



## **The Impact of Drug Shortages on Patients with Emergency Medical, Critical and Life-Threatening Illness or Traumatic Injury**

### **Background**

The nationwide drug shortage problem has recently developed into alarming impact on patients with an emergency medical, critical and life-threatening illness or traumatic injury. Emergency medical services (EMS) encompasses emergency medical and trauma care provided to patients at any point in the continuum of health care services. "Field EMS" refers to emergency medical and trauma care provided *outside* of the hospital, most often prior to and during transport to a hospital. Field EMS providers conduct nearly 25 million transports for more than 8 percent of the US population per year, predominantly by ground, but also by air. Of those transports, patients who are critically ill or injured are transported by specialized critical care transport (CCT) providers by ground and air, including approximately 400,000 patients flown by fixed and rotor wing air ambulances every year. Field EMS and CCT providers administer life-saving care, often through the use of specialized equipment or drug therapies, while transporting a patient from the scene to a medically appropriate receiving hospital or between hospitals, typically moving patients to a higher tertiary care facility. While the drug shortage crisis emerged largely around sterile injectables, particularly in oncology, the crisis has spread to EMS, including emergency departments, CCT and Field EMS with a direct and adverse impact on extremely vulnerable patients with emergency medical and life-threatening critical care conditions.

At least 30 drugs on the FDA's current shortage list are commonly used as part of EMS, Field EMS and CCT. Among these drugs are ones used to treat cardiac, stroke, seizure, severe pain and high-risk obstetrical patients in the field. If patients do not have access to these drugs within a very short time window, it can mean the difference between life and death or serious disability. In addition, certain sedatives that are used to treat combative patients are in short supply, putting the transport team and patient at risk as they attempt to treat and transport an agitated or non-compliant patient. Air ambulance providers have already had to turn away critical care patient transports due to their inability to secure and maintain life-saving drugs, putting patients at extraordinary risk.

Our nation depends upon EMS, CCT and Field EMS providers to be able to respond to mass-casualty events, as well as individual emergencies. However, without the proper drug supply,

these essential providers are severely limited in their ability to provide ample surge capacity or ensure that they will be able to meet the needs of patients with emergency and critical care conditions whose lives are literally and immediately at stake.

### **Limitations of Stop-Gap Measures**

EMS, CCT and Field EMS providers are working to manage their drug supplies despite ongoing shortages as best they can, but certain stop-gap solutions are particularly difficult for medical and critical care transport providers to implement. Physician medical directors are now routinely facing difficult choices in directing nurses and paramedics in the utilization of suboptimal substitute and expired drugs, as well as having to reserve limited and essential drug supplies for those patients in the greatest need. This puts patients at risk and physician medical directors in the untenable position of jeopardizing their medical licenses to best meet the needs of all of their patients with emergency medical, critical and life-threatening illness or traumatic injuries.

- **Substitutions** - While therapeutic alternatives may exist for certain drugs, they are often in the form of non-preferred drugs and are sometimes only available in unfamiliar concentrations or vial sizes. Despite additional training, such substitutions can lead to dangerous situations involving medical errors of dosages when using different concentrations, especially in emergency situations when professionals are moving quickly, transport conditions are suboptimal, and time is of the essence.
- **Expiration Date Extensions** - Under medical direction some providers are extending the expiration dates of select drugs for lack of a better alternative. There is no formal mechanism for extending medication shelf-life in the civilian environment. Therefore, medical directors are left to make individual decisions that may put their license on the line because they believe it is in the best interest of their patients to receive an expired drug instead of no drug.
- **Scope of Practice Issues** - Certain substitutions may involve drugs that can only be administered by a specific type of trained professional. For example, in some states the scope of practice delineates the specific drugs an EMS provider may deliver. A substitute for that drug may not be included in that state's scope of practice, making it illegal for a paramedic to deliver that substitute drug. These and other "scope of practice" issues are of particular concern in the medical transport setting.

To illustrate further by example, in the State of Oregon, there are no injectable benzodiazepines available for purchase. These medications are used to stop active seizures (among other things). It is possible that a child could be left to seize for an entire transport because these drugs were unavailable. This could lead to significant disability or death of the patient. In addition, these medications are utilized for sedation to help EMS place breathing tubes into critical patients. Other drugs used to facilitate this procedure are also unavailable, putting our nation's trauma patients at risk.

## **Proposed Solutions**

As Congress considers legislative options to address the drug shortage issue, our organizations stand ready to work with Members on a range of solutions to help improve the drug supply and mitigate the effects of shortages on patient care. We support Congressional efforts to require and expand advance notification systems so EMS, CCT and Field EMS providers are better able to manage potential shortages with additional lead time. We are concerned, however, that addressing drug shortages for pharmaceuticals that are "life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition" does not adequately capture the situation of drugs used for patients with emergency medical, critical and life-threatening illness or traumatic injury. In medical circles, the terms "life-sustaining and life-supporting" do not apply to acute emergency medical, critical and life-threatening conditions.

