

Policy Title: <b>APPROVING / ISSUING / EXCHANGING DRUGS &amp; SUPPLIES</b>			No. D - 3
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## References:

IDPH. (April 15, 1997). EMS Rules: Sections 515.330 EMS Program Plan; 515.360 Approval of Additional Drugs and Equipment.

Illinois Pharmacy Act Subpart R: Pharmacy or drug and medicine service, Section 250.2110.

JCAHO. (12/15/00). Pharmacy FAQs Care Function: Medication Use Standards.

Dept. of Health & Human Services Office of Inspector General (OIG) (December 4, 2001). Final rule: Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute [FR 65(99), 62979-62991].

I. **POLICY**

- A. The EMS Program Plan shall contain a list of all drugs and equipment required for each type of System vehicle and procedures for obtaining replacements at System hospitals (EMS Rules).
- B. Restocking arrangements are implemented by and monitored by the EMS System in cooperation with all members.
- C. All hospitals and ambulance providers must otherwise comply with all federal, state, and local laws regulating emergency medical care and the provision of drugs and medical supplies, including the laws relating to the handling of controlled substances.
- D. **General restocking:** Each System hospital agrees to replace drugs and medical supplies and provide for equipment exchange for items on the NWC EMSS Drug & Supply List on an equal basis for all EMS vehicles that bring emergency patients to their facility (Section 3.20(b) of the EMS Act) in one or more of three categories:
  1. All ambulance providers;
  2. All non-profit and State or local government ambulance service providers (including, but not limited to municipal and volunteer ambulance services providers); or
  3. All non-charging providers (typically volunteer providers) (OIG Rule).
- E. A receiving facility can offer restocking to more than one category, and can offer a different restocking program to each category that it restocks, so long as the restocking is uniform within each category (OIG Rule).
- F. Except for government-mandated or fair market value restocking protected restocking arrangements must be conducted in an open and public manner. A restocking arrangement will be considered to be conducted publicly if: (i) A disclosure notice is posted conspicuously in the receiving facility's emergency department or other location where ambulance providers deliver patients that outlines the terms of the restocking program and copies are available to the public upon request (subject to reasonable photocopying charges) (see sample disclosure form); or (ii) The restocking program operates in accordance with a plan or protocol of general application promulgated by an EMS Council or comparable organization (with copies available to the public upon request). NWC EMSS policy satisfies this requirement.
- G. **Fair market value restocking:** This category protects restocking arrangements where an ambulance provider pays the receiving facility fair market value based on an arm-length transaction, for restocked medical supplies (including linens). The final OIG rule does not include the resale of drugs in this category.
  1. The restocking must be at fair market value, and
  2. Payment arrangements must be commercially reasonable and made in advance.

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- H. **Government-mandated restocking:** This final safe harbor protects restocking of drugs and supplies undertaken in accordance with a State or local statute, ordinance, regulations, or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to restock ambulances that deliver patients to the hospital with drugs or medical supplies that are used during the transport of that patient. This safe harbor does apply to all NWC EMSS provider agencies.
- I. All drugs and supplies available for EMS exchange shall be stored by hospitals in a "reasonably secure" manner to prevent diversion or tampering with the products. They shall be inspected to ensure the appropriateness of the drug/concentration/packaging, integrity of the packaging, to ensure that they are not near their expiration date (JCAHO), and shall be available to EMS personnel within a reasonable time frame to prevent prolonged down times at the hospitals awaiting exchange.
- J. Inclusion of any new drug, supply, solution or equipment on the Standard Drug and Supply List shall be a collaborative process between hospital and prehospital System members unless the EMS Medical Director (EMS MD) believes there are unusual and compelling medical reasons for requiring a product based on his prerogative alone.
- K. All drugs and equipment, other than those covered by the United States Department of Transportation National Standard Curriculum for each EMT level of licensure, must be approved by IDPH in accordance with Section 515.360, subsections (b), (c), and (d) of the EMS Rules before being used by the System.
- L. All new products added to the System Drug and Supply List that are consumable, patient exchange items are issued by the hospitals to those Provider agencies assigned to them through the System organizational chart. The cost of the initial inventory will be sustained by system hospitals. All durable medical goods (non-exchange items) will be purchased by the EMS providers.
- M. Either the hospitals or the ambulance providers must maintain records of restocked items and make the records available to the Department of Health and Human Services upon request (OIG).
- N. All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.
- O. Compliance with Section M will be determined separately for the receiving facility and the ambulance provider (and first responder, if any) so long as the receiving facility, ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations.

