

ABC's of Emergency Preparedness According to the Medicare Conditions of Participation

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Speaker

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Over 30 years experience teaching and assisting hospitals and other healthcare facilities in understanding applicable Federal and State laws, rules, regulations and interpretative guidelines.

Previous experiences include:

- Director of Integrity & Compliance, Privacy Official at Mercy Medical Center, Des Moines
- Director of Regulatory Compliance, UnityPoint Health, West Des Moines
- Twenty years with Iowa Department of Inspections and Appeals

Learning Objectives

- Describe basic policies and procedures to comply with the regulations and interpretative guidelines.
- Discuss required training and exercises.
- Describe latest updates to CMS interpretative guidelines on emergency preparedness.
- Discuss most commonly cited emergency preparedness deficiencies.

Resources

- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf
- April 2021 interpretative guidelines are the latest revision
- <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions.html>
- This website contains the latest directions to the surveyors
 - May 2022—Update to Emergency Preparedness

State Operations Manual

Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types

Interpretive Guidance

Table of Contents *(Rev. 204, Issued: 04-16-21)*

Transmittals for Appendix Z

§403.748, Condition of Participation for Religious Nonmedical Health Care Institutions (RNHCIs)

§416.54, Condition for Coverage for Ambulatory Surgical Centers (ASCs)

§418.113, Condition of Participation for Hospices

§441.184, Requirement for Psychiatric Residential Treatment Facilities (PRTFs)

§460.84, Requirement for Programs of All-Inclusive Care for the Elderly (PACE)

§482.15, Condition of Participation for Hospitals

§482.78, Requirement for Transplant Programs

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

DATE: September 28, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance related to Emergency Preparedness- Exercise Exemption based on
A Facility's Activation of their Emergency Plan

Ref: QSO-20-41-ALL
REVISED 06.21.2021
REVISED 05.26.2022

**** Revised to provide additional guidance and clarifications due to the ongoing
COVID-19 public health emergency (PHE) ****

Memorandum Summary

- ***Emergency Preparedness Training and Testing Program Exemption - CMS***
regulations for Emergency Preparedness (EP) require facilities to conduct exercises to test the facility's EP plan to ensure that it works and that staff are trained appropriately about their roles and the facility's processes. During or after an actual emergency, the regulations allow for a one-year exemption from the requirement that

Potential Opportunities for CMS Surveys

- Routine Surveys of non-accredited hospitals and CAHs (about every 3-5 years)
- Routine Surveys of long-term care facilities (every 9-15 months)
- Validation Surveys—Conducted on ~5% of all accredited hospitals and CAH in each state annually
 - Used to validate the accreditation process
- Complaint Investigations-
 - All complaints in non-accredited hospitals, long-term care facilities and CAH investigated
 - For accredited hospitals--Complaints are reviewed by the CMS Regional Office to determine if there is a possibility that a Condition of Participation is Out of Compliance
 - CMS Regional Office will then authorize the State Survey Agency to investigate one or more Conditions of Participation
 - State Survey Agency will use the regulations, survey procedures and interpretative guidelines to determine compliance

Why Do Accredited Hospitals Have to Allow Surveys?

- All hospitals that receive Medicare monies must meet the Medicare COP
- TJC, DNV and ACHC hospitals are “deemed” to meet the Medicare COP
- If a complaint is registered with State Survey Agency or CMS, there is authority to investigate using the Medicare COP.
- If there are Condition level deficiencies, CMS can remove a hospital’s deemed status and put under local state survey agency oversight

Can a Hospital, CAH or LTC Refuse CMS or State Survey Agency the Right to Survey

- NO.
- 42 CFR 488.7(b) requires a provider/supplier allow CMS or designated State Survey Agency to conduct complaint investigations or validation surveys
- If organization refuses to allow the complaint or validation survey to occur, 42 CFR 488.7(c), provides for removal of deemed status and hospital will still be subject to a full review by the SA
- May also be subject to termination of its provider agreement under 42 CFR 489.53.

What Does Immediate Jeopardy Mean?

- Most serious of all deficiencies
- Situation in which non-compliance has caused or is likely to cause serious injury, harm, impairment or death
- Required to be corrected prior to surveyors leaving premises

What Does Condition Level Deficiency Mean?

- Serious Deficiency
- Represents a serious or critical health or safety breach
- Substantially limits the organization's capacity to furnish adequate care or which may adversely affects health or safety of patients

