CMS Final Rule:

Conditions of Participation Establishing Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

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Overview

- Overview of four core elements of emergency preparedness
  - Who must comply
  - Key deadlines for compliance
  - Alignment with The Joint Commission Standards
- Specific provisions of the final rule for hospitals and Critical Access Hospitals
- Resources and Next Steps
- Questions

CMS Goals

Address systemic gaps.

Establish consistency

Encourage coordination

Background

- The proposed rule was published in the *Federal Register* on Friday, December 27th and comments were submitted in February 2014
- CMS got hundreds of comments and took two years to finalize this rulemaking
- CHA comments available at www.calhospital.org/regulatory-tracker under the final rules tab along with a final rule summary and redlines of regulatory text

Background (continued)

- CMS released the Emergency Preparedness Requirements on September 8, published on September 16
  - www.calhospital.org/sites/main/files/file-attachments/2016-21404.pdf
- Applicable to 17 provider types, including hospitals
- The COPs are effective as of November 16, 2016 however, all providers and suppliers must comply by November 15, 2017
- CMS Hosted a National Provider Call
  - www.cms.gov/outreach-and-education/outreach/npc/national-provider-calls-and-events.html

17 Impacted Provider and Supplier Types

Below are the statutory and regulatory citations for the providers and suppliers for which CMS propose emergency preparedness regulations for Hospitals and Critical Access Hospitals:

- **Hospitals** — section 1861(e)(9) of the Act and 42 CFR 482.1 through 482.66
- **Critical Access Hospitals** (CAHs) — sections 1820 and 1861(mm) of the Act and 42 CFR 485.601 through 485.647

What Is a Medicare Condition of Participation/Coverage?

"CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs.

These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs/CfCs."

What Is a Medicare Condition of Participation/Coverage? (cont.)

CMS website:

- CMS contracts with the California Department of Public Health to ensure compliance through a survey and certification process that must take place every three years
- The Joint Commission does the vast majority of survey compliance for hospitals in California through its deemed authority. TJC Standards must meet/comply with CMS standards, but may also exceed the Medicare CoP standards
- A violation of a CoP may lead to any number of cited deficiencies, including an immediate jeopardy (in California, IJs may trigger administrative penalties)
- **How an organization is surveyed is dependent on how they are licensed**

Final Rule Overview

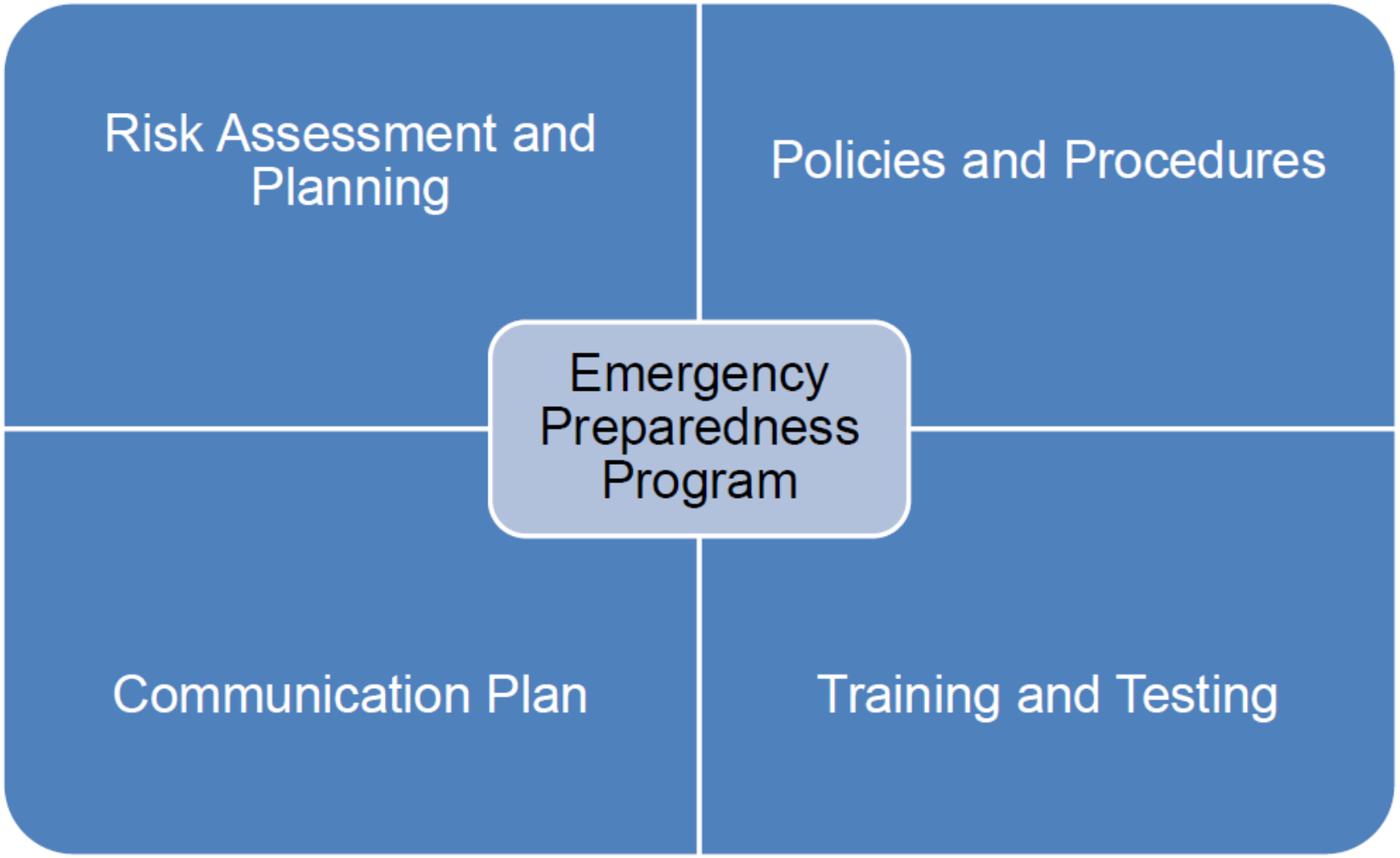
Preamble in both proposed and final rules will inform surveyor interpretive guidance

