Navigating the Regulatory Morass

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Morass: a situation that traps, confuses, or impedes

- There are many federal, state and local government agencies with regulatory authority over one or more aspect of EMS
  - Some know and understand EMS
  - Some have agendas can have a significant personal impact on you – fines, licenses, or more.

Regulatory Agencies to Know About

- Dozens of federal, state, and local agencies that may have a significant impact on and/or regulatory authority over your EMS practice
- Many of these agencies do not coordinate their activities with each other
- Be familiar with all of them, but especially those that have significant enforcement authority
Federal Agencies That May Impact Your EMS Practice

- Department of Transportation (2)
- National Transportation Safety Board (1)
- Department of Health and Human Services (12+)
- Department of Homeland Security (4+)
- Department of Agriculture (1)
- Department of Justice (2)
- US Department of Labor (1)
- US Equal Employment Opportunity Commission (1)
- Federal Communications Commission (1)

US Department of Transportation
Key Programs Impacting EMS

- National Highway Traffic Administration
  - Office of EMS
- Federal Aviation Administration
National Highway Traffic Safety Administration (NHSTA)

- Office of EMS
- De facto lead agency since 1980
- National standard curricula => National EMS Education Standards
- EMS Agenda for the Future (plus education and research agendas)
- NEMSIS (with HRSA EMSC)
- FICEMS & National EMS Advisory Committee
- Evidence Based Guidelines for EMS

Navigating NHTSA

- Important resource
- EMS.gov good to follow
- Issues to monitor:
  - National EMS Education Standards
  - NEMSAC – emerging role / recommendations
  - FICEMS coordination efforts
  - NEMSIS
  - EMS EBG development
- How to input – through national organizations – NAEMSP, ACEP

US DOT: Federal Aviation Administration (FAA)

- Issues and enforces regulations and minimum standards covering manufacturing, operating, and maintaining aircraft... certifies airmen and airports that serve air carriers
Navigating the FAA

- Be aware of the Airline Deregulation pre-emption issues – State and local entities:
  - May establish destination criteria and credentials of crew, require medical equipment, medical protocols, etc.
  - Can’t mandate bases or response areas or require a CON.
  - Can’t regulate flight crew or air safety issues such as tail lighting or internal communications

US Department of Health and Human Services

- Assistant Secretary for Preparedness and Response
  * ECCC
  * Health Resources and Services Administration
    * EMSC
    * DTEMS
    * ORHP
  * Center for Medicare and Medicaid Services
    * Fraud and Abuse
  * Office of Civil Rights
  * CDC
    * NCICP – Injury Control Division
    * NIOSH
  * Food and Drug Administration
  * Indian Health Service

Office of the Assistant Secretary for Preparedness and Response (ASPR)

http://www.phe.gov/about/pages/default.aspx

Federal lead in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters
HHS/ASPR Roles

• Preparedness planning and response
• Federal emergency medical capability
• Countermeasures research, development, and procurement
• Preparedness grants to hospitals and health care systems (HPP Program)
• Federal support through National Disaster Medical System (NDMS) and Disaster Medical Assistance Teams (DMAT)

HHS/ASPR: Emergency Care Coordination Center (ECCC)

http://www.phe.gov/Preparedness/planning/eccc/Pages/default.aspx

• Promotion and enhancement of Federal programs to support the effectiveness of emergency care and the emergency care system
• Extends across the entire continuum of patient care

Navigating ASPR

• Monitor developments with the ECC. Could become a major player in EMS and regionalization of emergency care.
• Monitor HPP at the state and local level to ensure that funding addresses EMS needs
• Establish relationship with DMATs
Health Resources and Services Administration
http://www.hrsa.gov/index.html

- Primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable
- Key programs impacting EMS
  - EMS for Children
  - Office of Rural Health Policy

