

# 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

## DEA



- ❧ 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

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

# FDA PENALTIES



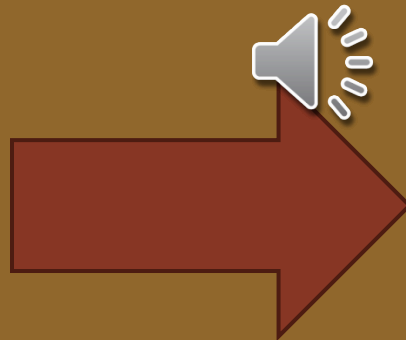
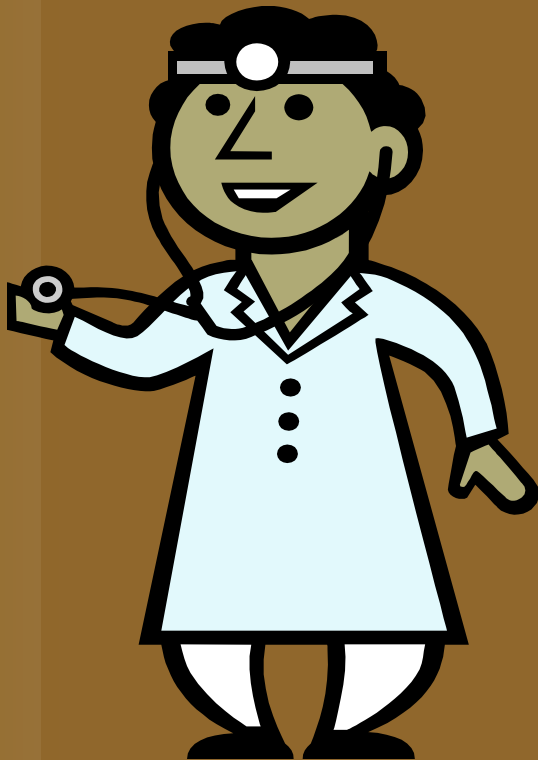
- ❧ Cessation of manufacturing of medication
- ❧ Restriction in manufacturing or administration of medication
- ❧ Seize, arrest, and prosecute for the possession and sale of non-FDA approved substances
- ❧ Advisory role, rather than a primary role, during admonishment, citation, or litigation against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

# DEA PENALTIES



# DRUG SHORTAGES AND IMPACTS TO EMS



☞ EMS and Drug Supplier

☞ EMS and Drug Shortage

☞ EMS and Patients



# EMS & DRUG SUPPLIER

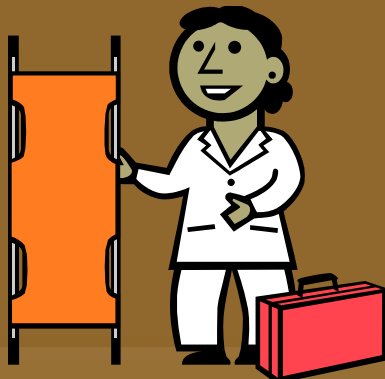


- ❧ Impact of state and federal regulations
- ❧ Impact of pharmaceutical companies on cost and availability
- ❧ Impact of hospital supplies and distribution practices
- ❧ Impact of hoarding





# EMS & DRUG SHORTAGE

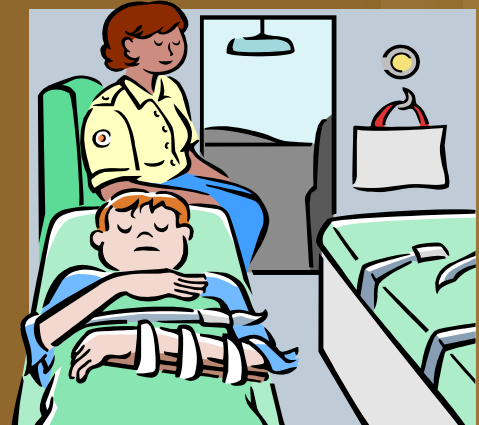


- ❧ Impact of scope of practice
- ❧ Impact on medical direction and protocols
- ❧ Impact of approved medications and pharmacy licensure
- ❧ Impact of training opportunities
- ❧ Impact of EMS provider experience

# 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


# UNTAPPED OPPORTUNITIES



- ❧ 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

