NAVIGATION FROM BETWEEN A ROCK AND HARD PLACE

NASEMSO EMS DRUG SHORTAGES SUMMIT 2014

March 5, 2014

Carol A. Cunningham, M.D., FAAEM, FACEP
THE NETWORK

- Drug Enforcement Agency (DEA)
- Food and Drug Administration (FDA)
- Pharmaceutical Manufacturers
- Hospitals
- Pharmacies
- EMS (Providers and Medical Directors)
- Patients
MISSION OF FEDERAL AGENCIES

**FDA**
- U.S. Department of Health and Human Services
- Public health/patient safety
- Scheduled and non-scheduled medications included along with food, blood, medical and radiation-emitting devices, vaccines, cosmetics, tobacco and veterinary products

**DEA**
- U.S. Department of Justice
- Law enforcement/diversion control systems/drug trade and trafficking
- Scheduled medications, legal and illegal narcotics
FDA PENALTIES

- Cessation of manufacturing of medication
- Restriction in manufacturing or administration of medication
- Seize, arrest, and prosecute for the possession and sale of non-FDA approved substances
- Advisory role, rather than a primary role, during admonishment, citation, or litigation against physicians
DEA PENALTIES

- Restriction of scheduled medication categories issued on a DEA narcotics registration
- Issuance of fines
- Citation of a DEA narcotic registration
- Revocation of a DEA narcotic registration
DRUG SHORTAGES AND IMPACTS TO EMS

- EMS and Drug Supplier
- EMS and Drug Shortage
- EMS and Patients
EMS & DRUG SUPPLIER

- Impact of state and federal regulations
- Impact of pharmaceutical companies on cost and availability
- Impact of hospital supplies and distribution practices
- Impact of hoarding
EMS & DRUG SHORTAGE

- Impact of scope of practice
- Impact on medical direction and protocols
- Impact of approved medications and pharmacy licensure
- Impact of training opportunities
- Impact of EMS provider experience
EMS & PATIENT CARE

- Impact of lack of drugs
- Impact of alternative drugs
- Impact of transport times
- Impact on medication error rates
- Impact of patient-related factors (allergies, weight-based doses, etc.)
LONG-TERM SOLUTIONS

- Ongoing relationship of FICEMS with the DEA to ensure coordination to meet the needs of the dynamic and progressive practice and profession of EMS

- Provision of a foundation of knowledge of the critical needs of EMS to all involved stakeholders
LONG-TERM SOLUTIONS

- Incorporation of EMS-specific administrative and operational factors into future federal and state regulations
- Establishment of a formal EMS liaison or designated legislative committee position within federal and state stakeholder organizations
SHORT-TERM SOLUTIONS

- Provision of detailed information regarding current DEA regulations and procedures to all EMS colleagues

- Encourage EMS medical directors to create “just in time” prehospital protocols for alternative scheduled (and non-scheduled) medications if legislatively permitted
SHORT-TERM SOLUTIONS

- Enhance networking with hospitals, pharmacies, and other EMS partners to explore viable options

- Initiate a formal relationship/liaison with the DEA agents assigned to the local and state jurisdictions
UNRESOLVED HURDLES

- Off-line medical direction and administration of scheduled medications
- DEA narcotic registrations of EMS agencies, hospitals, and physicians
- Utilization/distribution of scheduled medications from the Strategic National Stockpile assets
UNRESOLVED HURDLES

EMS medical director risk
- Provision of medical direction/protocols
- Diversion prevention, detection, and reporting

Patient risk secondary to lack of availability and/or administration of scheduled medications
UNTAPPED OPPORTUNITIES

- Prevention of medication shortage by utilization of any available avenue
- Prioritize the provision of critical lifesaving medications to EMS agencies
Waiver of additional fees for federal and state pharmaceutical licensure amendments that are associated with a medication shortage

Federal-based cost-effective shelf life extension programs
THE COMMON THREAD FOR ALL SOLUTIONS

- Foundation of knowledge of the mission and needs of EMS
- EMS representation at all stakeholder levels
- Interagency cooperation at the horizontal and vertical levels of the healthcare system
- Patients must be the top priority