## II. PROCEDURES

- A. **Approving drugs:** Any new product being considered for use in the NWC EMSS must go through the following process prior to being added to the Standard Drug and Supply List:
1. Review by the EMS MD to determine if further evaluation or consideration is warranted or approved. If the EMS MD rejects the product for prehospital use in this System, the investigation process stops at this point.
  2. If the EMS MD approves the product for further review, the manufacturer/distributor shall be directed to the Research & Development (R&D) Committee to discuss the merits of the item with potential users.

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3. The R&D Committee will provide feedback on the strengths and perceived limitations of a product and may decide to conduct field-testing.
4. After evaluation and/or field-testing, the results shall be shared with the prehospital and hospital EMS Coordinators/Educators for further discussion and recommendations to the EMS MD.
5. The System is committed to responsible stewardship and agrees that any product purchase that would impact the capital budgets of providers or hospitals shall be brought to the Chiefs/Administrators PRIOR to making a decision for approval or developing a timeline for compliance.

**B. ISSUING NEW DRUGS AND SUPPLIES**

1. The Resource hospital EMS MD or his designee is responsible for communicating to hospital and Provider EMS Coordinators the name, approved manufacturer(s), type of packaging, amount and cost of product(s) to be added along with a compliance date.
2. Provider EMS Coordinators are accountable for ensuring that all EMS vehicles are appropriately stocked by compliance dates or a request for variance/waiver must be submitted to the Resource Hospital EMS office.
3. Provider chiefs or their designees are responsible for notifying their hospital EMS Coordinator of all proposed vehicle additions at least three months prior to their implementation to allow for appropriate inventory and budgetary planning for initial stocking.

**C. Security of EMS medications and supplies at System hospitals**

1. All Schedule II controlled substances (morphine) must be secured under lock and key based on DEA laws and regulations (JCAHO standard TX.3.4). These products must be stored in a "substantially constructed locked cabinet". Any controlled substance must be tightly controlled and accounted for, under law and regulation (See controlled substance policy).
2. Other drugs and products must be kept in areas that are not readily accessible to the public and/or easily removed by visitors. All areas restricted to authorized hospital personnel only are considered "secure" areas. Non-narcotic drugs stored in these areas do not need to be locked (JCAHO).
3. The security of EMS Medications should be addressed in a hospital's security management plan (JCAHO standard EC.1.4). As part of this plan, theft, pilferage and tampering should be reported. If medication security becomes a problem, it is expected that the hospital take additional steps to prevent it.

**D. Dispensing drugs/supplies on the Drug and Supply List**

1. Hospitals must adhere to internal policies and JCAHO standards with respect to dispensing ambulance supplies.
2. If using an Automated Dispensing Machine (e.g. Pyxis, etc), the machine is not a medical control system, but rather a tool that is part of the medication control system. Hospitals must ensure that the proper medication control systems (designed to prevent medication related sentinel events) are still in place when these machines are used.

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3. All medication use standards apply to drugs obtained via an automated dispensing device to the same extent as medications dispensed via the traditional unit-dose drug distribution system or floor stock (JCAHO).
4. IDPH has approved the use of automated dispensing machines for EMS drugs as long as the hospital has a policy on using these machines for controlled dispensing of supplies and drugs (Leslee Stein-Spencer letter to EMS Coordinators, 3/2/01).
5. Drugs kept in an automated dispensing machine are considered secure as long as access is limited to those people with a password and those people with a password are limited to those who have a need for access to the medications (nurse, pharmacy technician, pharmacists, physicians, paramedics) (JCAHO).
6. Hospital that use automated dispensing machines need to determine back-up systems for the distribution of medications if the machine breaks or the power fails (JCAHO).

**E. Adding drugs/equipment not included in the DOT curriculum**

1. It shall be the EMS Administrative Director's responsibility to seek approval from IDPH to use any new medications or equipment not included in the DOT National Standard Curriculum as well as to document training on the new medication/equipment. This documentation should include a copy of any curriculum used. See section (b) of the rules for specific information to be provided to IDPH.
2. IDPH shall either approve the drug and/or equipment, approve the drug and/or equipment on a conditional basis, or disapprove the drug and/or equipment. IDPH's decision shall be based on a review and evaluation of the documentation submitted, the application of technical and medical knowledge and expertise; consideration of relevant literature and published studies on the subject; and whether the drug and/or equipment has been reviewed or tested in the field. The Director may seek the recommendations of medial specialists and/or other professional consultants to determine whether to approve or disapprove the specific drug(s) or equipment.
3. An EMS MD shall not approve an EMT/PHRN to use new drugs or equipment unless that EMT/PHRN has completed the IDPH-approved training program and examination, and has demonstrated the required knowledge and skill to use that drug or equipment safely and effectively (EMS Rules).
4. An EMS MD is not required to provide new drug or equipment training to System EMTs who will not be using the new drugs or equipment.

