

Appendix 12

R5MCAN EMS Medication Replacement, Exchange and Security Procedure

DEFINITIONS:

- R5MCAN: Region 5 Medical Control Authority Network
- EMS: Emergency Medical Service
- LOCAL: EMS agencies and hospitals that commonly work together as defined in appendix 7
- MCA: Medical Control Authority
- ALS: Advanced Life Support
- ADM: Automated Dispensing Machine (e.g. Pyxis® or Omnicell®)
- EMS Provider: An emergency medical technician (EMT) or paramedic
- Paramedic: An advanced provider of pre-hospital emergency medical care with formal training that includes, but is not limited to, human physiology, pharmacology and medication administration techniques.

LEGAL AUTHORITY:

This procedure has been developed in accordance with the State of Michigan EMS Protocols [JH1] and, where delegated tasks and responsibilities are concerned, with section 333.16215 of the Michigan Public Health Code and R 338.490(5) of the Pharmacy – General Rules adopted by the Michigan Board of Pharmacy.

PURPOSE [JH2]:

The R5MCAN EMS medication bag and controlled substance box regional exchange program is designed to improve the efficiency of the pre-hospital care system through the standardization of the EMS formulary of medications (type, quantity, and concentrations), simplification of the restocking procedures for perishable supplies, and the reduction of EMS personnel and pharmacy management time through the ability to re-stock at various transport destinations throughout Region 5. This procedure outlines the **participation, responsibilities, exchange procedures, accountability, and oversight** processes for the Region 5 EMS medication bags and controlled substance boxes. The procedure also provides guidance to ensure that the pharmacies receive all appropriate paperwork, thereby remaining compliant with applicable rules, regulations, policies and laws. All activities undertaken through the implementation of this procedure are to promote and ensure the universal ability for Region 5 EMS agencies to restock/exchange EMS medications at any participating hospital in the region. Despite procedural variance among the region's hospitals, a mechanism will be in place to allow for timely medication bag/box exchange for Region 5 EMS agencies including those not serving as primary EMS affiliates to hospitals.

PARTICIPATION:

1. This procedure applies to all hospital pharmacies, EMS agencies and MCAs participating in Region 5 as members of the Region 5 Medical Control Authority Network (R5MCAN).
2. Selection of the R5MCAN EMS Medication Bag and Controlled Substance Box Regional Exchange Program as a pick option in the MCA agreement will signify adoption of this procedure and will allow an MCA and its corresponding EMS agencies/pharmacies to enter into the medication bag exchange system. [JH3]
3. Each participating EMS agency should have a replenishment agreement with the hospital(s) it plans to exchange with. See Appendix 2 for a sample agreement.
4. Each participating MCA must have a minimum of one identified representative and one alternate to serve on the R5MCAN EMS Medication Bag Oversight Committee. Each MCA is encouraged to have an EMS and a pharmacy representative on the Oversight Committee.
5. The R5MCAN EMS Medication Bag Oversight Committee will meet on a regularly scheduled basis to review incident reports / concerns, follow up on inquiries, evaluate system performance and evaluate process improvement opportunities.
6. A regional formulary, based on the State of Michigan EMS Protocols, will be used to stock the bags/boxes in a uniform configuration to ensure interoperability between Region 5 pharmacies and EMS agencies. See Appendix 3 for contents lists, including pictures, for R5MCAN medication bags and controlled substance boxes.
7. MCA's electing to participate in the R5MCAN EMS medication bag and controlled substance exchange program are required to approve this system protocol by checking the appropriate MCA box below and submitting the adopted protocol for approval with a formal effective date to the MDHHS along with a medical director signature on the corresponding physician signature page presented in appendix 12.