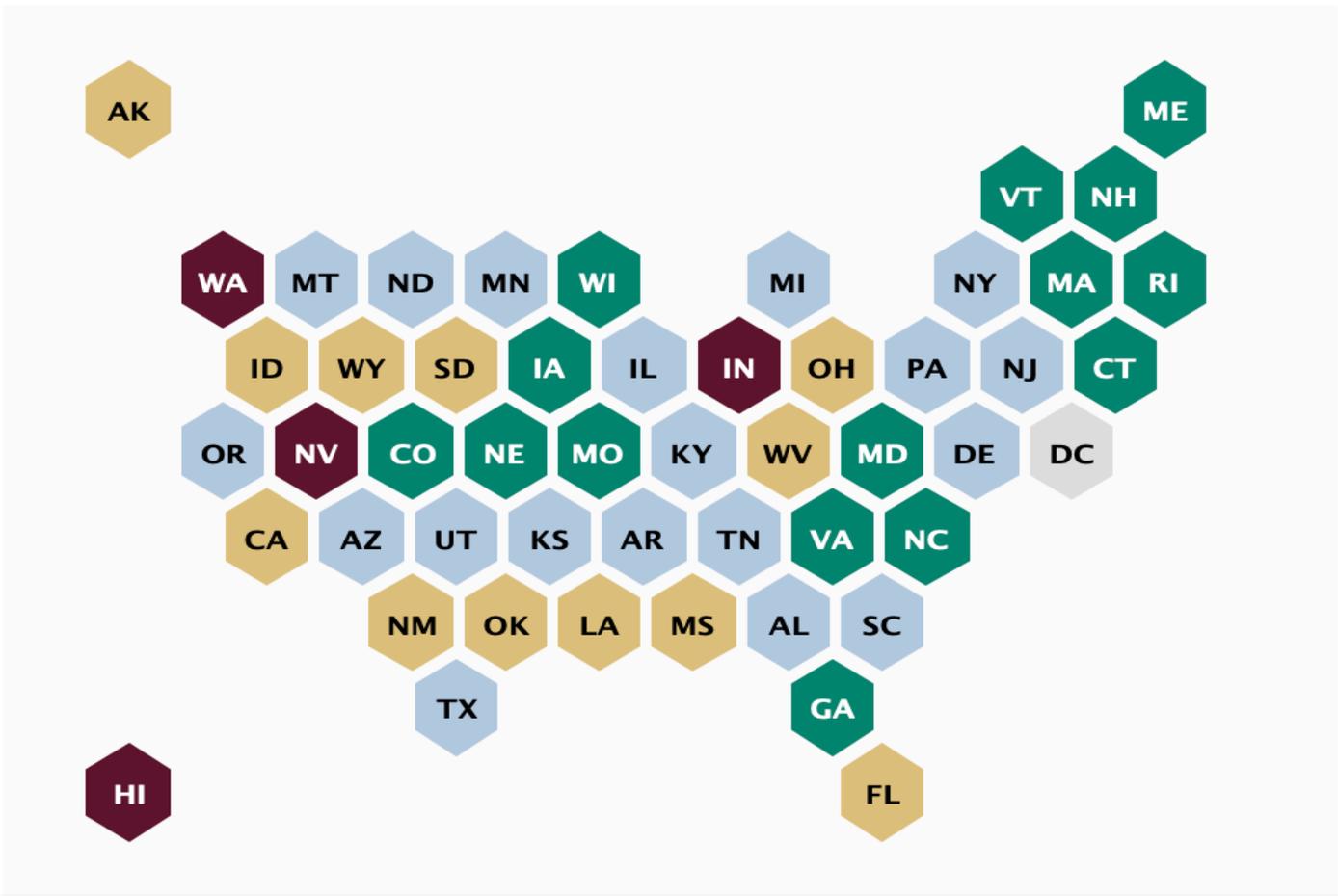
Latest Emergency Preparedness Study

- Preparedness slows
- Study conclusion -- “fragile” healthcare safety net
- Only 22% surveyed said hospital thoroughly prepared
- 44% somewhat updated plans
- 22% not “really” updated
- 8% have done nothing
- Modern Healthcare May 13, 2019

Almost a third of states in 2019 were found to be below average by an index that measures national health security preparedness. Of those 16, four saw their index score decline from the previous year

The chart below is interactive: **click** or **touch** to see more.

- Above U.S. average
- Within U.S. average
- Below U.S. average
- Below average, decline from previous year
- No Data



Emergency Preparedness Requirements

- Establishes national emergency preparedness requirements for all Medicare participating providers
- Strives to be consistent across provider types
- Requirements focus on 3 key essentials for maintaining access to healthcare during disaster:
 - Safeguarding human resources
 - Maintaining business continuity
 - Protecting physical resources
- Developed to support adoption of a standard all-hazards program

Emergency Preparedness Requirements

- Adoption allows providers to better anticipate and plan for needs and rapidly respond and recover following disaster
- Assists in integration with local public health and emergency management agencies
- Allows for the uniqueness of each provider type
- Allows individualization based upon potential disasters unique to physical location

Emergency Preparedness Requirements

- Surveyed as part of routine survey
- Normally conducted by the state authority conducting the Life Safety Code

Definitions

- **All-Hazards Approach:** An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. *Planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others.* All facilities must develop an all-hazards emergency preparedness program and plan.

Definitions

- **Disaster:** A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. Despite a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) and change from routine management methods to an incident command/management process, the outcome is lower than expected compared with a smaller scale or lower magnitude impact (see “emergency” for important contrast between the two terms).
- **Emergency/Disaster:** An event that can affect the facility internally as well as the overall target population or the community at large or community or a geographic area.

Definitions

- **Emergency:** A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. It requires a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) to meet the expected outcome, and commonly requires change from routine management methods to an incident command process to achieve the expected outcome (see “disaster” for important contrast between the two terms).
- **Emergency Plan:** An emergency plan provides the framework for the emergency preparedness program. The emergency plan is developed based on facility- and community-based risk assessments that assist a facility in anticipating and addressing facility, patient, staff and community needs and support continuity of business operations.
- **Emergency Preparedness Program:** The Emergency Preparedness Program describes a facility’s comprehensive approach to meeting the health, safety and security needs of the facility, its staff, their patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan that is based on a Risk Assessment and incorporates an all hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

Definitions

- **Facility-Based:** We consider the term “facility-based” to mean the emergency preparedness program is specific to the facility. It includes but is not limited to hazards specific to a facility based on its geographic location; dependent patient/resident/client and community population; facility type and potential surrounding community assets- i.e. rural area versus a large metropolitan area.
- **Full-Scale Exercise:** A full scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. “boots on the ground” response activities (for example, staff treating mock patients). **Recommended it is collaborative exercise involving a minimum of local or state emergency officials and is robust to develop community -based responses (NEW)**

