control tag is intact. The inventory control tag number shall be recorded in the daily special equipment log, accompanied by the signatures of both crewmembers. If the inventory control tag is missing or broken, the Shift Commander shall be immediately notified. The Shift Commander or designee will then conduct an inventory of the box and reseal the case with a new inventory control tag.

DRUG INVENTORY DOCUMENTATION

1. The controlled medication inventory for Schedule II, Schedule III, Schedule IV drugs, and Rocuronium shall be performed at the beginning and the end of each shift with two paramedics present simultaneously; one from the shift that is ending and one from the shift that is beginning when possible. Recognizing that personnel sometimes alternate between vehicle operation and primary patient care duties throughout the course of a shift, the paramedic acting as the primary "attendant" at the beginning of the shift is responsible for checking out all of the equipment and supplies inside the vehicle, including the AED/Monitor/Defibrillator, jump kit / first aid bag(s), oxygen and associated delivery devices at the beginning of each shift, or as soon as practicable thereafter, and ensuring that the medication inventory is completed and properly documented.
2. Paramedics performing the inventory shall visually ensure that the plastic kit seal is intact, the seal number matches the CSR number, the kit is not damaged, the contents of the kit appear undamaged, and that there is no liquid in the kit. They shall also verify the presence of one yellow auxiliary seal for the controlled substance box. These findings shall be documented on the DCSAL by circling the 'Y' or 'N' in the appropriate place.

3. Whenever a unit is dispatched but unable to immediately respond (performing narcotic inventory, changing on-board oxygen tank, etc.), the crew should acknowledge the response, state the reason for their delay, and give the estimated time until they will be able to respond. The dispatcher shall supplement this into the CAD incident history, and poll other units to determine if there is another appropriate resource with a shorter ETA.
4. The inventory check and the time (military time) will be documented in the appropriate space on the DCSAL along with the corresponding CSR number. Simply writing “no change” is not acceptable. Both paramedics will attest to the accuracy of the inventory check with their signatures and medic ID numbers. All documentation shall be in black or blue ink. The serial numbers from the inventory control tags on the “black box” and the “grey box” shall be noted in the appropriate spot on the DCSAL. When not in use, the drug logbook shall be kept in the vehicle. Any signature without having visually inspected the drug box and the plastic medication kit will be considered falsification of documentation and will result in termination.
5. Schedule VI drugs are stocked inside locked cabinets at the ALS Stations. Paramedics removing drugs from or adding drugs to the cabinets shall record the amount taken or added, indicate the remaining balance, and write their name and ID number on the inventory form.
6. A shift commander shall inspect the drug box inventory control tag of each ALS drug box containing controlled substances stored at the Theodore Glynn Way station daily. Shift commanders will audit in-service ALS units daily to ensure it matches the number noted in the associated DCSAL form. These inspections shall be reported to Professional Standards and the Shift Commander group daily. Each ALS unit will have an inventory of the drug box, the ambulance, and the ALS station performed at least monthly by a Shift Commander. A copy of the ALS Drug Inventory form shall be kept on file by Professional Standards for at least three years.
7. Any drug box or plastic medication kit found to be missing shall immediately be reported to the on-duty shift commander and the unit will be placed out of service. The shift commander will then notify the Superintendent of Field Operations. If the drug box is unable to be located, the Medical Director or designee shall be notified. If/when found, the shift commander and one of the on-duty paramedics will conduct a full inventory full review of contents, any irregularities in the narcotics kit will be reported to the Superintendent of Field Operations, Medical Director and BMC Pharmacy as soon as possible.

INITIAL ACCESS / SECURING CONTROLLED SUBSTANCE KIT (BLUE SEAL)

1. In accordance with Statewide Treatment Protocol and/or on-line medical control order, Department paramedics needing to access a controlled substance will remove the plastic medication kit from the secured drug box and break off the RED security plastic seal to access the medications. The red seal will then be placed inside the medication kit.
2. Vials that are labeled as single-dose or single-use should be used for a single patient and single case/procedure. Even if a single-dose or single-use vial appears to contain multiple doses or contains more medication than is needed for a single patient, that vial should not be used for more than one patient. Once a single-use vial has been opened or accessed, subsequent doses for the same patient should be drawn from that vial until the contents are exhausted before accessing another vial for the purposes of minimizing waste.