Also see: http://www.hrsa.gov/EMS/index.html

HRSA: EMS for Children
http://bolivia.hrsa.gov/emsc/

- Designed to ensure that all children & adolescents receive appropriate care in a health emergency
- EMSC partnership grants to all 50 states - increasingly data and outcome driven
- Budgeted $20 million/year
- Two resource centers: EMSC Resource Center (CNMC in DC) and the National EMS Data Analysis Resource Center (U of Utah)
- PECARN – pediatric research network

Navigating EMSC

- Monitor state grant activities – can have major impact on EMS care for children and state regulatory efforts
- National Pediatric Readiness Project – impact on categorization and transport destination?
- Grant opportunities
- PECARN – impact of studies on the EMS care of children
Office of Rural Health Policy (ORHP)

http://hrsa.gov/ruralhealth/

- Coordinates activities related to rural health care within the U.S. Department of Health and Human Services
- Administers grant programs designed to build health care capacity in all 50 states
- Grants to upgrade EMS systems
- Grants for the use of automatic external defibrillators for the public

Navigating ORHP

- Many grant opportunities for EMS in rural areas
- ORHP is a collaborative agency that is willing to look at broader role for EMS, e.g. community paramedicine

Centers for Medicare and Medicaid Services

https://www.cms.gov

- Impacts EMS in many ways
  * Reimbursement
  * Certified Laboratory Improvement Amendment (CLIA) Program
  * Office of Civil Rights
CMS Reimbursement

- By law, Medicare benefit is for ambulance transportation only (exception: death after dispatch)
- Negotiated national fee schedule with regional variations

CMS Reimbursement Landmines!

- Beneficiary must be transported to the closest appropriate facility (hospital, SNF, home, or dialysis center)
- Transportation by ambulance must be medically necessary (other means of xpt contraindicated)
- Level of service (BLS, ALS1, ALS2, SCT) must also be medically justified – transport by ALS is not automatically an ALS reimbursement
- Must document medical necessity and have available for carrier if requested

Another potential landmine: Non-Emergency Transports

- Must be bed-confined before and after the ambulance trip:
  * Unable to get up from bed without assistance;
  * Unable to ambulate; and
  * Unable to sit in a chair or wheelchair.
- Transported to or from a Medicare reimbursable service (such as ESRD)
Air Medical Transport

• The beneficiary’s medical condition requires immediate and rapid ambulance transportation that could not have been provided by ground ambulance; and either
  * 1. The point of pickup is inaccessible by ground vehicle or;
  * 2. Great distances or other obstacles are involved

Medicare Fraud and Abuse

• Increased CMS focus
• Recent MedPAC concerns re: non-emergency
• CMS can audit and recover overpayments with 3X penalties and fines
• DOJ may become involved with potential criminal repercussions
• This could potentially involve a medical director – know the rules and know what your service is billing for.

https://www.cms.gov/center/ambulance.asp

Navigating CMS

• Know the rules and what your EMS services are doing with billing
• Be sure that billing is based on medical necessity and properly coded
• Carefully consider your email and written correspondence
Clinical Laboratory Improvement Amendments (CLIA)
https://www.cms.gov/clia

• The Centers for Medicare & Medicaid Services (CMS) certifies and regulates all laboratory testing (except research)
• 60% of laboratories have waivers.
• CLIA works through state agency intermediaries.

CLIA Waiver

• To receive a waiver
  * A lab must only perform tests which are simple and relatively error free (e.g. glucometer)
  * FDA and the CDC have determined which of these tests that may be waived and promulgate a list

CLIA Waiver

Waived laboratories must meet only the following requirements under CLIA:

• Enroll in the CLIA program;
• Pay applicable certificate fees biennially; and
• Follow manufacturers' test instructions.
HHS: Office for Civil Rights

http://www.hhs.gov/ocr

- Federal Civil Rights Laws: unfair treatment or discrimination
- HIPAA Privacy Rule: individually identifiable HI
- HIPAA Security Rule: national standards for the security of electronic protected health information
- Patient Safety and Quality Improvement Act - Patient Safety Rule: confidentiality provisions to protect identifiable information

Who Is Impacted HIPPA Privacy and Security Rules?