Definitions

- **Functional Exercise (FE):** *The Department of Homeland Security's (DHS's) Homeland Security Exercise and Evaluation Program (HSEEP) explains that FEs are an operations-based exercise that is designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FEs are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions. For additional details, please visit HSEEP guidelines located at:*
https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Apr13_Fina_l.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da **(NEW DEFINITION)**
- **Mock Disaster Drill :** A mock disaster drill is a coordinated, supervised activity usually employed to validate a specific function or capability in a single organization. Mock disaster drills are commonly used to provide training on new equipment, validate procedures or practice and maintain current skills. For example, mock disaster drills may be appropriate for establishing a community-designated disaster receiving center or shelter. Can also be used to determine if plans can be executed as designed, to assess whether more training is required or to reinforce best practices. Is useful as a stand-alone tool, but a series of drills can be used to prepare several organizations to collaborate in a FSE. (Full scale exercise) **(NEW DEFINITION)**

Definitions

- **Risk Assessment:** The term risk assessment describes a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population and identify gaps and challenges that should be considered and addressed in developing the emergency preparedness program. The term risk assessment is meant to be comprehensive, and may include a variety of methods to assess and document potential hazards and their impacts. The healthcare industry has also referred to risk assessments as a Hazard Vulnerability Assessments or Analysis (HVA) as a type of risk assessment commonly used in the healthcare industry.

Definitions

- **Staff:** The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act
- **Table-top Exercise (TTX):** A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.
- **Workshop:** *A workshop, for the purposes of this guidance, is a planning meeting, seminar or practice session, which establishes the strategy and structure for an exercise program. We are aligning our definitions with the HSEEP guidelines. For additional details, see HSEEP guidelines at: [https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revisi on Apr13 Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da](https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revisi%20on_Apr13_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da). (NEW DEFINITION)*

E0001 482.15 , 483.73 and 485.625

- Must establish and maintain a comprehensive emergency preparedness program that meets all requirements utilizing an all-hazards approach.
- Condition Level
- Plan must describe comprehensive approach to the meeting health, safety and security needs of staff and patients during emergency or disaster
- Must address coordination with other healthcare facilities and whole community
- Surveyors interview leadership and reviewing plan including policies/procedures, communication plan and training/testing

E0001 Surveyor Guidance

- Review and update program and elements every two years (LTC-annually)
- Make changes if necessary more frequently
- Must include emergency infectious diseases during public health emergency
 - Encompass how entity will plan, coordinate and respond to localized AND widespread pandemic
 - Align plan with state and local plans

Surveyor Guidance

- How to document is subject to facility discretion
 - Paper
 - Electronic
- Must be able to demonstrate plan is in writing
- Recommend development of crosswalk as to where documents located
 - Binder
 - Where policies/procedures for specific requirements are located
- Recommend keep at least for two years (inpatient) providers (due to exercise requirements)
- Do not require “official sign-off”

E0004 482.15, 483.75(a) and 485.625(a)

Required Elements of Plan

- Plan must be updated at least every 2 years--hospitals and CAH(new-effective 11/29/2019) NOTE: if policy states annually, must follow
- Note if there is SNF or NF, emergency preparedness plan still must be updated annually
- Plan must include:
 - Facility and community-based risk assessment
 - Identify needs of patient population
 - Identify continuity of business operations to provide support during emergency
 - Supports, guides and ensures collaboration with local emergency preparedness officials
 - Consider duration of disaster
 - Needed contracts or arrangements including time frame to initiate services, how they will be procured and delivered and ongoing support til end of emergency
 - CMS realizes no guarantees in disaster

E0004 Surveyor Guidance

- Must be specific to location and consider particular hazards
 - Natural disasters
 - Man-made disasters
 - Bioterrorism
 - Cyberattacks
 - Facility based disasters-equipment failure, loss of essential resources
 - Hazardous waste
 - Emerging Infectious diseases such as Influenza, Ebola, Zika Covid-19, monkey pox and others **NEW GUIDANCE-GREATER EMPHASIS**
 - How operations will be affected
 - How will continuity of care be affected
- Reflect organization's patient population

Surveyor Guidance

- Plan needs to reflect continuity of business
- Continuity of business is concept to incorporate all continuity operations and business operations including:
 - All services to maintain patient/resident care
 - Quality of care
 - Patient/resident safety

E0006 482.15(a)(1)(2),483.73 (a)(1)(2) and
485.625 (a)(1)(2)

Risk Assessment and Strategies

- Facility and community-based risk assessment utilizing all hazards approach and development of strategies to address
- Must document assessment
- Must prepare for full spectrum of emergencies or disasters
- Utilize concepts outlined in National Preparedness System published by FEMA and also use guidance from Agency for Healthcare Research and Quality
- <https://www.fema.gov/national-preparedness-system>
- <https://www.ahrq.gov/topics/emergency-preparedness.html>
- <https://www.cdc.gov/cpr/readiness/healthcare/planning.htm>

E0006

Risk Assessment and Strategies

- Community not defined-define in plan
- Goal is collaboration by healthcare providers for integrated response
- Collaborative planning assists in gap identification
- May use community-based risk assessment developed by others or conduct own
 - Must have copy of community assessment to ensure facility plan is aligned

