

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

PURPOSE

The purpose of this protocol is to define the process by which pre-hospital providers will exchange medication boxes/A-Packs.

PROTOCOL

- A. Pharmacies operating within the member hospitals of the Medical Control Authority participate in the medication exchange system established by this protocol.
- B. The pharmacy is responsible for ensuring that restocked EMS medication boxes/A-Packs are available to EMS units who bring in a used box for replacement. The Administrative Rules of the Michigan Board of Pharmacy (R 338.486(4)(c) require that “The pharmacist shall routinely inspect these medications and, after use, shall verify the contents and replace the medications as necessary”.
- C. The pharmacy is responsible for providing a secure environment for restocked medication boxes/A-Packs awaiting pickup by an EMS unit and used boxes brought back for restocking.
- D. Upon receipt of a used/sealed box/A-Pack from a pre-hospital provider, the pharmacy will check to ensure that the box/A-Pack is properly sealed and contains physician signed documentation of medication use. The documentation will be checked, by the pharmacist, against the remaining contents of the box to ensure accountability for all medications.
- E. The pharmacy will replace the used contents of the medication box/A-Pack, and verify that all supplies and medications listed on the Medical Control Authority medication box/A-Pack inventory form are present. The box/A-pack will be sealed and secured.
- F. The refilled medication boxes/A-packs will then be relabeled with an orange pharmacy label which contains, at a minimum:
 - I. The hospital name.
 - II. The name of initials of the pharmacist checking the box.
 - III. The date the box was restocked and checked.
 - IV. The expiration date of the first drug to expire in the box (this date must be at least 90 days from the date the box is being restocked and checked).
 - a. For products in short supply hospital pharmacies may stock the Medication Boxes/A- Packs with drugs with less than a 90 day expiration date.
 - V. The tag number of the locks assigned to the box.
- G. Medication box/A-Pack contents remain the property of the participating pharmacy. The medication box itself is owned by the entity (EMS or hospital) that purchased it and entered it into the system. The Medical Control Authority will maintain a listing of the drug box numbers currently “in service”, and will assign new drug box numbers, as needed.

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

VEHICLE STOCK

- A. Each approved ALS unit will carry one GREEN LOCK SEALED Macomb County Medication Box and SEM Regional A-Pack (Ancillary Pack). Only appropriately numbered boxes and A-Packs issued by the participating Medical Control Authority are to be stocked by participating hospital pharmacies and issued to approved ALS units.
- B. Each EMS agency will be responsible for providing any additional equipment required by Michigan Department of Community Health - EMS Division (MDCH).
 - 1. Items are available for a one-for-one exchange as listed on the MCMCA Ambulance Supply Replacement Form.
- C. Medication Boxes/A-Packs will remain sealed at all times except when in actual use.
- D. Medication Boxes/A-Packs are to be inspected daily by the crew of the unit for evidence of loss, theft, discrepancy, and expiration date. Inspection items include, but are not limited to; the Medication Box/A-Pack is locked in a compartment, the green lock is intact, the lock # matches number on sticker, medications are not expired. It is recommended that this inspection be included in a standard documented vehicle checklist.
- E. Unopened Medication Boxes/A-Packs are to be exchanged within seven (7) days of the, "Use or Replace By" date.

USE/REPLACEMENT/EXCHANGE

- A. Medication Boxes/A-Packs will only be opened by a Paramedic when presented with a patient requiring Advanced Life Support care (when acting on written or transmitted orders from a physician at an appropriate On-Line Medical Control Facility) or pre-contact provisions of approved treatment protocols.
- B. Red/Green Lock Procedure for Medication Boxes/A-Packs
 - 1. The Box/A-Pack will be sealed using a green lock bearing the number indicated on the label.
 - 2. After the pharmacy inventory/restocking is complete, a red lock bearing the number indicated on the label will be placed in the Medication Box/A-Pack to be used by the Paramedic to seal the Box after it has been used.
 - 3. When the Box/A-Pack is opened by the Paramedic the broken numbered green lock will be placed in the Box/Pack and delivered with the used Box/Pack to the replacing pharmacy.
 - 4. After use the Paramedic will seal the Medication Box/A-Pack for exchange with the red lock from the Box/A-Pack bearing the number indicated on the label.

