

EMS Drug Shortages: The States Respond



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States' Options Limited



- ❧ FDA regulates drug manufacturing at the federal level
- ❧ FDA cannot mandate that manufacturers produce (or increase production) of a drug
- ❧ Expiration dates set by manufacturers
- ❧ So...what's a state to do about these nasty drug shortages?

All EMS is Local



- ❧ These drug shortages, whatever the cause, affect *our* patients
 - ❧ That's the next patient your medics see with a seizure...and no valium
 - ❧ Or has a broken femur, and no fentanyl
 - ❧ Or severe emesis, and no droperidol or promethazine
- ❧ What do your medics do NOW, with THIS patient in front of them?

Coping with and Mitigating the Effects of Shortages of Emergency Medications

December 2012



<http://www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Drug-Shortage-Report-2012/>

State Strategies



❧ Do nothing

- ❧ State actions is severely limited by state statute or rule, pharmacy or medical board opinions
- ❧ Most states still have creative options available

Partnerships between EMS and Hospitals

- ❧ Rotation of medications between EMS and hospitals
 - ❧ Hospitals trade meds near expiration for fresher
 - ❧ Best in states where hospitals allowed to stock EMS
 - ❧ Safe Harbor regulations?
- ❧ EMS “swap out” programs
 - ❧ Hospitals “swap out” meds used by EMS on a patient for new

Virginia

18VAC110-20-500

3/5/2014

LIS > Administrative Code > 18VAC110-20-500

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18VAC110-20-500. Licensed emergency medical services agencies program.

The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.
2. The drug kit is sealed in such a manner that it will deter theft or loss of drugs and aid in detection of such.
3. Drugs may be administered by an emergency medical technician upon an oral or written standing protocol of an authorized medical practitioner in accordance with § [54.1-3408](#) of Virginia. Oral orders shall be reduced to writing by the technician and shall be signed by the medical practitioner. Written standing protocols shall be signed by the operational medical practitioner for the emergency medical services agency. The emergency medical technician shall maintain a record of all drugs administered to a patient.
4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit and be exchanged. An accurate record shall be maintained by the pharmacy on the exchange of kits for a period of one year.
5. The record of the drugs administered shall be maintained as a part of the pharmacy's records.

Drug Kit Resupply



Federal Safe Harbor OIG Opinion

- ❧ “Despite the potential for a violation, the OIG believes that the vast majority of ambulance restocking arrangements are lawful under the anti-kickback statute.”
- ❧ “We fully recognize the importance of ambulances being restocked and ready for emergency use at all times. Properly structured restocking arrangements contribute to this laudable goal without significant risk of fraud or abuse.”

Citation Waivers



- ❧ State regulators allow documented medication shortages when inspecting ambulance
- ❧ Agencies must demonstrate good faith effort to obtain shortage meds
- ❧ Helps avoid penalties for agencies;
- ❧ Doesn't help patients much

Arizona GD-104-PHS-EMS: Drug Shortages

GD-104-PHS-EMS: Drug Shortages

ΣΤΑΤΕ ΟΦΑΡΙΖΟΝΑ □ ΕΜΕΡΓΕΝΧΥ ΜΕΔΙΧΑΑ ΣΕΡ ζ ΙΧΕΣ ΑΝΔ ΤΡ ΑΥΜΑ ΣΥΣΤΕΜ Drug Shortages

Background

In the past few years, emergency medical services (EMS) providers have periodically been unable to comply with minimum supply requirements for certain drugs due to national or regional shortages of these agents. The intent of this guidance document is to inform EMS providers how the Bureau of Emergency Medical Services and Trauma System (Bureau) will accommodate an EMS provider who, despite efforts to locate and obtain a required agent, formulation, concentration, or delivery vehicle, is unable to meet the minimum supply requirements.

Process

Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Article 5, Table 1 establishes the agents and minimum supplies that an EMS provider or base hospital must furnish for use by an emergency medical technician (EMT). The Bureau is aware that some of the agents required in Table 1 may periodically be unavailable for purchase due to a national or regional shortage.