- **Hospital preamble language runs pages 63861 — 63896**
- Followed by preamble discussion of all other provider types
- Cost and Burden Estimates – Summary Table on 64007
- Regulatory Impact Analysis
- Regulatory text begins 64021
  - CHA provided a comparison between the proposed regulatory text and the final to reflect changes and additional clarification
  - The definitions of terms in the regulatory text is discussed in preamble and in Q and A

Current Status

- CMS is currently developing interpretive guidance (CMS State Operations Manual) and surveyor training
  - Recent FAQs are posted to the CMS website at http://www.calhospital.org/post/cms-emergency-preparedness-cop-rule
  - The State Operations Manual (SOM) anticipated release is Spring 2017
  - CMS is developing web-based (self-paced) training accessible to surveyors, and intends to make available to providers/suppliers
- The Joint Commission standards under review at CMS
- CHA actively engaged with CMS staff
  - Seeking member feedback on the final rule and identification of areas for greater clarity

Four Core Elements



§ 482.15 Condition of Participation: Emergency preparedness

"The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness **program** that meets the requirements of this section, utilizing an all-hazards approach.

- All-hazards approach: an integrated approach to emergency preparedness planning
  - NOT managing separate planning initiatives for a multitude of threat scenarios
  - INSTEAD, focuses on developing capacities and **capabilities**

(a) Emergency Plan

(a) Emergency Plan. The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment utilizing all-hazards approach.

- Identification of essential business functions that should be continued in an emergency;
- Identification of all risks or emergencies that the hospital may reasonably expect to confront;
- Identification of all contingencies for which the hospital should plan
- Consideration of the hospital's locations, including patient services and business operations;
- Assessment of the extent to which emergencies may cause the hospital to cease or limit operations and
- Determination of whether arrangements with other hospitals or entities might be needed to ensure the provision of essential services

(a) Emergency Plan

(2) Include strategies for addressing emergency events identified by the risk assessment.

- CMS expects strategies to include consideration of collaboration with hospitals and suppliers across state lines

(a) Emergency Plan

(3) Address patient population, including, but not limited to persons at risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

CMS Defines: Persons at risk include: infants/children, senior citizens, pregnant women, persons who have physical or mental disabilities, who live in institutionalized settings, from diverse cultures, have limited English proficiency, lack transportation, have chronic medical disorders or have pharmacological dependency.