E0006

Risk Assessment Considerations

- **MUST BE DOCUMENTED**
- Identification of all essential business functions
- Identification of all risks or emergencies that are reasonably to confront
- Identification of all contingencies to plan for
- Location considerations
- Assessment of extent that any man-made or natural emergencies could limit or cause facility to cease operations
 - **INCLUDE LISTED PANDEMICS AND EID**
 - **INCLUDE UNFORSEEN WIDESPREAD COMMUNICABLE DISEASES**
- What arrangements may be necessary with other healthcare facilities to ensure essential services
- **What are your facilities vulnerabilities?**
 - **Near nuclear power plants**
 - **Population highly dependent on medical equipment**
- If provider does not own building –make arrangements with landlord

E0006

Possible Strategies

- Develop staffing strategy for possible staff shortages
- Develop surge capacity strategy-if will be requested to accept additional patients/residents
- Consider evacuation plan
- Consider alternate sites
- Have backup evacuation plan in case nearby facilities can not accept patients/residents
- Contingencies for power failures and natural disasters

NEW SURVEYOR GUIDANCE

- Power loss and potential disruptions of service
 - Consider using heat index or heat risk assessment
 - Must maintain safe temperatures (E0015)
- Public health emergencies
 - Need for PPE
 - Screening patients, residents and visitors
 - Testing patients, residents and visitors
 - Transfers/discharges
 - Home based healthcare
 - Telehealth
 - Physical Environment changes
 - Isolation
 - Social distancing
 - Surge/capacity

E0007 482.15(1)(3), 483.73(a)(3) 485.625(a)(3)

Population Considerations

- Plan must specify population served—inpatient and outpatient and any unique vulnerabilities
- Address persons at risk—any individual who may need additional response assistance including:
 - Children and infants
 - Senior citizens
 - Pregnant women
 - Individuals with disabilities
 - Persons from diverse cultures and racial and ethnic backgrounds
 - Persons with limited English proficiency or non-English speaking
 - Persons who lack transportation
 - Persons with chronic medical disorders or pharmacological dependency

E0007

Facility Emergency Services

- What type of services will facility be able to provide
 - Plans on how to address services not able to provide
- Succession planning—what if CEO on vacation or Facility Director out of town
 - Process to identify key positions by title
 - Assists in increasing the availability of experienced and capable leaders
 - At a minimum-must have qualified person to act as administrator, in their absence.
 - Must be authorized in writing to act in absence
- Continuity of operations
 - Essential persons and functions
 - Critical resources
 - Vital records
 - IT data protection
 - Alternate facility identification and location
 - Financial resources

E0009 482.15(a)(4), 483.73(a)(4) 485.624(a)(4)

Collaboration Process

- Plan must include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response to a disaster or emergency situation
- CMS deleted effective November 30, 2019, the requirement to document **ALL** efforts to contact officials and of the facility's participation in collaborative efforts
 - Determined the documentation requirements to be burdensome
 - Still must collaborate and have a process for such collaboration
 - **Must have sufficient details to support verification of process**

E0013 482.15(b), 483.73(b) and 485.625(b)

Emergency Preparedness Policies and Procedures

- Must be based upon the emergency plan, the risk assessment and the communication plan
- Policies and procedures must be reviewed and updated at least every two years effective November 30, 2019 (long-term care is still annually)
 - **Clearly document date of review and update and what update entailed**
- Policies and procedures must include:
 - Management of medical and non-medical emergencies
 - Fire
 - Equipment, power or water failure
 - Care-related emergencies
 - Natural disasters likely to threaten health or safety of patients, staff or public
 - Can be part of emergency plan or Standard Operating Procedures
 - Need to consider emergencies that last longer than expected
 - All emergency preparedness program documents should be centralized

E0015 482.15(b)(1), 483.73(b)(1) and 485.625(b)(1)

Policies and Procedures

Subsistence Needs

- Must cover needs for staff and patients whether evacuate or shelter in place
 - Food, water, medical and pharmaceutical supplies
 - Alternate sources of energy to maintain
 - Temperature to protect patient health and safety and to protect safe and sanitary storage of provisions (food, drugs)
 - Emergency power and lighting for operating, recovery, ICU, and emergency rooms and stairwells
 - Battery lamps and flashlights must be available elsewhere
 - Fire detection, extinguishing and alarm systems
 - Sewage and waste disposal
 - Continuity of treatments

E0015

Alternate Energy Source

- Not required to update but..
 - May find prudent after risk assessment
- Hospitals and CAH required to have essential electric system with generator that complies with NFPA 99
- Must have policies/procedures that determine how required heating and cooling will be maintain during emergency if loss of primary power
 - Not required to heat and cool entire building evenly
 - Must ensure safe temperatures
- If risk assessment determines best to use portable or mobile generator- must comply with NFPA 70
 - Wiring installed per Chapter 3 and manufacturer instructions
 - Designed and located to minimized hazards that may cause failure such as Floods, fires, icing and vandalism
 - Located with adequate ventilation—leave outside building
 - Located and protected so sparks can not reach adjacent combustible material
 - Operated, tested and maintained per manufacturer and State requirements
- No extension cord or temporary wiring can be used to connect electrical devices to portable/mobile generator
- Protection of fuel depends on amount and location
- Permanent generator must meet LSC surveys and E0041

E0015

Energy Sources

- Must confer with health department and emergency management officials to determine types and duration of emergency sources that could be available
- Not required to provide onsite treatment of sewage or waste
 - Must maintain in accordance with facility COP