When an EMS provider or base hospital does not have, and is unable to obtain, the minimum supply of an agent, the EMS provider or base hospital must submit to the Bureau the documentation specified below. The Bureau will review the method proposed by the EMS provider to address the shortage to ensure that the health and safety of the public is protected. If the request meets those standards, the Bureau will not cite the deficiency for 90 days after the Bureau receives the documentation. If, after 90 days, the EMS provider remains unable to obtain the minimum supply of the agent, the EMS provider must submit to the Bureau the documentation specified below, reflecting new efforts to obtain the agent.

During an inspection, an EMS provider must provide the inspector with a copy of the Bureau's response to the submitted documentation specified below if the EMS provider or base hospital does not meet the minimum supply requirements of any agent in Table 1. The documentation specified below will not be accepted retroactively after a citation, but the EMS provider may submit it to the Bureau to prevent further citations if the EMS provider cannot obtain the required minimum supply of the agent.

Documentation of good-faith effort to obtain a required agent:



Tennessee



TN Division EMS
Heritage Place, Metro Center
227 French Landing, 303
Nashville, TN 37243

MEMO

To: EMS Service Directors and Medical Directors
From: Dr. Joe Holley, State Medical Director
Donna G. Tidwell, State EMS Director
Date: January 20, 2012
Re: Ambulance Inspections: National Drug Shortage

The Division of Emergency Medical Services recognizes the current problem with drug shortages nationally. Neither the Division nor the Department of Health has the authority to extend shelf life of medications. Until this shortage is rectified with the manufactures the Division will be using the following practice when inspecting ambulances.

- Medications not on the ambulance due to backorder:
 - Copy of backorder notification from manufacture should be placed in the protocol book found in each ambulance. Consultants will look for this document when inspecting ambulances with missing drugs.
 - It is recommended outdated drugs be removed for ambulance.
 - Medical Directors should be consulted to determine if a therapeutic equivalent could be ordered and substituted in the protocols. If a therapeutic equivalent is used a document signed by the Medical Director will be placed in the protocol books indicating the name of the



Medication Substitution



- ❧ Allows meds to be substituted by category
 - ❧ Benzodiazepines: diazepam for midazolam
 - ❧ Opiates: fentanyl for morphine
 - ❧ Anti-arrhythmics: lidocaine for amiodarone
 - ❧ Anti-nausea: ondansetron for prochlorperazine
- ❧ Variant: same med, but different concentration or packaging
 - ❧ High risk of introducing dosing errors

Use of Expired Medications



- ❧ Allow use of recently expired medications that are in short supply
 - ❧ Utah
 - ❧ Pennsylvania
 - ❧ Orange County, CA
 - ❧ Alabama (policy is drafted, but not currently implemented)
 - ❧ Oregon (emergency rule has expired)
 - ❧ Texas (“we might not prosecute you...maybe...for using expired meds”)

Utah



Utah Department of Health

W. David Patton, Ph.D.
Executive Director

Division of Family Health and Preparedness

Marc E. Babitz, M.D.
Division Director

Bureau of Emergency Medical Services

Paul R. Patrick
Bureau Director

State of Utah

GARY R. HERBERT
Governor

Spencer J. Cox
Lieutenant Governor

January 1, 2014

Utah EMS medication shortage procedure: for emergency medication use up to six months beyond labeled expiration date

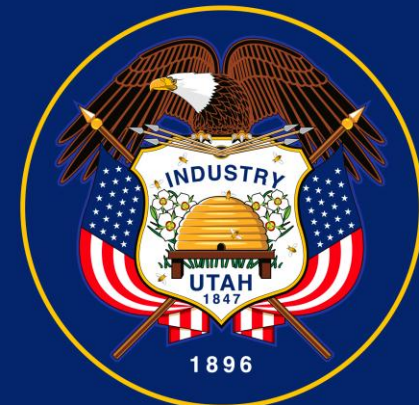
Nationally, many emergency medications used by EMS continue to be in severe shortage. The following medications utilized by Utah EMS agencies are currently in short supply and are critical to emergency prehospital patient care:

adenosine	dopamine	lactated ringers	nitroglycerin
atropine	droperidol	lidocaine	ondansetron
calcium	Duodote	lorazepam	promethazine
Cyanokit	epinephrine	magnesium	procainamide
dextrose	fentanyl	midazolam	
diphenhydramine	haloperidol	nalbuphine	

In order to ameliorate the current shortage, and prevent patient harm resulting from inadequate supplies of emergency medications, the Utah State EMS Committee, with the support of the Utah Bureau of EMS and Preparedness, has approved this policy for the use of expired critical shortage medications.

