



DOH
New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT
Supersedes/Updates: 09-13

No. 13 - 04

Date: March 15, 2013

Re: Alternative
Medication Formulary For
Prehospital Drug
Shortages

Page 1 of 8

BACKGROUND

Drug shortages, including controlled substances, are occurring frequently. Drug shortages can adversely affect patient care and may result in medication errors. According to the American Society of Health-System Pharmacists (ASHP) Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems (8/1/09), pharmacy departments must take a leadership role in efforts to develop and implement appropriate strategies and processes for informing practitioners of shortages and ensuring the safe and effective use of therapeutic alternatives. EMS agencies that have contracts or MOUs with a hospital pharmacy, are considered "practitioners" and therefore should be notified by the pharmacy.

The main sources to use for the most up to date information should be your pharmacy or medication vendor as well as the Federal Drug Administration (FDA). The FDA has a web site that contains the most current information on national drug shortages. The web site is: <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>

Planning for any type of drug shortage can be divided into three phases: identification and assessment, preparation, and contingency.

1. Identification and Assessment

Assessment requires a critical evaluation of the current situation and the potential effect the shortage may have on the healthcare system. For patients whose treatment depends on the unavailable drug product must have alternative therapies identified. EMS agencies should review their past patient data to determine the needs for their community.

2. Preparation

EMS agencies should first review their current medication inventory policies to determine if changes to those policies need to be made. For example, only stocking first line EMS units with medications and assuring those units that are out-of-service or not used for primary emergency response are not carrying any medications that may be in short supply. Sub-stocks of medications should be reviewed to determine the need for the amounts of medications in the sub-stock.

The first step for pharmacies is to identify therapeutic alternatives to the unavailable drug product. Communication of this information is essential to ensuring patient safety and preventing medication errors caused by confusion over differences between drug products, drug labeling, dosages, concentrations, drug actions, interactions, and other factors. Second, when applicable, the pharmacy should establish collaborative arrangements with other institutions within a regional network or system.

3. Contingency

At no time can an EMS agency borrow, supply or sell any medication to another entity unless they possess a distributor's license. The movement of medications is strictly regulated by the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA).

10 NYCRR §80.136 - Controlled substances for emergency medical services: purchasing, possessing, delivering, administering and safeguarding of controlled substances authorizes a certified advanced life support EMS agency to possess the following controlled substances approved by the Department and BEMS Policies; ketamine, midazolam, diazepam, morphine and fentanyl.

The Department is working to change the Controlled Substance (CS) licenses for all EMS agencies to include Schedules II,III,IV, and V. This will allow EMS agencies to possess and administer medications that are approved by Department to address drug shortage issues and changes in protocols. Agencies that currently have CS licenses will be notified by BEMS.

Medication Expiration Dates

All medications have expiration dates that are developed by each specific manufacturer and reviewed by the FDA. When a drug shortage occurs, the FDA is able to review data from manufacturers pertaining to using a drug past its expiration date. The FDA may determine if they will approve extended expiration dating to increase supplies until new productions are available. If the FDA does allow this, it will be posted on the aforementioned FDA web site, however, the Department has not approved the extension medication expiration dates at this time.

Commissioner's Ruling Exempt Distribution

A hospital pharmacy may purchase or transfer controlled substances from another hospital or retail pharmacy for their immediate, legitimate medical needs.

Definition of an immediate need exists when the facility or retail pharmacy is not capable of preparing a controlled substance medication or does not have a controlled substance in stock and immediate administration or dispensing of the drug is necessary for proper treatment.

Procedures

DOH - Bureau of EMS

- Will establish a state-wide medication formulary for alternative medications. This formulary will allow REMACs to better prepare for, and initiate changes to regional protocols to meet the changing needs of a region.
- Continue its work with the State Emergency Medical Advisory Committee (SEMAC) to make additions and subtractions to the alternative formulary as necessary.

REMAC

- Will open communication with hospital systems within their region to identify and share information regarding drug shortage issues.
- Establish communication with all EMS agencies with-in the region to monitor potential local drug shortage issues.
- When a region-wide drug shortage issue has developed, submit a letter of request to BEMS that advising that a portion of the state-wide alternative medication formulary is being utilized. Specific medications and protocol changes must accompany this letter of request. BEMS will review the request and issue a determination
- The alternative medication formulary was developed to include up to four (4) alternative medications. Alternate A should be the first consideration, followed by alternate B, alternate C and then finally alternate D. Each REMAC needs to evaluate which of the alternative medications is best for their region.
- Will coordinate provider education for all new medications or uses of medications using the provided educational template.
- Every 30 days after approval of the alternative formulary, the REMAC must evaluate the need to continue the use of the alternative formulary.
- Every 6 months after approval of the alternative formulary., the REMAC must submit a written request for extension to BEMS.

EMS Agencies

- Must continue to evaluate potential drug shortages within their operating territory.
- Notify the REMAC of any potential or current drug shortages.
- If any changes are made to the controlled substances inventory at an agency, an updated CS plan must be submitted and approved by the Department.
- Assure education of certified providers within the agency follows the BEMS educational template.
- If a specific medication is no longer available, and there is no BEMS approved alternative, the EMS agency must still continue to provide care to the best of its ability. The lack of a medication should not prohibit any response and care of patients in your area. EMS agencies must follow their regionally approved protocols to the best of their ability with the medications available to them.