E0018 482.15(b)(2), 483.73(b)(2) and 485.625(b)(2)

Policies and Procedures

- Need system to track location of on-duty staff and sheltered patients during emergency
 - If relocated. Must document the specific name and location of the receiving facility
 - No specific means required-may use electronic database, hard copy documentation or some other means
 - Must be readily available, accurate and shareable among officials
 - If using electronic database, should consider back up in event of power outage
 - Who compiles this information or secures patient records
 - Some states have these tracking systems- need to leverage this support
 - Not required to track location of patients who left voluntarily or have been appropriately discharged. Document appropriate information in the medical record

E0020 482.15(b)(3), 483.73(b)(3) and 485.625(b)(3)

Safe Evacuation Policies and Procedures

- Safe evacuation—patient safety #1 priority
 - Care and treatment needs of evacuees
 - Consider needs of specific patient population
 - Triage most critical patients first
 - How to handle patient refusal to evacuate
 - Develop triage criteria
 - Staff responsibilities
 - Communication of patient care needs to receiving facilities
 - Abbreviated health condition/history, allergies, family member contact information
 - Transportation
 - Identification of evacuation locations
 - Primary and alternate means of communication with external sources of assistance
 - Alternate means could include satellite phones

E022 482.15(b)(4, 483.73(b)(4)and 485.625(b)(4)

Means to Shelter in Place

- Communication plan needs to describe for plan to shelter in place in case evacuation not possible or inappropriate
- Need to plan for patients, residents, staff, visitors and volunteers
- Needs to align with risk assessment
- Criteria should be defined
 - What is the disaster?
 - Can building survive ?
 - What proactive steps should be considered prior?
 - Is it safe to transfer?
- Need various approaches

E0023 482.15(b)(5), 483.73(b)(5) and 485.625(b)(5)

Medical Record Requirements

- Policies and procedures must address:
 - How to preserve patient information
 - Protection of confidentiality of patient information
 - Security and maintain record availability
- Must still comply with HIPAA

E0024 482.15(b)(6), 483.73(b)(4) and 485.625(b)(6)

Role of Volunteers

- Policies and procedures need to address:
 - Role of Volunteers in emergency
 - Need to address varying skill levels and training
 - Volunteering healthcare –need to address any privileging and credentialing process
 - As part of emergency staffing strategy
 - What is the process and role for integration of State/Federal designated healthcare professionals to address surge such as Public Health Service
 - How to contact off-duty staff during emergency and what to do when these staff can not report to duty

Surveyor Guidance

- How has facility planned to mobilize all aspects of the healthcare system to reduce transmission of disease, direct people to the right level of care, and decrease the burden on the healthcare system.
- Will the facility choose not to use volunteers
- How to shelter and feed volunteers
- What types of emergencies will organization use volunteers
- What types of volunteers be used
- Include in surge staffing planning
 - Align with risk assessment
 - Plan for surge staffing needs for natural disasters, pandemics

E0025 482.15(b)(7), 483.73(b)(7) and 495.625(b)(7)

Arrangements with Other Facilities

- Must develop arrangements with other facilities
- Purpose is to receive patients in event of limitations or cessation of operation in order to maintain patient care
 - Consider patient population
 - Consider ability of other facility to re accommodate
 - What if not able to accept
- Pre-arranged transfer agreements
- Need to address what facilities are nearby and outside disaster area to accept patients
- Need pre-arranged transportation agreements
- Can be Memorandum of Understanding or Transfer Agreement
- All agreements must in writing

E0026 482.15(b)(8) and 485.625(b)(8)

Federal Declared Disasters

- #1 most frequent cited emergency preparedness regulation
- Must have policies and procedures related to the role of the organization when a waiver under Section 1135 declared by Secretary of HHS
- Waivers may be granted to waive physician licensure to assist hospital, other examples include waivers to some EMTALA requirements and HIPAA
- Remember only Federal declaration not Governor declaration of disaster
- Can only use if your organization directly impacted or challenged in meeting the specific regulation waived

Surveyor Guidance

- Must understand what waivers have been granted
 - Plan for waiver of physician and other staff licensure
 - What oversight is needed
- Must have provisions for alternate sites of care (ACS)
 - What types of disasters
 - Anticipated length of operating
 - Level of care provide
 - What types of patient population
 - What supplies, equipment and staffing needed
- Part of proactive planning
- Can only use when CMS authorizes
- Waivers only effective until termination of emergency period OR 60 days after published—may be extended for 60 day periods
currently set to expire 10-15-22
- How will entity resume normal operations (deactivate alternate care sites and other waivers used)

E29 482.15(c), 483.7(c) and 485.625 (c)

Communication Plan

- Review every 2 years (new effective November 30, 2019) If hospital and annually for long-term care
- How will the facility coordinate patient care within facility, across healthcare providers and with state/local public health
- How will facility interact and coordinate with emergency management agencies to protect patient health and safety
- Communication plan should support coordination of care
- Flexibility in how to operationalize communication plan requirements
- If in area with limited connectivity to Internet and cellular, then plan needs to address communication needs and how to comply without these communication methodologies
 - Satellite phones
 - Radios
 - Short wave radios

E0030 482.15(c)(1), 483.73(c)(1) and 485.625(c)(1)

Communication Plan Contacts

- Names and Contact Information
 - Staff
 - Entities providing services under arrangements
 - Residents/Patient's physicians (or other provider such as ARNP or PA)
 - Other contacts such as hospitals and CAH
 - Volunteers
- Must include at least one contact for another provider of same type
- Must be available at a minimum to emergency preparedness coordinator and management during emergency (**NEW**)
- May find it appropriate to have LTC facility contact information within geographic area as may assist in facilitating patient transfers
- Must update with incoming and departing staff
- Transplant centers must be included in communication plan

