I. **POLICY**

A. The Northwest Community EMS System (NWC EMSS) is committed to the safe and secure stocking, storage, administration, documentation, disposal, replacement, and reporting of sentinel events relative to EMS drugs, pharmacologics, and medical supplies.

B. *The EMS Program Plan shall contain a list of all drugs and equipment required for each type of System vehicle and procedures for obtaining* initial stock and *replacements at System hospitals (EMS Rules).*

C. Drug/Pharmacologic and Supplies Management policies are implemented and monitored by the NWC EMS Medical Director (EMS MD) in cooperation with all members.

D. Drugs and pharmacologics stocked for EMS use shall be of suitable quality, quantity, concentration, and formulation for approved routes of administration per the SOPs and Drug & Supply List. Only those drugs and pharmacologics listed in the SOPs, the System Drug and Supply List, and/or approved by the EMS MD in written format shall be given by NWC EMSS personnel.

E. The EMS MD has the overall responsibility for ensuring that systems in place for the safe and secure handling of drugs and pharmacologics are followed.

1. Hospitals and EMS providers must comply with all federal, state, and local laws rules, and guidelines regulating ~~emergency medical care and~~ the provision, storage, exchange, and inventory management of drugs and medical supplies, including the laws relating to the handling of controlled substances.

2. Hospitals and EMS providers shall take all reasonable precautions to mitigate risks to patients and staff arising from the use of drugs/pharmacologics, medical supplies & equipment including but not limited to the safe use and security of those items.

3. Medications and pharmacologics shall be issued and stored in their original manufacturer's packaging or if reformulation is necessary, in packaging produced and labeled by a hospital pharmacist.

4. Provider Chiefs/Administrators or their designees are responsible and accountable for the day to day safe and secure handling of drugs and pharmacologics within the operational environment of their agency and must ensure that staff understand and are competent to carry out the duties described in this policy.

5. EMS personnel have a responsibility to maintain their competency in the management of drugs and pharmacologics and to ensure their familiarity with and compliance with changes to therapeutic guidelines as they are adopted in the SOPs.

II. **APPROVING NEW DRUGS AND SUPPLIES within the National EMS Education Standards and State Scope of Practice models:**

A. 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 MD believes there are unusual and compelling medical reasons for requiring a product based on his or her prerogative alone.

B. New products being considered for use in the NWC EMSS will usually 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.

3. The R&D Committee will provide feedback on the strengths and perceived limitations of a product and may decide to conduct field-testing with the prior authorization of the EMS MD.

4. After evaluation and/or field-testing, the results shall be shared with the Provider 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.

6. The EMS Administrative Director will file a System plan amendment with IDPH.

C. The EMS MD or designee will ensure the creation of educational materials, mandatory implementation of the education, and documented competency of all users prior to implementing the new drug/pharmacologic. ~~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.~~

III. **APPROVING NEW DRUGS AND SUPPLIES NOT within the National EMS Education Standards and State Scope of Practice models:**

A. The EMS MD or designee will seek approval from IDPH to use any new medications or equipment not included in the ~~DOT~~ National EMS Education Standards ~~Curriculum~~ and/or State Scope of Practice model.

B. 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 medical specialists and/or other professional consultants to determine whether to approve or disapprove the specific drug(s) or equipment.

C. If approved by IDPH, the EMS MD or designee will create education and competency measures as specified in Section II (C) above.

IV. **ISSUING NEW DRUGS AND SUPPLIES**

A. The Resource hospital EMS MD or his designee is responsible for communicating to the Chiefs/Administrators and Hospital and Provider EMS Coordinators (PEMSCs) the name, approved manufacturer(s), type of packaging, amount and cost of product(s) to be added along with a compliance date.

B. An EMS MD shall not approve EMS personnel to use new drugs or equipment unless that individual has completed the IDPH-approved education program and has demonstrated the required competencies and met the performance standards to use that drug or equipment safely and effectively (EMS Rules).

C. An EMS MD is not required to provide new drug or equipment training to System EMS personnel who will not be using the new drugs or equipment.

D. Provider Chiefs/Administrators or their designees are accountable for ensuring that all EMS vehicles are appropriately stocked by compliance dates or a waiver request must be submitted to the Resource Hospital EMS office and approved prior to the compliance date.

E. Provider Chiefs/Administrators or their designees are responsible for notifying their assigned hospital EMSC/educator of all proposed vehicle additions at least three months prior to their implementation to allow for appropriate inventory and budgetary planning for initial stocking.

