CMS Rule for Long-Term Care Facilities

Note: This document was prepared by the W MA HMCC as a tool for partners to self-assess their ability to meet the requirements of the CMS Preparedness Rule. It is an extraction of all language specific to the indicated provider type. Facility managers should use this tool in conjunction with the CMS Interpretive Guidance for greater understanding of 1: how the rule could be interpreted by surveyors, and 2: the types of documentation that would aid the surveyor in considering elements of the rule met.

Headings with E-#### refer to a section number within the CMS Implementation Guidance document.

This extraction does not constitute any specific assurances by the Health and Medical Coordinating Coalition.

(E-0001)
The facility[1] must comply with all applicable Federal, State and local emergency preparedness requirements. The facility must establish and maintain a [comprehensive] emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(E-0004) - The facility must comply with all applicable Federal, State and local emergency preparedness requirements. The facility must develop establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section.

The emergency preparedness program must include, but not be limited to, the following elements:

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

(E-0006)

1. Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents.
2. Include strategies for addressing emergency events identified by the risk assessment.

(E-0007)

3. Address patient/client population, including, but not limited to, persons

[1] Unless otherwise indicated, the general use of the terms "facility" or "facilities" in this Appendix refers to all provider and suppliers addressed in this appendix. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations

at-risk; the type of services the facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(E-0009)

4. 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 facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(E-0013)

(b) <u>Policies and procedures</u>. Facilities 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:

(E-0015)

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 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.

(E-0018)

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

(E-0020)

3. Safe evacuation from the facility, 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.

(E-0022)

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

(E-0023)

5. A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.

(E-0024)

6. The use of volunteers in an emergency or 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.

(E-0025)

7. The development of arrangements with other facilities and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.

(E-0026)

8. The role of the facility 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.

(E-0029)

(c) The facility 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:

(E-0030)

1. Names and contact information for the following:
    i. Staff.
    ii. Entities providing services under arrangement.
    iii. Patients' physicians.
    iv. Other facilities.
    v. Volunteers.

(E-0031)

2. Contact information for the following:
    i. Federal, State, tribal, regional, and local emergency preparedness staff.
    ii. The State Licensing and Certification Agency.
    iii. The Office of the State Long-Term Care Ombudsman.
    iv. Other sources of assistance.

(E-0032)

3. Primary and alternate means for communicating with the following:
    i. Facility staff.
    ii. Federal, State, tribal, regional, and local emergency management agencies.

(E-033)

4. A method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health providers to maintain the continuity of care.
5. A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).
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).

(E-0034)

7. A means of providing information about the facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(E-0035)

8. A method for sharing information from the emergency plan that the facility has determined is appropriate with residents [or clients] and their families or representatives.

(E-0036)

(d) <u>Training and testing</u>. The facility 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.

(E-0037)

1. <u>Training program</u>. The facility must do all of the following:
   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.
   ii. Provide emergency preparedness training at least annually.
   iii. Maintain documentation of all emergency preparedness training.
   iv. Demonstrate staff knowledge of emergency procedures.

(E-0039)

2. <u>Testing</u>. The LTC facility must conduct exercises to test the emergency plan at least annually, including unannounced staff drills using the emergency procedures. The facility must do all of the following:
   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 facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the facility 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.
   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.
   iii. Analyze the facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the facility's emergency plan, as needed.

(E-0041)

(e) <u>Emergency and standby power systems</u>. The facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of the section.

1. <u>Emergency generator location</u>. The generator must be located in accordance with location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2. TUIA 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.
2. <u>Emergency generator inspection and testing.</u> The facility must implement the emergency power system inspection, testing, and [maintenance] requirements found in the Health Care Facilities Code, NFPA 110, Life and Safety Code.
3. <u>Emergency Generator Fuel.</u> Facilities 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.

(E-0042)

(f) <u>Integrated Healthcare systems</u>. If a facility 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 facility 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 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 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.