(a) Emergency Plan

(4) Include a process for ~~ensuring~~ cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to ~~ensure~~ maintain an integrated response during a disaster or emergency situation, including documentation of the hospitals' efforts to contact such officials and when applicable, its participation in collaborative and cooperative planning efforts

CMS Comments/Response

- CMS clarifies in the final rule that the risk assessment is equivalent to a hazard vulnerability risk assessment and as such documentation regarding that process should be kept
- CHA raised concerns regarding surveyor variability in how plans are evaluated
  - CMS clearly states the format is at the discretion of the facility, but must meet all the requirements
- CMS allows for other community assessments to be used, or for the hospital to conduct their own assessment (consistent with TJC standard)

CMS Discussion/Response

- "Persons at risk" discussed in response; CMS clearly states that "facilities would not be expected to take care of all needs in the community during an emergency," but makes no changes to the persons at risk population definition, despite comments to broaden it
  - Rather CMS notes that hospitals are encouraged to participate in coalitions to ensure that there are alternate locations and that there is a responsibility to make efforts to collaborate and coordinate (hospitals should document those efforts)

(b) Policies and Procedures

(b) Policies and procedures. The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. **The policies and procedures must be reviewed and updated at least annually.** At a minimum, the policies and procedures must address the following:

CMS Q and A: Policies and Procedures are NOT the same as Operating Guidelines. "Policies are considered a more formal, definite method or course of action to be adhered to. Therefore facilities must develop and maintain "policies" and procedures to meet the requirements of the regulation." …….Facilities should be aware that surveyors may ask to see a copy of the facilities "policies" and not "operating guidelines."

CMS Comments/Response (continued)

CMS Response 63880: ……Secondly, we are not specifying the amount of subsistence that must be provided as we believe that such a requirement would be overly prescriptive. Facilities can best manage this based on their own facility risk assessments. We disagree with setting a rigid amount of subsistence to have on hand at any given time in the event of an emergency…….

"We believe the rule allows flexibility so that facilities can determine how they will acquire provisions and use them for the needs of patients and staff."

Title 22 Provisions Sections 70277 and Sections 70741 should be reviewed

(b) Policies and Procedures

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include but are not limited to the following:

(i) food, water, medical and pharmaceutical supplies

(ii) alternate sources of energy to maintain

(A) temperatures to protect patient health and safety and for safe and sanitary storage of provisions

(B) emergency lighting

(C) fire detection, extinguishing, and alarm systems

(D) sewage and waste disposal

(b) Policies and Procedures

(2) A system to track the location of on-duty staff and sheltered patients in the hospital's care ~~both~~ during ~~and after~~ the emergency. If on-duty staff and sheltered patients are relocated during the emergency, the hospital must document the specific name and location of the receiving facility or other location.

CMS response: By "system to track," we mean that facilities will have the flexibility to determine how best to track their patients and staff, whether they utilize an electronic database, hard copy documentation, or some other method" –**p. 63881**

(b) Policies and Procedures

(3) Safe evacuation from the hospital

(4) A means to shelter in place for patients, staff and volunteers who remain in the facility

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ~~ensures records are secure and readily available~~ secures and maintains the availability of records.

- Policies must be HIPAA privacy and security compliant

CMS Comments/Response

CMS Response P 63881: We are not requiring EHRs as part of the medical record documentation requirements. Medicare and Medicaid-participating facilities are in varying stages of EHR adoption, and therefore, many would be unable to electronically share relevant patient care information with other treating healthcare facilities during an emergency**. However, we do expect facilities to be able to provide a means to preserve and protect patient records and ensure that they are secure, in order to provide continuity in the patient's care and treatment.** We would expect facilities' plans to address how a provider, in the event of an evacuation, would release patient information, as permitted under 45 CFR 164.510 of the HIPAA Privacy Rule.

(b) Policies and Procedures

(6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

CMS Response p 63883:

The intent of this requirement is to address any volunteers. We believe that in an emergency a facility or community would need to accept volunteer support from individuals with varying levels of skills and training and that policies and procedures should be in place to facility this support. **Health care volunteers would be allowed to perform services within their scope of practice and training and nonmedical volunteers would perform non-medical tasks. As such, we disagree with limiting this requirement to just medical volunteers.**

(b) Policies and Procedures

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ~~ensure~~ maintain the continuity of services to hospital patients.

