

Regulations and Standards



Presentation to:

Basic Healthcare Emergency Management Course

We Protect Lives.



Objectives

- Understand the regulatory context in which healthcare facilities/systems operate
- Identify the accreditation Standards
- Identify applicable regulatory agency for your facility and organization
- Identify the current standards, frameworks, and key organizations in healthcare management

Context of Healthcare Emergency Management

These organizations can be grouped into the following categories:

- Accrediting organizations
- Regulatory organizations
- Standard-setting bodies
- Providers of guidance, grants, and training
- Governmental agencies

Accreditation

Many accrediting bodies exists for all types of healthcare settings, for example:

- The Joint Commission (TJC)
- DNV Healthcare, Inc. (DNV)
- Accreditation Commission for Health Care (ACHC)
- Health Facilities Accreditation Program (HFAP)
- Community Health Accreditation Program (CHAP)

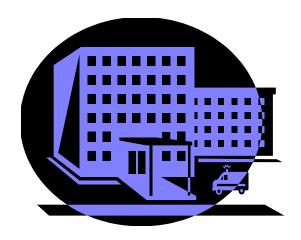
Regulation

Regulation of healthcare facilities and systems is conducted by overlapping federal, state, and local agencies



State and Local Standards and Regulations

- Most regulatory requirements for individual healthcare facilities are established and enforced at the state and local level (Healthcare Facility Regulation, HFR-formerly ORS)
- State and local agencies
 have standards and
 regulations specific to
 every jurisdiction in the country



State and Local Standards and Regulations

- Some jurisdictions have specific emergency management provisions
- Some topics related to emergency management include:
 - Privacy and patient protection
 - Worker health and safety
 - Environmental protection
 - Others...

Healthcare Regulatory Entities

- Food and Drug Administration (FDA)
- Centers for Medicare & Medicaid Services (CMS)
- Occupational Safety and Health Administration (OSHA)
- Environmental Protection Agency (EPA)

Occupational Safety and Health Administration (OSHA)

OSHA regulates the safety and health of America's workers by setting and enforcing standards, as well as providing training, outreach, and education

 Nearly every employee in the U.S. is under OSHA jurisdiction

OSHA

- Seeks to establish partnerships and encourage continual improvement in workplace safety and health
- Publishes guidance on a variety of topics specific to the healthcare community, including personal protective equipment (PPE) and respirator use



OSHA Regulations

- General Health and Safety
 - OSHA has many regulations for general worker health and safety, including hazardous materials, privacy, ergonomics, blood-borne pathogens, etc.
- In an emergency, OSHA is concerned with:
 - 29 Code of Federal Regulations (CFR) 1910.36
 Design and construction requirements for exit routes

OSHA Code Of Federal Regulations

- 29 CFR 1910.37 Maintenance, safeguards, and operational features for exit routes
- 29 CFR 1910.38 Emergency action plans
- 29 CFR 1910.39 Fire prevention plans
- 29 CFR 1910.132 Personal Protective Equipment (PPE) requirements
- 29 CFR 1910.134 Respiratory Protection
- 29 CFR 1910.120 HAZWOPER—Requires incidents to be managed by the Incident Command System (ICS)
- 29 CFR 1910.151 Medical services and first aid
- 29 CFR 1910.157 Portable fire extinguishers
- 29 CFR 1910.165 Employee alarm systems
- 29 CFR 1910.1200(h) Hazard Communication

OSHA Regulations

- Hazardous Waste Operations and Emergency Response (HAZWOPER) 29 (CFR) 1910.120
 - Requires employers, including hospitals, to plan for emergencies if they expect their employees to handle an emergency involving hazardous substances
 - Requires varying levels of training for personnel involved in hazardous material releases or clean-up



HAZWOPER

- Requires the use of an Incident Command System
- Requires developing a written response plan that includes:
 - personnel roles
 - lines of authority and communication
 - site security and control
 - medical and emergency alert procedures
 - Requires provision of appropriate protective equipment for workers