- HIPPA applies only to covered entities.
- You are a covered if your service bills and conducts electronic transactions.
HHS OCR Audits

• Random privacy and security audits may be conducted under the HITECH Act
• Audited entities will undergo comprehensive reviews of their privacy and security policies and procedures, documentation, and operations.

Breach Notification

• Now required under the Health Information Technology for Economic and Clinical Health (HITECH) Act (2009)
• HIPAA covered entities must notify individuals and, in some cases, the HHS Secretary and the news media—when "unsecured protected health information" is breached or compromised.

Navigating HHS OCR

• Know the privacy rules and follow them
• Educate EMS providers and management on the importance of following the rules
Centers for Disease Control and Prevention (CDC)

Collaborating to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats

Key Agencies to Know

• National Institute for Occupational Safety and Health (NIOSH)
• National Center for Injury Control and Prevention – Injury Response Division
• Office of Public Health Preparedness and Response

National Institute for Occupational Safety and Health

• NIOSH mission is to prevent work-related illness, injury, disability, and death
• Research and standards agency… not enforcement, but…
• OSHA will use and enforce NIOSH standards
National Center for Injury Prevention and Control

• Guides national efforts to reduce the incidence, severity and adverse outcomes of intentional and unintentional injury in the United States.
  • Three divisions
    * Violence Prevention
    * Unintentional Injury Prevention
    * Injury Response

NCIPC – Division of Injury Response

• Works to improve injury care and response by improving field triage, acute care, and mass casualty event response
  * Field Trauma Triage Guidelines (with ACS-COT)
  * Advanced Automated Crash Notification (AACN)
  * MCI and MCI Triage (MUCC)
  * Blast Injury Guidelines
  * Helicopter Utilization (NTSB/FICEMS)

Office of Preparedness and Response

• Emergency Operations
  * CDC EOC
• State and Local Readiness
  * $9 Billion in grants for all hazards
• Strategic National Stockpile
• Select Agents and Toxins
  * Regulates possession, use or transfer of biologicals or toxins that pose a threat
• Office of the Director
Navigating CDC

- Good source of information on injury prevention and response
- Field trauma triage guidelines
- Helicopter utilization (in press)
- Enroll in Health Alert Network for a good source of information
- NIOSH - good source of information on EMS occupational safety

HHS Indian Health Service

- Responsible for providing federal health services to American Indians and Alaska Natives.
- Involved in providing both trauma and EMS services on tribal lands.

U.S. Food and Drug Administration

- Approves and regulates medical devices
- Issues safety alerts
- Approves and regulates the use of medications
- Emergency Use Authorization
- Involved in addressing medication shortages
- Establishes standards for the use of PPE that are enforced by OSHA (e.g.) N95 respirators
The Department of Homeland Security has a vital mission: to secure the nation from the many threats we face.

Key DHS Programs Impacting EMS

- Office of Health Affairs
- Federal Emergency Management Agency
  * US Fire Administration
- Agencies that may provide EMS services

Office of Health Affairs

- Provides expert health and medical advice to Department leadership
- Builds national resilience against health incidents
- Enhances national and department medical first responder capabilities
- Protects the Department workforce against health threats
OHA – Evolving role in managing and credentialing DHS EMS Employees

- USCG
- USSS (especially tactical)
- ICE
- US Border Patrol
- Other non-DHS federal agencies providing EMS
  - Department of Interior: National Park Service and US Park Police (ground and air)
  - DOJ: FBI (especially tactical medicine)
  - USDA: US Forest Service wildland fire contractors
  - US Military including National Guard