State Operations Manual
Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance
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(Rev. XXXX, TBD)

Transmittals for Appendix Z

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

§418.113, Condition of Participation for Hospices

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

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

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Introduction

The "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" Final Rule (81 FR 63860, Sept. 16, 2016) ("Final Rule") establishes national emergency preparedness requirements for participating providers and certified suppliers to plan adequately for both natural and man-made disasters, and coordinate with Federal, state, tribal, regional and local emergency preparedness systems. The Final Rule also assists providers and suppliers to adequately prepare to meet the needs of patients, clients, residents, and participants during disasters and emergency situations, striving to provide consistent requirements across provider and supplier-types, with some variations. The new emergency preparedness Final Rule is based primarily off of the hospital emergency preparedness Condition of Participation (CoP) as a general guide for the remaining providers and suppliers, then tailored based to address the differences and or unique needs of the other providers and suppliers (e.g. inpatient versus out-patient providers). The requirements are focused on three key essentials necessary for maintaining access to healthcare during disasters or emergencies: safeguarding human resources, maintaining business continuity, and protecting physical resources. The interpretive guidelines and survey procedures in this appendix have been developed to support the adoption of a standard all- hazards emergency preparedness program for all certified providers and suppliers while similarly including appropriate adjustments to address the unique differences of the other providers and suppliers and their patients. Successful adoption of these requirements will enable all providers and suppliers wherever they are located to better anticipate and plan for needs, rapidly respond as a facility, as well as integrate with local public health and emergency management agencies and healthcare coalitions' response activities and rapidly recover following the disaster.

Because the individual regulations for each specific provider and supplier share a majority of standard provisions, we have developed this Appendix Z to provide consistent interpretive guidance and survey procedures located in a single document Unless otherwise indicated, the general use of the terms "facility" or "facilities" in this Appendix refers to all provider and suppliers addressed in the Final Rule and in this appendix. Additionally, the term "patient(s)" within this appendix includes patients, residents and clients unless otherwise stated. Finally, as some specific citations between providers vary, but the language is the same, we have inserted the citation to reflect as [(z) or (y), (x)] as the only the citation number varies by provider or supplier type.

Survey Protocol

These Conditions of Participation (CoP), Conditions for Coverage (CfC), Conditions for Certification and Requirements follow the standard survey protocols currently in place for each facility type and will be assessed during initial, revalidation, recertification and complaint surveys as appropriate. Compliance with the Emergency Preparedness requirements will be determined in conjunction with the existing survey process for health and safety compliance surveys or Life Safety Code (LSC) surveys for each provider and supplier type.

Important Note: Unless otherwise indicated, the general use of the terms "facility" or "facilities" in this Appendix refers to all provider and suppliers addressed in this appendix. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations. For varying requirements, the specific regulation for that provider/supplier will be noted as well. This Appendix annotates under the Interpretive Guidelines sections for which providers or suppliers the specific standard does not apply to, unless the standard only applies to one provider or supplier type.

Definitions

Emergency/Disaster: An event that can affect the facility internally as well as the overall target population or the community at large or community or a geographic area.

Emergency: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. It requires a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) to meet the expected outcome, and commonly requires change from routine management methods to an incident command process to achieve the expected outcome (see "disaster" for important contrast between the two terms).
Reference: Assistant Secretary for Preparedness and Response (ASPR) *2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms)* (November 2016).

Disaster: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. Despite a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) and change from routine management methods to an incident command/management process, the outcome is lower than expected compared with a smaller scale or lower magnitude impact (see "emergency" for important contrast between the two terms).
Reference: Assistant Secretary for Preparedness and Response (ASPR) *2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms)* (November 2016).

Emergency Preparedness Program: The Emergency Preparedness Program describes a facility's comprehensive approach to meeting the health, safety and security needs of the facility, its staff, their patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan

that is based on a Risk Assessment and incorporates an all hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

Emergency Plan: An emergency plan provides the framework for the emergency preparedness program. The emergency plan is developed based on facility- and community-based risk assessments that assist a facility in anticipating and addressing facility, patient, staff and community needs and support continuity of business operations.

All-Hazards Approach: An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. All facilities must develop an all-hazards emergency preparedness program and plan.

Facility-Based: We consider the term "facility-based" to mean the emergency preparedness program is specific to the facility. It includes but is not limited to hazards specific to a facility based on its geographic location; dependent patient/resident/client and community population; facility type and potential surrounding community assets- i.e. rural area versus a large metropolitan area.

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

Full-Scale Exercise: A full scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. ''boots on the ground'' response activities (for example, hospital staff treating mock patients).

Table-top Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.

Staff: The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act.

E-0001

(Issued XX-XX-17)

§403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.22, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12

The [*facility*, except for Transplant Center] must comply with all applicable Federal, State and local emergency preparedness requirements. The [*facility*] must establish and maintain a [comprehensive] emergency preparedness program that meets the requirements of this section.* The emergency preparedness program must include, but not be limited to, the following elements:

* (*Unless otherwise indicated, the general use of the terms "facility" or "facilities" in this Appendix refers to all provider and suppliers addressed in this appendix. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations. For varying requirements, the specific regulation for that provider/supplier will be noted as well.*)

*[*For hospitals at §482.15:*] **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. The emergency preparedness program must include, but not be limited to, the following elements:**

*[*For CAHs at §485.625:*] **The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:**

Interpretive Guidelines applies to: §403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.22, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12.