3. Once on arrival at the hospital (or sooner, if access to controlled medications is no longer anticipated), the plastic case with its remaining medications and the RED security seal will be closed and sealed with the corresponding BLUE security seal. The resealing of the kit shall be documented by both paramedics in the “Kit Resealed” section of the CSR.

SPECIAL EVENT AND MULTI-CASUALTY INCIDENT/ALS ADMINISTRATION EXCEPTIONS

Rare situations, such as multi-casualty incidents, may require ALS providers to administer Schedule II, III or IV medications to patients out of direct line of sight of a fellow department ALS provider. In such cases, during demobilization of patient care, ALS providers shall do the following: 1) witness the waste of any medications still in syringes, 2) seal remaining unopened vials per protocol, 3) update the shift commander of the situation, 4) complete all necessary documentation, including an Unusual Occurrence Form, 5) notify the “*Physician Group” via email.

In some circumstances, most likely special events or MCI’s, a solo department ALS provider may need to administer Schedule II, III or IV controlled substances with a physician present. The only physicians allowed will be designated BMC Medical Control physicians with designated MD #'s in the Boston EMS system. These physicians have been credentialed by BMC Medical Staff Services and have both federal and state drug control numbers that are active. The MD will be responsible to witness waste as well as document as per SOP. All necessary documentation must be completed, including an unusual occurrence form.

DOCUMENTATION OF CONTROLLED MEDICATIONS ADMINISTERED OR WASTED

1. After administration of a Schedule II, III or IV drug, the paramedic shall document usage of the drug on the CSR and the DCSAL. The documentation shall include the date, the time, the patient’s name, ALS unit, the drug, the dose, the waste, the Medical Control Physician’s call sign or “s/o” (standing order), the paramedic’s signatures and medic numbers, and the balance remaining in the kit. The Patient Care Report shall include the name of the drug, the CSR number, the dose, waste of open or remaining drugs, route and the time of each dose administered, and the effect of the drug.
2. Whenever there is a Schedule II, III or IV drug open or remaining after the physician’s orders have been carried out, all unused drugs shall be immediately discarded upon arrival at the receiving facility before exiting the ambulance. Unused medications shall be discharged from the syringe by one Department paramedic with a second Department paramedic physically present with direct visualization of the process as a witness. “Wasted” drugs shall be documented on the CSR under “medication administration” in the “waste” column and on the DCSAL. Both paramedics shall sign the CSR, DCSAL, and the PCR.
3. Sharps/controlled substance waste, in the red receptacle, shall be discarded prior to exceeding $\frac{3}{4}$ full.

DOCUMENTATION REVIEW

1. The designated Boston EMS pharmacy liaison will regularly retrieve completed original CSRs from the BMC pharmacy.
2. The Boston EMS designated pharmacy liaison will review the CSR and supporting documents (PCR, Daily Inventory forms) to ensure the controlled medications are properly and completely documented. The CSR is then forwarded to the Medical Director's office for clinical review.
3. The Medical Director (or designee) will review the controlled medication administration for clinical appropriateness and sign the CSR when appropriate.
4. If inappropriate documentation is discovered (with the CSR or DCSAL) or a clinical issue identified, a copy of the relevant document(s) will be forwarded to the Professional Standards Division for prompt review. The Professional Standards Division and /or the Medical Director will determine the necessary corrective actions to ensure a timely resolution. The Professional Standards Division will notify the BMC pharmacy of any inappropriate or incorrect documentation or accounting of controlled medications. Any corrected document(s) will be returned to the BEMS designated pharmacy liaison who will add them to the record.
5. The documents supporting the correct administration and discard of controlled medication will be saved in pdf. These will include the PCRs, a scanned image of the CSR and the DCSAL) and stored in an electronic file that is routinely backed up.
6. The original signed CSRs will be returned to the BMC pharmacy along with all supporting documentation. All paperwork shall be reconciled and returned to BMC pharmacy within 14 business days.
7. During weekly meetings, the Boston EMS designated pharmacy liaison and BMC pharmacy will review kit expirations. BMC pharmacy shall validate receipt of expired kits and the completeness of documentation to ensure all CSKs are accounted for.
8. The controlled substance log, maintained by the Boston EMS designated pharmacy liaison, will be reviewed in coordination with Professional Standards and the Medical Director. Any discrepancies, including accuracy and timeliness for completing necessary review steps, will be assessed and a corrective action plan established.

