



# Regulatory Advisory

October 17, 2016

## CMS Issues Emergency Preparedness Requirements

### *AT A GLANCE*

#### **At Issue:**

On Sept. 16, the Centers for Medicare & Medicaid Services (CMS) published a [final rule](#) establishing new emergency preparedness requirements for Medicare and Medicaid-participating health care facilities. The regulations apply to 17 different provider types, including hospitals, critical access hospitals (CAHs), ambulatory surgical centers, long-term care facilities (LTCs), intermediate care facilities for individuals with intellectual disabilities, and rural health clinics. **All organizations will need to conduct a thorough evaluation of their existing emergency preparedness programs to determine necessary changes and additions needed to comply with the final rule.**

The final standards require health care facilities to conduct risk assessments using an all-hazards approach; develop emergency preparedness plans, policies, and procedures, including distinct communications plans; and establish training and testing programs. Hospitals, CAHs and LTC facilities will also be required to have emergency and standby power systems that reflect their emergency plans. **The new requirements have an implementation date of November 15, 2017.**

#### **Our Take:**

AHA and the American Society for Healthcare Engineering (ASHE), a personal membership group of the AHA, believe that the new requirements reflect a commonsense approach to help hospitals protect our patients and communities during disasters. In the final rule, CMS took steps to align the requirements with other key standards-setting organizations, such as the National Fire Protection Association and The Joint Commission. Along with creating a consistent set of emergency planning regulations across provider-types, CMS has provided flexibility in meeting the new standards. ASHE has produced a [table](#) that outlines key provisions of the new CMS requirements; explains CMS's intent behind the changes; and provides guidance on the implications of the rule.

#### **What You Can Do:**

- ✓ Share this advisory with your emergency management and facility management professionals, as well as compliance officers.
- ✓ Review existing emergency management plans, evaluate their compliance with the new regulations, and make changes as needed.
- ✓ Access additional tools and resources as needed at [www.ashe.org/emergencypreparedness](http://www.ashe.org/emergencypreparedness).

#### **Further Questions:**

For further questions, contact Evelyn Knolle, senior associate director for policy at AHA, at [eknolle@aha.org](mailto:eknolle@aha.org), or Jonathan Flannery, senior associate director of advocacy at ASHE, at [jflannery@aha.org](mailto:jflannery@aha.org).



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## **CMS Issues Emergency Preparedness Requirements**

### **BACKGROUND**

On Sept. 16, the Centers for Medicare & Medicaid Services (CMS) published a [final rule](#) establishing new emergency preparedness requirements for Medicare- and Medicaid-participating health care facilities. The regulations apply to 17 different provider types, including hospitals, critical access hospitals (CAHs), ambulatory surgical centers, long-term care facilities (LTCs), intermediate care facilities for individuals with intellectual disabilities and rural health clinics.

The final standards require health care facilities to conduct risk assessments using an all-hazards approach; develop emergency preparedness plans, policies, and procedures; create distinct communications plans; and establish training and testing programs. Hospitals, CAHs and LTC facilities also will be required to have emergency and standby power systems that reflect their emergency plans. The implementation date for the new requirements is Nov. 15, 2017. Health care facilities will need to review and update their emergency preparedness plans on an annual basis if they do not do so already.

Many health care organizations currently comply with either the 2012 edition of National Fire Protection Association (NFPA) 99 or The Joint Commission emergency preparedness standards. Organizations that already comply with these existing standards will need to make fewer changes than those not currently following NFPA or The Joint Commission standards. **All organizations will need to conduct a thorough evaluation of their existing emergency preparedness programs to determine necessary changes and additions needed to comply with the final rule.**

## **AT ISSUE**

Key aspects of the final rule for hospitals and CAHs include the following.

### ***Generator Location and Testing***

As urged by the AHA, CMS provided flexibility with regard to the location of generators. The final rule will require generators to be located in accordance with NFPA standards when a new structure is built or an existing structure is renovated. Further, CMS will not require increased hours of testing, as it had originally proposed. The agency cited American Society for Healthcare Engineering (ASHE) research showing that increased generator testing would not lead to more reliable generators under emergency conditions.

### ***Community Involvement***

The proposed rule emphasized the need for community collaboration in disaster planning, and the AHA agrees that community involvement is essential. However, many stakeholders believed that CMS's statements in the proposed rule created an expectation that hospitals should be the designated entities for coordinating the community response. The AHA urged CMS to clarify the roles of state and local governments in leading community-wide efforts to prepare for disasters. In the final rule, CMS agrees that "the responsibility for ensuring a community-wide coordinated disaster preparedness response is under the state and local emergency authorities." However, the final regulations require hospitals/CAHs to have a process for cooperating with the efforts of local, tribal, regional, state, and federal emergency preparedness officials to maintain an integrated response during an emergency. This includes documentation of the hospital/CAH's efforts to contact these officials and, when applicable, participation in collaborative planning efforts.

### ***Integrated, System-wide Planning***

As recommended by the AHA, CMS will allow integrated health systems to have the option to maintain one coordinated emergency plan in cases where a single plan improves preparedness. Specifically, in the final rule, CMS added a new standard for health care systems that consist of multiple, separately certified, health care facilities and that elect to have a unified and integrated emergency preparedness program. Hospitals/CAHs in those systems may elect to participate in the health care system's coordinated emergency preparedness program if the program meets certain conditions. For example, each separate facility must participate in the development of the program, which must reflect each facility's unique circumstances, patient populations, and services offered.

