



POSITION STATEMENT

National Drug Shortage

Submitted by the EMS Section Board of Directors

Fire departments and EMS agencies throughout the United States are experiencing critical shortages of drugs that are used to save the lives of patients that may be suffering from trauma or a medical emergency. These drugs are essential for paramedics who must administer these pharmaceutical products to patients in the field prior to arriving at the hospital. Paramedics must have the crucial and necessary drugs to save the lives of their patients. Sometimes waiting 10-15 minutes to give a patient a drug in the emergency room can mean the difference between life and death. Currently, there is no comprehensive data on the impact caused by drug shortages on the fire service's ability to treat patients. However, drug shortages create situations in the field which very likely could result in errors in treatment and unnecessary risks to patients.

While a very small number of drugs in the United States experience a shortage in any given year, the number of drug shortages in the United States nearly tripled between 2005 and 2010ⁱ, and shortages are becoming more severe as well as more frequentⁱⁱ. Addressing the national drug shortage should be a top priority for the entire fire and emergency service since the fire service is part of almost every EMS system in the United States. While examining the causes and impacts of drug shortages, the International Association of Fire Chiefs (IAFC) finds that:

1. Drugs, that are fundamental and essential to emergent patient care, affect this nation's provision of pre-hospital care and impact the most vulnerable patients. Without access to the preferred or most clinically appropriate drug treatment, paramedics are forced to use alternatives, which may result in human errors when drawing up medicationsⁱⁱⁱ, less effective treatment, or increased risk of adverse outcomes. Some EMS systems may not have alternative medications to treat patients.
2. Causes of drug shortages are many and complex. Manufacturing issues that lead to drug shortages include:
 - a. Product quality issues that result in production halts or recalls^{iv}.
 - b. Product discontinuations, and unavailability of active pharmaceutical ingredients (APIs) or other raw materials^v.
 - c. Secondary shortages—or shortages that occur based on shifts in market demand caused by an initial shortage of another drug—also are common^{vi}.
 - d. Quality issues that arise from an increasing reliance on foreign ingredient and manufacturing sources^{vii}.
 - e. A lack of Food and Drug Administration (FDA) resources to expedite approval of supplemental new drug applications or conduct foreign inspections^{viii}.

- f. Manufacturing and inventory practices by product distributors and practice sites have reduced the buffer previously provided by larger inventories. This results in an immediate impact of drug shortages on patient care^x. This practice is shared at the local level with many local community hospitals providing a buffer of only a few days.
 - g. Fewer manufacturers producing critical drugs^x.
3. Some fire-based EMS systems are reporting the following adverse situations:
- a. Pulling drugs from ALS engine companies to place on ambulances as the shortages worsen.
 - b. Creating, with their medical directors, "just-in-time" protocols or multiple protocols for similar conditions.
 - c. Purchasing and using more expensive brand name medications but unable, due to current reimbursement models, to pass along the additional cost to patients.

Based on the above evidence, the IAFC supports:

- 1. Appropriate funding levels for the FDA to fulfill their mission, including production facility inspections and timely approval of new drug applications.
- 2. The development of regulations or laws to:
 - a. Require pharmaceutical manufacturers to notify the appropriate government body at least 12 months in advance of voluntary discontinuation or the inability to meet the average historic demand of medically necessary pharmaceuticals purchased by EMS systems.
 - b. Require prompt public disclosure of a notification to voluntarily discontinue, or an inability to meet average historic demand of, a medically necessary pharmaceutical product purchased by EMS systems.
 - c. Provide incentives for manufacturers to maintain an adequate supply of medically necessary pharmaceuticals purchased by EMS systems.
 - d. Provide effective sanctions for manufacturers that do not comply.
- 3. Cooperation between the appropriate government agencies and drug manufacturers in maintaining or improving the supply of medically necessary pharmaceuticals purchased by EMS systems.
- 4. An examination of the drug approval process to find opportunities for expedited approval processes for alternative medically necessary products purchased by EMS systems after notification to the appropriate government agencies of voluntary discontinuations or an inability to meet average historic demand of a medically necessary product purchased by EMS systems.
- 5. Collaboration between the Drug Enforcement Agency (DEA) and the FDA to address Schedule II drug shortages, including an examination of DEA quota requirements to determine the impacts on a manufacturers' ability to increase production of controlled substances in short supply.
- 6. Collaboration between the IAFC EMS Section and the Joint National EMS Leadership Forum.

The IAFC encourages chief fire officers and EMS managers to:

- 1. Stay abreast of the latest shortages by frequently visiting the Food and Drug Administration's website pertaining to drug shortages^{xi}.
- 2. Re-evaluate current EMS inventories to ensure we are not contributing to the shortage.
- 3. Actively report to their commanding officers, medical director, and the appropriate government agencies drug shortages impacting their department^{xii}. Work with local EMS medical directors to implement a medication shortage list with the primary,

secondary and tertiary medications within protocols to limit the impact of short notice.

4. Develop policies and procedures to build agility into protocol changes and a tracking mechanism to allow for quality assured compliance.
5. Examine other medically appropriate and approved solutions such as using multi-dose vials to pre-draw up medications in syringes and seal them in tamper-proof bags or containers that are clearly marked with the drug, expiration date, and lot number.
6. Explore the requirements to provide a fully functional pharmacy internally to lessen dependence on local hospital supply.
7. Regionalize pharmaceutical plans to assist in limiting shortages or their impact.
8. Develop a more formal MOU with local hospital pharmacies which identify the impacts of medication shortages and the expected remedy/actions when they occur. Also incorporate discussions on how to increase on-hand storage) such as shared remote secure storage.
9. Enhance paramedic training to include the implications of pharmaceutical shortages and to improve proficiency in drug calculations and medications.

ⁱ Compiled by U.S. Food and Drug Administration and stated by Secretary of the U.S. Department of Health and Human Services 10/31/2011.

ⁱⁱ FDA [Drug Shortages Information](#)

ⁱⁱⁱ Gatesman, Mandy; Smith, Thomas; 20111103; *New England Journal of Medicine*. [The Shortage of Essential Chemotherapy Drugs in the United States](#); 365: 1653-1655.

^{iv} FDA [Drug Shortages Information](#)

^v FDA [Drug Shortages Information](#)

^{vi} FDA [Drug Shortages Information](#)

^{vii} FDA [Drug Shortages Information](#)

^{viii} GAO Report: FDA's Ability to Respond Should Be Strengthened. 20111215.

^{ix} GAO Report: FDA's Ability to Respond Should Be Strengthened. 20111215.

^x FDA [Drug Shortages Information](#)

^{xi} FDA List of Drug Shortages:

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

^{xii} Drug shortages can be reported via:

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm>

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