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March 1, 2012

To: Ohio EMS agencies, EMS medical directors, hospitals, and hospital pharmacists  
From: Ohio Department of Public Safety, Division of Emergency Medical Services

Subject: The February 22, 2012 announcement of drug shortages from the FDA. In light of recent events, your prompt attention is requested to review practices by your agency for substituting drugs that are unavailable or in limited supply that are used by EMS agencies.

### **BACKGROUND**

The recent announcement of drug shortages from the FDA has impacted on hospitals and may have a negative impact on the ability of EMS professionals to provide the traditional standard of care in the pre-hospital environment for some patients, as about half of the medications on the FDA's list are commonly stocked and administered by EMS agencies.

### **RATIONALE FOR REVIEW**

The following suggestions for alternative drugs are solely based upon the February 22, 2012 drug shortage report from the FDA; therefore, continuous communication with the pharmacists and frequent reassessment of the FDA drug shortage list is imperative. The ongoing drug shortage situation is a dynamic one and the medications in short supply may change on a daily basis.

The highest priority must be given to maintaining patient care while at the same time following Ohio law. All transitions to alternative medications must be done in compliance with Ohio's State Board of Pharmacy and the DEA's regulations. It is also imperative that EMS medical directors serve as the party to initiate the transition to and implementation of alternative medications for EMS agencies. The addition of any alternative medication to an EMS protocol must be paired with training, continuing education, competency assessment, and continuous performance improvement measures.

The National Association of State EMS Officials (NASEMSO) Medical Directors Council has discussed this issue as well as the increased risk of potential conflict with DEA regulations when EMS professionals and EMS medical directors may contemplate administration of expired scheduled medications. Temporary waivers of drug expiration dates are currently being explored for potential viability as an avenue of relief.

The NASEMSO Medical Directors Council acts in an advisory role to NASEMSO and does not have the authority to grant states the ability to waive the expiration dates of medications for EMS agencies or emergency care facilities nor does it have the authority to create policies for the FDA or DEA. Nevertheless, we are committed to be a lead partner with EMS organizations and other stakeholders within our emergency care system to definitively address this dilemma that we believe that the incidences of drug shortages will be ongoing for some time.

The FDA has ultimate authority of approval for the administration of medications beyond the expiration dates. An additional consideration is that the FDA's list of drug shortages includes scheduled

#### **Mission Statement**

*"To promote quality and professionalism in the hiring, training, education, and delivery of fire and Emergency Medical Services with equal consideration given to all diverse populations and constituents."*

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medications. For these medications, approval from the DEA, in addition to the FDA, may be required to waive the expiration date of a scheduled medication.

The presence of active and involved EMS medical direction is critical and required. EMS medical directors may wish to create and/or implement "just in time" protocols for alternative medications to ensure seamless quality patient care and to maintain patient safety in the pre-hospital setting.

Best regards,  
Dr. Carol Cunningham  
State Medical Director  
Ohio Department of Public Safety, Division of EMS

## The Drug Shortage List from the FDA with the Greatest Impact upon EMS

February 22, 2012

**Atropine:** There really is no alternative for this medication. For symptomatic bradycardia, external cardiac pacing with sedation is the most rapidly implementable treatment modality. Although some ALS units are training in the use of dobutamine, many are not. For pretreatment prior to a pediatric/neonatal intubation, alternative sedatives can be used, but epinephrine should be readily available and on stand-by if needed.

**Bupivacaine:** Parenteral analgesia/conscious sedation would have to be used in light of the fact that lidocaine is also on the FDA drug shortage list. Topical anesthetics could be substituted for care of wounds that are very superficial.

**Diltiazem:** Although it has a slower action of onset, digoxin is still used for rate control in atrial fibrillation. If a patient does not have COPD, cardiac electrical conduction abnormalities, or asthma, careful administration of intravenous or oral beta blockers could be used for rate control.

**Etomidate:** Go back to the way we sedated people in the good old days and use the benzodiazepine that is available.

**Furosemide:** Alternative intravenous diuretics include bumetanide (Bumex<sup>®</sup>), acetazolamide (Diamox<sup>®</sup>), metalozone (Zaroxyn<sup>®</sup>, Mykrox<sup>®</sup>). As the alternatives have significant actions and side effects, rigorous medical direction and training should be provided by the EMS medical director.

**Lidocaine:** Use parental analgesia/conscious sedation for the clinical indication of local anesthesia. Amiodarone can be used for the cardiac arrhythmia clinical indication.

**Lorazepam:** Use another benzodiazepine for sedation or seizure control. Currently, diazepam (Valium<sup>®</sup>) is not on the February 22<sup>nd</sup> FDA drug shortage list.

**Magnesium sulfate:** As a clinical indication for this medication in the pre-hospital setting includes the treatment of seizures secondary to eclampsia or for certain cardiac arrhythmias, the lack of this medication places a stronger emphasis on emergent transport. With all of the advanced treatment modalities that are now available in the prehospital setting, we must not forget that there will always be a role for “load and go” (AKA use gasoline). This is a good example. Put the pedal to the metal and initiate emergent transport to the emergency department.

**Mannitol:** Not used as frequently in the pre-hospital setting as in the past. If needed, “load and go” and initiate emergent transport to the emergency department.

**Metoclopramide:** Use another anti-emetic that is available. Currently, promethazine (Phenergan<sup>®</sup>) is not on the February 22<sup>nd</sup> FDA shortage list.

**Midazolam:** Use an alternative benzodiazepine that is available. Currently, diazepam (Valium<sup>®</sup>) is not on the February 22, FDA drug shortage list.

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**Morphine sulfate:** Use an alternative analgesic that is available. Currently fentanyl hydromorphone (Dilaudid®) and ketorolac (Toradol®) are not on the FDA drug shortage list.

**Naloxone:** There is no intravenously administered alternative. The patient's airway should be supported by the method deemed appropriate for the clinical scenario, oxygen should be administered, and the patient should be transported emergently to the emergency department.

**Ondansetron:** Use another anti-emetic. Currently, promethazine (Phenergan®) is not on the February 22<sup>nd</sup> FDA Drug shortage list.

We encourage EMS agencies to monitor the FDA's drug shortage updates at the link below to maintain currency following the release of the FDA report of February 22, 2012:  
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>