Navigating HHS OHA

- Newcomer on the federal EMS related scene, but impact is growing and has become a major player in Federal EMS
- Many staff members with emergency medicine and/or EMS backgrounds
- Monitor activities for evolving EMS role and credentialing of DHS EMS providers (NASEMSO compact)

Federal Emergency Management Agency

http://www.fema.gov

FEMA’s mission is to support our citizens and first responders to ensure that as a nation we work together to build, sustain, and improve our capability to prepare for, protect against, respond to, recover from, and mitigate all hazards.
FEMA – Major Program Areas
• Service to Disaster Victims
• Integrated Preparedness
• Operational Planning and Preparedness
• Incident Management
• Disaster Logistics
• Hazard Mitigation
• Emergency Communications
• Public Disaster Communications
• Continuity Programs

Navigating FEMA
• Grant opportunities – (e.g.) UASI, SHSGP. Need to be aware of these grants and become part of the state and local processes to prioritize funding
• Good guidelines for preparing for and responding to catastrophic events
• Get to know key FEMA personnel in your region

Mission
* To provide national leadership to foster a solid foundation for our fire and emergency services stakeholders in prevention, preparedness, and response.

http://www.usfa.fema.gov
USFA - Major Activity Areas

- Grants and funding
  * Assistance to Firefighters Grants
- Training and education
  * National Fire Academy
- Firefighter fatalities - data
- Fire prevention
  * Training and public education
- National Fire Incident Reporting System
- Fire department census (data)
- Research
  * Including EMS related projects

Navigating the USFA

- Great guidance for fire bases EMS services that is applicable to all EMS
- EMS and other related educational resources at the National Fire Academy are outstanding
- Grant opportunities for fire and non-fire based EMS services

Department of Agriculture
US Forest Service

http://www.fs.fed.us

- The mission of the USDA Forest Service is to sustain the health, diversity, and productivity of the Nation's forests and grasslands to meet the needs of present and future generations.
**USDA USFS Wildland Fires**

- Fight wildland fires which frequently cross state boarders
- Contractors provide EMS and occupational medical support
- These contract EMS providers may not be licensed in your state
- There may be little coordination with local EMS and medical oversight
- National Interagency Fire Center
  [http://www.nifc.gov](http://www.nifc.gov)

**Navigating US Forest Service**

- If you have wildland fires in your jurisdiction… maintain situational awareness
- Be prepared to develop local interface with civilian EMS contractors and potentially support their efforts

**Department of Justice**

- Drug Enforcement Administration
- Criminal enforcement of Medicare fraud and abuse
DOJ- Drug Enforcement Administration

http://www.justice.gov/dea

• DEA is a federal enforcement agency
• Also work through states and is therefore impacted by state laws on controlled substances
• Federal drug laws do not address the unique role and operating environment of EMS services and providers

DEA and EMS

• To store and dispense a controlled substance, an EMS service must be registered with the state and the DEA
• Registration is generally under the medical director... but may vary by state
• Not the same as practitioner registration
• Accurate records must be maintained
  * Each time a controlled substance is dispensed
  * Inventory

Areas of CS Accountability

• Ordering, distributing, storing and dispensing CS in a manner c/w state and DEA regulations
  * Documenting usage and wastage
  * Resupplying only with documentation of usage
  * Conducting routine and random audits
  * Having a procedure to investigate PRN
Navigating the DEA

- DEA can and does enforce CS security and record keeping
- Violation of their rules can result in fines, sanctions against a medical directors license, and imprisonment
- Know the rules, be proactive with your service, and monitor closely
- If questions, talk to DEA or state
- National dialogue with DEA has begun

US Department of Labor
Occupational Safety and Health Administration
http://www.osha.gov

Mission: To assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

OSHA Jurisdiction

- Covers private sector employers
- Excludes self-employed, family farm workers, and government workers
- OSHA approves and monitors 27 State Plan states which may cover government employees
**Most Frequently Accessed OSHA Standards**