Note: This does not apply to Transplant Centers.
Note: The word comprehensive is not used in the language for ASCs.

Under this condition/requirement, facilities are required to develop an emergency preparedness program that meets all of the standards specified within the condition/requirement. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation. The program must also address how the facility would coordinate with other healthcare facilities, as well as the

whole community during an emergency or disaster (natural, man-made, facility). The emergency preparedness program must be reviewed annually.

A comprehensive approach to meeting the health and safety needs of a patient population should encompass the elements for emergency preparedness planning based on the "all-hazards" definition and specific to the location of the facility. For instance, a facility in a large flood zone, or tornado prone region, should have included these elements in their overall planning in order to meet the health, safety, and security needs of the staff and of the patient population. Additionally, if the patient population has limited mobility, facilities should have an approach to address these challenges during emergency events. The term "comprehensive" in this requirement is to ensure that facilities do not only choose one potential emergency that may occur in their area, but rather consider a multitude of events and be able to demonstrate that they have considered this during their development of the emergency preparedness plan.

Survey Procedures

- Interview the facility leadership and ask him/her/them to describe the facility's emergency preparedness program.
- Ask to see the facility's written policy and documentation on the emergency preparedness program.
- For hospitals and CAHs only: Verify the hospital's or CAH's program was developed based on an all-hazards approach by asking their leadership to describe how the facility used an all-hazards approach when developing its program.

E-0002

(Issued XX-XX-17)

§482.78 Condition of participation: Emergency preparedness for transplant centers. A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

Interpretive Guidelines for §482.78.

A representative from each transplant center must be actively involved in the development and maintenance of the hospital's emergency preparedness program, as required under §482.15(g)(1).

Transplant centers would still be required to have their own emergency preparedness policies and procedures as required under §482.78(a), as well as participate in mutually-agreed upon protocols that address the transplant center, hospital, and OPO's duties and responsibilities during an emergency.

Survey Procedures

- Verify that a representative from the transplant center was included in the planning of the emergency preparedness program of the hospital in which the transplant center is located.

E-0003
(Issued XX-XX-17)

§494.62 Condition for Coverage: The dialysis facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

Interpretive Guidelines for §494.62.

Under this condition, the ESRD facility is required to develop and update an emergency preparedness program that meets all of the standards contained within the condition. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health and safety needs of their patient population during an emergency; as well as the whole community during and surrounding an emergency event (natural or man-made).

Survey Procedures
- Ask to see written or electronic documentation of the program.

E-0004
(Issued XX-XX-17)

§403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.22(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a).

The [*facility*] must comply with all applicable Federal, State and local emergency preparedness requirements. The [*facility*] must develop establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section.

***** [*For hospitals at §482.15 and CAHs at §485.625(a)*:] **The [*hospital or CAH*] must comply with all applicable Federal, State, and local emergency preparedness requirements. The [*hospital or CAH*] must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.**

The emergency preparedness program must include, but not be limited to, the following elements:]

(a) Emergency Plan. **The [*facility*] must develop and maintain an emergency preparedness plan that must be [reviewed], and updated at least annually. The plan must do all of the following:**

* [*For ESRD Facilities at §494.62(a)*:] **Emergency Plan**. **The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least annually.**

Interpretive Guidelines applies to: §403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.22(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a).

Note: This does not apply to Transplant Centers.

Facilities are required to develop and maintain an emergency preparedness plan. The plan must include all of the required elements under the standard. The plan must be reviewed and updated at least annually. The annual review must be documented to include the date of the review and any updates made to the emergency plan based on the review. The format of the emergency preparedness plan that a facility uses is at its discretion.

An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. This approach is specific to the location of the facility and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to:

- Natural disasters
- Man-made disasters,
- Facility-based disasters that include but are not limited to:
  - Care-related emergencies;
  - Equipment and utility failures, including but not limited to power, water, gas, etc.;
  - Interruptions in communication, including cyber-attacks;
  - Loss of all or portion of a facility; and
  - Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).

When evaluating potential interruptions to the normal supply of essential services, the facility should take into account the likely durations of such interruptions. Arrangements or contracts to re-establish essential utility services during an emergency should describe the timeframe within which the contractor is required to initiate services after the start of the emergency, how they will be procured and delivered in the facility's local area, and that the contractor will continue to supply the essential items throughout and to the end of emergencies of varying duration.