V. **DRUG/PHARMACOLOGIC STORAGE and SECURITY of EMS supplies at System HOSPITALS**

A. 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 (JC), and shall be available to EMS personnel within a reasonable time frame to prevent prolonged down times at the hospitals awaiting exchange.

B. All Schedule II controlled substances (FentaNYL) must be secured under lock and key based on DEA laws and regulations (JC 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).

C. 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 (JC).

D. The security of EMS Medications should be addressed in a hospital's security management plan (JC 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.

E. 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.

VI. **DRUG/PHARMACOLOGIC STORAGE and SECURITY at EMS AGENCIES**

A. Drugs and pharmacologics shall be stored per the manufacturer's recommendations in a safe environment, and in an area that is not accessible by the public from the time of receipt to the point of use or disposal.

B. EMS personnel are personally responsible for the security of all drugs and pharmacologics while they are in their possession (chain of custody). This includes but is not limited to ensuring that ambulances are locked when out of ambulance quarters and not occupied by EMS personnel.

C. EMS vehicles shall be inventoried daily to ensure that drugs and pharmacologics are of suitable quality, quantity, sterility, concentration, formulation and within expiration dates.

D. It is recommended that stock be rotated between front line and reserve vehicles to encourage use prior to expiration dates.

E. Provider EMS Coordinators shall make random, unannounced checks of each vehicle within their agency plan at least every six months to ensure compliance with this policy. A record book must be kept including the identity of the person conducting the checks and retained for a period of two years from the date of the last entry.

F. **CLIMATE CONTROL**

1. Any place where medications are stored shall be sufficiently climate-controlled so that the medications and solutions are kept within the temperature range recommended by the manufacturer.

2. Standards for medications are set by the United States Pharmacopeial Convention Inc. (USP), a nongovernmental entity that establishes standards intended to ensure the quality of medicines and other healthcare technologies. The role of USP and its "National Formulary" (USP-NF) is recognized under the Federal Food, Drug and Cosmetic Act, including their authority to prescribe the packaging, storage, and distribution of medications.

3. Most medications used by EMS are intended for storage at "**controlled room temperature**". "A temperature maintained thermostatically that encompasses the usual and customary working environment of 20°-25° C (68°-77° F) that results in a mean kinetic temperature calculated to be not more than 25° C; and that allows for excursions between 15°-30° C (59°-86° F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40° C are permitted, as long as they do not exceed 24 hours. Spikes above 40° C may be permitted if the manufacturer so instructs. Articles may be labeled for storage at "controlled room temperature" or at up to 25° C (86° F), or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations.

Medication	Recommended Storage Temperature
Adenosine	15° - 30° C (59°-86° F); Do not refrigerate
Albuterol sulfate	2° - 25° C (36°-77° F)
Amiodarone	Controlled room temp 25° C (77° F);
Atropine	15° - 30° C (59°-86° F)
Diazepam	At or below 25° C (77° F)
Diltiazem	25° C (77° F); excursions permitted to15° - 30° C (59°-86° F)
Diphenhydramine	15° - 30° C (59°-86° F); protect from freezing
Dopamine	Controlled room temp -15° - 30° C (59°-86° F);
Epinephrine 1:1,000	15° - 30° C (59°-86° F);
Epinephrine 1:10,000	15° - 30° C (59°-86° F);
Glucagon	Controlled room temp 20°-25° C (68°-77° F)
Ipratropium	2° - 25° C (36°-77° F)
Lidocaine 2%	2° - 25° C (36°-77° F)
Magnesium	15° - 30° C (59°-86° F); protect from freezing
Midazolam	15° - 30° C (59°-86° F);
Naloxone	Controlled room temp -15° - 30° C (59°-86° F);
Sodium bicarb	15° - 30° C (59°-86° F);
Normal Saline	The expiration dating is based on stability data generated from product samples stored at the equivalent of a constant 25°C (77° F). While stored under labeled conditions, our product remains pharmaceutically acceptable. Prolonged storage at higher temperatures may accelerate concentration and pH changes in the final product (Baxter)

4. ~~Items requiring **refrigeration** (cold saline) must be stored in a cooling unit, solely for that purpose. Maintain minimum of 2 liters NS in (minimum of one) cooler set at 4° C / 39° F. Temperatures coolers must be recorded daily by a designated person within the agency.~~

5. Items requiring **warming** (at least 1 bag 1000 mL NS) must be stored in a heating unit, solely for that purpose. Temperatures of warming units/drawers must be recorded daily by a designated person within the agency. We do not recommend heating IV solutions in a microwave oven.