### ***Development of a Communications Plan***

Many hospitals and CAHs currently include communications plans as part of an overall emergency preparedness program, and CMS places a heavy emphasis on communication in the new standards. The final rule requires hospitals/CAHs to have a detailed communications plan that includes contact information for staff, physicians, other hospitals/CAHs, entities providing services under arrangement, volunteers, and relevant emergency preparedness officials. Among other

provisions, the communications plan must define primary and alternate means for communicating with hospital/CAH staff and emergency management agencies, as well as a method for sharing information and medical documentation for patients, as permitted under federal privacy regulations.

### ***Development of Policies and Procedures for Various Provisions***

CMS will require hospitals and CAHs to develop policies and procedures based upon the risk assessment, emergency plan, and communications plan. At a minimum, the policies and procedures will need to address the following: subsistence needs for staff and patients; tracking the location of on-duty staff and sheltered patients; safe evacuation as well as sheltering in place; a system of medical documentation; the use of volunteers; arrangements with other providers to receive patients; and the role of the hospital under an 1135 waiver related to the provision of care and treatment at an alternate care site.

### ***Testing of the Emergency Plan***

Hospitals and CAHs will need to conduct two exercises annually to test the emergency plan, monitor and document these tests, analyze the results, and update the plan as needed. First, the final rule requires hospitals and CAHs to participate in a community-based, full-scale exercise, unless a community exercise is not available. In that case, the hospital or CAH must conduct a full-scale facility-based exercise. If a hospital or CAH activates its emergency plan in response to an actual emergency, it will be exempt from this testing requirement for one year. The hospital or CAH must also conduct a second exercise each year, such as a full-scale drill or a tabletop exercise. (Note that The Joint Commission Standards do not allow tabletop exercises.)

## **NEXT STEPS**

All health care facilities should evaluate their current emergency plans to determine what changes and additions must be made to comply with the final rule. To help stakeholders as they implement the final rule's provisions, CMS has created a [website](#) with important information and resources.

In addition, CMS has set up an email address for stakeholders to send questions regarding the final rule: [SCGEmergencyPrep@cms.hhs.gov](mailto:SCGEmergencyPrep@cms.hhs.gov). For questions regarding training, please contact [SCG\\_Training@cms.hhs.gov](mailto:SCG_Training@cms.hhs.gov). We encourage AHA members to submit questions about the rule to CMS and to copy the AHA and ASHE at the email addresses below.

ASHE also will provide resources for hospitals and CAHs at [ASHE Emergency Preparedness Resources](#).

## **FURTHER QUESTIONS**

For further questions, contact Evelyn Knolle, senior associate director for policy at AHA, at [eknolle@aha.org](mailto:eknolle@aha.org), or Jonathan Flannery, senior associate director of advocacy at ASHE, at [jflannery@aha.org](mailto:jflannery@aha.org).



## ASHE Resource: Implications of the CMS emergency preparedness rule

CMS EMERGENCY PREPAREDNESS RULE TEXT	CMS INTENTION (excerpted from CMS final rule)	IMPLICATIONS FOR HEALTH CARE FACILITIES (ASHE interpretation)
<p><b>§ 482.15 Condition of participation: Emergency preparedness.</b> The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements.</p> <p><b>§ 485.625 Condition of participation: Emergency preparedness.</b> The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements.</p>	<p>While we agree that the responsibility for ensuring a community-wide coordinated disaster preparedness response is under the state and local emergency authorities, healthcare facilities will still be required to perform a risk assessment, develop an emergency plan, policies and procedures, communication plan, and train and test all staff to comply with the requirements in this final rule.</p> <p>These new requirements will require a coordinated and collaborative relationship with state and local governments during a disaster.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will have addressed community involvement within their emergency operations plan, but will need to evaluate the detail to which this cooperative effort is documented and ensure that it indicates how a collaborative relationship with state and local governments is to be coordinated.</p>
<p><b>§ 482.15 Condition of participation: Emergency preparedness.</b> The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.</p> <p><b>§ 485.625 Condition of participation: Emergency preparedness.</b> The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach.</p>	<p>An all hazards planning approach is considered "a more efficient and effective way to prepare for emergencies. Rather than managing planning initiatives for a multitude of threat scenarios, all hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters." Thus, all-hazards planning does not specifically address every possible threat but ensures that hospitals and all other providers will have the capacity to address a broad range of related emergencies.</p> <p>The providers and suppliers discussed in this regulation should utilize an all-hazards approach to perform a "hazard vulnerability risk assessment."</p> <p>This final rule will require each of the Medicare- and Medicaid-participating providers and suppliers to perform a risk analysis; establish an emergency preparedness plan, emergency preparedness policies and procedures, and an emergency preparedness communication plan; train staff in emergency preparedness, and test the emergency plan.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will have completed a detailed hazard vulnerability assessment (HVA), but will need to evaluate the HVA process to ensure that this documentation includes an all hazards approach.</p>



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<p><b>§ 482.15</b> (a) Emergency plan. The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually.</p> <p><b>§ 485.625</b> (a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually.</p>	<p>To ensure that all hospitals operate as part of a coordinated emergency preparedness system, we proposed at §482.15 that all hospitals establish and maintain an emergency preparedness plan that complies with both federal and state requirements. Additionally, we proposed that the emergency preparedness plan be reviewed and updated at least annually. As part of an annual review and update, staff are required to be trained and be familiar with many policies and procedures in the operation of their facility and are held responsible for knowing these requirements. Annual reviews help to refresh these policies and procedures which would include any revisions to them based on the facility experiencing an emergency or as a result of a community or natural disaster. Thus, we expect that TJC-accredited hospitals have already developed and are maintaining Emergency Operation Plans that comply with the requirement for an emergency plan in this final rule.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will have a detailed Emergency Operations Plan that should satisfy this requirement.</p>
<p><b>§ 482.15(a)(1)</b> Emergency plan. The plan must do the following: Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.</p> <p><b>§ 485.625</b> (a)(1) Emergency plan. The plan must do the following: Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.</p>	<p>CMS expects hospitals to consider, among other things, the following: (1) identification of all business functions essential to the hospitals operations that should be continued during an emergency; (2) identification of all risks or emergencies that the hospital may reasonably expect to confront; (3) identification of all contingencies for which the hospital should plan; (4) consideration of the hospital's location, including all locations where the hospital delivers patient care or services or has business operations; (5) assessment of the extent to which natural or man-made emergencies may cause the hospital to cease or limit operations; and (6) determination of what arrangements with other hospitals, other healthcare providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency. Performing an HVA will require a hospital to identify the events that could possibly affect demand for the hospital's services or the hospital's ability to provide services. A TJC-accredited hospital also must determine the likeliness of the identified risks occurring, as well as their consequences. Thus, we expect that TJC-accredited hospitals already conduct an HVA that complies with our requirements.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will have a detailed Emergency Operations Plan that should satisfy this requirement. However, currently most HVAs (including <a href="#">HVAs available on the ASHE website</a>) do not address item (6) arrangements with other entities.</p>