RETURNING CONTROLLED SUBSTANCES

1. All controlled medications need to be returned to the BMC Pharmacy as soon as possible after the CSK has been accessed. If the pharmacist on duty is not available, or refuses to accept returned medications, paramedics should keep the medications and the corresponding CSR and notify the on-duty shift commander. Under no circumstances should controlled medications be returned to the Pyxis machine.
2. When returning medications, the paramedics will fill in the appropriate parts of the CSR and both paramedics will sign the CSR. The paramedics shall have the pharmacist on duty sign the white CSR acknowledging receipt of the returned medications. After the pharmacist has signed the "Kit Received by" section, separate the pages of the CSR, keeping the pink page as your receipt, and leaving the white original with the pharmacist.
3. When logistics make it necessary, paramedics may return a used kit, with the blue or yellow security seal, to the on-duty Shift Commander in exchange for a new kit (the new kit will be sealed with a RED security seal which was applied by the pharmacist who prepared the kit).

This exchange should be documented on the DCSAL in the appropriate spaces. The Shift Commander will then be responsible for returning the used kit to the BMC Pharmacy.

SECONDARY ACCESS / SECURING CONTROLLED SUBSTANCE KIT (YELLOW SEAL)

The Shift Commander should be notified whenever an ALS unit with a previously used medication kit is dispatched to another response. If possible, the Shift Commander should respond and exchange the medication kits prior to use. The controlled substance kit is primarily intended to be a single-use kit that is returned to the BMC Pharmacy or exchanged with a Shift Commander after initial use. Circumstances may cause the ALS crew to break the BLUE security seal to access controlled medications to treat a second patient whose clinical presentation necessitates the administration of a controlled substance.

1. In accordance with Statewide Treatment Protocol and/or on-line medical control order, Department paramedics needing to access a controlled substance will remove the plastic medication kit from the secured drug box and break off the previously applied BLUE security plastic seal to access the medications. The BLUE seal will then be placed inside the box along with the corresponding RED seal which should already be in the kit.
2. Once on arrival at the hospital (or sooner, if the access to controlled medications is no longer anticipated), the plastic case with its remaining medications will be closed and sealed with the unit's YELLOW security seal.
3. In addition to the standard documentation, the ALS Crew will document the reason for entry into the resealed, previously used, controlled substance kit on an "Unusual Occurrence Form" and submit it to the on-duty shift commander.
4. After returning a medication kit with a YELLOW security seal, the crew will receive a replacement YELLOW seal from the Shift Commander and store it in the metal medication box mounted in the drug box.

UNUSUAL OCCURRENCE / DISCREPANCIES

1. Whenever a controlled key, inventory control tag of a grey or black pelican case, or security envelope is noted to be damaged, missing, lost or stolen, the ALS crew shall immediately notify the Shift Commander, and document the circumstances in an incident report which is submitted to Professional Standards.
2. Whenever a controlled medication kit is found to be damaged, the kit seal is damaged or missing, the kit seal number does not match the CSR number, any of the contents of a kit appear damaged, or there appears to be liquid in the kit, the paramedics making the discovery shall immediately notify the on-duty Shift Commander. The paramedic(s) shall complete a Controlled Medication Unusual Occurrence Form, and the entire kit, including any damaged vials, syringes, and associated packaging shall be returned to the BMC pharmacy. The on-duty Shift Commander taking the report shall notify Professional Standards of the incident, and promptly forward all associated documentation (incident report(s), controlled medication unusual occurrence form, etc.) to Professional Standards for review.
3. Unusual occurrences will be reviewed on a weekly basis during the designated Boston EMS pharmacy liaison's regularly scheduled meeting with the BMC pharmacy.