E31 482.15(c)(2), 483.73(c)(2) and 485.625(c)(2)

Additional Required Contacts

- Communication plan must include:
 - Federal, State, regional and local emergency preparedness staff contact information
 - State public health department
 - FEMA
 - Fire, police, public health
 - May be generic line and not specific individual
 - Tribal emergency preparedness contact information (if applicable)
 - Other sources of assistance such as State Licensing and Certification Agency
- Encouraged to maintain electronically and in hard copy format
- Must review entire communications plan every 2 years (if LTC-annually)

E32 482.15(c)(3) 483.73(c)(3) and 485.625(c)(3) Primary and Alternate Communication Means

- Plan must include both primary and alternate means of communicating with:
 - Facility staff
 - Federal, State, tribal, regional, and local emergency management agencies
- Need to identify both primary and alternate communications means (**NEW**)
- Discretion to use whatever alternate systems that work
- Plan needs to include procedures as to when and how alternate methods used and who uses them
- Need to ensure alternate means is compatible with other facilities and governmental agencies
- Prudent to consider whether the systems can communicate on same frequency

E0033 482.15(c)(4-6), 483.73 (c)(4-6) and 485.625(c)(4-6)

Patient Information Sharing

- Communication plan needs to include:
 - Means to share information and medical record documentation to ensure continuity of care
 - Need to ensure information available if evacuated to next healthcare provider or available when sheltered in place
 - Means in evacuation to release patient information as permitted under 45 CFR 164.510 (b)(1)(ii)
 - Do not delay transfer to assemble all patient reports. Need to send all necessary information available and should include: Name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (inpatient), blood type, advance directives and next of kin/emergency contacts
 - Means of providing information about general condition and location of patients as permitted under 45 CFR 164.510(b)(4)
 - System must generate timely, accurate information to family members
 - HIPAA requirements not suspended during disaster
 - Permit certain disclosures in emergency and for disaster release
 - Coordinate with facility privacy officer

E34 482.15 (c)(7), 483.73 (c)(7) and 485.625(c)(7)

Communication with Incident Command Center

- Communication Plan must have means to provide information to government emergency agencies, public health and Incident Command Center:
 - Facility Needs
 - Food, water, medical supplies
 - Facility's ability to provide assistance
 - Facility's need to evacuate or transfer patients
 - Requests for transport assistance
 - Loss of part or all function
 - Staffing shortages
 - Other information requested by Federal or state governments
 - Facility's occupancy
 - Number of current patients and how many capable of taking care of
 - Plan needs to describe how information will be provided

E36 482.15(d), 483.73(d) and 485.625(d)

Training and Testing Program

- Based upon emergency plan, risk assessment and communication plan
- Must be reviewed and updated every 2 years (effective November 30, 2019) Annually for long term care facilities
- Training is the facility's responsibility to provide education and instruction to staff, contractors and volunteers to ensure all are aware of emergency preparedness program
- Testing is the concept that training is operationalized
 - Must evaluate effectiveness of training
 - Must evaluate the overall emergency preparedness program
 - Includes conducting drills or exercises to test plan and identify gaps and opportunities for improvement

E36 Surveyor Guidance (**NEW**)

- Training—hospital or long-term care facility's responsibility to provide education to all staff, contractors and volunteers
- Process outlined in program
- Staff training-minimum
 - Policies and procedures
 - Written documentation of sign-in or individual certificates

E36 Surveyor Guidance (**NEW**)

- Testing requirements based upon provider type
 - Inpatient-two testing exercises annually
- Process must include all staff over time
- Consider the exercise and which departments most involved
- Not specific as to which minimum equipment to use
- No minimum number of patients/residents to include
- Must test based upon HOW staff will respond to emergency

E37 482.15(d)(1), 483.73(d)(1) and 485.625(d)(1)

Training Program

- Initial Training for all new and existing staff, individuals providing services under arrangement and volunteers
 - Includes agency staff or individuals who provide services PRN
 - Includes individuals who would be expected to assist in emergency
 - Must be done during orientation or shortly after
 - No delays in training
 - If multi-campus –training is specific to location and must be re-trained if assigned to new location
- Training must be consistent with expected role in emergency
- Must maintain training documentation
 - Documentation must show what specific training was completed
- Staff must be able to demonstrate knowledge of emergency procedures
 - Flexible in how to demonstrate competency
 - Test-if computer generated
 - Instructor led-quality and answer session

Surveyor Guidance (**NEW**)

- Must include individual based responses in event of natural disasters
- Include process for how to shelter in place or evacuate
- Should include how to manage continuity of care
 - Triage process
 - Transfer/discharge during mass casualty or surge event
- Must be based upon risk assessment

Surveyor Guidance (**NEW**)

- Must provide upon orientation
- Continued training must be provided every two years OR if policies and procedures significantly updated
 - Relocation to new facility or other facility modifications
 - Lessons learned

E37 482.15(d)(1), 483.73(d)(1) and
485.625(d)(1)

Training Program

- Flexibility to determine focus of every two-year training
 - Should be modified based upon lessons learning during exercises or real-life emergencies
- Flexible to determine what level of training for each staff person based upon involvement or role
 - May be core topics for everyone
 - May exempt some from evacuation procedures such as dietary staff
 - However this staff may do training on proper preparation and storage for food during emergency
 - External training may suffice-up to facility

