

EMS Information Bulletin 2013-008

DATE: July 31, 2013

SUBJECT: **Pennsylvania EMS Medication Shortage Procedure: For Emergency Medication Use up to Six Months beyond Labeled Expiration Date**

TO: EMS Agency Directors **THRU:** Martin Raniowski, Deputy Secretary
EMS Agency Medical Directors Health Planning & Assessment

FROM: Richard Gibbons, Director
Bureau of Emergency Medical Services

This process, as outlined below, has been approved by the Bureau of EMS, including the Commonwealth EMS Medical Director Douglas Kupas, MD. In addition, it has been approved by Secretary of Health, Michael Wolf and Commonwealth Physician General Carrie DeLone, MD.

Nationally, many emergency medications used by EMS are in severe shortage. The following medications utilized by Pennsylvania EMS agencies are currently in short supply:

Adenosine
Albuterol (with or without ipratropium)
Amiodarone and lidocaine
Atropine
Calcium chloride and calcium gluconate
Dextrose 10-50% and glucagon
Diazepam and lorazepam and midazolam
Diphenhydramine
Epinephrine (1:1000)
Epinephrine (1:10,000)
Fentanyl and morphine
Magnesium sulfate
Naloxone
Ondansetron
Oxytocin

In order to ameliorate the medication shortages and to prevent patient harm resulting from inadequate supplies of emergency medications, the Pennsylvania Department of Health, Bureau of EMS has approved this policy for use of expired emergency medications during a critical shortage.

EMS agencies may apply for an exemption to use the following medications up to six months beyond the labeled expiration date when the medication, and listed alternative when appropriate, is not available due to shortage and the EMS agency follows the process in this directive:

The BEMS will follow medication shortages and this list of medications will be updated as necessary.

Process for requesting exemption:

- 1) Exemption will only be considered and applicable for medications packaged for single-patient use
- 2) The EMS agency may only apply for exemption after attempting to obtain unexpired medication from several sources and when the agency is not aware of any supplier that can provide the medication
- 3) The EMS medical director will request the exemption by communicating to the local regional EMS council a) the name of the medication, b) the list of suppliers that can't currently provide the medication, and c) the manufacturer, expiration date, and lot numbers of the medications for which an exemption is requested
- 4) The EMS regional council will provide approval to the EMS agency to use the expired medication for no more than six months beyond the labeled expiration date, and the EMS regional council will communicate this approval (including the name of the EMS agency and the name of the medication) to the BEMS

Once the request is approved, the EMS agency will be authorized to use the excepted medications up to six months after their posted expiration dates, with the following restrictions:

- 1) This authorization will be for a period of six months, and a new authorization is needed for any additional lots of expired medications before they may be used.
- 2) Use of expired medications is at the discretion of the EMS agency and must be approved by the agency medical director.
- 3) Expired medications must be stored in reserve until the EMS agency has used all of its supply of a medication that has not passed the expiration date before placing expired medications into EMS vehicles or drug bags/boxes. EMS agencies should develop procedures that lead to preferential use of medications that are closest to expiring to preserve medications that have not yet expired.

- 4) The EMS agency will follow availability with suppliers and will obtain unexpired medications as soon as they are available. When unexpired medications become available to the EMS agency, the use of expired medications will cease and the unexpired medications will be used.
- 5) Expired medications kept in reserve must be stored and maintained according to the manufacturer's instructions. EMS agencies must have a thermometer where medications are stored in reserve, and temperature must be documented daily. Documentation of temperatures within the storage area must be available for inspection by the regional EMS council or BEMS. Temperature monitoring of medication storage areas on EMS vehicles is ideal but currently not required.
 - a. Lorazepam – BEMS policy requires that any EMS agency that carries lorazepam must store this medication under refrigeration until it is moved to the EMS vehicle at which time the medication must be relabeled with a new expiration date that may not exceed 60 days. If an agency's lorazepam expiration is extended using this policy for medication shortage, the 60 day expiration after removal from refrigeration must still be followed.
- 6) When possible, patients should be made aware that they are receiving an expired medication and should give verbal consent for use of expired medications. This discussion and verbal consent should be documented on the patient care report.
- 7) A record must be kept of the use of all expired medications, which will be submitted to the regional EMS council or the Bureau of EMS for review upon request.
- 8) Upon arrival at the healthcare facility, the information that expired medications were used during patient transport and which medications were expired will be given verbally to the receiving healthcare provider.

If you require additional information regarding the guidance please contact your regional EMS Council.



Application to use expired medications due to shortages

EMS Agency Name:

Medication(s) unavailable:	Manufacturer	Expiration Date	Lot#	Date Supplier Checked

I have contacted the following vendors and have been notified that the requested medications are not available at this time.

ALS Service Medical Director: _____

EMS Agency Director: _____

The _____ Regional EMS Council has approved the use of _____ until unexpired medications are available. Approval is based on EMS Information Bulletin 2013-008.

Date forwarded to the Bureau of EMS: _____