MEDICATION BOXES:

- A. All Participating Hospitals will have Medication Boxes/A-Packs, with contents as approved by the participating Medical Control Authorities and MDCH, available for replacement of supplies used by approved ALS Units. Replacement Boxes/Packs will be maintained in a locked area, under the control of hospital staff, which is available 24 hours a day, 7 days a week. This area will be located within either the Emergency

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

Page 3 of 8

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- Department or Pharmacy of the Participating Hospital. Appropriate record keeping and security measures are required at each exchange site to ensure that only appropriately licensed and authorized personnel have access to medications, and other related supplies.
- B. Medication Boxes/A-Packs used by approved ALS units for patients transported will be replaced, at the time of the run, by the receiving hospital according to established procedure. Where the receiving facility does not participate in the Macomb County Exchange System and/or supplies are expended for a patient who subsequently is not transported, the unit will proceed immediately to the nearest Macomb County Participating facility to complete the exchange. A PCR will be submitted when completed.
 - C. Use of any supplies contained in the Macomb County Medication Box or SEM Regional A-Pack will be documented on the Use/Replacement Form for exchange and the ALS Run Report or printed ePCR form of the patient for whom the supplies were used. This includes any medications or supplies prepared for use but not actually administered to the patient.

BOX CLEANING

- A. All empty containers, packaging and used materials will be properly disposed of by the ALS crew that used the Medication Box/A-Pack.
- B. The EMS crew using standard hard surface decontamination techniques will clean any blood or body fluid contamination to the exterior of the drug box.
- C. If there is blood or body fluid contamination to the interior of the Box/Pack, or to any unused materials or packaging, the EMS crew will clean and dispose of contaminated material per protocol. If direction is needed in the cleaning and disposal of contaminated materials the crew can contact the receiving hospital pharmacy.
- D. All unused, un-contaminated supplies will be returned to the Medication Box/A-Pack.

THE ALS CREW WILL:

- A. For all Macomb County runs, complete the Use/Replacement Form contained in the Medication box/A-Pack. The form shall serve as the permanent medical record of physician orders for drugs administered. This record shall not be valid without a physician signature.
- B. The ALS crew is responsible for proper distribution of the completed forms.
- C. The expended Medication Box/A-Pack (cleaned as described above and red sealed) and the completed Documentation of Use Form will be presented to an appropriate member of the hospital staff who will issue a fresh Medication Box/A-Pack (green seal). A member of the ALS crew and the hospital staff member will complete the exchange log sheet.
- D. In the event that controlled substances are prepared for use and not used or the entire contents of a container are not used, the remaining medication will be appropriately wasted by ALS crew member in the presence of licensed hospital personnel/or other ALS crew member. Documentation of waste must be completed before the physician signs the Documentation of Use Form.

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

The following will be recorded on the Documentation of Use Form:

- 1) The name and amount of the medication wasted.
 - 2) The initials of the ALS crew member and hospital personnel or other ALS crew member witnessing the waste.
- E. All requests for information concerning the “Document of Use Form” by other agencies are to be directed to the appropriate Medical Control Authority.

EXPIRATION OF DRUGS/SOLUTIONS

- A. All items in a SEM Regional Medication Box/A-Pack will have expiration dates not less than 90 days after the Box/Pack is prepared.
- B. Any unused items bearing expiration dates less than ninety (90) days subsequent shall be removed from the Box/Pack and replaced with fresh stock as described in letter A above.

MEDICATION BOXES – ALTERNATIVE PACKAGING AND SHORTAGES:

- A. Routinely, participating hospital pharmacies must provide items only in the dosage, concentration, and packaging listed. Use of alternative vendors or manufacturers is acceptable if consistent with the required contents.
- B. For products in short supply hospital pharmacies may stock the Medication Boxes/A-Packs with less than a 90 day expiration date.
- C. When a medication in alternative packaging is the only product available, place alternative medication, use directions and supplies for medication preparation inside the Medication Box/A-Pack.
- D. Attach the green Macomb County Altered Contents sticker to the exterior top of the Medication Box or inside the clear label window of the A-Pack stating the substitution.

DISCREPANCIES

DEFINITION: For purposes of this policy, a "discrepancy" is any breakage, expiration, shortage, theft or diversion of a Medication Box/A-Pack, or any contents thereof.

- A. A standard "DRUG BOX INCIDENT REPORT FORM" will be completed each time a discrepancy occurs. The form may be initiated by either pre-hospital or hospital staff discovering the discrepancy. The person initiating the report will be responsible for distributing the forms as required.
 1. The “Drug Box Incident Report Form” is page two of the MCMCA Medication Replacement Form and may be obtained from the MCA office or online at: www.mcemsmca.org (“Resources” tab).
- B. The Medical Control copy of incident/discrepancy reports will be sent to the Medical Control Authority in which the discrepancy occurred, which will serve as the central filing point.
- C. A copy of the ALS run form for the run on which the discrepancy occurred/was discovered is to be attached to each copy of the discrepancy report where applicable.
- D. The participating hospital pharmacist is to be notified immediately if controlled substances are involved in a discrepancy. The participating hospital pharmacist, in

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

Page 5 of 8

cooperation with the MCA Medical Director, Pharmacy Committee Chair, and MCA CQI Coordinator will determine if the discrepancy constitutes a diversion of controlled substances.

