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
  * Most can be a resource and would like to see you succeed
  * Others have different agendas more specifically targeted to their respective areas of authority
  * Some of these agendas can have a significant personal impact on you – fines, licenses, or more.

Government agencies that EMS medical directors should be aware of

- Potentially, dozens of federal agencies, 6 or more state agencies, as well as regional and local agencies may have a significant impact on and/or regulatory authority over your EMS practice
- Many of these agencies do not coordinate their oversight efforts
- You should have familiarity with all, but working knowledge of several that have significant regulatory authority (highlighted in presentation)
Major/Independent Federal Agencies That May Impact Your EMS Practice

- Department of Transportation (3)
- 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 Motor Carriers Safety Administration
- 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)
- National EMS Advisory Committee
- EBGs and other roles
Navigating NHTSA
• Important resource
• EMS.gov good to follow
• Issues to monitor:
  * National EMS Education Standards
  * NEMSAC recommendations
  * FICEMS coordination efforts
  * NEMSIS
  * EMS EBG development
• How to input – through national organizations
  – NAEMSP, ACEP

US DOT: Federal Aviation Administration (FAA)
http://www.faa.gov/
• Issues and enforces regulations and minimum standards covering manufacturing, operating, and maintaining aircraft… certifies airmen and airports that serve air carriers
• HEMS aircraft may be public use or certified as civil aircraft under FAR Part 91 or Part 135

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
Key programs Impacting EMS

- 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
- Building federal emergency medical operational capabilities
- Countermeasures research, advance development, and procurement
- Grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters (HPP Program).
- Provides federal support, including medical professionals through National Disaster Medical System (NDMS), to augment state and local capabilities during an emergency or disaster.
HHS/ ASPR: Emergency Care Coordination Center (ECCC)
http://www.phe.gov/Preparedness/planning/eccc/Pages/default.aspx

- Promotion and enhancement of Federal programs, resources, and tools that will improve the resiliency, efficiency, and effectiveness of emergency care and the emergency care system
- The purview of the ECS extends across the entire continuum of patient care—from the pre-hospital environment, to the Emergency Department (ED), to patient transfer and/or final disposition

Navigating ASPR

- Monitor developments with the ECCC. Could become a major player in EMS and regionalization of emergency care
- Monitor HPP at the state and local level to ensure that preparedness 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://boliwia.hrsa.gov/emsc/

• Designed to ensure that all children and 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)
• Also: PECARN, NEMSIS and NEDARC

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

• Collaborative group that is willing to look at broader role for EMS, e.g. community paramedicine

Centers for Medicare and Medicaid Services

https://www.cms.gov

• May impact 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
  * Base plus mileage
  * Base = BLS, ALS1, ALS2, SCT, PI
  * Rural and regional adjustments
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 (any other method of transportation is 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

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

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 (this condition could be met in Hawaii, Alaska, and in other remote or sparsely populated areas of the continental United States), or
  * 2. Great distances or other obstacles are involved in getting the patient to the nearest hospital with appropriate facilities as described in §10.4.4.
Medicare Fraud and Abuse
- Increased CMS focus on reducing F&A by the feds
- 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)
- The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S.
- In total, CLIA covers approximately 225,000 laboratory entities (60% of these have waivers).
- The objective of the CLIA program is to ensure quality laboratory testing.
- CLIA works through state agency intermediaries.

https://www.cms.gov/clia
To receive a certificate of waiver under CLIA, a lab must only perform tests like the glucose meter test which the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have determined to be so simple that there is little risk of error.

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

• Enforcement areas:
  * Federal Civil Rights Laws: unfair treatment or discrimination, because of race, color, national origin, disability, age, sex (gender), or religion.
  * HIPAA Privacy Rule: individually identifiable health information
  * 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 used to analyze patient safety events and improve patient safety.

Who Is Impacted HIPPA Privacy and Security Rules?

• Applies only to covered entities.

• You are a covered if your service bills and conducts electronic transactions.

A HIPAA Covered Entity

<table>
<thead>
<tr>
<th>A Health Care Provider</th>
<th>A Health Plan</th>
<th>A Health Care Clearinghouse</th>
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<tbody>
<tr>
<td>This includes providers such as:</td>
<td>This includes:</td>
<td>This includes entities that process unstandard health information they receive from another entity into a standard (i.e., standard electronic format or data content), or vice versa.</td>
</tr>
<tr>
<td>• Doctors</td>
<td>• Health insurance companies</td>
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<tr>
<td>• Nurses</td>
<td>• HMOs</td>
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<td>• Psychologists</td>
<td>• Company health plans</td>
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<td>• Chiropractors</td>
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<td>• Nursing Homes</td>
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<td>• Pharmacies</td>
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<td>• EMS</td>
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<td>— but only if they transmit any information in an electronic form in connection with a transaction for which HHS has adopted a standard.</td>
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HHS OCR Audits

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has begun the process of notifying covered entities that they are among the unlucky few who have been selected for the first Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security audits under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

The selected entities represent a cross sample of the health care industry—from billion-dollar health care systems to small physician practices. Audited entities will undergo comprehensive reviews of their privacy and security policies and procedures, documentation, and operations.