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<p><b>§ 482.15(a)(2)</b> Emergency plan. The plan must do the following: Include strategies for addressing emergency events identified by the risk assessment.</p> <p><b>§ 485.625 (a) (2)</b> Emergency plan. The plan must do the following: Include strategies for addressing emergency events identified by the risk assessment.</p>	<p>The emergency plan include strategies for addressing emergency events identified by the risk assessment. Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this final rule.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15(a)(3)</b> Emergency plan. The plan must do the following: 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.</p> <p><b>§ 485.625 (a)(3)</b> Emergency plan. The plan must do the following: Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.</p>	<p>Expectation is that a hospital's emergency plan address its patient population, including, but not limited to, persons at-risk. "At-risk individuals" means children, pregnant women, senior citizens, individuals with disabilities, those from religious, racial and ethnically diverse backgrounds; and people with limited English proficiency and other individuals who have special needs in the event of a public health emergency as determined by the Secretary. Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this final rule.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will have addressed the patient population expectations of this requirement, but plans will need to be evaluated to ensure that all "at-risk" populations are addressed.</p>
<p><b>§ 482.15(a)(4)</b> Emergency plan. The plan must do the following: Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials'</p>	<p>That a hospital have a process for ensuring cooperation and collaboration with local, tribal, regional, state, or federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate plans to ensure</p>



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<p>efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.</p> <p><b>§ 485.625 (a)(4) Emergency plan.</b> The plan must do the following: Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the CAHs efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.</p>	<p>Providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this final rule.</p>	<p>that sufficient detail is provided in plans regarding community involvement. Additionally, organizations will have to document efforts to include community partners within their emergency management program.</p>
<p><b>§ 482.15 (b) Policies and procedures.</b> 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.</p>	<p>That a hospital be required to develop and implement emergency preparedness policies and procedures based on the emergency plan proposed at §482.15(a), the risk assessment proposed at §482.15(a)(1), and the communication plan proposed at § 482.15(c). We proposed that these policies and procedures be reviewed and updated at least annually. Facilities are free to update as needed but at least annually. We believe that hospitals already review their emergency preparedness plans periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for hospitals.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>



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<p><b>§ 485.625</b> (b) Policies and procedures. The CAH 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.</p>		
<p><b>§ 482.15</b> (b) (1) policies and procedures must address the following: The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:</p> <p><b>§ 485.625</b> (b) (1) policies and procedures must address the following: The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:</p>	<p>We are requiring certain facilities to have policies and procedures to address the provision of subsistence in the event of an emergency. This does not mean that facilities would need to store provisions themselves. We agree that once patients have been evacuated to other facilities, it would be the responsibility of the receiving facility to provide for the patients' subsistence needs. Local, state and regional agencies and organizations often participate with facilities in addressing subsistence needs, emergency shelter, etc. 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. Based on our experience with inpatient healthcare facilities to allow each facility the flexibility to identify the subsistence needs that would be required during an emergency, mostly likely based on level of impact, is the most effective way to address subsistence needs without imposing undue burden.</p> <p>The provision on subsistence needs applies only for staff and patients.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to evaluate current plans to verify that they appropriately address the specific subsistence needs.</p>



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<p><b>§ 482.15</b> (b) (1) (i) Food, water, medical, and pharmaceutical supplies.</p> <p><b>§ 485.625</b> (b) (1) (i) Food, water, medical, and pharmaceutical supplies.</p>	<p>TJC-accredited hospitals are required to make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMH, Standard EC.4.14, EPs 1-8 and 10-11, p. EC-13d). In addition, hospitals must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases when their usual supply is disrupted or compromised (CAMH, Standard EC.4.17, EPs 1-5, p. EC-13f). Thus, we expect that TJC-accredited hospitals will be in compliance with our provision of subsistence requirements in §482.15(b)(1).</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to evaluate current policies and procedures to verify that they appropriately address the specific subsistence needs listed.</p>
<p><b>§ 482.15</b> (b) (ii) policies and procedures must address the following: Alternate sources of energy to maintain the following: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (B) Emergency lighting. (C) Fire detection, extinguishing, and alarm systems. (D) Sewage and waste disposal.</p> <p><b>§ 485.625</b> (b) (ii) policies and procedures must address the following: Alternate sources of energy to maintain: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (B) Emergency lighting. (C) Fire detection, extinguishing, and alarm systems. (D) Sewage and waste disposal.</p>	<p>Alternate sources of energy depend on the resources available to a facility, such as battery-operated lights, propane lights, or heating, in order to meet the needs of a facility during an emergency. We would encourage facilities to confer with local health department and emergency management officials, as well as and healthcare coalitions, to determine the types and duration of energy sources that could be available to assist them in providing care to their patient population during an emergency.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate current plans to verify that they appropriately address alternate sources of energy to maintain the specified utilities.</p>