Warming recommendations for intravenous (IV) solutions in plastic bags:

- IV solutions of volumes 150mL or greater can be warmed in their plastic overpouches to temperatures not exceeding 40°C (104°F), and for a period no longer than 14 days.
- Label bags with warming expiration date before placing in the warmer.
- Once the VIAFLEX plastic containers have been in the warming cabinet for their maximum time period, remove the container from the warming

cabinet and identify as having been warmed. They should not be subsequently returned to the warmer.

- They may continue to be used until the labeled expiration date from the manufacturer provided they have not been warmed more than once (Baxter, 2015).

Note: Intentional warming of IV containers does not affect the sterility of those containers and the solutions they contain. IV containers are terminally sterilized at higher temperatures and container seals are able to withstand those temperatures. Unless the container has been breached during shipping, handling, or storage, the solution remains sterile throughout its life. Clinicians must check the integrity of all of containers prior to use, whether intentionally warmed or not. The warming temperatures listed in this policy are provided only as a guideline to insure the chemical stability of the warmed products (Baxter, 2015).

6. **Recommended Practice from USP-NF Chapter**

a. Monitor and verify temperature profiles to compare with established limits, especially on hot summer days and cold winter days.

b. On-board cabinets must be insulated and should use active heating and cooling if necessitated by the local climate.

c. Consider using insulated portable carrying cases and, when they are not in use, keep them inside or in a climate-controlled cabinet to maintain controlled room temperature.

d. Consider using portable cases exclusively, instead of on-board cabinets, to facilitate rotation. Time-temperature indicators can be used to monitor temperature exposures of the portable case's entire contents.

e. Consider using time-temperature indicators to monitor individual medication packages, especially for environmentally sensitive and thermally sensitive preparations.

f. All medications should be protected from excessive heat (40° C+). Some medications may need to be stored in a cold and/or dry place, and "environmentally sensitive" medications should not be stored on EMS vehicles unless the storage cabinet is temperature-controlled or individual time-temperature indicators are attached to each medication package.

g. Consider stock rotation on a schedule based on local climate, perhaps every three days or so. The stock should be rotated into a climate controlled environment. Stock rotation may be especially necessary for environmentally sensitive preparations.

h. Consider temperature exposures when parking ambulances. Park in heated and air-conditioned garages if possible. When parking outside, attempt to park in the shade.

i. **Note:** Because the USP classifies this chapter as general information, it does not view compliance as mandatory. The recommendations are offered to guide EMS agencies in efforts to ensure stability of medications and identify practices that will help achieve that goal.

VII. **DISPENSING REPLACEMENT drugs/supplies on the Drug and Supply List**

A. Hospitals must adhere to internal policies and JCAHO standards with respect to dispensing ambulance supplies.

B. 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 (JC).

C. IDPH has long 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).

D. 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) (JC).

Hospital that use automated dispensing machines need to determine back-up systems and downtime procedures for the distribution of medications if the machine breaks, power fails, or electronic programming is off line (JC).

VIII. DRUG REPLACEMENT

A. **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).

B. 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).

C. 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.

D. **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.

E. **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.

F. All drugs and equipment, other than those covered by the United Sates 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.

G. 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.

H. 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).

I. 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.

J. Compliance with Section M will be determined separately for the receiving facility and the ambulance provider (and first responder, if any) as 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.

IX. **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).

X. **Medication administration errors:** Reference Policy R7 Reportable Incidents

XI. **Unused drugs/pharmacologics**

A. Drugs/pharmacologics removed from their container/packaging, drawn up into a syringe, or engaged (preload) for potential use on a patient and not (fully) administered must be appropriately discarded at the hospital and presented for exchange.

B. They shall not be put back into active EMS vehicle stock.

XII. **Recalled and medications unsuitable for use**

A. Immediately pull from use.

B. If possible, pull suitable drug from reserve vehicles to ensure adequate supply on front-line ambulances.

C. Store in a locked space until returned to the hospital for exchange.

XIII. **Out of date medications**

A. Stock shall be regularly inspected and rotated to ensure that they have not expired**.**

B. The EMS MD may grant authorization to use drugs after their expiration date in situations of shortages without approved alternatives.

XIV. **Lost, non-exchanged, misused, or damaged drugs/pharmacologics**

A. The loss or suspected loss or misuse of any drug or pharmacologic must be reported according to the R-7 Reportable Incidents Policy within the same shift of the discovery.

B. 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.

C. 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).

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].

U.S. Pharmacopeia

U.S. Food and Drug Administration: General Biologic Products Standards. 21 CFR 610.

Federal Good, Drug and Cosmetic Act, 21 USC 321.

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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:

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

   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: _____

_____

Signature of appropriate officer or official