Briefing Regarding EMS Drug Enforcement Administration (DEA) Issues
March 13, 2012

Prepared by:
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Background:

The current practice of EMS medicine is of significant importance to a community's health and public safety. Thousands of physicians serving as EMS medical directors provide medical oversight to tens of thousands of EMS professionals, including over 72,500 Paramedics (source: 2010 Annual Report of National Registry of EMTs).

EMS providers routinely administer controlled substance medications to abate life-threatening seizures and control pain from traumatic injuries, such as fractures, burns, and amputations. To provide optimal patient care using these medications, a clear understanding of DEA regulations and expectations regarding the practice of EMS medicine is vital to promoting and ensuring the proper ordering, storing, supplying, administering, and disposal of these controlled substance medications. Physician medical directors of EMS agencies advocate appropriate controlled substance handling to maintain their EMS medical practice with regulatory and ethical integrity as well as to prevent diversion and abuse of these controlled substance medications.

Due to the routinely encountered clinical need for controlled substance medications in the practice of EMS medicine, all physician medical directors of EMS agencies desire to be in full compliance with DEA regulations. However, considerable confusion exists as to what practices properly fulfill the relevant DEA regulations and expectations regarding controlled substance medications in the EMS environment as noted from anecdotal discussions among EMS medical directors, EMS administrators, and officials at DEA offices across the United States. This confusion may partly arise from the fact that the current regulations do not take into account the significant differences between EMS practice / work environment and that of other healthcare entities and individuals covered by the same regulations. To wit, a comprehensive review of the current DEA regulations (source 21 CFR Part 1300 to End, Revised as of April 1, 2011) yields no matches to searches for the following search terms: "emergency medical services", "ambulance services", or "paramedic". (source: Dr. Sabina Braithwaite, January 12, 2012, Tucson, Arizona, Presentation at 2012 NAEMSP Annual Meeting)

Partnership:

To support the desire of EMS physicians to better understand the application of DEA regulation to their EMS practice and maintain compliance with said regulations, the ACEP EMS Committee was tasked by ACEP's President (David C. Seaberg, MD, CPE, FACEP) with the following objective for the 2011-2012 year: *Explore ways to develop evidence-based resources for EMS system to address emerging operational issues.* (source: acep.org accessed March 13, 2012)

Among the ACEP EMS Committee meeting attendees, the first subject identified for this objective by need and interest concerned DEA regulations and expectations in the EMS environment. A multiple-step plan to address the objective was conceived by Jeffrey M. Goodloe, MD, NREMT-P, FACEP and supported by Dr. Braithwaite. The core components of that plan were:

a) Educate ACEP members serving as EMS medical directors on DEA regulations and expectations relevant to their practice of EMS medicine.
b) Engage DEA leadership in discussions advocating for clearer regulations and expectations relevant and appropriate to the practice of EMS medicine.
c) Assist DEA leadership in developing clearer regulations and expectations relevant and appropriate to the practice of EMS medicine.

In the effort to prepare educational materials, pervasive confusion and inconsistencies in the understanding and practices for the utilization of DEA regulations in the practice of EMS medicine were repeated obstacles to creating a clear guide for EMS physicians. Moreover, it became clear that not only was there lack of understanding on the part of physicians and EMS agencies, but there were significant inconsistencies in explanations and/or interpretations of existing regulation on the part of various DEA field offices across the country. It became clear that these inconsistencies in application of DEA regulations to the practice of EMS medicine were an insurmountable barrier to creating definitive guidance or reliable, national-level educational materials. Discussions with other organizations (NAEMSP, NASEMSO, AAEM) revealed shared concerns regarding these issues. As a result, work on creating educational materials was suspended and a multi-organization task force of EMS physician leaders convened in Tucson, Arizona in January in conjunction with the 2012 NAEMSP Annual Meeting and Scientific Assembly to strategize on next steps. (See final page for organization and representative information)

The task force agreed it would be best to survey membership of organizations with a large sector of physician EMS medical directors for specific information on experience with application of DEA regulation to EMS practice to substantiate the issues, and specifically identify what common themes existed that required most urgent attention. An open-ended brief survey was designed by Dr. Goodloe and approved by the multi-organization task force. The survey was distributed to the membership of the ACEP's EMS Committee and EMS Section, NAEMSP, and the NASEMSO Medical Directors Council by their respective organizations. The survey asked respondents to anonymously answer the following questions:

1. *What problems or concerns have you encountered in working with the DEA within your EMS practice of medicine? (e.g. inconsistencies of regulation explanations or applications--be specific, confusing explanations of regulations, inability to identify unique attributes of the practice of EMS medicine).*
2. *What suggestions do you have to address the problems or concerns you identified in question 1?*
3. *Are there additional questions or topics you would like us to raise with the DEA related specifically to the practice of EMS medicine? (e.g. issues you are unsure of the correct path to take based on regulation, but do not wish to raise through your agency for whatever reason)*

Please specifically indicate the DEA office you are working with in your practice of EMS medicine (e.g. Dallas, Washington D.C.).