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<p><b>§ 482.15 (b) (ii) (A)</b> policies and procedures must address the following:          Alternate sources of energy to maintain the following:          Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.</p> <p><b>§ 485.625 (b) (ii) (A)</b> policies and procedures must address the following:          Alternate sources of energy to maintain the following:          Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.</p>	<p>Facilities should include as part of their risk assessment how specific needs will be met to maintain temperatures to protect patient health and safety. We are not requiring facilities to upgrade their electrical systems, but after their review of their facility risk assessment, facilities may find it prudent to make any necessary adjustments to ensure that patients' health and safety needs are met and that facilities maintain safe and sanitary storage areas for provisions.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate current plans to verify that they appropriately address temperatures as outlined in this requirement.</p>
<p><b>§ 482.15 (b) (ii) (B)</b> policies and procedures must address the following:          Alternate sources of energy to maintain the following:          Emergency lighting.</p> <p><b>§ 485.625 (b) (ii) (B)</b> policies and procedures must address the following:          Alternate sources of energy to maintain the following:          Emergency lighting.</p>	<p>Alternate sources of energy depend on the resources available to a facility, such as battery-operated lights in order to meet the needs of a facility during an emergency. We would encourage facilities to confer with local health department and emergency management officials, as well as healthcare coalitions, to determine the types and duration of energy sources that could be available to assist them in providing care to their patient population during an emergency.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate current plans to verify that they appropriately address alternate sources of energy to maintain the specified utilities.</p>
<p><b>§ 482.15 (b) (ii) (C)</b> policies and procedures must address the following:          Alternate sources of energy to maintain the following:</p>	<p>Alternate sources of energy depend on the resources available to a facility, such as battery-operated lights, propane lights, or heating, in order to meet the needs of a facility during an emergency. We would encourage facilities to confer with local health department and emergency management officials, as well as and healthcare coalitions, to determine the types and duration of energy sources</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate current plans to</p>



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<p>Fire detection, extinguishing, and alarm systems.</p> <p><b>§ 485.625</b> (b) (ii) (C) policies and procedures must address the following: Alternate sources of energy to maintain the following: Fire detection, extinguishing, and alarm systems.</p>	<p>that could be available to assist them in providing care to their patient population during an emergency.</p>	<p>verify that they appropriately address alternate sources of energy to maintain the specified utilities.</p>
<p><b>§ 482.15</b> (b) (ii) (D) policies and procedures must address the following: Sewage and waste disposal.</p> <p><b>§ 485.625</b> (b) (ii) (D) policies and procedures must address the following: Sewage and waste disposal.</p>	<p>Facilities should identify and assess their sewage and wastewater systems as part of their facility-based risk assessment and make necessary plans to maintain these services. We are not requiring onsite treatment of sewage but that facilities make provisions for maintaining necessary services.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate current plans to verify that they appropriately address alternate sources of energy to maintain sewage and waste disposal.</p>
<p><b>§ 482.15</b> (b) (2) policies and procedures must address the following: A system to track the location of on-duty staff and sheltered patients in the hospital's care during an 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.</p> <p><b>§ 485.625</b> (b) (2) policies and procedures must address the following:</p>	<p>We would expect facilities to track their on-duty staff and sheltered patients during an emergency and document the specific location and name of where a patient is relocated to during an emergency (that is, to another facility, home, or alternate means of shelter, etc.). We did not propose a requirement for a specific type of tracking system. By "system to track" we mean that facilities will have the flexibility to determine how best to track patients and staff, whether they utilize an electronic database, hard copy documentation, or some other method. We would expect that the information would be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient.</p> <p>TJC accredited hospitals must plan for communicating with patients and their families at the beginning of and during an emergency (CAMH, Standard EC.4.13, EPs 1, 2, and 5, p. EC-13c).</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>



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<p>A system to track the location of on-duty staff and sheltered patients in the CAHs care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.</p>	<p>We expect that TJC-accredited hospitals will be in compliance with §482.15(b)(2).</p>	
<p><b>§ 482.15 (b) (3)</b> policies and procedures must address the following: Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.</p> <p><b>§ 485.625 (b) (3)</b> policies and procedures must address the following: Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.</p>	<p>TJC-accredited hospitals are required to make plans to evacuate patients as part of managing their clinical activities (CAMH, Standard EC.4.18, EP 1, p. EC-13g). They also must plan for the evacuation and transport of patients, as well as their information, medications, supplies, and equipment, to alternative care sites (ACSs) when the hospital cannot provide care, treatment, and services in their facility (CAMH, Standard EC.4.14, EPs 9-11, p. EC-13d). Section 482.15(b)(3) also will require hospitals to have "primary and alternate means of communication with external sources of assistance." TJC-accredited hospitals must plan for communicating with external authorities once the hospital initiates its emergency response measures (CAMH, Standard EC.4.13, EP 4, p. EC-13c). Thus, TJC-accredited hospitals will be in compliance with most of the requirements in §482.15(b)(3). However, we do not believe these requirements will ensure compliance with the requirement that the hospital establish policies and procedures for staff responsibilities.</p>	<p>Organizations compliant with Joint Commission emergency management requirements will be in compliance with the majority of this requirement, but will need to evaluate current plans to verify that they appropriately address the specific procedures required especially procedures in relation to staff responsibilities.</p> <p>Organizations compliant with 2012 NFPA 99 will need to evaluate current plans to verify that they appropriately address the specific procedures required.</p>
<p><b>§ 482.15 (b) (4)</b> policies and procedures must address the following:</p>	<p>Section 482.15(b)(4) will require hospitals to have policies and procedures that address a means to shelter in place for patients, staff, and volunteers who remain at the facility. The rationale for CAMH Standard EC.4.18 states, "a catastrophic emergency may</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency</p>