Survey Procedures

- Verify the facility has an emergency preparedness plan by asking to see a copy of the plan.
- Ask facility leadership to identify the hazards (e.g. natural, man-made, facility, geographic, etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted.
- Review the plan to verify it contains all of the required elements
- Verify that the plan is reviewed and updated annually by looking for documentation of the date of the review and updates that were made to the plan based on the review

E-0005

(Issued XX-XX-17)

§482.78(a) Standard: Policies and procedures. A transplant center must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

Interpretive Guidelines for §482.78(a).

Transplant centers must be actively involved in their hospital's emergency planning and programming under §482.15(g). The transplant center's emergency preparedness plans must be included in the hospital's emergency plans. All of the Medicare-approved transplant centers are located within certified hospitals and, as part of the hospital, must be included in the hospital's emergency preparedness plans. The transplant center needs to be involved in the hospital's risk assessment because there may be risks to the transplant center that others in the hospital may not be aware of or appreciate. However, most of the risk assessment of the hospital and transplant center would be the same since the transplant center is located within the hospital. Therefore a separate risk assessment would be unnecessary and overly burdensome.

Survey Procedures

- Verify the transplant center has emergency preparedness policies and procedures.
- Verify that the transplant center's emergency preparedness policies and procedures are included in the hospital's emergency preparedness program.

E-0006

(Issued XX-XX-17)

§403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.22(a)(1)-(2), §485.68(a)(1)-(2), §485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §486.360(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2)

[(a) Emergency Plan. The [*facility*] 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 an all-hazards approach.*

*[*For LTC facilities at §483.73(a)(1):*] **(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents.**

*[*For ICF/IIDs at §483.475(a)(1):*] **(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.**

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

* [*For Hospices at §418.113(a)(2)*:] **(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.**

Interpretive Guidelines applies to: §403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.22(a)(1)-(2), §485.68(a)(1)-(2), §485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2).

Note: This does not apply to Transplant Centers.

Facilities are expected to develop an emergency preparedness plan that is based on the facility-based and community-based risk assessment using an "all-hazards" approach. Facilities must document both risk assessments. An example consideration may include, but is not limited to, natural disasters prevalent in a facility's geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies. Facilities are encouraged to utilize the concepts outlined in the

National Preparedness System, published by the United States Department of Homeland Security's Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ).

"Community" is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes. 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. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency.

Facilities may rely on a community-based risk assessment developed by other entities, such as public health agencies, emergency management agencies, and regional health care coalitions or in conjunction with conducting its own facility-based assessment. If this approach is used, facilities are expected to have a copy of the community-based risk assessment and to work with the entity that developed it to ensure that the facility's emergency plan is in alignment.

When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following:

- Identification of all business functions essential to the facility's operations that should be continued during an emergency;
- Identification of all risks or emergencies that the facility may reasonably expect to confront;
- Identification of all contingencies for which the facility should plan;
- Consideration of the facility's location;
- Assessment of the extent to which natural or man-made emergencies may cause the facility to cease or limit operations; and,
- Determination of what arrangements may be necessary with other health care facilities, or other entities that might be needed to ensure that essential services could be provided during an emergency.

In situations where the facility does not own the structure(s) where care is provided, it is the facility's responsibility to discuss emergency preparedness concerns with the landlord to ensure continuation of care if the structure of the building and its utilities are impacted.

For LTC facilities and ICF/IIDs, written plans and the procedures are required to also include missing residents and clients, respectively, within their emergency plans.

Facilities must develop strategies for addressing emergency events that were identified during the development of the facility- and community-based risk assessments. Examples of these strategies may include, but are not limited to, developing a staffing strategy if staff shortages were identified during the risk assessment or developing a surge capacity strategy if the facility has identified it would likely be requested to accept additional

patients during an emergency. Facilities will also want to consider evacuation plans. For example, a facility in a large metropolitan city may plan to utilize the support of other large community facilities as alternate care sites for its patients if the facility needs to be evacuated. The facility is also expected to have a backup evacuation plan for instances in which nearby facilities are also affected by the emergency and are unable to receive patients

Hospices must include contingencies for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.

Survey Procedures

- Ask to see the written documentation of the facility's risk assessments and associated strategies.
- Interview the facility leadership and ask which hazards (e.g. natural, man-made, facility, geographic) were included in the facility's risk assessment, why they were included and how the risk assessment was conducted.
- Verify the risk-assessment is based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards.