In the event that a diversion of controlled substances is substantiated, the following will be notified:

1. Michigan State Board of Pharmacy
 - a. This report will be completed and filed by the assigned base hospital pharmacist handling the investigation.
 - b. The State Pharmacy Board will notify the DEA should they decide it is necessary.
2. Appropriate local law enforcement agency (for the jurisdiction where the diversion most likely took place)
 - a. Contact made by base hospital pharmacy
3. Michigan Department of Community Health (MDCH).
 - a. Contact made by MCA Staff.

- E. The participating hospital pharmacist, in conjunction with MCA staff, will assure that all appropriate notifications are made.

USE OF COMPOUNDING PHARMACIES

Only FDA approved commercially available products will be used whenever possible. If normal procurement procedure fails all reasonable attempts to procure an alternative, commercially available product must be made prior to using a compounded product. If no FDA approved commercially available products are available then all compounded products must come from a pharmacy that is accredited by the Pharmacy Compounding Accreditation Board (PCAB), must follow all USP guidelines, must be licensed as a pharmacy in the State of Michigan and must have a current Michigan Controlled Substances license if a controlled substance is being ordered. Compounded products when placed in an MCMCA drug box or SEM A-Pack shall be in tamper-resistant packaging. A compounded product will not be used once a commercially manufactured product becomes available.

THIS SPACE LEFT BLANK:
Macomb Drug Box and SEM Regional A-Pack Contents and Exchange Forms Below
(Contact MCA Office for Printable Versions of Forms)

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

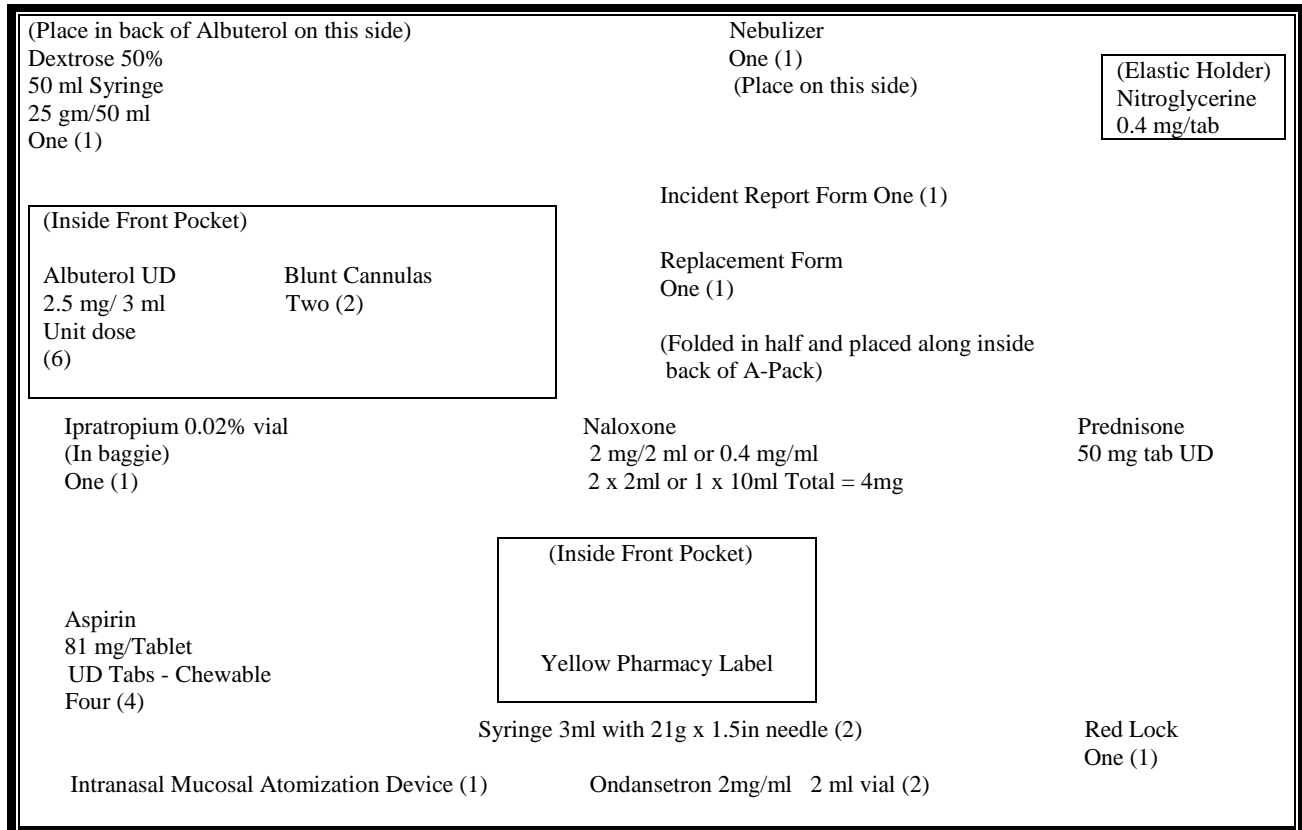
SEM/EMS ACCESSORY PACK (A-PACK) CONTENTS