RESTOCKING

1. Schedule II, III and IV drug kits shall be procured from the Pyxis machine located in the Boston Medical Center Emergency Department. Two department certified paramedics must be present simultaneously to remove medications from the Pyxis. Whenever possible, both paramedics should be from the same unit, but it is acceptable for the second / witness member to be a Shift Commander or paramedic from another unit, if necessary. Shift commanders may restock kits for the command vehicle from the Pyxis without the need of a second signature.
2. Controlled Medications are dispensed in sealed clear plastic kits. The kits will be accompanied by a numbered CSR consisting of a white original page and attached pink carbon copy listing the controlled medications in the kit. The kits are sealed with a numbered RED plastic security seal. The number on the red security seal should match the number of the accompanying CSR. The kits will contain a numbered BLUE security seal to secure the kit after controlled medications have been initially accessed for patient administration. The number on the blue seal should be the same as the number on the red seal and on the CSR. The kit will contain all the controlled medications approved to be stocked in BEMS ALS units. When restocking controlled medications, both paramedics shall complete the "Kit Removed By" section of the CSR (including signature, badge number, and printed name of both members, ALS unit, and date removed) as well as documenting the issuance of a new kit on the "Inventory Change Record" portion of the DCSAL form.
3. Rocuronium is restocked from the refrigerator in the ALS equipment room at Materials Management and should be appropriately dated

GRAY NERVE AGENT BOX ("GRAY BOX")

1. Each ALS unit shall store a gray pelican case containing drugs necessary to treat a patient exposed to organophosphate based nerve agents. Each box will contain the following:
 - 30 Duodotes
 - 30 auto injector diazepam 10 mg
 - 18 pralidoxime chloride (Protopam) (2-Pam) 1 gm/vial
 - 25 atropine 1mg/ml vials
 - 50 syringes, 3 ml with needle
 - 2 patient belonging bags for splitting contents of box during an MCI
 - Instructions on dosing for atropine, pralidoxime chloride and diazepam for nerve agent poisoning
 - Instructions on dilution of pralidoxime
 - Isopropyl alcohol prep pads
2. There are two (2) keys for the lock on each gray box so each paramedic can secure the box. The box shall be kept in a locked interior compartment of the ALS ambulance. An inventory control tag with an imprinted number will be affixed to the outside of the gray box. If the seal is missing or broken, the crew shall immediately notify the Shift Commander and a full inventory of the box shall take place.
3. On the outside of each box there is a sticker indicating the expiration date of the item with the earliest expiration date. One (1) month before the indicated expiration date the crew shall do

an inventory of the box and exchange soon to expire items at Materials Management. A new inventory control tag and a new expiration sticker shall then be secured.