Additional CAH Requirements

- Interpretative guidelines refer to CAH regulations
- C930- Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

E39 482.15(d)(2), 483.73 (d)(2) and 485.625(d)(2)

Testing Program

- Must conduct emergency plan exercises at least twice per year
- Must do the following
 - Annual full-scale exercise –community based
 - If community based not available-must conduct annual individual facility based functional exercise OR
 - If experience an actual emergency (natural or made made) and emergency plan activated provider is exempt from next full scale or individual facility-based exercise
 - An additional annual exercise may include
 - Second full-scale exercise-either community or individual based
 - Mock disaster drill
 - Tabletop exercise or workshop led by facilitator
 - Group discussion
 - Use narrated clinically relevant emergency scenario
 - Problem Statements
 - Directed messages
 - Prepared questions
 - Analyze facility response to exercise
 - Maintain documentation
 - Revise emergency plan as needed

Testing Program

- Full scale exercise defined and accepted as any operations-based exercise (drill, functional or full -scale exercise) that assess the functional capabilities by simulating a response to emergency that would impact facility operations and given community
- Full scale exercise also operations-based exercise that involves multiple agencies and disciplines performing functional or operational elements
- Flexibility to participate in realistic exercises reflecting risks and composition of community (rural, metro, suburban)
- Consider physical location, facility responsibilities and community needs
- If emergency management agency or other coalition conducts annual full-scale exercise, provider should participate to identify potential opportunities to integrate and coordinate with broader community
- Should contact local and state agencies to determine if opportunity exists

Testing Program

- If no full-scale community-based exercise can do either individual facility-based plan which requires full activation of emergency plan
 - Must demonstrate how this exercise addresses risks previously identified in risk assessment
- OR smaller community-based exercise with other nearby facilities
 - Assists in identification of gaps
 - Minimizes financial impact of regulations
 - If elect to do smaller community exercise, should contact state and local emergency officials
- Documentation must be maintained for a minimum of 3 years
 - Document lessons learned
 - Document changes made –may complete an after-action review process
 - What was supposed to happen
 - What occurred
 - What went well
 - What could improve on
 - Plan and timeline for improvements

Testing Program

- Must include leadership and department heads
 - Include clinical staff in area of emergency test
- Chose different scenarios annually
- If actual emergency event occurs of such magnitude to activate emergency plan—meets annual exercise and exempts organization from next full community-based organization NOT from exercise of choice
 - Demonstrate through written documentation

Exemption Example

- Completed full scale exercise in January 2020
 - Schedule for exercise of choice in November 2020
- Actual emergency in March 2020
- Exempt from next required full-scale exercise in January 2021
- If organization had conducted exercise of choice in January 2020 and required full-scale exercise scheduled for November 2020, would be exempt from full scale exercise
- IF still operating under actual emergency (without any break in plan operation), then will be considered exempt from 2021 exercise
- Exercises of choice are not considered as the required full-scale community or facility-based exercise
- Must document activation of emergency program to use exemption

Exemptions

- Full-scale exemptions due to an actual disaster are based on any activation of the emergency plan during the facility's 12-month cycle. Exemptions do not accumulate or carry over to following full-scale exercises.
- For example, if a facility was required by their testing cycle to conduct a full-scale exercise in 2022, but is operating under their activated emergency plan in January 2022 for COVID-19 response and faces a winter storm/wildfire, etc. and activates additional protocols under its plan, the exemption for a full-scale exercise will apply to their full-scale exemption in 2022. It would not carry over because the facility was faced with two separate emergency activations.

E41 482.15(e). 483.73 (e)and 485.625(e)

Condition for Participation Emergency and Standby Power

- Must implement emergency and standby power system based upon emergency plan
- Emergency generator must be located in accordance with NFPA 99, NFPA 101 and related Tentative Interim Amendments
- Must implement emergency power inspection, testing and maintenance in accord with NFPA 101
- Must maintain onsite fuel source to power emergency generator and have a plan for how emergency power systems will be maintained unless facility evacuates

E41 482.15(e) and 485.625(e)
Condition for Participation
Emergency and Standby Power

- Hospitals , CAHs and Long Term Care Facilities must comply with NFPA 101 (Life Safety Code) 2012 edition and NFPA 99-Health Care Facilities Code-2012 edition
- Must have Essential Electric System (EES) in areas where failure of equipment may likely cause patient/caregiver injury or death
 - Must install, maintain, inspect and test
 - System includes alternate source of power-designed to ensure continuity of electricity to specified areas and functions during interruption of normal power
 - Typically a generator
 - NFPA 99 also references NFPA 110 which addresses performance requirements for emergency and standby power systems
 - Installation, maintenance, operation and testing requirements

Emergency and Standby Power

- NFPA 99 covers emergency power for emergency lighting, fire detection, extinguishing and alarm systems
- NFPA 99 does not specify emergency power requirements for maintaining supplies
- NFPA 99 does address facility temperature requirements for operating, delivery, recover, intensive care, coronary care, nurseries, infection/isolation rooms, emergency treatment spaces and general patient rooms
- NFPA 99 does not require heating in general patient rooms during power disruption if temperature outside is greater than 20 F
- EES must consider additional electrical load to maintain subsistence needs as identified in emergency plan