OSHA Dialysis Center

494.60 Condition: Physical Environment (d)

 (1) Emergency Preparedness of staff.
 Appropriate training and orientation in emergency preparedness of staff
 (2) Contact its local disaster management agency annually



OSHA Regulations

Requires employers, including healthcare facilities, to implement a <u>respiratory</u> <u>protection program</u> if they expect to use their employees to handle an emergency involving hazardous substances



Environmental Protection Agency (EPA)

- Protection of human health and the environment
- Develops and enforces regulations that implement environmental laws
- Researches and sets national standards
- Delegates enforcement to the state level



National Fire and Protection Association (NFPA) Standards

NFPA 1: Uniform Fire Code and NFPA 101: Life Safety Code

 Provides standards for building design elements and materials, fire alarms and suppression, etc., for occupant safety

NFPA 70: National Electrical Code

 Provides standards for design and modification of electric systems and components

NFPA 99: Standard for Healthcare Facilities

 Chapter 12: Health Care Emergency Management provides a brief framework for an emergency management program

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NFPA Standards (cont.)

NFPA 110: Standard for Emergency and Standby Power Systems

 Provides standards for the installation and use of generators

NFPA 1600: Standard on Disaster/Emergency Management and Business Continuity Programs

 Standard establishes a common set of criteria for disaster/emergency management and business continuity

Georgia Disaster Preparedness Regulations and Laws

Georgia HFR 290-9-7.15 (Hospital)

 The hospital shall prepare for emergency situations could affect patients care by the development of a disaster preparedness plan that identifies emergency situations and outlines a course of action.

Georgia HFR 290-5-45 (Nursing Homes)

 Every facility shall have an approved or provisionally approved Disaster Preparedness Plan.
 Disaster Plan rehearsals shall be regularly conducted with a minimum of two rehearsals in each calendar year.

Georgia Disaster Preparedness Regulations and Laws

Georgia HFR 111-8-63-.14 (Assisted Living)

 Each assisted living community must develop and utilize a comprehensive emergency plan for responding to internal and external disasters and emergency situations which address obtaining emergency transportation, sheltering in place, loss of power, and water, evacuation, and transporting the residents away from the community.

Georgia HFR 290-9-43.11 (Hospice)

- Every hospice shall have a current Disaster Preparedness
 Plan that address potential situations
- The plan must be reviewed annually

Georgia HFR 290-9-7.15 (hospital) and 290-9-43.11 (hospice)

The disaster preparedness plan shall include, at a minimum, plans for the following emergency situations:

- Local and widespread weather emergencies or natural disasters, such as:
 - > Tornadoes
 - > Hurricanes
 - > Earthquakes
 - Ice or snowstorms
 - > Floods



Georgia HFR 290-9-7.15 (Hospital)

The disaster preparedness plan shall include at a minimum, plans for the following emergency situations:

 Manmade disasters, such as acts of terrorism and hazardous materials spills





Georgia HFR 290-9-7.15 (hospital) and 290-9-43.11 (hospice)

The disaster preparedness plan shall include, at a minimum plans, for the following emergency situations:

 Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area



Georgia HFR 290-9-7.15 (hospital)

 There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation



Georgia HFR 290-5-8.18 (nursing home)

Emergency lighting supplied by an emergency generator or a battery with automatic switch, shall be provided for exits, stairs, and corridors



Georgia HFR 290-9-7.15 (hospital) and 290-9-43.11 (hospice)

There shall be plans for the emergency transport or relocation of all or a portion of the patients, should it be necessary, in vehicles appropriate to the patient's

condition(s) when possible, including written agreements with any facilities which have agreed to receive patients in these situations.