Issued and authorized by the Bureau of EMS Director

LESSON PLAN GUIDE

Cognitive Objectives

At the completion of this session, the advanced EMT student will be able to:

1. Describe mechanisms of drug action.
2. List and differentiate the phases of drug activity, including the pharmaceutical, pharmacokinetic, and pharmacodynamic phases.
3. Describe the process called pharmacokinetics, pharmacodynamics, including theories of drug action, drug-response relationship, factors altering drug responses, predictable drug responses, iatrogenic drug responses, and unpredictable adverse drug responses.
4. Differentiate among drug interactions.
5. Discuss considerations for storing and securing medications.
6. List the component of the drug profile by classification.
7. Integrate pathophysiological principles of pharmacology with patient assessment.
8. Synthesize patient history information and assessment findings to form a field impression.
9. Synthesize a field impression to implement a pharmacologic management plan.

Components of a drug profile

- A. Drug names
- B. Classification
- C. Mechanisms of action
- D. Indications
- E. Pharmacokinetics
- F. Side/adverse effects
- G. Routes of administration
- H. How supplied
- I. Dosages
- J. Contraindications
- K. Considerations for pediatric patients, geriatric patients, pregnant patients, and other special patient groups
- L. Other profile components

Educational Resources:

- A. New York State EMS certification curriculum
- B. Physician's Desk Reference
- C. Drug manufacture's information
- D. Federal Food and Drug Administration
- E. Paramedic text books
- F. Additional resources as necessary

New York State EMS Alternative Medication Formulary

Valid Through December 31, 2013

Current Medication	Alternate A	Alternate B	Alternate C	Alternate D	Notes
Ondansetron (Zofran)	Promethazine 12.5 mg IM	Droperidol 0.625 mg IV/IM	Metoclopramide (Reglan) 10mg IV/IM	Diphenhydramine 25-50 mg IV/IM	ADULT ONLY Anti-emetic Ondansetron 4 mg ODT also an option
Etomidate	Midazolam C _{IV} (Versed) 5 mg IV	Lorazepam C _{IV} (Ativan) 2 mg IV	Ketamine C _{III} 1 mg/kg IV <u>OR</u> 3 mg/kg IM	Propofol 2 mg/kg IV	Induction <i>Ativan (Lorazepam) must be refrigerated following manufacturers guidelines</i>
Morphine C _{II}	Fentanyl C _{II} 50 mcg IV <small>(Inventory 400 mcg)</small>	Ketorolac (Toradol) 30 mg IV or IM	Remifentanyl C _{II} 0.5 mcg/kg or 50 mcg IV	Hydromorphone C _{II} (Dilaudid) 0.5 mg	Pain Management Protocol Only
Fentanyl C _{II}	Morphine C _{II} 4-6 mg IV	Ketorolac (Toradol) 30 mg IV or IM	Remifentanyl C _{II} 0.5 mcg/kg or 50 mcg IV	Hydromorphone C _{II} (Dilaudid) 0.5 mg	Pain Management Protocol Only
Fentanyl C _{II}	Remifentanyl C _{II} 0.5 mcg/kg or 50 mcg IV				ROSC Protocol Only (shivering)
Midazolam C _{IV} (Versed)	Lorazepam C _{IV} 2 mg or 0.05 mg/kg IV	Diazepam C _{IV} 5 mg IV			Seizure management
Diazepam C _{IV} (Valium)	Midazolam C _{IV} 5 mg IV	Lorazepam C _{IV} 2mg IV			Seizure management

New York State EMS Alternative Medication Formulary

Lorazepam C _{IV} (Ativan)	Midazolam C _{IV} 5 mg IV	Diazepam C _{IV} 5 mg IV		Seizure management
Ketorolac	ibuprofen (Caldolor) 400-800 mg IV			NSAID pain management (not mandatory substitution because of cost)
Ketamine C _{III}	Etomidate 0.1 mg/kg IV	Midazolam C _{IV} 2-5 mg IV and/or Fentanyl 50 mcg IV		Patient disentanglement
Sodium Bicarbonate				No substitution available
Midazolam C _{IV} (Versed)	Droperidol 2.5 mg IM	Haloperidol 5 mg IM	Ketamine 1-3 mg/kg IM	Patient chemical restraint
Epinephrine 1:10,000	Epinephrine 1:1,000 30mL Vial 1. Expel 1mL of normal saline from a 10mL syringe (pre- filled) 2. Instill 1mg(mL) of Epinephrine 1:1,000 from 30 mL vial in to pre-filled syringe 3. 30mL vials are to be single patient use only	Epinephrine 1:1,000 1mg/ml Ampule 1. Expel 1mL of normal saline from a 10mL syringe (pre- filled) 2. Instill 1mg(mL) of Epinephrine 1:1,000 from ampule in to pre-filled syringe		

New York State EMS Alternative Medication Formulary

Suggestion:

Make medication substitutions that will allow minimal formulary changes when possible, even when this means moving into secondary alternates to allow for maximum safety. Example: if adding Droperidol for nausea, consider adding an option for patient restraint.