The Regional Emergency Medical Advisory Committee (REMAC) of New York City is responsible to develop, approve and implement prehospital treatment and transport protocols for use within the five boroughs of the City of New York. The Regional Emergency Medical Advisory Committee (REMAC) of New York City operates under the auspices of Article Thirty of the New York State Public Health Law.

This Advisory identifies:

1. FDA Extension of expiration dates for Pfizer limited and specific medications during this drug shortage.
   - Atropine Sulfate Injection in ANSYR syringes,
   - Dextrose 50% Injection in ANSYR syringes, and
   - Sodium Bicarbonate products in ABBOJECT syringes.
2. Formula changes to allow for continued administration of Atropine and Dextrose during this drug shortage.
3. There is no substitution for Sodium Bicarbonate. ALS units may remain in service even if Sodium Bicarbonate is not available. NYC REMAC must be notified by agencies operating without Sodium Bicarbonate.

Attached are:
- NYS DOH BEMS Alternative Formulary approval letter
- NYS DOH Policy 13-04 Alternative Drug Formulary
- Office of Medical Affairs Directive 2017-12: Dilution of Epinephrine
- Office of Medical Affairs Directive 2017-08: Intravenous Dextrose Formulation

If your agency has, or anticipates a medication shortage, advise the NYC REMAC as soon as possible, by emailing mdiglio@nycremsco.org. The REMAC is investigating alternate medications that may be utilized.

Current and Updated Protocols can be accessed at the Regional EMS Council website: www.nycremsco.org.

Owners/operators of Ambulance and ALS First Response Services providing prehospital medical treatment within the five boroughs of the City of New York are responsible to provide copies of the NYC REMAC Prehospital Treatment Protocols to their personnel, and to ensure that Service Medical Directors and EMS personnel are informed of all changes/updates to the NYC REMAC Prehospital Treatment Protocols.

Josef Schenker, MD, FACEP
Chair, Regional Emergency Medical Advisory Committee of New York City

Marie C. Diglio, EMT-P, CIC
Executive Director Operations, Regional Emergency Medical Services Council of New York City
Drug Shortages: Epinephrine, Sodium Bicarb and Dextrose

1. **FDA Extension of expiration dates for Pfizer limited and specific medications during this drug shortage.**
   - Atropine Sulfate Injection in ANSYR syringes,
   - Dextrose 50% Injection in ANSYR syringes, and
   - Sodium Bicarbonate products in ABBOJECT syringes.

   Extended Use Dates Provided by Pfizer to Assist with Emergency Syringe Shortages: Product and lot numbers of:
   - **Atropine Sulfate** Injection in ANSYR syringes,
   - **Dextrose 50%** Injection in ANSYR syringes, and
   - **Sodium Bicarbonate** products in ABBOJECT syringes

   **ALL ARE ELIGIBLE FOR USE BEYOND THE MANUFACTURER’S LABELED EXPIRATION DATE (AS OF JUNE 23, 2017).**

   Here is the link to medications manufactured by Pfizer that have had expiration dates extended by FDA: [https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm](https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm).

   We have been advised that for now, this list is limited to Pfizer products. The reason for this may be because other manufacturers do not have the same type of information on their products as Pfizer, so the FDA cannot make decisions for shelf-life extensions. This could include manufacturers not having stability testing information beyond the date stamped on medications or if their stability test information does not support extended shelf life.

2. **Formula changes to allow for continued administration of limited and specific medications during this drug shortage.**

   The FDNY Office of Medical Affairs has developed Medical Affairs Directives identifying formulas for the dilution of Epinephrine and Dextrose for use in REMAC Protocols. **These should be reviewed by agency medical directors and shared with agency Paramedics. This will require brief training by the agency medical director or his/her designee. Lists of paramedics updated in new procedures should be kept on file in the specific agency.**

   **Dilution of Epinephrine**
   - Refer to FDNY Office of Medical Affairs Directive 2017-12 for dilution formulas (attached).

   **Dilution of Dextrose:**
   - Refer to FDNY Office of Medical Affairs Directive 2017-08 for dilution formulas (attached).