**F. Lost, non-exchanged or damaged consumable items**

1. Any drug/supply that is lost, stolen damaged or not replaced at the time of use will be the fiscal responsibility of the Provider Agency to replace. Provider agencies should contact their designated System hospital to arrange for dispensing of replacement prescription drug products under these circumstances. They may replace other consumable supplies at the designated System hospital or per their own internal policies.
2. Ambulance providers shall be charged the fair market value for the replenished drugs or supplies. Commercially reasonable and appropriate payment arrangements must be made in advance. Nonprofit receiving hospitals may sell to nonprofit ambulance providers at cost (OIG).

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III. **Conditions applicable to all safe harbor restocking arrangements**

- A. Appropriate billing of Federal health care programs: All Federal health care programs must be billed appropriately. The ambulance provider and the hospital may not both bill for the same restocked drug or supply. This includes submitting claims for bad debt.
- B. **Documentation requirements:** Either the hospital or the ambulance provider may generate the necessary documentation so long as the other party receives and maintains a copy of it for 5 years. The prehospital patient care report is sufficient to satisfy this requirement if it (i) identifies the drugs and supplies used on the patient and subsequently restocked and (ii) a copy of the report is filed with the receiving facility within a reasonable amount of time. An exchange of linens will be presumed to occur with each run, absent documentation to the contrary.
- C. **No ties to referrals:** Restocking arrangements are prohibited that are conditioned on, or otherwise take into account, the volume or value of any referrals or other business generated between the parties for which payment may be made in whole or in part by a Federal health care program (other than delivery to the receiving facility of the particular patient for whom the drugs and medical supplies are restocked).
- D. **Compliance with all other applicable laws:** Both receiving facilities and the ambulance provider must comply with all Federal, State, and local laws regulating ambulance services including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances (OIG Rule).

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## SAMPLE NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers that bring patients to our hospital (or to a subpart of our hospital, such as the emergency department) in the following category or categories: (insert a description of the categories you agree to restock, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers) [Optional: We only offer restocking of emergency transports].
2. Restocking will include the following drugs and medical supplies, and linens, used for a patient prior to delivery of the patient to our hospital.

**NWC EMSS System Drugs as specified in the SOPs and Standard Drug and Supply List:**

<b>Adenosine</b> (Adenocard)	<b>Glucagon</b>
<b>Albuterol</b> (Proventil, Ventolin)	<b>Ipratropium</b>
<b>Amiodarone</b>	<b>Lidocaine</b> (xylocaine)
<b>Aspirin</b> (chewable form)	<b>Magnesium sulfate</b>
<b>Atropine</b>	<b>Midazolam</b> (Versed)
<b>Benzocaine 20%</b> spray	<b>Naloxone</b> (Narcan)
<b>Dextrose 50%</b> (glucose 50%)	<b>Nitroglycerin</b> (individual bottles of 25)
<b>Diphenhydramine</b> (Benadryl)	<b>Nitrous oxide</b> (Nitronox)
<b>Dopamine</b> premixed drip (Intropin)	<b>Ondansetron</b>
<b>Epinephrine 1:10,000</b>	<b>Sodium bicarbonate 8.4%</b>
<b>Epinephrine 1:1000</b> bisulfate free	<b>Tetracaine</b> (0.5% solution Pontocaine)
<b>Epinephrine 1:1000 adult &amp; peds</b> autoinjectors	<b>Vasopressin</b> (Pitressin)
<b>Etomidate</b> (Amidate)	<b>Verapamil</b>
<b>Fentanyl</b>	

**Medical supplies:** Those listed as exchange supplies on the NWC EMSS Standard Drug & Supply List

3. All non-profit and Federal, State or local government ambulance service providers (including, but not limited to municipal and volunteer ambulance services providers [will/ will not] be required to pay for the restocked drugs and medical supplies, and linens.  
  
All non-charging providers (typically volunteer providers) [will/ will not] be required to pay for the restocked drugs and medical supplies, and linens.  
  
All ambulance services that do not meet the criteria of one of the above categories [will/ will not] be required to pay for the restocked drugs and medical supplies, and linens.
4. The restocked drugs and medical supplies, and linens, must be documented at a minimum on the patient care report approved by each individual EMS System, filed with the receiving hospital within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.
5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.
6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.
7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.
8. For further information about our restocking program or to obtain a copy of this notice, please contact

Name \_\_\_\_\_ at Telephone number \_\_\_\_\_

Dated: \_\_\_\_\_

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Signature of appropriate officer or official