- Bloodborne Pathogens – 1910.1030
- Hazard Communication – 1910.1200
- Respiratory Protection – 1910.134
- Occupational Noise Exposure – 1910.95
- Powered Industrial Trucks – 1910.178
- Permit-required Confined Spaces – 1910.146
- Lockout/Tagout – 1910.147
- Hazardous Waste Operations and Emergency Response – 1910.120
- Guarding Floor and Wall Openings and Holes – 1910.23
- Personal Protective Equipment – 1910.132

**Most Frequently Enforced Standards**

- 1926.451 – Scaffolding
- 1926.501 – Fall Protection
- 1910.1200 – Hazard Communication
- 1910.134 – Respiratory Protection
- 1910.147 – Lockout/Tagout
- 1910.305 – Electrical, Wiring Methods
- 1910.178 – Powered Industrial Trucks
- 1926.1053 – Ladders
- 1910.303 – Electrical, General Requirements
- 1910.212 – Machine Guarding

**Employee Rights Under OSHA**

- Use their rights under the law without retaliation and discrimination
- Ask OSHA to inspect their workplace
- Receive information and training about hazards, methods to prevent harm, and the OSHA standards that apply to their workplace
- Get copies of test results done to find hazards
- Review records of work-related injuries and illnesses
- Get copies of their medical records
OSHA Enforcement

• Employers are responsible for providing a safe and healthful workplace.
• Employer must have policies consistent with OSHA or state rules
• Employees must be trained and have the necessary PPE and equipment
• Employer must enforce policies

Navigating OSHA

• Be knowledgeable of the OSHA rules
• You may be asked by providers and/or management about OSHA compliance issues

US Equal Employment Opportunity Commission

http://www.eeoc.gov

• Enforce federal laws that make it illegal to discriminate against a job applicant or an employee
• Includes race, color, religion, sex (including transgender), pregnancy, national origin, age (40 or older), disability or genetic information.
• It is also illegal to retaliate
EEOC

• Most employers with at least 15 employees are covered by EEOC laws
• EEOC apply to all types of work situations, including hiring, firing, promotions, harassment, training, wages, and benefits.

Real Examples of EEOC Issues

• Failing to hire or credential limits of hearing or sight challenged providers (ADA reasonable accommodation issue)
• Challenges to clinical skills and job performance evaluations and/or remediation requirements based on sex (includes transgender) or race
• Failure to promote to clinical supervisor based on gender, age or race

Navigation the EEOC

• Know the rules and follow them
• Do not ignore potential EEO issues… pass them on to the appropriate entity in your service as soon as possible. Let them investigate.
• Established by statute in 2005 at the US DOT and recently upgraded
• Enables coordination among Federal agencies that impact EMS
• Currently, 10 federal agencies and 1 state EMS director are represented on FICEMS by high level officials

FICEMS Member Agencies
• DOT – NHTSA
• HHS – ASPR, HRSA, CDC, CMS, IHS
• DHS – OHA, USFA
• DOD
• FCC
• State EMS director

State EMS Office
• In all 56 states and territories
• Authority, role, and staffing varies
• License EMS services and providers
• Establish EMS education standards
• Define scope of EMS practice
• Promulgate statewide EMS protocols
• State EMS director and medical director can be key resources. Get to know them!
### Other State Regulators

- Medical Licensing Boards
  - Licenses the medical director
  - May have some degree of authority over EMS providers, protocols, scope of practice and other standards
- State CDS Registration
- State CLIA agency
- State OSHA agency
- State Medicare

### Local Regulators

- Depending on state, there may be regional or local EMS entities with regulatory authority over EMS

### Final Thoughts on Navigating the Regulators

- Know of and work with federal and state agencies that can support you… they can be a significant resource of guidance, information and funding
- Maintain situational awareness
  - While regulatory compliance is not the first thing on your mind as a medical director, ignoring it could be painful
Continuously assess and ensure that you and your service are in compliance…

…and always navigate safety!