ALS UNIT OUT OF SERVICE

1. When an ALS unit goes out of service (OOS), the two paramedics on duty shall conduct a controlled substance inventory. They shall complete the 'If OOS at end of shift' portion of the DSCAL indicating the CSR# ____, the Seal Tag # ____ they are securing the box with, and the Time OOS: ____. Both Medics shall sign the OOS portion of the DSCAL. (For example, if P-40 days goes in for shift change at 15:00 and there is no evening shift, they would complete the OOS at end of shift section of the DCSAL under Day Shift. When P3 goes OOS at 22:30, they would complete the OOS at end of shift section under the evening shift.)
2. The drug keys shall be placed in a controlled envelope and sealed. The paramedic placing the keys in the envelope shall sign on the line "Sealed By" and include date and time. The other paramedic shall sign on the line "Witnessed By". The keys shall be placed inside the drug box, and a uniquely numbered inventory control tag shall then be affixed to the drug box, preventing it from being opened. The serial number of the inventory control tag shall also be recorded on the DSCAL sheet in the OOS at end of shift section at the bottom of the DCSAL.
3. If the ALS unit is anticipated to be out of service for a single shift (e.g. P3, P16), the gray nerve agent drug box and orange medication box (containing sealed key envelope), and DCSAL will be secured inside the ALS closet in the station if so equipped. When the unit will be out of service for longer than one shift (e.g. P40, P41), or if there is a problem with the stations secure drug closet, the gray nerve agent drug box and orange medication box (containing sealed key envelope), and DCSAL will be stored in the ALS equipment storage closet at Theodore Glynn Way.
4. All user access transactions for the ALS closets will be reviewed by Professional Standards monthly.

RESTRICTED ACCESS

1. Only personnel authorized by Boston EMS to administer Schedule II, Schedule III or Schedule IV drugs may be allowed unaccompanied in the patient compartment of any unit when these drugs are accessible. Personnel not authorized by Boston EMS to administer these drugs must be accompanied by authorized personnel when Schedule II, Schedule III or Schedule IV drugs are accessible.
2. All ALS drugs, equipment and supplies shall be removed from an ambulance prior to being sent to a vendor for repair or other service. Fleet Services shall notify the Shift Commander so that Materials Management Personnel may facilitate the removal of drugs, equipment and supplies.

PYXIS MACHINE: REGISTRATION PROCESS

Requests to establish, suspend, or terminate access to the Pyxis dispensing unit, including any password changes, shall be made in writing to the Professional Standards Division, who in turn will coordinate all changes in access with BMC Pharmacy personnel. The list of active users within Pyxis will be reviewed monthly by the Boston EMS Pharmacy Liaison, with any inappropriate access immediately reported to Professional Standards for review.

PYXIS: NARCOTIC REMOVAL PROCEDURE

1. First paramedic logs in to Pyxis using their name and fingerprint and selects “ALL AVAILABLE Patients” icon at the bottom left of the screen.
2. On the next screen, select the “Add Temporary Patient” icon on the bottom right.
3. On the next screen, enter the information as follows:
 - 3.1. The last name field will always be “Boston EMS”
 - 3.2. The first name field will always be the Paramedic Unit designation (i.e. 3P55)
 - 3.3. Select “EMS” from the drop-down box in the Unit field. Everything else, including the “patient ID” field should remain blank, and click the Accept icon.
4. On the next screen, select “EMS Go To Kit”, select “1” and OK. “EMS Go To Kit” will move to the right side of the screen. Click on “Remove Med” at the bottom right.
5. PYXIS will now advise that a witness is required for the transaction and will prompt the witness (second Paramedic) to enter their username and BIO-ID
6. PYXIS drawer and pocket will now open and the screen will ask for a count. After confirming that there is one kit, enter “1” and click “accept”. Remove kit and click “accept” again.
7. The next screen will prompt you for the LOT Number. Enter the CSR number that appears on the kit you just removed and click “accept”.
8. Close the lid of the pocket, and then close the drawer, and sign out.
9. The Paramedics should then inspect the Kit ensuring that the Kit is intact, the red kit seal is intact, the contents of the kit appear undamaged, there is a blue replacement seal in the kit, and that the CSR number matches both the red and blue security seal numbers.
10. If there is anything wrong with the kit, its contents, the CSR, or any error messages or unusual behavior of the PYXIS machine immediately notify the on-duty Shift Commander, return the kit and CSR to the BMC Pharmacy on the and complete an unusual occurrence form.

EMPLOYEE RESPONSIBILITY TO REPORT DRUG DIVERSION

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of the Drug Enforcement Agency that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer (which, in the case of Boston EMS shall be Professional Standards and the Medical Director). The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy. (see: [21CFR1301.91](#))