Emergency and Standby Power

- Facilities may choose to evacuate all patients or relocate to only certain internal areas based upon ability to provide emergency power
- Example: if able to maintain temperature in 50% in inpatient locations during power outage, emergency plan should reflect if bringing in alternate power, partial relocation or evacuation of patients rather than installing additional power to maintain 100% of all inpatient areas
- Make decisions based upon risk assessment
- If portable and mobile generator best based upon emergency preparedness plan, NFPA requirements on location, inspection, testing and fuel in accord with NFPA 70

Emergency and Standby Power

- NFPA 110 has minimum requirements for installation of Emergency Power Supply System equipment
 - Must be designed and located to minimize damage during disaster (such as flooding)
 - Does not apply to portable generators
- NFPA 110 contains routine maintenance and operational testing requirements for emergency and standby power systems
- NFPA 100 allows generator fuel sources to be gas, diesel, propane, natural or synthetic gas
 - Must have plan to keep EES operational for duration of emergencies as defined by emergency plan unless evacuation
 - Make written arrangements for fuel delivery during emergency
 - What limitations or delay
 - What will be rest of community needs
 - What are possible delays and limitations
 - How much fuel is maintained onsite

Deficiency Examples

Emergency Preparedness Condition Level Deficiency

Based on interview, record review, and policy review, the provider failed to ensure:

*Immediate cyber security training for all staff for an identified June 4, 2019 encryption virus that affected ninety-five percent (%) of the hospital computers.

*Policies and procedures were revised and updated to meet the requirements of Emergency Preparedness (EP) for their facility that identified internal and external risks. *A comprehensive EP program was developed and implemented that included internal and external risks identified in the facility risk assessment on 7/18/18.

Findings include:

1. Interview on 7/8/19 at 9:20 a.m. with chief executive officer (CEO) A regarding the encryption virus called Ruyk that had been identified on June 4, 2019 revealed: *Security Metrics was in the facility two weeks ago to complete a forensic investigation of the encryption virus. *Security Metrics would be submitting a report seven to ten days prior to the sixty day deadline. The CEO indicated the report would be available the first part of August. *There was no data breach identified, just malware. *They identified the issue on June 4, 2019 when staff could not log on to their computers. *After investigation there had been a phishing email suspected of causing the encryption virus. Ninety-five % of the provider's computers had been affected. *All the provider's files were encrypted. *The electronic medical records were not affected. *The Internet was shut down for two weeks. *The staff were given laptops to access and document patient care information using hotspots. *No protected patient information had been breached
2. Review of the provider's expired 6/30/14 Hospital Disaster Plan revealed: *The purpose of the policy was for both external and internal disaster situations that might affect hospital staff, patients, visitors, and the community. *Identify responsibilities of individuals and departments in the event of a disaster situation. *There was a clear delineation of roles and responsibilities for staff defined in the policy. *The policy had been created on 10/18/13 and had expired on 6/30/14. *There had been no further revisions or updates to the policy since the approval date of 10/18/13.

Emergency Preparedness Condition Level Deficiency

Based on review of facility documents, an interview with the facility Physician owner it was determined, the facility failed to:

(E-0004) develop and maintain an EP plan that must be reviewed, and updated at least annually.

(E-0007) incorporate documentation on the EP plan to include the needs of the patient population they serve or a delegation of authority as part of the continuity of operations.

(E-0013) develop and implement emergency preparedness policies and procedures, based on the Emergency Plan.

(E-0015) develop and implement emergency preparedness policies and procedures, based on subsistence needs for staff and patients.

(E-0018) develop and implement a policy and procedure for tracking of on-duty staff and sheltered patients in the facility's care during an emergency in the emergency plan.

(E-0024) develop and implement a policy and procedure for the use of volunteers in an emergency.

(E-0025) develop and implement a policy and procedure for having arrangement with other facilities.

(E-0029) develop and implement an emergency preparedness Communication Plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually.

(E-0032) identify a primary and alternate means of communication during an emergency.

(E-0034) develop a means to sharing information on occupancy, needs, and it's ability to provide assistance to the authority having jurisdiction.

(E-0036) develop a facility based emergency planning, training and testing program.

The cumulative effect of these systematic deficient practices resulted in the facility's failure to meet the requirement for the Condition of Participation for Establishment of the Development of an Emergency Preparedness Plan, which poses a high potential risk to the health and safety of patients and staff related to potential harm if staff and patients are not aware of what to do during an emergency situation.

Other Emergency Preparedness Deficiencies

- **E001—Lack of Comprehensive Plan**
 - The EPP was being stored in a business managers office that was locked at the time of survey and available staff did not have keys to the office, which makes the plan unavailable for staff on all shifts.
- ***E004 – Develop EP Plan, Review & Update Annually***
 - The EPP did not contain documentation of an annual review date.
- ***E006 – Plan Based on All Hazards Risk Assessment***
 - The EPP failed to contain emerging infectious disease within the documented risk assessment.
 - The facility had not documented the identification of which staff would assume specific roles in another's absence through succession planning and delegations of authority. The Continuing Operations Plan was lacking the specific identification of essential personnel within the organization.
- ***E013 – Development of EP Policies and Procedures***
 - The EPP policies and procedures were not updated upon new ownership of the facility.
- ***E015 – Subsistence Needs for Staff and Patients***
 - The facility did not have a policy or procedure for provisions of medical supplies and pharmaceutical needs in the event of an emergency.
- ***E026 - Roles Under a Waiver Declared by Secretary***
 - The facility did not have a policy that addressed the facility's role in emergencies and the 1135 waiver process.
 - The facility failed to have a procedure that addressed the facility's role in emergencies and general awareness of the 1135 process.

Questions?



Speaker

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