CMS Response p 63882: We understand that during an emergency other available healthcare resources may be strained, but the development of arrangements in collaboration with other facilities to receive patients is necessary in order to provide the continued needed care and treatment for all patients. If arranged resources are unavailable during an emergency, then the facility should use available resources in its community. Facilities are encouraged to participate with its local healthcare coalition to gain a broader understanding of other facilities and potential resources, both facility and community, that may be available during an emergency.

ASHE: Does not likely meet current TCJ standards alone as currently articulated. TJC standard likely to be revised to meet CoP.

(b) Policies and Procedures

(8) The role of the hospital under a waiver declared by the Secretary, in accordance with Section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

- CMS intends this to encourage collaboration with emergency officials in proactive planning
- **CMS Response p. 63879**: We would expect that state or local emergency management officials would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites

III. Communications Plan

(c) Communication plan. The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following: staff, entities under arrangement; patients' physicians; other hospitals and CAHs; volunteers

(2) Contact information for the following: federal, state, tribal, regional or local emergency preparedness staff and other sources of assistance

(3) Primary and alternate means for communicating with the following: hospital staff, federal, state, tribal regional and local emergency management agencies

CMS recognizes difficulties with communications systems. While they are not specifying the type of alternate communication equipment they do make some suggestions such as mobile phones, satellite phones, HAM radio etc.

III. Communications Plan

(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to ~~ensure~~ maintain the continuity of care.

CMS expects a system of communication that allows for:

- Comprehensive patient care information could be disseminated across providers and suppliers in a timely manner
- Information was sent with an evacuated patient to the next care provider or supplier
- Information would be readily available for patients being sheltered in place
- Electronic information backed up, both within and outside of the hospital's geographic location –
  - *This is a best practice, not a requirement as CMS is not requiring use of an EHR system p 36887*

III. Communications Plan

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii)

- System that can generate timely, accurate information that could be disseminated, as permitted by HIPAA privacy regulations, to family members and others (not required for RHCs)

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4)

- HIPAA privacy "use and disclosures for disaster relief purposes"; e.g. American Red Cross

(7) A means of providing information about the hospital's occupancy, needs and its ability to provide assistance, to the authority having jurisdiction, the Incident Commander or designee

IV. Training and Testing

(d) Training and testing. The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (c) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

IV. Training and Testing

(1) Training Program. The hospital must do all of the following:

(i) Initial training in EP policies and procedures to *all* new and existing staff, individuals providing services under arrangement, and volunteers

(ii) Provide EP training at least annually

(iii) Maintain documentation of the training

(iv) ~~Ensure that staff can demonstrate~~ Demonstrate staff knowledge of emergency procedures.

CMS Comments/Response

CMS Response P. 63892: We appreciate all of the detailed feedback that we received from commenters on this requirement. **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.**

According to our regulations, governing boards, or a legally responsible individual, ensures that a facility’s policies and procedures are carried out in such a manner as to comply with applicable federal, state and local laws. We believe that anyone, including volunteers, providing services in a facility should be at least annually trained on the facility’s emergency preparedness procedures. As past disasters have shown, emergency situations or disasters can be either expected or unexpected.

CMS Comments/Response (cont.)

Therefore, training should be made available to everyone associated with the facility, and it is up to the facility to determine the level to which any specific individual should be trained. One way this could be determined is by that individual's involvement or expected role during an emergency. We stated at § 482.15(d)(1)(i) that training should be provided consistent with facility staff's expected roles. To mitigate costs it may be beneficial for facilities to take this approach when establishing their training programs. In addition, as we state elsewhere in this preamble, we encourage facilities to participate in healthcare coalitions in their area. Depending on their duties during an emergency, a facility may determine that documented external training is sufficient to meet the facility's requirements.

IV. Training and Testing

(2) Testing. The hospital must conduct ~~drills and~~ exercises to test the emergency ~~plan~~ at least annually. The hospital must do the following:

(i) Participate in a ~~community mock disaster drill at least annually. If not available, individual facility-based mock disaster drill at least annually~~ full scale exercise that is community-based or when a community-based exercise if not accessible, an individual, facility based exercise. ~~(ii)~~ If hospital experiences an actual natural or man-made emergency that requires activation of emergency plan, the hospital is exempt from engaging in a community-based or individual, facility based full-scale exercise for 1 year following the onset of the actual event. this exempts hospital from requirements for 1 year following.