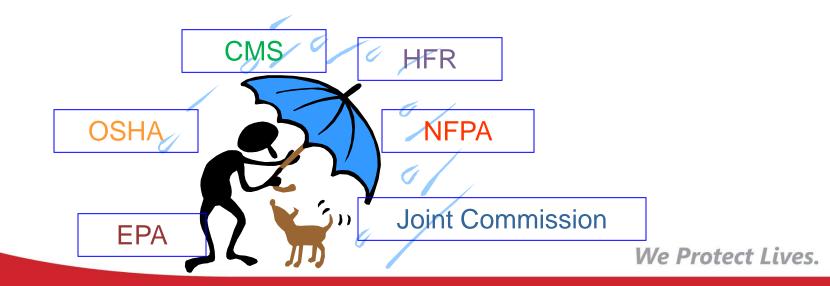
Georgia HFR 290-9-7.15 (hospital) and 290-9-43.11 (hospice)

Often referred to as the **Emergency Powers of the Governor**

- (i) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.
 - Authority O.C.G.A. Secs. 31-7-2.1, 31-7-3, 31-12-2.1. History. Original Rule titled "Disaster Preparedness," adopted. F. Nov. 22, 2002; effective. Dec. 12, 2002. http://hfr.dhr.georgia.gov/

Context of Healthcare Emergency Management

Each healthcare facility/system contends with a <u>multiplicity</u> of different standards, regulations, and requirements prescribed by <u>various</u> state-wide and nation-wide organizations



Healthcare Facility Regulatory Context

Applicability of these requirements varies greatly and stems from their diverse methods of implementation, for example:

- Inclusion in Code of Federal Regulations (CFR)
- Adoption into state laws and local codes
- Requirements for products and vendors
- Financial disincentives for non-compliance

Healthcare Facility Regulatory Context

The three most commonly applied standards and regulations to healthcare facilities are:

- Licensing
- Certification
- Accreditation

Licensing, Certification, and Accreditation

Licensing

- Issued by a government regulatory body, typically at the state level
- May be required for Medicaid/Medicare participation

Certification



- Issued by Centers for Medicare and Medicaid Service (CMS)
- Required for Medicaid/Medicare participation

Licensing, Certification, and Accreditation

Accreditation

- Theoretically voluntary, but can often be a de facto requirement
- May fulfill continuing state licensure and/or CMS certification obligations



Putting the Rules Together

- HFR
- Joint Commission Standards
- NFPA
- OSHA
- EPA
- State statutes
- Etc.



Joint Commission

- Regulations and standards are the cornerstone of Joint Commission accreditation.
- For hospital emergency management program, the Emergency Management (EM) Chapter is most important

The Joint Commission Planning Requirements

EM.01.01.01

... hospital [organization] engages in planning activities prior to developing the

EOP (as opposed to ...plans for managing the consequences of emergencies)



EM.02.01.01

- The [organization] has an EOP; there are 7 Elements of Performance:
 - Leadership must participate
 - There must be a comprehensive EOP
 - Capabilities must be known
 - Recovery strategies should be included
 - When to initiate and terminate phases
 - Name those in authority to activate the plan
 - Identify alternative sites of care

EM.02.02.01

 As part of its Emergency Operations Plan, the [organization] prepares for how it will communicate during emergencies.

EM.02.02.03

 As part of its Emergency Operations Plan, the [organization] prepares for how it will manage resources and assets

during emergencies



EM.02.02.05

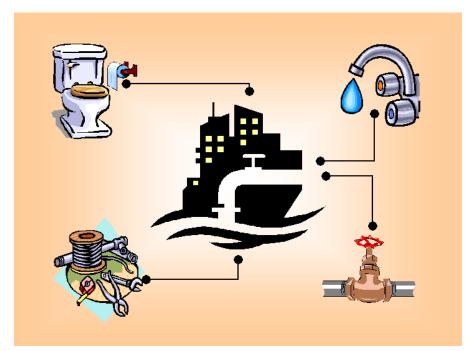
 As part of its Emergency Operations Plan, the [organization] prepares for how it will manage safety and security during an emergency

EM.02.02.07

 As part of its Emergency Operations Plan, the [organization] prepares for how it will manage staff during an emergency

EM.02.02.09

 As part of its Emergency Operations Plan, the [organization] prepares for how it will manage utilities during an emergency



EM.02.02.11

 As part of its Emergency Operations Plan, the [organization] prepares for how it will manage patients during emergencies