***Thus, whatever solutions the Congress chooses to employ should specifically encompass and reference drugs used for treatment of patients with emergency medical, critical and life-threatening illness or traumatic injury, promote access to life-saving drugs where they are most needed by patients, and seek to identify and remove impediments to the ability of providers to compensate for lack of access to a preferred drug in the best interest of their patients.*** In addition, we urge Congress to ensure that any stakeholder consultation process include representatives of the EMS, Field EMS and critical care transport communities. Accordingly, we recommend the following revisions to the legislative language that has been released to date:

### **I. House Energy & Commerce Committee's PDUFA discussion draft document:**

- Page 193, Sec. 901 – Under SEC. 506C(a)(1) – add "(D): or intended for use in the treatment of an emergency medical, critical or life-threatening illness or traumatic injury."
- Page 195, (B) – add "or intended for use in the treatment of an emergency, critical or life-threatening illness or traumatic injury."
- Page 198, Sec. 904 – add "or intended for use in the treatment of an emergency medical, critical or life-threatening illness or traumatic injury" to the title of the Section.
- Page 201, (3) Amend to read "Is there a reason why drug shortages have occurred primarily in the sterile injectable market, and in certain therapeutic areas including drugs used for patients with emergency medical, critical and life-threatening conditions?"
- Page 201, add new (7) "How does the drug shortage crisis affect particular patient populations for whom lack of access to drugs can mean the difference between life, death or severe disability?"
- Page 201, add new (8) "How are providers, including hospitals, physicians and physician medical directors compensating for lack of access to preferred drugs in caring for their patients and are there impediments to their ability to adjust accordingly that can be ameliorated?"
- Page 201, (c) – add "emergency medical services and critical care transport providers."
- Page 205, (11) – add "emergency medical services and critical care transport providers."

### **II. Senate HELP PDUFA discussion draft on prescription drug shortages:**

- Page 3 - following (1)(C) add "(D) drugs intended for use in the treatment of an emergency medical, critical or life-threatening illness or traumatic injury."

*Advocates for Emergency Medical Services*  
*Air Medical Physician Association*  
*American College of Emergency Physicians*  
*American Heart Association/American Stroke Association*  
*American Trauma Society*  
*Association of Air Medical Services*  
*Association of Critical Care Transport*  
*National Association of EMS Educators*  
*National Association of EMS Physicians*  
*National Association of State EMS Officials*  
*National EMS Management Association*  
*National Association of Emergency Medical Technicians*  
*Trauma Center Association of America*

## **DRUGS USED FOR EMS, FIELD EMS and CCT PATIENTS CURRENTLY IN SHORTAGE**

- Amiodarone – for lethal heart arrhythmias that left untreated will stop the heart
- Atropine – to increase a heart rate which is too slow to sustain life
- Calcium Chloride and Calcium Gluconate – antidote for life threatening high potassium that threatens our dialysis patients
- Dexamethasone – for life threatening allergic reactions and asthma. Additionally for adrenal crisis that can lead to severe shock, death and disability
- Diazepam, Midazolam, Lorazepam – to stop active seizures and for sedation
- Diltiazem – to slow a very fast heart rate, which compromises cardiac function
- Diphenhydramine – for severe allergic reactions
- Epinephrine – (adrenaline) used for life threatening allergic reactions and acute pediatric asthma (intermittent shortages)
- Etomidate – sedative used to facilitate emergent intubation before placing someone on a ventilator
- Fentanyl – pain relief (similar to morphine)
- Forphenytoin – to prevent and stop seizures
- Furosemide – diuretic for serious heart failure
- Haloperidol – major sedative for combative patients
- Labetalol – to treat high blood pressure in patients with life threatening conditions
- Lidocaine – used in cardiac arrest - major stoppage of the heart as well as a local anesthetic
- Magnesium – to treat life threatening cardiac arrhythmias and also used as an adjunct in the treatment of emergent asthma conditions
- Mannitol – reduces brain swelling in serious head injury
- Morphine – pain medication
- Nifedipine – to treat dangerously high blood pressure in medical conditions such as stroke
- Nitroglycerin – used in the treatment of patients with heart attacks and angina
- Ondansetron – prevents vomiting. Significant during transport of a head injured patient
- Oxytocin – after delivery of a baby to prevent maternal uterine bleeding
- Phenylephrine – to increase blood pressure if the blood pressure is dangerously low
- Pancuronium – muscle relaxant used to facilitate ventilation and oxygenation in a patient with a breathing tube in place
- Phytonadione – to reverse the effects of oral blood thinning drugs in patients with life threatening bleeding
- Potassium – to increase the blood potassium level which left untreated can produce life threatening cardiac arrhythmias
- Procainamide – heart drug for life-threatening rhythm problems
- Prochlorperazine and Promethazine – to prevent vomiting
- Terbutaline – for pre-term labor and severe asthma
- Vasopressin – to restart the heart in cardiac arrest
- Vecuronium – muscle relaxant used to facilitate ventilation and oxygenation in a patient with a breathing tube in place