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<p>A means to shelter in place for patients, staff, and volunteers who remain in the facility.</p> <p><b>§ 485.625</b> (b) (4) policies and procedures must address the following: A means to shelter in place for patients, staff, and volunteers who remain in the facility.</p>	<p>result in the decision to keep all patients on the premises in the interest of safety" (CAMH, Standard EC.4.18, p. EC-13f). We expect that TJC-accredited hospitals will be in compliance with our shelter in place requirement in §482.15(b)(4).</p>	<p>management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15</b> (b) (5) policies and procedures must address the following: A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.</p> <p><b>§ 485.625</b> (b) (5) policies and procedures must address the following: A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.</p>	<p>The CAMH chapter entitled "Management of Information" requires TJC-accredited hospitals to have storage and retrieval systems for their clinical/service and hospital-specific information (CAMH, Standard IM.3.10, EP 5, CAMH Refreshed Core, January 2008, p. IM-10) and to ensure the continuity of their critical information "needs for patient care, treatment, and services (CAMH, Standard IM.2.30, Rationale for IM.2.30, CAMH Refreshed Core, January 2008, p. IM-8). They also must ensure the privacy and confidentiality of patient information (CAMH, Standard IM.2.10, CAMH Refreshed Core, January 2008, p. IM-7) and have plans for transporting and tracking patients' clinical information, including transferring information to ACSs (CAMH Standard EC.4.14, EP 11, p. EC-13d and Standard EC.4.18, EP 6, pp. EC-13d and EC-13g, respectively). Therefore, we expect that TJC-accredited hospitals will be in compliance with the requirements we proposed in §482.15(b)(5).</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15</b> (b) (6) policies and procedures must address the following: The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated</p>	<p>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 non-medical volunteers would perform non-medical tasks. As such, we disagree with limiting this requirement to just medical volunteers.</p>	<p>Organizations compliant with the 2012 edition of NFPA 99 will be in compliance with this requirement. Organizations compliant with current Joint Commission emergency management requirements will need to include policies regarding</p>



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<p>health care professionals to address surge needs during an emergency.</p> <p><b>§ 485.625</b> (b) (6) policies and procedures must address the following: 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.</p>	<p>Although TJC accreditation requirements partially address our requirements, we do not believe these requirements will ensure compliance with all requirements in in §482.15(b)(6).</p>	<p>volunteers who are not licensed independent practitioners.</p>
<p><b>§ 482.15</b> (b) (7) policies and procedures must address the following: The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to hospital patients.</p> <p><b>§ 485.625</b> (b) (7) policies and procedures must address the following: The development of arrangements with other CAHs and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.</p>	<p>Section 482.15(b)(7) will require hospitals to have policies and procedures that will address the development of arrangements with other hospitals or other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. TJC-accredited hospitals must plan for the sharing of resources and assets with other healthcare organizations (CAMH, Standard EC.4.14, EPs 7 and 8, p. EC-13d). However, we will not expect TJC-accredited hospitals to be substantially in compliance with the requirements we proposed in §482.15(b)(7) based on compliance with TJC accreditation standards alone.</p>	<p>Those organizations compliant with either 2012 NFPA 99 or current TJC emergency management requirements will need to evaluate current plans to verify that they appropriately address the specific procedures required.</p> <p>Note: CMS's evaluation in the middle column is based on the Joint Commission's "Comprehensive Accreditation Manual for Hospitals: The Official Handbook 2008 (CAMH)." ASHE's interpretation is based on the July 1, 2016, online edition of the Joint Commission Comprehensive Accreditation and Certification Manual.</p>
<p><b>§ 482.15</b> (b) (8) policies and procedures must address the following:</p>	<p>Section 482.15(b)(8) will require hospitals to have policies and procedures that address the hospital's role under an "1135 waiver" (that is, a waiver of some federal rules in accordance with §1135 of</p>	<p>Organizations compliant with current Joint Commission emergency management</p>



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<p>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.</p> <p><b>§ 485.625</b> (b) (8) policies and procedures must address the following: The role of the CAH 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.</p>	<p>the Social Security Act) in the provision of care and treatment at an ACS identified by emergency management officials. TJC-accredited hospitals must already have plans for transporting patients, as well as their associated information, medications, equipment, and staff to ACSs when the hospital cannot support their care, treatment, and services on site (CAMH, Standard EC.4.14, EPs 10 and 11, p. EC-13d). We expect that TJC-accredited hospitals will be in compliance with the requirements we proposed in §482.15(b)(8).</p>	<p>requirements will be in compliance with the majority of this requirement, but will need to evaluate current plans to verify that they appropriately address the specific procedures required especially procedures in relation to an 1135 waiver. Organizations compliant with the 2012 edition of NFPA 99 will need to evaluate current plans to verify that they appropriately address the specific procedures required.</p>
<p><b>§ 482.15</b> (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.</p> <p><b>§ 485.625</b> (c) Communication plan. The CAH 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.</p>	<p>During an emergency, it is critical that hospitals, and all providers/suppliers, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner. Updating the plan annually would facilitate effective communication during an emergency. Providers and suppliers are to have contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance. Patient care must be well coordinated across healthcare providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.</p> <p>We expect that all hospitals currently have some type of emergency preparedness communication plan. We expect that under this final rule, hospitals will review their current communication plans, compare them to their emergency preparedness plans and</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate their current plans to verify compliance with the specific listed requirements and to create a separate communications plan.</p>