Allegan County MCA

Barry County MCA

Berrien County MCA

Branch County MCA

Calhoun County MCA

Cass County MCA

Kalamazoo County MCA

St. Joseph County MCA

Van Buren County MCA

RESPONSIBILITIES:

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1. MCA Responsibilities:

- A. Participating MCAs will promote a relationship with local hospital pharmacies and EMS agencies ensuring communication pathways are in place to optimize system performance and accountability with regard to medication use and exchange.
- B. MCA physicians and staff agree to communicate changes in EMS medication bag/box formulary to system providers and pharmacists as changes are made by the R5MCAN EMS Medication Bag Oversight Committee.
- C. In collaboration with local EMS agencies and local pharmacies the MCA will ensure a process is in place to allow for EMS agency medication exchange.
- D. MCAs agreeing to participate in the EMS Medication Replacement and Exchange procedure must agree to enforce the provisions of this procedure.
- E. Each medical director or his/her designee at each participating MCA is responsible for ensuring MCA compliance with this procedure.

2. Pharmacy ^[JHH4] Responsibilities:

- A. Pharmacies will ensure a process is in place to restock and exchange EMS medication bags and controlled substance boxes.
- B. Pharmacies will ensure that EMS medication bags and controlled substance boxes are stocked in compliance with the regional medication formulary.
- C. Pharmacies will arrange for a secure environment for EMS medication bags and controlled substance boxes that are restocked and awaiting pickup or are used and have been dropped off for exchange.
- D. In collaboration with local EMS agencies and the local MCA, pharmacies may elect to have a process in place that delegates limited re-stock of common use items within the EMS medication bags to paramedics who have received appropriate, documented training. At a minimum, a process for “full-bag” exchanges with local and regional EMS agencies will be in place at each participating hospital.
- E. Pharmacies may have a separate exchange process for local EMS agencies versus non-local regional EMS agencies.
 - i. **Example:** A paramedic from a local EMS agency who has been granted access to the EMS Pyxis (or the designated, secured EMS restock cabinet) may perform limited paramedic re-stock when transporting to their local hospital(s). When transporting away from their local hospital(s) to another hospital in the region, the paramedic would do a full-bag (1 for 1) exchange.
- F. Pharmacies are required to routinely inspect EMS medication bag and EMS controlled substance box contents in compliance with the administrative rules of the Michigan board of pharmacy (R 338.486(4)(c)) and replace medications as necessary.
 - i. Pharmacies are responsible for verifying that all pharmacy-stocked supplies and medications listed on the regional medication and equipment formulary are present and in-date upon stocking/restocking. See Appendix 4 for a sample pharmacy EMS bag restocking sign-off form.
 - ii. Whenever possible, medications that are 60 days or less away from expiration will be rotated out of the medication bags and controlled substance boxes.
 - iii. After restocking, controlled substance boxes and the pharmacy-stocked compartments of the medication bags will be secured by pharmacy, utilizing numbered green tamper-resistant locks.
 - iv. In instances where the medication bag comes to pharmacy for restocking, pharmacy staff will *also* verify that all EMS agency stocked medications listed on the regional medication formulary are present and in-date. That pouch will then be sealed with a green lock with the item name and expiration date of the next item to expire in the compartment written on it^[JHH5].
 - v. Each EMS medication bag and controlled substance box shall have a label indicating the bag/box number, stocking hospital/pharmacy that filled it, fill date, next medication to expire, date of expiration, and the name or initials of the individuals that filled/checked it.
- G. Medication bag and controlled substance box contents remain the property of the participating pharmacies.
- H. The Pharmacist in charge at each participating hospital is responsible for assuring compliance with this procedure.

3. EMS Agency Responsibilities:

- A. Paramedics are responsible for turning in used medication bags and/or controlled substance boxes in a serviceable condition free from trash, contaminated waste and any potential sharps. Unsecured sharps and biohazard materials left in / on bags may result in disciplinary action by the agency.
- B. Paramedics will complete the appropriate documentation for medications/supplies used.