Breach Notification

• Required under the Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of the American Recovery and Reinvestment Act of 2009 (ARRA).
• 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 programs impacting EMS
  * National Institute for Occupational Safety and Health
  * National Center for Injury Control and Prevention
    – Injury Response Division
  * Office of Public Health Preparedness and Response
  * Others: Infectious Disease, Epidemiology, and more

National Institute for Occupational Safety and Health

http://www.cdc.gov/NIOSH

NIOSH provides national and world leadership to prevent work-related illness, injury, disability, and death by gathering information, conducting scientific research, and translating the knowledge gained into products and services, including scientific information products, training videos, and recommendations* for improving safety and health in the workplace.

* Note: frequently enforced by OSHA

National Center for Injury Prevention and Control

http://www.cdc.gov/injury

• 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
http://www.cdc.gov/injuryresponse

- 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)

Navigating CDC

- Good source of information on injury prevention and response
  - Field trauma triage guidelines
  - Helicopter utilization (in press)

- NIOSH - good source of information of EMS occupational safety

HHS Indian Health Service
http://www.ihs.gov

- 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
http://www.fda.gov

• Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
• Protecting the public from electronic product radiation
• Assuring cosmetics and dietary supplements are safe and properly labeled
• Regulating tobacco products
• Advancing the public health by helping to speed product innovations
• Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health

FDA and EMS

• Approves and regulates medical devices, (e.g.) AEDs, ventilators, ETCO2 detectors, etc.
• Issues safety alerts
• Approves and regulates the use of medications, (e.g.) Duodote for EMS providers to administer to civilians
• Emergency Use Authorization
• Involved in addressing medication shortages
• Establishes standards for the use of PPE that are enforced by OSHA (e.g.) N95 respirators

US Department of Homeland Security
http://www.dhs.gov

The Department of Homeland Security has a vital mission: to secure the nation from the many threats we face. This requires the dedication of more than 230,000 employees in jobs that range from aviation and border security to emergency response, from cybersecurity analyst to chemical facility inspector. Our duties are wide-ranging, but our goal is clear - keeping America safe.
Key DHS Programs Impacting EMS

- Office of Health Affairs
- Federal Emergency Management Agency
  - US Fire Administration
- CONTOMS
- Agencies that may provide EMS services
  - USCG
  - USSS
  - ICE
  - US Border Patrol

DHS – Many employees may provide EMS in your jurisdiction

- USCG
- USSS (especially tactical)
- ICE
- US Border Patrol
- Other federal agencies and military as well…
  - 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

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

http://www.dhs.gov/xabout/structure/editorial_0880.shtm
Navigating HHS OHA

- Newcomer on the federal EMS related scene, but impact is growing and has potential to be a major player
- Many staff members with emergency medicine and/or EMS backgrounds
- Monitor activities with respect to their federal EMS providers and the evolving oversight of OHA

Federal Emergency Management Agency

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 – MMRS, UASI, SHSP. 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.

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

http://www.usfa.fema.gov
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

USDA 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
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

The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.
DEA and EMS

- To store and dispense a controlled substance, an EMS service must register with the DEA.
- Registration is under the medical director – exception in Kansas?
- This is a separate registration from a medical directors 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 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

- They can and do 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 regional DEA staff
- Nationals dialogue with DEA has begun
With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) 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 (except in state plan states)
- Approves and monitors 27 State Plan states which cover private and public sector employees.
- Assists Federal Agency Programs

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’s Rights Under OSHA Law

- Ask OSHA to inspect their workplace;
- Use their rights under the law without retaliation and discrimination;
- Receive information and training about hazards, methods to prevent harm, and the OSHA standards that apply to their workplace. The training must be in a language you can understand;
- Get copies of test results done to find hazards in the workplace;
- 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.
- Must have policies consistent with OSHA or state standards
- Employees must be trained and have the necessary PPE and equipment
- Employer must enforce policies
Navigating OSHA

• Be knowledgeable of the OSHA rules
• Use your medical expertise to advise providers and management on how to comply

US Equal Employment Opportunity Commission

http://www.eeoc.gov

• Responsible for enforcing federal laws that make it illegal to discriminate against a job applicant or an employee because of the person's race, color, religion, sex (including pregnancy), national origin, age (40 or older), disability or genetic information.
• It is also illegal to discriminate against a person because the person complained about discrimination, filed a charge of discrimination, or participated in an employment discrimination investigation or lawsuit.

EEOC

• Most employers with at least 15 employees are covered by EEOC laws (20 employees in age discrimination cases). Most labor unions and employment agencies are also covered.
• The laws apply to all types of work situations, including hiring, firing, promotions, harassment, training, wages, and benefits.
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.

FICEMS was established in 2005 by the US Department of Transportation Reauthorization, Public Law 109-59 (Section 10202), to ensure coordination among Federal agencies involved with State, local, tribal, and regional emergency medical services and 9-1-1 systems.

- Most would agree there is a clear need for FICEMS!

- Department of Homeland Security.
- Health Resources and Services Administration, Department of Health and Human Services.
- Centers for Disease Control and Prevention, Department of Health and Human Services.
- Centers for Medicare and Medicaid Services, Department of Health and Human Services.
- The Under Secretary of Defense for Personnel and Readiness.
- Indian Health Service, Department of Health and Human Services.
- A representative of any other Federal agency appointed by the Secretary of Transportation or the Secretary of Homeland Security through the Under Secretary for Emergency Preparedness and Response, in consultation with the Secretary of Health and Human Services, as having a significant role in relation to the purposes of the Interagency Committee.
- A State emergency medical services director appointed by the Secretary
**State Regulators**
State Office of EMS
- 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
- May serve as both resource and regulator
- State EMS director and medical director – 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 navigate safely!