The Utah State EMS Committee and the Utah Bureau of EMS and Preparedness authorize the use of the above 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, expiring June 1, 2014, and will be reviewed every six months by the Bureau of EMS and Preparedness for renewal until shortages resolve
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 used only for emergency medical services



1896

Pennsylvania



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:

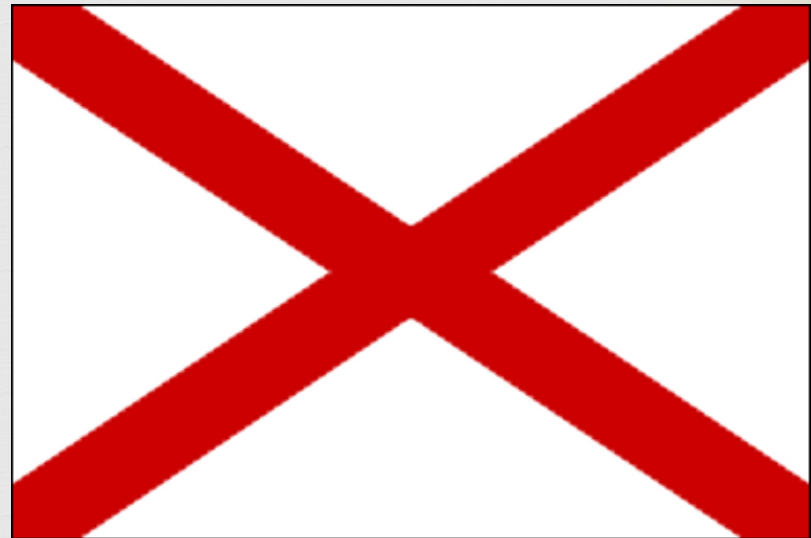
- Adenosine
- Albuterol (with or without ipratropium)
- Amiodarone and lidocaine
- Atropine
- Calcium chloride and calcium gluconate
- Dextrose 10-50% and glucagon
- Diazepam and lorazepam and midazolam
- Diphenhydramine
- Epinephrine (1:1000)
- Epinephrine (1:10,000)
- Fentanyl and morphine
- Magnesium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



Alabama



- ⌘ Allows med usage 6 months beyond expiration date
- ⌘ Drafted, but not yet implemented
- ⌘ Source: Dr. Elwin Crawford



Orange County, CA

Orange County, California EMS Agency



1. Usual drug & presentation (concentration and dosage form); progressively becoming more difficult to obtain
2. Usual drug, change dosage form (e.g. PFS to MDV or SDV with notification of EMS providers)
3. Usual drug, change concentration (with structured education of EMS providers)
4. Change drug within same drug class (coordinated through LEMSA and CA EMSA)
5. Change drug outside of drug class (coordinated through LEMSA and CA EMSA)
6. Usual drug used post-expiration date
 - a. maintain community standard of care by having all in-use drug in-date or post-expiration but not mixed
 - b. report post-expiration drug use to PRC and LEMSA, documenting use on the PCR/ePCR
 - c. LEMSA notifies specific patient for whom post-expiration drug was used as full disclosure
7. Don't treat (consequences range for undesirable to unethical [e.g. anticonvulsants])

The exact solutions will vary depending on the chemistry, pharmacology and clinical indications of a specific drug but the above strategy helps us organize our thoughts. This situation has become visible to our local hospital pharmacists with at best variable concurrence (with some outspoken discordance).

AUTHORIZATION FOR EMERGENCY EXTENSION FOR EXPIRATION OF SELECTED FIELD MEDICATIONS

This memorandum is to review the process for County EMS authorization to extend the expiration date for medications used to treat life-threatening field conditions. Extension of expiration for specific medications has become necessary because of persistent national pharmaceutical shortages.

The justification for extending expiration of specific medications is that treatment of a life-threatening condition with a medication that is available beyond shelf-life expiration is preferred over no treatment. This procedure applies only to EMS field cases.

The process for authorization is as follows:



Texas



DSHS Drug Shortage Statement for the website

DSHS is aware of drug shortages cited by the U.S. Food and Drug Administration (FDA).