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	<p>emergency policies and procedures, and revise their communication plans, as necessary.</p>	
<p><b>§ 482.15 (c) (1)</b> The communication plan must include all of the following:          (1) Names and contact information for the following:          (i) Staff.          (ii) Entities providing services under arrangement.          (iii) Patients' physicians.          (iv) Other hospitals and CAHs          (v) Volunteers.</p> <p><b>§ 485.625 (c) (1)</b> The communication plan must include all of the following:          (1) Names and contact information for the following:          (i) Staff.          (ii) Entities providing services under arrangement.          (iii) Patients' physicians.          (iv) Other CAHs and hospitals          (v) Volunteers.</p>	<p>We stated that, during an emergency, it is critical that hospitals have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner.</p> <p>As a best practice, most hospitals maintain an up-to-date list of their current staff for staffing directories and human resource management. In addition, most hospitals have procedures or systems in place to handle their roster of volunteers. We believe that a hospital would have a comprehensive list of their staff, given that these lists are necessary to maintain operations and formulate a payroll. In addition, we continue to believe that it is critically important that hospitals have a way to contact appropriate physicians treating patients, and entities providing services under arrangement, other hospitals, and volunteers during an emergency or disaster event to ensure continuation of patient care functions throughout the hospital and to ensure continuity of care.</p> <p>Furthermore, we clarify that we are not requiring hospitals to include in their communication plan contact information for the families of staff, or the families of patients who are not directly involved in the patient's care, or contractors not currently providing services under arrangement.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to evaluate their current plans to verify that current information addresses all specified groups of individuals, and will need to include this information within their new communications plan.</p>
<p><b>§ 482.15 (c) (2)</b> The communication plan must include all of the following:          Contact information for the following:          (i) Federal, State, tribal, regional, and local emergency preparedness staff.          (ii) Other sources of assistance.</p>	<p>TJC-accredited hospitals are required to establish emergency communication strategies (CAMH, Standard EC.4.13, p. EC-13b). In addition, TJC-accredited hospitals are specifically required to ensure communication with staff, external authorities, patients, and their families (CAMH, Standard EC.4.13, EPs 1-5, p. EC-13c). Thus, we expect that that TJC-accredited hospitals will be in compliance with §482.15(c)(1) through (4).</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to relocate this information within the new communications plan.</p>



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<p><b>§ 485.625 (c) (2)</b> The communication plan must include all of the following:          Contact information for the following:          (i) Federal, State, tribal, regional, and local emergency preparedness staff.          (ii) Other sources of assistance.</p>		
<p><b>§ 482.15 (c) (3)</b> The communication plan must include all of the following:          Primary and alternate means for communicating with the following:          (i) Hospital's staff.          (ii) Federal, State, tribal, regional, and local emergency management agencies.</p> <p><b>§ 485.625 (c) (3)</b> The communication plan must include all of the following:          Primary and alternate means for communicating with the following:          (i) CAHs staff.          (ii) Federal, State, tribal, regional, and local emergency management agencies.</p>	<p>We do not believe that scaling back the requirements for an alternate means of communication to be used during an emergency would be beneficial to hospitals and their patients. As we have learned over the years, landline telephones are often inoperable for an extended period of time during and after disasters. Cell phones also can be unreliable and are often without reception during an emergency event, or are completely unusable due to a lack of cellular coverage in certain remote and rural areas. Therefore, it is appropriate and vitally important for hospitals to have some alternate means to communicate with their staff and federal, state and local emergency management agencies during an emergency. While we are not endorsing a specific alternate communication system or requiring the use of certain specific devices, we expect that facilities would consider using the following devices:</p> <ul style="list-style-type: none"> <li>• Pagers.</li> <li>• Internet provided by satellite or non-telephone cable systems.</li> <li>• Cellular telephones (where appropriate). Facilities can also carry accounts with multiple cell phone carriers to mitigate communication failures during an emergency.</li> <li>• Radio transceivers (walkie-talkies).</li> <li>• Various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (ham) systems.</li> <li>• Satellite telephone communication system.</li> </ul>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to relocate this information within the new communications plan.</p>



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<p><b>§ 482.15 (c) (4)</b> The communication plan must include all of the following: A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to maintain the continuity of care.</p> <p><b>§ 485.625 (c) (4)</b> The communication plan must include all of the following: A method for sharing information and medical documentation for patients under the CAHs care, as necessary, with other health care providers to maintain the continuity of care.</p>	<p>We requires that facilities have a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare facilities to ensure continuity of care. We are not requiring, nor are we endorsing, a specific digital storage or dissemination technology. Furthermore, we note that we are not requiring facilities to use EHRs or other methods of electronic storage and dissemination. In this regard, we acknowledge that many facilities are still using paper-based documentation. However, we encourage all facilities to investigate secure ways to store and disseminate medical documentation during an emergency to ensure continuity of care.</p>	<p>Organizations compliant with the 2012 edition of NFPA 99 will be in compliance with this requirement. Organizations compliant with current Joint Commission emergency management requirements will need to include procedures to meet these requirements. All organizations will need to document these procedures in the communications plan.</p>
<p><b>§ 482.15 (c) (5)</b> The communication plan must include all of the following: A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).</p> <p><b>§ 485.625 (c) (5)</b> The communication plan must include all of the following: A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).</p>	<p>We believe that hospitals should have an established system of communication that would ensure that patient care information could be disseminated to other providers and suppliers in a timely manner, as needed, during an emergency or disaster. Hospitals will need to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted, to family members and others.</p> <p>We clarify that we are not requiring the use of EHRs within this regulation and we understand that some hospitals and other providers and suppliers may still be using paper medical records. However, we encourage these facilities to consider the use of alternative means of storing patient care information, to ensure that medical documentation is preserved and easily disseminated during an emergency or disaster.</p> <p>Facilities should also consider including in their communication plan information on what type of patient information is releasable and who is authorized to release this information during an emergency.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to include this information within the newly developed communications plan.</p>



