



April 5, 2012

The Honorable Tom Harkin
Chairman
Committee on Health, Education,
Labor & Pensions (HELP)
United States Senate
Washington, DC 20510

The Honorable Michael Enzi
Ranking Member
Committee on Health, Education,
Labor & Pensions (HELP)
United States Senate
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

We, as a coalition of representatives from the EMS community, are writing to thank you for the attention the HELP Committee has focused on drug shortages and to raise your awareness that drug shortages are at a crisis level for patients of pre-hospital emergency medical services (EMS) agencies across the United States. To date, very little attention has been focused upon the negative impact that this national health and preparedness crisis has had on EMS systems and our patients. We are requesting that your committee continue to work on drug shortage legislation and specifically improve access of life-saving, not just life-sustaining, medications emergency patients receive through EMS agencies before delays and disruptions in patient care become more widespread with adverse consequences.

While the drug shortages may be an urgent issue for hospitals and healthcare facilities, a crisis level has already been breached for EMS systems and the patients they serve. Nearly fifty percent of a recently released list of pharmaceutical shortages by the Food and Drug Administration (FDA) included drugs that are routinely utilized by EMS agencies. Most concerning, many of these medications are lifesaving and critical for the emergent care of patients treated at the scene of an emergency or en route by EMS practitioners. These medications have clinical applications for treatment of cardiac arrest and life-threatening cardiac arrhythmias, pain management, and protracted seizures.

Unlike hospitals, EMS practitioners may not have alternative options as replacements for these medications. EMS practitioners serve in the invaluable role as the primary care providers for patients being transported from the scene to a healthcare facility, a time period where a patient's life is hanging in the balance. EMS medical directors provide extensive training on the medications carried by EMS agencies; however, unanticipated or frequent adoption of alternative medications inherently increases the risk for human errors.

As the incidence of drug shortages is increasing exponentially, the primary causative factors within the drug manufacturing industry must be identified and aggressively addressed, including DEA regulations. Congress should revisit the current statute governing manufacturers' responsibility to report potential shortages. Under existing law, the FDA may penalize the drug manufacturer for non-compliance by seizing the drug. For medications that have one sole manufacturer, this results in complete unavailability of the medication to patients at their moment of need. The continuation of such a policy exacerbates drug shortage crises.

In the interim, we respectfully propose the consideration of the following potentially viable options to improve care for patients with emergency medical conditions treated by EMS agencies. EMS is usually the first medical contact with a patient and often provides the best or only access for these medications for the patients. When alternative medications are required, associated pharmaceutical licensure amendment fees could be waived to relieve EMS agencies from the burden of unanticipated drug purchases from their strained and limited budgets. Ideally, avenues to avoid the transition to alternative medications are preferable. For critical lifesaving medications, patients with emergency medical conditions should be assured that the EMS agencies who respond to their call have access to the stocks of drugs that are available. In addition, affordable shelf life extension programs, similar to the process that exists in the military, would increase the cache of medications for EMS and reduce waste from discarding medications that have maintained clinical efficacy beyond their expiration dates.

On behalf of the EMS community, we thank you in advance for your attention to these critical issues. As representatives from multiple facets of the EMS community, we also are willing and able to serve as resources and subject matter experts for you and your colleagues as additional solutions are developed in the future.

Sincerely,

International Association of Fire Chiefs (www.IAFC.org)

National EMS Management Association (www.NEMSMA.org)

National Association of Emergency Medical Technicians (www.NAEMT.org)

National Association of State EMS Officials (www.NASEMSO.org)

American Ambulance Association (www.THE-AAA.com)

National Association of EMS Physicians (www.NAEMSP.org)

Association of Air Medical Services (www.AAMS.org)

National Volunteer Fire Council (www.NVFC.org)

cc:

The Honorable Lamar Alexander
The Honorable Michael F. Bennet
The Honorable Jeff Bingaman
The Honorable Richard Blumenthal
The Honorable Richard Burr
The Honorable Robert P. Casey, Jr.
The Honorable Al Franken
The Honorable Kay R. Hagan
The Honorable Orrin G. Hatch
The Honorable Johnny Isakson

The Honorable Mark Kirk
The Honorable John McCain
The Honorable Jeff Merkley
The Honorable Barbara A. Mikulski
The Honorable Lisa Murkowski
The Honorable Patty Murray
The Honorable Rand Paul
The Honorable Pat Roberts
The Honorable Bernard Sanders
The Honorable Sheldon Whitehouse

att: Partial list of drugs used by EMS agencies currently with reported shortages

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This partial list with common usage descriptions is included to provide some specific examples of drugs EMS agencies use on a daily basis with recently reported shortages.

Diazepam (Valium®)

Used for treating acute seizures

Diphenhydramine (Benadryl®)

Used to treat acute allergic reactions from food, insect stings, etc.

Epinephrine 1:1,000

A very commonly used drug for life-threatening allergic reactions

Etomidate (Amidate®)

Used as a short -acting intravenous anesthetic agent for the induction of general anesthesia and for sedation for short procedures such as advanced airway intervention or cardioversion.

Fentanyl

One of the most common drugs used to treat severe pain

Magnesium Sulfate

Used to treat eclampsia and pre-eclampsia, a life-threatening condition for pregnant women and torsade de pointes, a serious cardiac arrhythmia

Mannitol

Used to control intracranial pressure after head trauma.

Midazolam (Versed®)

A potent sedative used widely in the pre-hospital and in-hospital setting

Morphine

An analgesic widely used in EMS for pain control.

Ondansetron (Zofran®)

Used to control nausea and vomiting.