   **Sodium Bicarbonate**
   - There is no substitution for Sodium Bicarbonate. ALS units may remain in service even if Sodium Bicarbonate is not available.
July 27, 2017

Josef Schenker, MD
NYC REMSCO Chair

Dear Josef,

The Bureau of EMS is in receipt of your request to utilize the NYS BEMS Alternative Formulary and/or FDA approved extended expiration dates, as outlined in BEMS Policy Statement 13-04. The BEMS is approving your request as it pertains to follow the FDA extended expiration use for:


2. Hospira/Pfizer Dextrose 50% (0.5 g/mL); 25 g/50 mL LifeShield™ Abboject™ Glass Syringe (18 G x 1 1/2”) (NDC 00409-4902-34). Next delivery date is for late July with estimated recovery December 2017. Follow FDA approved date extensions, found at: https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm.

3. epinephrine injection, USP 0.1 mg/mL 10 mL ABBOJECT syringes. Next delivery date is for late July with estimated recovery October 2017. Follow FDA approved date extensions, found at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Epinephrine%20Injection,%200.1%20mg%20/mL&st=c&tab=tabs-1.

4. sodium bicarbonate products in ABBOJECT syringes. Next delivery date expected late July with estimated recovery in Q1 2018. Follow FDA approved date extensions, found at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Bicarbonate%20Injection,%20USP&st=c&tab=tabs-1.

Please continue to monitor the FDA website for further updates regarding approved and rescinded extended expiration dates.

This approval is valid through December 29, 2017 or until such time the situation has been rectified. If the REMAC wishes to extend the approval beyond that date, they must submit their request in writing. The REMAC is required to evaluate this situation every 30 days to determine if it is still required or needs to be amended. Agencies must be notified in writing regarding this process and any educational requirements that must be met. Agencies must also understand that this approval is specific to specific manufacturers as approved by the FDA.
As a reminder, “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).”

Thank you for keeping the BEMS up-to-date with your current and future information regarding this situation. Please feel free to contact me if you have any additional questions or concerns.

Sincerely,

Andrew G. Johnson, Deputy Director
New York State Department of Health
Bureau of Emergency Medical Services
Education and Certification Units
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, alternative therapies must be identified. EMS agencies should review their past patient data to assess the projected 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, a new policy that may allow for only stocking first line EMS response units with medications that may be on the shortage list, while 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. Additionally EMS agencies should review their medication stock to determine the usage trends, current supplies, expiration dates and replacement availability or the need to order alternative medications.
3. **Compliance**

*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 has changed the Controlled Substance (CS) licenses for all EMS agencies to include Schedules II, III and IV. This will allow EMS agencies to possess and administer medications that are approved by Department to address drug shortage issues and changes in prehospital protocols.

**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. Please be advised, that the Department must also approve the extension of medication expiration dates. Therefore, no expired medications may be administered to patients without the approval of the FDA and the NYS Department of Health.

**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 within 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 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 (attached) 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
Requirements for any New Medication added to the Prehospital Formulary by any Region or EMS Agency

Background:

During the course of initial certification at the EMT- Critical Care and Paramedic levels, medications are introduced in a systematic fashion. This provides for extensive and detailed information on each medication they are authorized to use according to the NYS curriculum.

Issue:

After the providers are certified and are using their skills in the field, the education modalities used to introduce new medications or medications specific to a region have no uniformity or standardized educational methodology. Many times it is up to the individual certified provider to learn about medications.

Solution:

In consultation with the SEMAC, the Bureau of EMS has established a required outline to be used by all agencies, regions and course sponsors as a minimum requirement of objectives for any new medication added to the scope of practice, protocols or regional and state medication formulary.

Completion of all educational requirements must be kept on file for all personnel.
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.
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