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	Facilities and their legal counsel should review the HIPAA Privacy Rule carefully before deciding to share patient information.	
<p><b>§ 482.15 (c) (6)</b> The communication plan must include all of the following: 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).</p> <p><b>§ 485.625 (c) (6)</b> The communication plan must include all of the following: 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).</p>	We do not propose prescriptive requirements for how a hospital would comply with this requirement. Instead, we allow hospitals the flexibility to develop and maintain their own system.	Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to review their current plans to ensure that they specifically address the requirements stated, and will need to include this information within the newly developed communications plan.
<p><b>§ 482.15 (c) (7)</b> The communication plan must include all of the following: A means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.</p> <p><b>§ 485.625 (c) (7)</b> The communication plan must include all of the following: A means of providing information about the CAHs occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction,</p>	The rationale for Joint Commission Standard EC.4.13 states, "the hospital maintains reliable surveillance and communications capability to detect emergencies and communicate response efforts to hospital response personnel, patient and their families, and external agencies (CAMH, Standard EC.4.13, pp. EC-13b – 13c). We expect that most, if not all, TJC-accredited hospitals will be in compliance with §482.15(c)(5) through (7).	Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to include this information within the newly developed communications plan.



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<p>the Incident Command Center, or designee.</p>		
<p><b>§ 482.15</b> (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 (b) 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.</p> <p><b>§ 485.625</b> (d) Training and testing. The CAH 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 (b) 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.</p>	<p>A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. We proposed at §482.15(d)(1) that hospitals provide such training to all new and existing staff, including any individuals providing services under arrangement and volunteers, consistent with their expected roles, and maintain documentation of such training. In addition, we proposed that hospitals provide training on emergency procedures at least annually and ensure that staff demonstrate competency in these procedures.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will need to review their current plans to ensure that they specifically address the requirements stated and include this information within the training program.</p>
<p><b>§ 482.15</b> (d) (1) Training program. The hospital must do all of the following:</p>	<p>A well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. We proposed at §482.15(d)(1) that hospitals provide such training to</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint</p>



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<p>(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.</p> <p>(ii) Provide emergency preparedness training at least annually.</p> <p>(iii) Maintain documentation of the training.</p> <p>(iv) Demonstrate staff knowledge of emergency procedures.</p> <p><b>§ 485.625</b> (d) (1) Training program. The CAH must do all of the following:</p> <p>(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection and where necessary, evacuation of patients, personnel and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.</p> <p>(ii) Provide emergency preparedness training at least annually.</p> <p>(iii) Maintain documentation of the training.</p>	<p>all new and existing staff, including any individuals providing services under arrangement and volunteers, consistent with their expected roles, and maintain documentation of such training. In addition, we proposed that hospitals provide training on emergency procedures at least annually and ensure that staff demonstrate competency in these procedures.</p> <p>We believe that there is substantial evidence that provider and supplier staff need more training in emergency practices and procedures. Initial and annual staff training promotes consistent staff behavior and increases the knowledge of staff roles and responsibilities during a disaster. To offset some of the financial impact that training may impose on facilities, we have allowed facilities the flexibility to determine the level of training that any staff member may need. A provider could decide to base this determination on the staff member's involvement or expected role during a disaster.</p> <p>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.</p> <p>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.</p>	<p>Commission emergency management requirements will need to review their current plans to ensure that they specifically address the requirements stated and include this information within the training program</p> <p>Additionally, CAHs will need to verify that their initial training program addresses the prompt reporting and extinguishing of fires, protection and where necessary, evacuation of patients, personnel and guests, fire prevention, and cooperation with firefighting and disaster authorities</p>
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<p>(iv) Demonstrate staff knowledge of emergency procedures.</p>		
<p><b>§ 482.15</b> (d) (2) Testing. The hospital must conduct exercises to test the emergency plan at least annually. The hospital must do all of the following:</p> <p>(i) Participate in a full-scale exercise that is community-based or when a community based exercise is not accessible, an individual, facility-based. If the hospital experiences an actual natural or man-made emergency that requires activation of the 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.</p> <p><b>§ 485.625</b> (d) (2) Testing. The CAH must conduct exercises to test the emergency plan at least annually. The CAH must do the following:</p> <p>(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based exercise. If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community-based or individual, facility-based full-scale exercise for</p>	<p>The requirement for participation in a community disaster drill exercise is meant to require facilities to simulate an anticipated response to an emergency involving their actual operations and the community.</p> <p>We expect that a facility-based disaster drill would meet the requirement for a community disaster drill if a community disaster drill were not readily accessible.</p> <p>We expect a hospital or other healthcare facility to consider its physical location and the individuals who reside in their area when conducting their community involved testing exercises. We did not define "community", to afford providers the flexibility to develop disaster drills and exercises that are realistic and reflect their risk assessments. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response.</p> <p>The intention of this requirement is to not only assess the feasibility of a provider's emergency plan through testing, but also to encourage providers to become engaged in their community and promote a more coordinated response. Therefore, smaller facilities without close ties to emergency responders and community agencies are encouraged to reach out and gain awareness of the emergency resources within their community.</p> <p>"Emergency" or "disaster" can be defined as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of HHS, or the President of the United States. In addition, as noted earlier in the general comments section of this final rule, an emergency event could also be an event that affects the facility internally as well as the overall target population or the community at large. While allowing for the exemption of the community disaster</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>