EM.02.02.13

 ...the [organization] may grant disaster privileges to volunteer licensed independent practitioners

EM.03.01.01

- The [organization] evaluates the effectiveness of its emergency management planning activities
- Some of the Elements of Performance for this standard include:
 - An annual review of hazards, risks, and emergencies
 - An annual review of your EOP

2013 Standards Home Care

EM.03.01.03, EP 18, applies to all segments and describes the four common components that must be part of any well-designed exercise:

- 1. Staff roles
- 2. Communication with patients
- 3. Communication with response partners
- 4. Business continuity and recovery

2013 Standards Home Care

- **EM.03.01.03, EP 19**, defines two additional exercise requirements essential to safe patient care, treatment, and service during an emergency.
 - Patient acuity assignment and tracking
 - Service consistent with response efforts defined in the organization's EOP.
 - applies only to the segments identified as serving individuals who are likely to be especially vulnerable in an emergency

DNV Healthcare, Inc.

- DNV is only the third national hospital accreditation body to be approved by CMS
 - Its accreditation program is called NIAHO (National Integrated Accreditation for Healthcare Organizations)
 - This is the first new hospital accreditation organization in 30 years (in 2008)



Physical Environment (PE) PE.6 Emergency Management System

- Standard Requirement (SR).1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.
- SR.2 The organization shall meet the requirements set forth in NFPA 99, Chapter 12, Emergency Management.
- SR.3 The Emergency Management System shall require that the organization conduct a HVA to identify potential emergencies in the organization and the community.

EP.6 (Cont.), Standard Regulation 4

- SR.4 The Emergency Management System shall establish an emergency process to address the potential hazards to the organization and the community. The hospital shall conduct an organization-wide emergency management exercise, including the triage and disposition of patients. The organization-wide emergency management exercises, shall be conducted at least twice per year.
 - SR.4a. Exercises shall test the most threatening hazard(s) from the HVA & tax the resources of the organization.
 - SR.4b. At least every other exercise shall be conducted with the community to evaluate surge capacity, the integration of incident command and interoperability of communications.
 - SR.4c. The organization shall formulate an after action report of all exercises to identifying opportunities for improvements and revise its EOP accordingly.

EP.6 (Cont.), Standard Regulation 5

 SR.5 The Emergency Management System processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.



EP.6 (Cont.), Standard Regulations 6-7

- SR.6 The Emergency Management System shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organizational, community, or regional crisis.
- SR.7 The organization shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.



NIAHO Interpretive Guidelines

(National Integrated Accreditation for Healthcare Organizations)

Assuring the safety of patients would include developing and implementing appropriate EOPs and capabilities. The organization must develop and implement a comprehensive plan to ensure that the safety of patients are assured during emergency situations. The organization must coordinate with Federal, State, regional, and local emergency preparedness and health authorities to identify likely risks for their area (using an all-hazards approach) and develop appropriate responses for patient safety. The following issues should be considered when developing the plans(s):

- The differing needs of each location where the certified hospital operates;
- The special needs of patient populations being treated;
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, etc.);
- Communication among staff within the hospital itself;
- Qualifications and training needed by personnel, to implement and carry out emergency procedures

NIAHO Surveyor Guidance:

- Review and verify that the hospital has developed and implemented a comprehensive plan to ensure the safety of patients is assured during an emergency. This plan must address the elements listed within the Interpretive Guidelines.
- Review and validate that the hospital has conducted a HVA to identify
 potential emergencies in the organization and the community.

 Determine the method used to prioritize, and made preparations to
 address the potential hazards to the organization and community.
- Review and validate that:
 - organization has conducted appropriate and timely exercises.
 - AARs identified opportunities for improvements
 - organization revised its EOP according to the identified opportunities for improvement



Regulations and Laws Review

- Remember: ALL agencies, organizations, and standard-setting bodies should be kept in mind during the planning process
- Check local and state regulations to ensure EOP is compliant



Meet the Required Guidelines

If your facility does NOT meet the required guidelines, it may NOT receive accreditation or licensure.



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Questions?

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