IV. Training and Testing

~~(iii)~~ (ii) Conduct ~~a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan~~ an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

~~(iv)~~ (iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

CMS Comments/Response

CMS Response P 63893. Therefore, in this final rule we are revising our proposed provision at § 482.15(d)(2**) to require facilities to conduct one full-scale exercise and an additional exercise of their choice, which could be a second full-scale exercise or a tabletop exercise. We note that the full-scale exercise must be community-based unless a community exercise is not available. Facilities may opt to conduct more exercises, as needed, to improve their emergency plans and prepare their staff and patients and are encouraged to include community-based partners in all of their additional exercises where appropriate.**

We believe that this revision will give facilities the ability to determine which exercise is most beneficial to them as they consider their specific needs.

CMS Comments/Response

CMS Response p 63894.

We proposed to require at § 482.15(d)(2)(iv) that hospitals analyze their response to, and maintain documentation of, all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. **Demonstrating the thorough completion of an After Action Report or Improvement Plan would meet this requirement; however, we are not requiring completion of specific reports, in order to give facilities some flexibility in this area.**

CMS Q and A (Round 3)

Q: Regarding fulfilling the testing needs: Do we indeed to conduct two tests a year? And minimally one of them needs to be a community based test? If an emergency presents itself between November 15, 2017 and December 31, 2017, would that satisfy one testing need? Would that be the community-based need? And would that cover us for the period until November 15, 2018 or until the end of the calendar year 2017?

A: Facilities are required to participate in a full-scale exercise that is community-based or an individual facility-based exercise when a community-based exercise is not accessible AND conduct an additional exercise that may include a second full-scale community or facility-based exercise or a tabletop exercise (as described in the regulations.) So yes, a facility is required to conduct two tests annually. If the facility experienced an emergency and had to activate its emergency plan between November 15, 2017 and December 31, 2017 that would satisfy one of the annual testing requirements and would exempt the facility from engaging in a community- or facility-based exercise for one year following the date of the actual emergency event**. The "annual" testing requirement will not be measured on a calendar year basis which is January 1 through December 31. The annual requirement will be measured from the date of the last actual emergency event or the date the exercise/testing took place.**

V. Emergency and Standby Power Systems

(e) Emergency and standby power systems. The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs ~~(b)(2)(i)~~ (b)(1)(i) and (ii) of this section.

(1) Emergency generator location. ~~(i)~~ The generator must be in accordance with requirements in ~~NFPA 99, NFPA 101 and NFPA 110~~ the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

CMS Comments/Response

- CHA strongly opposed original requirements and were successful in getting the generator testing requirements changed
- Providers should continue to consult California state codes to ensure compliance as this is a complex regulatory framework in which to operate

V. Emergency and Standby Power Systems

(2) Emergency generator inspection and testing. ~~In addition to the emergency power system inspection and testing requirements found in NFPA 99 and NFPA 110:~~

~~(i) At least once every 12 months, test each emergency generator for minimum of 4 continuous hours. Test load must be 100% of load hospital anticipates it will require during an emergency~~

~~(ii) Maintain written record of generator inspections, tests, exercising, operation and repairs~~ The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 101, and Life Safety Code.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must ~~maintain a quantity of fuel capable of sustaining emergency power for duration of emergency or until likely resupply~~ have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) Integrated Healthcare Systems – All New Regulations Next

(f) Integrated healthcare systems. If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must —

Summary

- CMS has set the “floor”, CA regulation often exceeds federal regulation.
- Additional resources may be required to comply by November 17, 2017
- C-Suite and governing boards need to remain engaged
- Watch CHA news for updates, resources and additional training

Resources

CMS Resource Page:

www.cms.gov/Medicare/Provider-Enrollmentand-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html

CHA COP Website

- CHA has provided redlines of changes to the regulatory text for the provisions for hospitals and critical access hospitals as well as SNFs and HHA
- http://www.calhospital.org/post/cms-emergency-preparedness-cop-rule

CMS/ASPR website of resources

- https://asprtracie.hhs.gov/cmsrule

CMS Contact: SCGEmergencyPrep@cms.hhs.gov

Questions?

Thank you

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