E-0007

(Issued XX-XX-17)

§403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.22(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

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

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

Note: ["Persons at risk" does not apply to***: ASC, hospice, PACE, HHA, CORF, CMCH, RHC/FQHC, or ESRD facilities.]**

Interpretive Guidelines applies to: §403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.22(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

Note: This does not apply to Transplant Centers and OPOs.

The emergency plan must specify the population served within the facility, such as inpatients and/or outpatients, and their unique vulnerabilities in the event of an emergency or disaster. A facility's emergency plan must also address persons at-risk, except for plans of ASCs, hospices, PACE organizations, HHAs, CORFs, CMHCs, RHCs/FQHCs and ESRD facilities. As defined by the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision, and medical care. In addition to those individuals specifically recognized as at-risk in the PAHPA (children, senior citizens, and pregnant women), "at-risk populations" are also individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures and racial and ethnic backgrounds, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. At-risk populations would also include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities as well as others with access and functional needs, and infants and children.

Mobility is an important part in effective and timely evacuations, and therefore facilities are expected to properly plan to identify patients who would require additional assistance, ensure that means for transport are accessible and available and that those involved in transport, as well as the patients and residents are made aware of the procedures to evacuate. For outpatient facilities, such as Home Health Agencies (HHAs), the emergency plan is required to ensure that patients with limited mobility are addressed within the plan.

The emergency plan must also address the types of services that the facility would be able to provide in an emergency. The emergency plan must identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing internal people with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available. During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available. At a minimum, there should be a qualified person who "is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility."

In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and Assistant Secretary for Preparedness and Response (ASPR) when developing strategies for ensuring continuity of operations. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations.

Survey Procedures

Interview leadership and ask them to describe the following:

- The facility's patient populations that would be at risk during an emergency event;
- Strategies the facility (except for an ASC, hospice, PACE organization, HHA, CORF, CMHC, RHC/FQHC and ESRD facility) has put in place to address the needs of at-risk or vulnerable patient populations;
- Services the facility would be able to provide during an emergency;
- How the facility plans to continue operations during an emergency;
- Delegations of authority and succession plans.

Verify that all of the above are included in the written emergency plan.

E-0008

(Issued XX-XX-17)

§486.360(a)(3) Condition for Participation:
[(a) Emergency Plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:]

(3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

Interpretive Guidelines for §486.360(a)(3).

The emergency plan must address the type of hospitals with which the OPO has agreements and the types of services that the OPO would be able to provide in an emergency. The emergency plan must also identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing staff with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become necessary. During times of emergency, facilities must have internal employees who are capable of assuming various critical roles in the event that current staff and leaders are not available. At a minimum, facilities should designate a qualified person who is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility.

In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize

resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations.

Survey Procedures
Interview leadership and ask them to describe the following:

- Services the OPO would be able to provide during an emergency;
- How the OPO plans to continue operations during an emergency;
- Delegations of authority and succession plans.
- How the OPO has included/addressed all of the hospitals with which it has agreements into its emergency plan.

Verify that all of the above are included in the written emergency plan.

E-0009

(Issued XX-XX-17)

§403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.22(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4)

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

(4) 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 facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. **

* [*For ESRD facilities only at §494.62(a)(4)*]: **(4) 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 dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.**

Interpretive Guidelines applies to: §403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.22(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4).

Note: This does not apply to Transplant Centers.

While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility must document its efforts to contact these officials to engage in collaborative planning for an integrated emergency response. The facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources.

For ESRD facilities, §494.120(c)(2) of the ESRD Conditions for Coverage on Special Purpose Dialysis Facilities describes the requirements for ESRD facilities that are set up in an emergency (i.e., an emergency circumstance facility) which are issued a unique CMS Certification Number (CCN). ESRD facilities must incorporate these specific provisions into the coordination requirements under this standard.

Survey Procedures

Interview facility leadership and ask them to describe their process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation.

- Ask for documentation of the facility's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.
- For ESRD facilities, ask to see documentation that the ESRD facility contacted the local public health and emergency management agency public official at least annually to confirm that the agency is aware of the ESRD facility's needs in the event of an emergency and know how to contact the agencies in the event of an emergency.

E-0010

(Issued XX-XX-17)

§485.727(a)(4) Condition for Participation:
[(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:]

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

Interpretive Guidelines for §485.727(a)(4).