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- C. Paramedics will use the numbered red seal provided in the medication bag or controlled substance box to secure and tag a used/expired bag/box, alerting the pharmacy that attention to the bag/box is needed.
- D. EMS agencies are responsible for cleaning bags that become soiled or contaminated. In the event that a bag needs to be decontaminated or cleaned, an EMS agency may contact its local hospital pharmacy to arrange for securement of medications and to sign out a temporary replacement bag for use during the cleaning process.
- E. In collaboration with local pharmacies and their local MCA, EMS agencies will have the option to establish a process for limited paramedic re-stock of common use items within the EMS medication bags. At a minimum, a process for “full-bag” exchanges will be in place at participating region 5 hospitals.
- F. EMS agencies, in collaboration with the R5MCAN EMS Medication Bag Oversight Committee, will ensure paramedics receive documented training in the procedure for limited paramedic restocking and appropriate alternatives in case of omission/error in restocking before being delegated the authority to perform limited paramedic restock.
- G. EMS agencies will provide an end user agreement (Appendix 5) to the appropriate hospital pharmacy representative at each hospital granting access for each paramedic who will have access to an ADM or locked cabinet for the purpose of medication bag and controlled substance box exchange.
- H. EMS agencies are responsible daily for ensuring that all medication bags and boxes in their possession are current, without expired medications, and have appropriate seals and labels in place. Expired medications will be exchanged with the local hospital pharmacy.
- I. EMS agencies are accountable for the security of the bags / containers and the contents therein issued to their control by the participating pharmacies.
- J. EMS agencies are responsible for maintaining a chain of custody for EMS controlled substance boxes, including a procedure for documenting a dual sign off at least every 24 hours using the R5MCAN EMS Agency Controlled Substances Box Log Sheet (see Appendix 6) or an acceptable equivalent that has been approved by the R5MCAN EMS medication bag oversight committee.
- K. EMS agencies that do **not** have a one-to-one controlled substance box-to-truck assignment process will maintain a locked cabinet or safe in a fixed location. The cabinet will require TWO access means/keys and TWO State of Michigan Licensed EMS providers one of whom must be a paramedic [JHH6] to be present simultaneously for access.
- L. All applicable sign in/out documents (agency/hospital) must be fully completed for both bags and controlled substance boxes being issued/returned.
- M. The participating EMS agency director/manager or his/her designee is responsible for assuring compliance with this procedure.

Issuance of R5MCAN EMS Medication Bags and Controlled Substance Boxes

1. R5MCAN EMS medication bags will be uniquely numbered in a permanent fashion, both inside and outside, using the format 5D-YY-###. Controlled substance boxes will also be uniquely numbered in a permanent fashion using the format 5D-YY-###, and will be configured in such a way as to permit a visual inspection of the contents without opening the box.
2. Each medication bag and controlled substance box will have a restocking label prominently affixed to the outside of the bag/box, following the format below.

<p>REGION 5 MEDICAL CONTROL AUTHORITY NETWORK</p> <p>HOSPITAL NAME AND PHARMACY PHONE # PRE-PRINTED</p> <p>FILL DATE: _____ TECH/RPH: _____</p> <p>GREEN LOCK #: _____ RED LOCK #: _____</p> <p>NEXT TO EXPIRE: _____ EXP DATE: _____</p> <p>BAG/BOX #: _____</p>
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3. Refer to Appendix 3 for contents lists for R5MCAN medication bags and controlled substance boxes. [JHH7]
4. Any supplemental regional medication kits (such as the “TXA Kit”) must be individually labeled. Contents of these kits may be detailed in Appendix 3 or included as an additional appendix.
5. The R5MCAN EMS Medication Bag Oversight Committee will assign each EMS agency a number of bags and boxes consistent with their number of licensed ALS vehicles.
6. The R5MCAN EMS Medication Bag Oversight Committee will assign each participating hospital pharmacy a number of bags and boxes consistent with their expected volume of exchanges.
7. Additional bags and/or boxes will be issued to EMS agencies at the discretion of the local EMS Medical Director or his/her designee.
8. For special events requiring additional ALS vehicles or EMS staff to be in service, EMS agencies may contact their

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local hospital pharmacy to arrange to sign-out additional medication bags and/or controlled substance boxes temporarily.