<table>
<thead>
<tr>
<th>Current Medication</th>
<th>Alternate A</th>
<th>Alternate B</th>
<th>Alternate C</th>
<th>Alternate D</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ondansetron (Zofran)</strong></td>
<td>Promethazine 12.5 mg IM</td>
<td>Droperidol 0.625 mg IV/IM</td>
<td>Metoclopramide (Reglan) 10mg IV/IM</td>
<td>Diphenhydramine 25-50 mg IV/IM</td>
<td><strong>ADULT ONLY</strong> Anti-emetin Ondansetron 4 mg ODT also an option</td>
</tr>
<tr>
<td><strong>Etomidate</strong></td>
<td>Midazolam C\textsubscript{IV} (Versed) 5 mg IV</td>
<td>Lorazepam C\textsubscript{IV} (Ativan) 2 mg IV</td>
<td>Ketamine C\textsubscript{III} 1 mg/kg IV OR 3 mg/kg IM</td>
<td>Propofol 2 mg/kg IV</td>
<td><strong>Induction</strong> <em>Ativan (Lorazepam) must be refrigerated following manufacturers guidelines</em></td>
</tr>
<tr>
<td><strong>Morphine C\textsubscript{II}</strong></td>
<td>Fentanyl C\textsubscript{II} 50 mcg IV (Inventory 400 mcg)</td>
<td>Ketorolac (Toradol) 30 mg IV or IM</td>
<td>Remifentanil C\textsubscript{II} 0.5 mcg/kg or 50 mcg IV</td>
<td>Hydromorphone C\textsubscript{II} (Dilaudid) 0.5 mg</td>
<td><strong>Pain Management Protocol Only</strong></td>
</tr>
<tr>
<td><strong>Fentanyl C\textsubscript{II}</strong></td>
<td>Morphine C\textsubscript{II} 4-6 mg IV</td>
<td>Ketorolac (Toradol) 30 mg IV or IM</td>
<td>Remifentanil C\textsubscript{II} 0.5 mcg/kg or 50 mcg IV</td>
<td>Hydromorphone C\textsubscript{II} (Dilaudid) 0.5 mg</td>
<td><strong>Pain Management Protocol Only</strong></td>
</tr>
<tr>
<td><strong>Fentanyl C\textsubscript{II}</strong></td>
<td>Remifentanil C\textsubscript{II} 0.5 mcg/kg or 50 mcg IV</td>
<td></td>
<td></td>
<td></td>
<td><strong>ROSC Protocol Only (shivering)</strong></td>
</tr>
<tr>
<td><strong>Midazolam C\textsubscript{IV} (Versed)</strong></td>
<td>Lorazepam C\textsubscript{IV} 2 mg or 0.05 mg/kg IV</td>
<td>Diazepam C\textsubscript{IV} 5 mg IV</td>
<td></td>
<td></td>
<td><strong>Seizure management</strong></td>
</tr>
<tr>
<td><strong>Diazepam C\textsubscript{IV} (Valium)</strong></td>
<td>Midazolam C\textsubscript{IV} 5 mg IV</td>
<td>Lorazepam C\textsubscript{IV} 2mg IV</td>
<td></td>
<td></td>
<td><strong>Seizure management</strong></td>
</tr>
</tbody>
</table>
| 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 | 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 30  
mL vial in to pre-filled  
syringe  
3. 30mL vials are to be single  
patient use only | | 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 |
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.
1. **PURPOSE**

1.1 To inform Paramedics about a current Dextrose 50% shortage and provide instruction on the use of other formulations of dextrose.

2. **SCOPE**

2.1 This policy applies to all FDNY Paramedics.

3. **BACKGROUND**

3.1 There is currently a shortage of Dextrose 50% in water. The Department anticipates that the stock of Dextrose 50% will be depleted before the shortage is resolved.

3.2 Due to the current shortage of Dextrose 50%, the NYC REMAC has made an emergency change to the NYC REMAC adult protocols to allow any formulation of intravenous dextrose to be used, and to allow dosage up to 25 grams.

3.3 Recent literature supports the use of less concentrated formulations of dextrose in the emergent treatment of hypoglycemia, as they are equally effective, better tolerated, and have less risk of local tissue toxicity if extravasated.

4. **POLICY**

4.1 FDNY Paramedics may use any of the following formulations of dextrose to treat adult patients for any condition where intravenous dextrose is indicated:

a. Dextrose 5% in water or saline, up to 500 milliliters

b. Dextrose 10% in water, up to 250 milliliters

c. Dextrose 25% in water, up to 100 milliliters

d. Dextrose 50% in water, 50 milliliters

**Note:** *In patients with heart failure, kidney failure, or other risks for fluid overload, frequent reassessment of respiratory status is required. Discontinue fluids if respiratory status worsens or patient develops pulmonary edema.*

4.2 Dextrose 10% is preferred when available.

4.3 For hypoglycemic patients, Paramedics may administer dextrose until symptoms improve or resolve and are not required to administer the entire 25 grams.
5. **PROCEDURE**

5.1 FDNY Paramedics may use their discretion to decide which available formulation of dextrose to administer.

5.2 Paramedics shall use the following procedure when administering Dextrose 5%:

5.2.1 Dextrose 5% is available in IV bags of various sizes (500 milliliters contains 25 grams of dextrose).

5.2.2 Begin IV administration of up to 500 milliliters of Dextrose 5% as an IV drip.

5.2.3 Transport should not be delayed to complete the dextrose administration or to assess for response to the dextrose.

5.2.4 For hypoglycemic patients, if symptoms improve or resolve, recheck glucose level and stop administration of dextrose if glucose is above 60mg/dL.