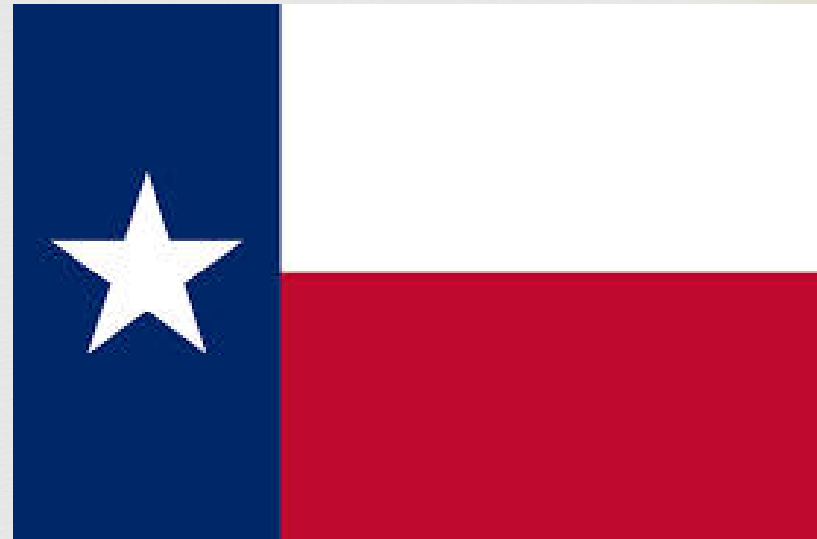
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>

Some of the drugs on the FDA list, such as fentanyl, magnesium sulfate and lidocaine, are being used to treat patients in the prehospital setting by emergency medical services providers.

If the department receives a complaint that a provider is using expired drugs or expired drugs are found on an ambulance during an inspection, the department will require the EMS organization to provide documentation from the manufacturer and the provider's medical director regarding the shortage of the specific drug(s) before considering an enforcement action. DSHS is recommending that the documentation is on any ambulance that has expired drugs approved by the MD

For additional information visit the Texas Medical Board at

<http://www.tmb.state.tx.us/news/press/2012/120224.php>



Oregon



Public Health Division
Emergency Medical Services and Trauma Systems

John A. Kitzhaber, MD, Governor



Date: June 25, 2012

TO: Interested Parties

FROM: Michael K. Harryman, MA
Director of Emergency Operations and
Emergency Medical Services and Trauma Systems

RE: Notice of Temporary Rulemaking for OAR 333-250-0051 – “Drug Shortages and Use of Expired Medications for Ambulance Services”

800 NE Oregon Street
Portland, OR 97232-2162
Voice (971) 673-0520
TTY (971) 673-0372

The Oregon Health Authority, Public Health Division has temporarily adopted OAR 333-250-0051 relating to drug shortages and the use of expired pharmacological and medical supplies in ambulance services. **This rulemaking is effective July 1, 2012 through December 27, 2012.**

The U.S. Food and Drug Administration has reported that drug shortages have been increasing in frequency and severity in recent years and the number of reported prescription drug shortages in the United States nearly tripled between 2005 and 2010, going from 61 to 178. Shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations of products. Emergency medical services (EMS) providers in Oregon may periodically be unable to obtain necessary and sometimes life-saving pharmacological and medical supplies due to national or regional shortages. Currently, ambulance services are prohibited from carrying expired pharmacological and medical supplies. The intent of this temporary rule is to provide that an ambulance service will not be subject to discipline for retaining expired pharmacological or medical supplies when certain standards are met. By adopting this temporary rule an ambulance service may carry expired pharmacological and medical supplies and use them, at the direction of a medical director, if not providing the drug would adversely affect patient care or if necessary to potentially save a patient's life.

For more details, please see the Statement of Need and Justification and the full text of the rules at the following website:

<http://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/Pages/index.aspx>

STATE OF OREGON



1859

Conclusions



- ❧ Different states have attempted to alleviate the shortage of EMS medications in different ways
- ❧ States constrained by individual legal interpretations, rule and statute
- ❧ Individual agency resource conservation is at the heart of any medication conservation program
- ❧ Questions?