Version 11 – March 2013 (Discard all previous versions)

DRUG/ITEM	CONCENTRATION	PACKAGING	QUANTITY
Albuterol	2.5 mg/3 ml	3 ml vial – UD	6
Aspirin	81 mg/tablet	UD Tabs – Chewable	4
Dextrose 50%	25 gm/50 ml	50 ml Syringe	1
Intranasal Mucosal Atomization Device			1
Ipratropium Bromide (in baggie)	0.02%	2.5 ml vial – UD	1
Naloxone	2 mg/2 ml or 0.4 mg/ml	2 x 2ml or 1 x 10ml	Total = 4mg
Nitroglycerin	0.4 mg/tab	Bottle	1
Nebulizer			1
Ondansetron	2mg/ml	2ml vial	2
Prednisone	50 mg tab	50 mg tab	1
Blunt Cannula 18 g – 1 inch			2
Syringe 3ml with 21g x 1.5in needle			2
Red Lock			1
Replacement Form			1
Incident Report Form			1

SEM/EMS ACCESSORY PACK (A-PACK) SCHEMATIC

NOTE: Green Lock through zipper and eyelet. Loose/Common Items to be placed in zip-lock bags.



Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

MACOMB COUNTY DRUG BOX/A-PACK SUPPLY USE/REPLACEMENT FORM Version: 001- August 2013

AGENCY/UNIT #: _____ **HOSPITAL:** _____ **DATE:** _____

INCIDENT #: _____ **EMS CREW (Names):** _____

MEDICATION	UNIT/SIZE	QNTY	USED	CHRG
Acetaminophen 650mg/20.3 ml 10 ml oral syringe in bag	Unit dose cup	1		
Adenosine 6mg/2ml	Vial/Syringe 2 ml	5		
Albuterol 2.5 mg/3 ml.*	Vial - UD 3 ml. A-Pack	6 6		
Amiodarone 150 mg/3 ml	Amp/Vial	3		
Aspirin 81 mg tablets*	Bottle - chewable Or 4 UD tabs A-Pack	1 4		
Atropine 1mg/10 ml.	Syringe 10 ml	3		
Calcium Chloride 1 gm/10 ml.	Vial 10 ml.	1		
Dextrose 50% 25 gm/50 ml*	Syringe 50 ml. A-Pack	2 1		
Diphenhydramine (Benadryl) 50 mg/1 ml	Vial 1 ml.	2		
Dopamine 400 mg/5 ml	Vial	1		
Epinephrine 1 mg/10 ml	Syringe 10 ml.	6		
Epinephrine 1:1,000	Ampule 1 ml	2		
Ipratropium Bromide 0.02% *	2.5 ml Vial - UD A-Pack	2 1		
Lidocaine 100mg/5ml	Syringe 5ml	3		
Lidocaine Jelly 2%	Tube 5 ml/30 ml.	1		
Lidocaine Infusion 0.04% / Dextrose (4mg/ml)	250 ml bag	1		
Magnesium Sulfate 1 gm/2 ml	Amp/Vial	2		
Methylprednisolone 125mg	Vial	1		
Naloxone* 2 mg/2 ml or 0.4mg/ml	Syringe 2 ml A-Pack	3 4mg		
Nitroglycerin* 0.4 mg/tab	Bottle A-Pack	1 1		
Ondansetron 2mg/ml*	2ml vial A-Pack	2 2		
Prednisone 50 mg tab*	50 mg. tab A-Pack	1 1		
Sodium Bicarbonate 50 mEq/50 ml	Syringe 50 ml.	1		
Sodium Chloride 0.9%	Bag 250 ml.	2		
Sodium Chloride 0.9%	Bag 500ml	1		
Dextrose 5%	Bag 500 ml	1		
CONTROLLED SUBSTANCES	UNIT/SIZE	QTY/ DOSE	USE/ WASTE*	CHRG
Diazepam 10 mg/2ml	Vial/syringe 2 ml.	2		
Fentanyl 50 mcg/ml	Vial/Amp 2 ml	3		
Midazolam 5mg/1ml	Vial 1ml	2		
Morphine 10 mg/1ml	Amp 1 ml	2		