5.3 Paramedics shall use the following procedure when administering Dextrose 10%:

5.3.1 Dextrose 10% is available in 250ml bags (each containing 25 grams of dextrose).

5.3.2 Begin IV administration of the 250ml bag of Dextrose 10% as an IV drip.

5.3.3 Transport should not be delayed to complete the dextrose administration or to assess for response to the dextrose.

5.3.4 For hypoglycemic patients, if symptoms improve or resolve, recheck glucose level and stop administration of dextrose if glucose is above 60mg/dL.

5.4 Paramedics shall use the following procedure when administering Dextrose 25%:

5.4.1 Dextrose 25% is available in 10ml prefilled syringes (each containing 2.5 grams of dextrose).

5.4.2 Administer one syringe at a time, up to 10 syringes.

5.4.3 Transport should not be delayed to complete the dextrose administration or to assess for response to the dextrose.

5.4.4 For hypoglycemic patients, if symptoms improve or resolve, recheck glucose level and stop administration of dextrose if glucose is above 60mg/dL.

5.5 Paramedics shall use the following procedure when administering Dextrose 50%:

5.5.1 Dextrose 50% is available in 50ml prefilled syringes (each containing 25 grams of dextrose).

5.5.2 Administer one syringe as an IV push.

5.6 The formulation and amount of dextrose administered shall be documented on the PCR.

**BY ORDER OF THE FIRE COMMISSIONER, CHIEF OF DEPARTMENT, CHIEF OF EMS AND THE OFFICE OF MEDICAL AFFAIRS**
1 PURPOSE

1.1 To inform Paramedics about a current Epinephrine 0.1mg/1ml (1:10,000) shortage and provide instruction on the dilution of Epinephrine 1mg/ml (1:1,000) for Intravenous (IV)/Intraosseous (IO) use.

2. SCOPE

2.1 This policy applies to all FDNY Paramedics.

3. BACKGROUND

3.1 There is currently a shortage of Epinephrine 0.1mg/1ml (1:10,000) and the Department anticipates that the stock of Epinephrine 0.1mg/1ml (1:10,000) may be depleted before the shortage is resolved.

3.2 Epinephrine 1mg/1ml (1:1,000) can be diluted in Normal Saline to achieve a 0.1mg/1ml (1:10,000) concentration.

4. POLICY

4.1 When Epinephrine 0.1mg/1ml (1:10,000) is unavailable, Paramedics shall dilute Epinephrine 1mg/1ml (1:1,000) to a concentration of 0.1mg/1ml (1:10,000) before Intravenous/Intraosseous administration.

5. PROCEDURE

5.1 Use ONLY the newer Epinephrine 1mg/ml (1:1,000) ampules or vials labeled for intravenous use. The older ampules labeled for Intramuscular (IM) or Subcutaneous (SQ) use only MAY NOT be used for Intravenous or Intraosseous administration (see Figure 1).

5.2 Draw up 9ml of Normal Saline.

5.3 Draw up 1ml of Epinephrine 1mg/1ml (1:1,000) into the syringe containing 9ml of Normal Saline, creating 10ml of Epinephrine 0.1mg/1ml (1:10,000).

5.4 Administer the 10ml syringe as an IV/IO bolus for any patient in whom Epinephrine 0.1mg/1ml (1:10,000) is indicated.

5.5 Due to the danger of mistaking a syringe with Epinephrine for a Normal Saline flush, do not store or pre-fill syringes with Epinephrine; draw up the Epinephrine immediately before use and discard the syringe in an appropriate container if not used immediately.
Epinephrine ampule labeled for SQ/IM use only
Epinephrine ampule labeled for Intravenous use (may be administered via IV/IO)

BY ORDER OF THE FIRE COMMISSIONER, CHIEF OF DEPARTMENT, CHIEF OF EMS AND THE OFFICE OF MEDICAL AFFAIRS