EXCHANGE PROCEDURES:

1. EMS Medication Bags

- A. R5MCAN EMS medication bags contain the following pockets:
 - i. Blue pocket – IV supplies, restocked by paramedic / EMS provider.
 - ii. Green pocket – Frequently used medications and supplies, paramedic or pharmacy restocked depending on facility/agency agreement and paramedic qualifications.
 - iii. Black (main) pocket – Medications restocked by pharmacy
 - iv. Red pocket – Sharps container
 - v. Yellow pocket – Controlled substance box restocked by pharmacy
- B. Refer to the R5MCAN EMS Medication Bag and Controlled Substance Box Exchange Matrix (Appendix 7) for exchange procedures specific to each participating hospital. Hospitals without 24 hour on-site pharmacy services may have procedures for “after hours” that differ from those during normal business hours.
- C. Paramedics must fill out the R5MCAN EMS Medication Bag Refill Form (Appendix 8) for any medications or supplies used from the black or green compartments when turning in the bag for restocking by pharmacy. The R5MCAN EMS Medication Bag Refill Form should be placed in the used bag after completion.
- D. When paramedic stocked compartments of the EMS medication bag are opened in the course of patient care, paramedics may restock those compartments following hospital-specific procedures with the following stipulations.
 - i. Paramedics must have successfully completed the R5MCAN limited paramedic restock training module before being granted ADM or medication cabinet access (if available).
 - ii. The hospital is one of the EMS agencies local hospital(s) as defined in appendix 7 and must allow limited paramedic restock.
 - iii. Paramedics are responsible for verifying that all paramedic stocked supplies and medications listed on the regional medication and equipment formulary are present and in-date upon stocking.
 - iv. Paramedic stocked compartments must be secured by a white lock [JHH8] with the identifier of the EMS agency, the name or initials of the paramedic restocking the compartment, and the name and expiration date of the next item to expire in the compartment written on it.
- E. When the pharmacy stocked compartment of the EMS medication bag is opened in the course of patient care, paramedics are to exchange the medication bag itself for another bag at the destination hospital.
 - i. When turning in a used medication bag, the paramedic must ensure trash, contaminated waste and any potential sharps have been removed from the bag and then seal the pharmacy stocked compartment with the included red tag.
 - ii. The paramedics must remove the LOCKED controlled substance box, sharps box, and IV kit from the open bag, moving those items to the new medication bag obtained from the destination hospital.
 - iii. If the bag exchange is occurring at a hospital in the region that is NOT the agency’s “local” hospital, or one without a provision for paramedic restock, a full bag exchange will be done. In those cases, any used compartments will be sealed with a red tag [JHH9] and the paramedic will remove the LOCKED controlled substance box, sharps box, and IV kit from the open bag, moving those items to the new medication bag obtained from the destination hospital.

2. EMS Controlled Substance Boxes

- A. Refer to the Regional EMS Medication Bag and Controlled Substance Box Exchange Matrix (Appendix 7) for exchange procedures specific to each participating hospital. Hospitals without 24 hour on-site pharmacy services may have procedures for “after hours” that differ from those during normal business hours.
- B. EMS ALS units should only operate with a confirmed LOCKED controlled substance box on board. Under NO circumstances will an open box go into service.
- C. Paramedics exchanging controlled substance boxes must be in uniform and have a valid picture ID (either a driver’s license or agency/regionally issued ID).
- D. When a controlled substance box is used, the R5MCAN Controlled Substances Documentation Form (Appendix 9) must be completely filled out prior to exchanging the box.
 - i. Any medication waste and/or disposal of empty vials must be witnessed and cosigned on the controlled substances documentation form by a registered nurse, pharmacist, or physician.
- E. A copy of the **EMS patient care record (PCR) or 5th District EMS Field Notes (appendix 1) [JHH10]** must be

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placed in the controlled substance box being turned in.

- i. The PCR/5th District EMS Field Note serve as a record of the prescription for the administration of medications given to a patient as prescribed in protocol or by medical control.
 - ii. PCR/5th District EMS Field Note must list the date of service, EMS agency run number, medication(s) administered, any wasted medication(s), name of the paramedic administering the medication and the corresponding controlled substances box number.
 - iii. PCR/ePCR/5th District EMS Field Note must include the wasted medication type, amounts, and volumes in addition to the narcotics box number and broken green tag number.
- F. When turning in a used controlled substance box, the paramedic must ensure trash, empty vials, contaminated waste and any potential sharps have been removed from the box and then seal it with the pharmacy-included, numbered red lock. The red lock number must match the one written on the box's label.
- G. Upon receiving a used box from an EMS service, pharmacy staff will check to assure that it is properly sealed with a red tag and includes a fully completed R5MCAN Controlled Substances Documentation Form and EMS PCR/5th District EMS Field Note. The submitted documentation will be checked by the pharmacist against the remaining contents of the box to assure accountability, with deficiencies reported as described in the next section.
- H. Pharmacies must carefully document paramedic narcotic utilization and restocking of controlled substance boxes. See Appendix 10 for a sample documentation log. PCRs/Field Notes, R5MCAN Controlled Substances Documentation Forms, and restocking logs must be saved for five years.
- I. Restocked controlled substance boxes must be secured by the pharmacist with a numbered green lock. Prior to taking a new controlled substance box, the paramedic must ensure that the box is properly secured/stocked, drugs are inaccessible, and that the green lock number matches the one written on the box's label.

