

DEA ISSUES AND THE IMPACT ON EMS

NAEMSO Annual Meeting
September 27, 2012

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Chair, NAEMSO Medical Directors Council

THE NETWORK

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

ORGANIZATIONAL MISSION

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

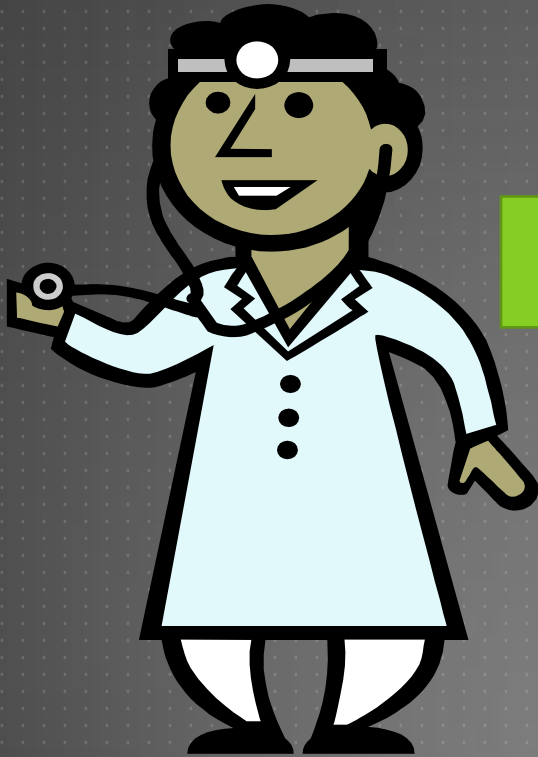
FDA PENALTIES

- ▶ 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

DEA PENALTIES



DEA WORKGROUP

- ▶ Sabina Braithwaite, MD, MPH
Chair, EMS Committee, ACEP
- ▶ Carol Cunningham, MD
Chair, Medical Directors Council, NASEMSO
- ▶ Jim Cusick, MD
Chair, EMS Section, ACEP
- ▶ Brent Myers, MD, MPH
Member-at Large, Board of Directors, NAEMSP
- ▶ Allen Yee, MD
EMS Committee, AAEM

DEA MULTI-ORGANIZATIONAL TASK FORCE

▶ ACEP

- Dr. Sabina Braithwaite
- Dr. Joseph Holley
- Dr. Jeffrey Goodloe
- Dr. Craig Manifold

▶ AAEM

- Dr. Allen Yee

▶ NAEMSP

- Dr. J. Brent Myers

▶ NASEMSO

- Dr. Carol Cunningham
- Dr. Joe Nelson

PINNACLE EVENTS

- ▶ October 31, 2011: Presidential Executive Order to the U.S. Department of Health and Human Services, the FDA, and to pharmaceutical manufacturers
- ▶ March 13, 2012: FICEMS TWG to move the DEA Medical Director Workgroup's proposal to FICEMS
- ▶ April 5, 2012: ACCT/ACEP letter to House of Representatives
- ▶ April 6, 2012: International Association of EMS Chief and EMS Labor Alliance letter to President Obama
- ▶ April 16, 2012: ASPR Workshop on Drug Shortages and EMS
- ▶ July 13, 2012: ASTHO Emergency Care Drug Shortage National Workgroup

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
- ▶ 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

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
- ▶ 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

UNTAPPED OPPORTUNITIES

- ▶ Prevention of medication shortage by utilization of any available avenue
- ▶ Prioritize the provision of critical lifesaving medications to EMS agencies
- ▶ Early notification of medication shortages by pharmaceutical manufacturers
- ▶ 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

LONG-TERM SOLUTIONS

- ▶ Provision of a foundation of knowledge of the critical needs of EMS to all involved parties
- ▶ Incorporation of EMS-specific administrative and operational factors into future DEA regulations
- ▶ Establishment of a formal EMS liaison or designated legislative committee position within the DEA
- ▶ Ongoing relationship of FICEMS with the DEA to ensure coordination to meet the needs of the dynamic and progressive practice and profession of EMS

THE FRIENDSHIP TRAIN

SHAKE A HAND..... MAKE A FRIEND



FDA

Secretary Kathleen Sebelius
Commissioner Margaret Hamburg

DEA

Attorney General Eric Holder, Jr.
Administrator Michele Leonhart