Over 100 respondents representing EMS agencies coast to coast, including urban and rural, volunteer and career, large and small agencies provided a broad view of the issue. A minority of respondents indicate no issues with DEA or simply a lack of personal investigation into whether their current

practices are in compliance with DEA expectations and regulations. Of those who reported concerns, the following predominant issues with DEA regulations as applied to the practice of EMS medicine were identified by respondents:

1. Conflicts between DEA and state-level counterparts' regulations that are mutually exclusive.
2. Poor applicability to EMS. No specific language involving EMS is contained within existing DEA regulations and traditional mid-level practitioner model written for licensed individuals. The result is a poor fit to the agency model, deployment practices and delegated practice of medicine found in the practice of EMS medicine. Closely related to this, there is lack of specific EMS guidance/education on how to interpret the current regulations.
3. Inconsistent answers to the same questions within the same DEA office and between different DEA offices. While there is one set of federal regulations, the federal regional offices appear to have broad latitude and often inconsistent interpretative powers, complicated by the lack of specific EMS language already noted. Examples include whether individual EMS stations require separate DEA registrations, whether specific EMS registrations should be as practitioner or distributor, what locking mechanism(s) are required for controlled substances and what inventory practices are required for controlled substances.
4. Lack of a consistent authority to provide guidance for DEA-registered physician EMS medical directors and agencies on regulatory questions, to provide needed clarification of existing regulation, and to make this information available to others.
5. Inconsistency with long-standing, widely-used operational standards. A prime example is unused controlled substance being "wasted" at hospital with witnessing of said wastage as opposed to more recent interpretations requiring reverse distribution of previously opened containers of controlled substance pharmaceuticals.

Respondents indicated that the ideal resolution to their concerns might ultimately be best addressed by the promulgation of new DEA regulations or guidance that specifically address the unique environment of EMS medicine.

The multi-organization task force wrote a letter to the Dr. Rick Hunt, Chair of the Medical Oversight Committee of the Federal Interagency Committee on EMS based on the information above to request:

> *that FICEMS seek to initiate a dialogue with the DEA regarding how to most effectively mesh the patient care goals of EMS with the administrative and operational goals of the DEA for controlled substances. We believe the establishment of such a linkage would promote a partnership that would facilitate beneficial discussions. Topics might include:*
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> 1. *Creating a partnership with DEA to mutually identify how our nation's EMS community can best assure consistent compliance with existing regulations at the local, regional, and state levels. An option to explore may be providing an authoritative, nation-wide repository for EMS stakeholders' questions and DEA answers.*
> 2. *Determining areas of focus that would benefit from best practices that can be applied at a national level to promote local compliance.*
> 3. *Identifying key regulations needing clarification for EMS to facilitate compliance and enhance patient care.*

This request was officially presented to the FICEMS Technical Working Group (TWG) at their March 13, 2012 meeting. Our request was well received and TWG agreed that the proposed idea should be moved forward from the TWG to the full FICEMS with a recommendation that FICEMS seek out opportunities for a mutual dialogue with DEA not only on the issue at hand (inconsistent application of regulation) but also long term as the interface between DEA and EMS. It was recognized that a mutual understanding of each other's problems and priorities is important to ongoing coordination. Susan McHenry will be the primary TWG point of contact for the issue. The TWG is aware that our organizations stand ready to assist in any way we can.

Representatives from the following organizations constitute the multi-organization task force:

American College of Emergency Physicians:	Dr. Sabina A. Braithwaite
	Dr. Jeffrey M. Goodloe
	Dr. Craig A. Manifold
	Dr. Joseph E. Holley, Jr.
American Academy of Emergency Medicine	Dr. Allen Yee
National Association of EMS Physicians	Dr. J. Brent Myers
National Association of State EMS Officials	Dr. Carol Cunningham
	Dr. Joe Nelson

Information on each organization is as follows:

Founded in 1968, the **American College of Emergency Physicians** (ACEP) is based in Dallas, Texas and today represents more than 28,000 emergency physicians, residents and medical students. (source acep.org, accessed March 13, 2012)

Founded in 1993, the **American Academy of Emergency Medicine** (AAEM) is based in Milwaukee, Wisconsin and today represents more than 6,500 emergency physicians, resident and medical students. (source aaem.org accessed March 13, 2012)

Founded in 1984, the **National Association of Emergency Medical Services Physicians** (NAEMSP) is based in Lenexa, Kansas and today represents more than 1,200 physicians, paramedics, nurses, administrators, educators, researchers and key EMS personnel. (source naemsp.org accessed March 13, 2012)

Founded in 1980 , the **National Association of State Emergency Medical Services Officials** (NASEMSO) is based in Falls Church, Virginia and today its membership represents 56 state and territorial EMS directors, medical directors, training coordinators, data managers, trauma managers, and EMS for Children managers. (source nasemso.org accessed March 13, 2012)