ACCOUNTABILITY:

1. Incident Reporting

- A. Controlled substance boxes that appear damaged from routine use / normal wear and tear must be reported to the R5MCAN EMS medication bag oversight committee via the R5MCAN on-line occurrence form and the box must be taken to the EMS agency's local hospital pharmacy for change out.
- B. Discrepancies found on pharmacy inspection of the medication bags should be reported to the Oversight Committee via the R5MCAN on-line occurrence form.
- C. Any suspected system diversion of controlled substances including but not limited to a missing controlled substance box, missing controlled substance vials in a box, evidence of tampering with controlled substance vials (including missing caps or vial breakage), or evidence of suspicious damage to / tampering with a controlled substance box, will immediately be reported to Kalamazoo County Medcom at **(269)-226-3366** [JHH11]
 - i. Kalamazoo County Medcom will notify the on-call R5MCAN EMS medication bag oversight committee member.
 - ii. The R5MCAN EMS medication bag oversight committee member will immediately notify the local MCA medical director, EMS agency manager / director, and the appropriate hospital pharmacy.
 - iii. The R5MCAN EMS medication bag oversight committee member will assist local level entities in the coordination of a timely formal investigation. Law enforcement investigation will be included as needed.
 - iv. Report of missing controlled substances will be made to the State of Michigan Board of Pharmacy and to the U.S. Drug Enforcement Agency by the pharmacy in accordance with State and Federal laws and regulations.
 - v. Pharmacies may, based on hospital policies, test patients that have received pre-hospital narcotics.
- D. Local Medical Control Authorities in cooperation with pharmacies may require that EMS controlled substances be tested prior to waste at any time.
- E. Suggestions for process improvement should be forwarded to the R5MCAN EMS Medication Bag Oversight Committee.

2. EMS Medication Bag and Controlled Substance Box Audits [JHH12]:

- A. All EMS medication bags and controlled substance boxes used in the regional exchange program must be accounted for on a monthly basis. On the first Tuesday of each month, each EMS agency, MCA or pharmacy having EMS medication bags or controlled substance boxes must perform an accounting of medication bags and controlled substance boxes between 6AM and 9AM and then log the bag or box numbers into the R5MCAN on-line audit form prior to noon that same day.

Approval of Medical Director from each MCA


Regional Medical Control Authority Network
Allegan, Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St Joseph & Van Buren Counties
Medical Directors' Acknowledgement/Approval:

To submit the proposed *EMS Medication Replacement, Exchange and Security Procedure* and associated appendices to the State of Michigan Bureau of EMS Trauma and Preparedness for review and approval, so that it may be implemented by the undersigned MCAs in Region 5.

MCA	Name (signature)	Title	Date
Allegan County	 Joshua Mastenbrook, MD	Medical Director	4-11-2018
Barry County	 Matt Scarff, MD	Medical Director	4/13/18
Berrien County	 Jonathan Beyer, DO	Medical Director	4/13/18
Branch County	 David Fuchs, MD	Medical Director	5-2-18
Calhoun County	 Tyler Vaughn, MD	Medical Director	4/15/18
Cass County	 GREG HAMMONS, DO	Medical Director	4/16/2018
Kalamazoo County	 William D. Fales, MD	Medical Director	4.11.18
St Joseph County	 Christopher Milligan, DO	Medical Director	4/16/2018
Van Buren County	 Andrea Allman, DO	Medical Director	4/13/18