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<p>1 year following the onset of the actual event.</p>	<p>drill requirement when an actual emergency event is experienced, we also proposed to require that facilities maintain documentation of all exercises and emergency events. To that extent, upon survey, a facility would need to show that an emergency event had occurred and be able to demonstrate how its emergency plan was put into action as a result of the emergency event.</p>	
<p><b>§ 482.15</b> (d) (2) (ii) Conduct 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.</p> <p><b>§ 485.625</b> (d) (2) (ii) Conduct 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.</p>	<p>We define a tabletop exercise as 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.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.          It should be noted that the CMS requirement will allow a table top exercise once per year, while current Joint Commission standards will not accept a table top exercise.</p>



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	<p>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.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p> <p>It should be noted that the CMS requirement will allow a table top exercise once per year, while current Joint Commission standards will not accept a table top exercise.</p>
<p><b>§ 482.15 (d) (2) (iii)</b> 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.</p> <p><b>§ 485.625 (d) (2) (iii)</b> Analyze the CAHs response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAHs emergency plan, as needed.</p>	<p>We require 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.</p> <p>We believe that this requirement is necessary to ensure that hospitals are benefiting from the lessons learned through testing their plans and revising them as necessary, based on these lessons. We believe that, if a hospital experiences an actual emergency and develops an after-action review, it would be practical for the hospital to use this as an opportunity to revise and update their plan accordingly.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15 (e)</b> 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)(1)(i) and (ii) of this section.</p>	<p>We appreciate the support of the commenters that agreed with the proposed requirement that generators be located in accordance with the requirements found in NFPA® 99, NFPA® 101, and NFPA ® 110. These codes require hospitals that build new structures, renovate existing structures, or install new generators to place backup generators in a location that would be free from possible flooding and destruction. As such, the CMS requirements are aligned with the Life Safety Code (NFPA® 101), (which has been generally</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>



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<p>(1) Emergency generator location. The generator must be located in accordance with the location requirements found in 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.</p> <p><b>§ 485.625 (e)</b> Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.</p> <p>(1) Emergency generator location. The generator must be located in accordance with the location requirements found in 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</p>	<p>incorporated into CMS regulations) which cross-references 2012 NFPA® 99 and NFPA® 110, at §482.15.</p> <p>The requirements for an emergency generator and onsite fuel source to power the emergency generator would apply only to hospitals, CAHs and LTC facilities.</p>	
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<p>NFPA 110, when a new structure is built or when an existing structure or building is renovated.</p>		
<p><b>§ 482.15</b> (e) (2) Emergency generator inspection and testing. The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.</p> <p><b>§ 485.625</b> (e) (2) Emergency generator inspection and testing. The CAH must implement the emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.</p>	<p>After carefully considering all of the comments we received and reviewing reports on Hurricane Sandy and Hurricane Katrina we believe that there are not sufficient data to assume that additional testing would ensure that generators would withstand all disasters, regardless of the amount of testing conducted prior to an actual disaster. Therefore, we have decided against finalizing the proposed requirement for additional generator testing at this time. We would expect facilities that have generators to continue to test their equipment based on NFPA® codes in current general use and manufacturer requirements.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15</b> (e) (3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.</p> <p><b>§ 485.625</b> (e) (3) Emergency generator fuel. CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.</p>	<p>We realize that it would be difficult, if not impractical in certain circumstances, for a facility to have a fuel supply that would be sufficient for the duration of all disasters because the magnitude of the disaster might require facilities to evacuate patients/residents. After a careful evaluation we have changed the final rule to require a hospital, CAH, or LTC facility to have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>



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<p><b>§ 482.15 (f)</b> 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—</p> <p>(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.</p> <p>(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.</p> <p>(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.</p> <p>(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency</p>	<p>This is an option for those hospitals that are part of a hospital system providing the opportunity for these organizations to participate in a comprehensive system program.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement, but will need to evaluate the system's coordinated emergency preparedness program to make sure that it covers those specific requirements listed.</p>
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plan must also be based on and include the following:

- (i) A documented community-based risk assessment, utilizing an all-hazards approach.
- (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

**§ 485.625** (f) Integrated healthcare systems. If a CAH 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 CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

- (1) Demonstrate that each separately certified facility within the system actively participated in the



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development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include -

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the



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<p>requirements of paragraphs (c) and (d) of this section, respectively.</p>		
<p><b>§ 482.15</b> (g) Transplant hospitals. If a hospital has one or more transplant centers (as defined in § 482.70)--</p> <p>(1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program; and</p> <p>(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant center, and the OPO for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.</p>	<p>We note that a transplant center is not individually responsible for the emergency preparedness requirements set forth in §482.15, except as detailed. Section 482.78(a) will require transplant centers to have policies and procedures that address emergency preparedness. Section 482.78(b) will require transplant centers to develop and maintain mutually-agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is located, and the OPO during an emergency.</p> <p>All of the Medicare-approved transplant centers are located within hospitals and, as part of the hospital, should be included in the hospital's emergency preparedness plans. We expect that since transplants are part of the hospital, they are usually involved in the hospital's programs as part of their normal business practices.</p>	<p>Organizations that are compliant with either the 2012 edition of NFPA 99 or current Joint Commission emergency management requirements will be in compliance with this requirement.</p>
<p><b>§ 482.15</b> (h) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the <b>Federal Register</b> in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.</p> <p>(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.</p> <p>(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.</p>		<p>Incorporating these standards by reference implies that these standards by reference implies that these standards are part of the requirements of this final rule.</p>



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<p>(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.</p> <p>(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.</p> <p>(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.</p> <p>(v) TIA 12-5 to NFPA 99, issued August 1, 2013.</p> <p>(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.</p> <p>(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.</p> <p>(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.</p> <p>(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.</p> <p>(x) TIA 12-3 to NFPA 101, issued October 22, 2013.</p> <p>(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.</p> <p>(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.</p> <p><b>§ 485.625</b> (g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the <b>Federal Register</b> in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.</p>		
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