Documentation of Controlled Substance Waste (Please Print)

Witness: _____ **Medic:** _____

Needless stock only! * Items in both Medication Box and A-Pack

MISCELLANEOUS	UNIT/SIZE	QNTY	USE D	CHRG
Replacement Form *	Ex.	1		
Primary IV Set 60 gtt/ml Micro	Ex.	3		
Primary IV Set 10 gtt/ml Macro	Ex.	1		
IV Extension Set Amsino or other pressure rated.	Ex.	1		
Tubex Holder	Ex.	1		
Intranasal Mucosal Atomization Device *	Ex.	1		
Nebulizer	Ex.	1 A-Pack Only		
Blunt Cannula 18g - 1 inch	Ex.	2 A-Pack Only		
Syringe w/ needle 3 ml - 21g 1.5 inch	Ex.	2 A-Pack Only		
Red Lock*	Ex.	1		
Fluids Used (Circle Used)				
		NACL 0.9% 1000 ml	NACL 0.9% 500 ml	

Ordering Hospital: _____

Ordering Physician: _____

Replacing Hospital: _____

Receiving Physician Signature: _____

Date: _____

PARAMEDIC'S STATEMENT

Macomb EMS Medication Box SEM Regional A-Pack (check one)
 number _____ has been opened and the above noted medication(s)
 used as prescribed. I accept pharmacy sealed Macomb EMS Medication
 Box / A-Pack Number _____ sealed with breakaway tag number
 _____.

Paramedic Signature: _____ **Date:** _____

REPLACING PHARMACIST'S STATEMENT

The medications in the sealed Macomb EMS Medication Box / SEM
 Regional A-Pack No. _____ have been distributed according to the
 Medication/Use and Replacement Policy of the participating Medical
 Control Authority. All medications are in the correct concentration,
 dosage form, volume, amount, and not expired.
 Name of Pharmacist on the Seal: _____

Signature of Replacing Pharmacist: _____

Date: _____ **Hospital:** _____

Patient Name: _____

Address: _____

City/State/Zip: _____

Macomb County
System Protocols
MEDICATION EXCHANGE AND REPLACEMENT PROCEDURE

SEM A-PACK SUPPLY USE/REPLACEMENT FORM

Agency/Unit #: _____ **Incident#:** _____ **Date:** _____ **EMS Crew Names:** _____

Replacing Hospital: _____

Paramedic's Statement

SEM EMS A-Pack # _____ **has been opened and the noted medication(s) used as prescribed. I accept pharmacy sealed SEM EMS A-Pack #** _____ **sealed with breakaway #** _____.

Paramedic Signature: _____ **Date:** _____

Replacing Pharmacist's Statement

The medications in the sealed SEM EMS A-Pack # _____ **have been distributed according to the Medication/Use and Replacement Policy of the participating MCA. All Medications are in the correct concentration, dosage, form, volume, amount, and not expired.**

Signature of Replacing Pharmacist: _____

Hospital: _____ **Date:** _____

Patient Name: _____

Address: _____

MEDICATION	UNIT/SIZE	QNTY	USED	CHRG
Albuterol 2.5 mg/3 ml	Vial – UD 3 ml	6		
Aspirin 81 mg tablets	Bottle –chewable or UD tablets	4		
Dextrose 50% 25 gm/50 ml	Syringe 50 ml.	1		
Ipratropium Bromide 0.02% (In Baggie)	2.5 ml Vial – UD	1		
Naloxone 2 mg/2 ml or 0.4 mg/ml	Vial 2 ml Or 20 ml	4 mg		
Nitroglycerin 0.4 mg/tab	Bottle	1		
Ondansetron 2 mg/ml	2 ml Vial	2		
Prednisone 50 mg tab	50 mg Tab	1		
Nebulizer		1		
Blunt Cannula 18g – 1 inch	18g-1 inch	2		
Intranasal Mucosal Atomization Device		1		
Syringe w/needle 3 ml – 22g 1.5 inch	Syringe 3 ml	2		
Red Lock		1		
Replacement Form	A-Pack Form	1		

Needleless Stock Only! Version 12 August 2013

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(Contact MCA Office for Printable Versions of Forms)