The Organizations' emergency plan must address the location and use of alarm systems and signals. The plan must also include the methods used for containing fires, such as fire extinguishers, sprinkler systems and other current methods used. The National Fire

Protection Association (NFPA) at section A.20.1.1.1.6, recognizes that certain functions necessary for the life safety of building occupants, such as the closing of corridor doors, the operation of manual fire alarm devices, and the removal of patients from the room of fire origin, require the intervention of facility staff. Therefore, the plan should follow guidelines set forth by the NFPA.

Survey Procedures

- Ask facility leadership to show the section of the plan which addresses location(s) and use of fire alarms.
- Ask facility staff to describe the facility's current procedure for containing fires.

E-0011

(Issued XX-XX-17)

§485.68(a)(5) Condition for Participation:
[(a) Emergency Plan. **The Comprehensive Outpatient Rehabilitation Facility (CORF) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:]**

(a)(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

§485.727(a)(6) Condition for Participation:
[(a) Emergency Plan. **The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:]**

(a)(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

Interpretive Guidelines applies to: §485.68(a)(5), §485.727(a)(6).

The CORF and Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services must collaborate with fire, safety and other appropriate experts to develop and maintain its emergency plan. They must document their collaboration with these experts and include them in the annual review of the plan.

Survey Procedures

- Ask for a list of/documentation for which experts were collaborated with to develop and maintain its plan.

E-0012

(Issued XX-XX-17)

§ 482.78 Condition of participation: Emergency preparedness for transplant centers. A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) ***Standard: Policies and procedures.***
A transplant center must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

(b) ***Standard: Protocols with hospital and OPO.*** **A transplant center must 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 operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.**

Interpretive Guidelines applies to: §482.78(a), and §482.78(b).

Hospitals which have transplant centers must include within their emergency planning and preparedness process one representative, at minimum, from the transplant center. If a hospital has multiple transplant centers, each center must have at least one representative who is involved in the development and maintenance of the hospital's emergency preparedness process. The hospital must include the transplant center in its emergency preparedness plan policies and procedures, communication plans, as well is the training and testing programs.

Both the hospital and the transplant center are required to demonstrate during a survey that they have coordinated in planning and the development of the emergency program. Both are required to have written documentation of the emergency preparedness plans. However, the transplant center is not individually responsible for the emergency preparedness requirements under §482.15.

Survey Procedures

- Verify the hospital has written documentation to demonstrate that a representative of each transplant center participated in the development of the emergency program.
- Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the transplant center and the associated OPOs.

E-0013

(Issued XX-XX-17)
§403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.22(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §486.360(b), §491.12(b), §494.62(b).

(b) Policies and procedures. [*Facilities*] 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.

**Additional Requirements for PACE and ESRD Facilities:*

*[*For PACE at §460.84(b):*] **Policies and procedures. The PACE organization 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 address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. The policies and procedures must be reviewed and updated at least annually.**

*[*For ESRD Facilities at §494.62(b):*] **Policies and procedures. The dialysis facility 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. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.**

Interpretive Guidelines applies to: §403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.22(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §486.360(b), §491.12(b), §494.62(b).

Note: This does not apply to Transplant Centers.

Facilities must develop and implement policies and procedures per the requirements of this standard. The policies and procedures are expected to align with the identified hazards within the facility's risk assessment and the facility's overall emergency preparedness program.

We are not specifying where the facility must have the emergency preparedness policies and procedures. A facility may choose whether to incorporate the emergency policies and procedures within their emergency plan or to be part of the facility's Standard Operating Procedures or Operating Manual. However, the facility must be able to demonstrate compliance upon survey, therefore we recommend that facilities have a central place to house the emergency preparedness program documents (to include all policies and procedures) to facilitate review.

Survey Procedures

Review the written policies and procedures which address the facility's emergency plan and verify the following:

- Policies and procedures were developed based on the facility- and community-based risk assessment and communication plan, utilizing an all-hazards approach.
- Ask to see documentation that verifies the policies and procedures have been reviewed and updated on an annual basis.

E-0014

(Issued XX-XX-17)

§482.78(b) Standard: Protocols with hospital and OPO. A transplant center must 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 operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

Interpretive Guidelines for §482.78(b).

Transplant centers must be involved in the development of mutually agreed upon protocols that address the duties and responsibilities of the hospital, transplant program and the designated OPO during emergencies.

All transplant centers are located within Medicare participating hospitals. Any hospital that furnishes organ transplants and other medical and surgical specialty services for the care of transplant patients is defined as a transplant hospital (42 CFR 482.70). Therefore, transplant centers must meet all hospital CoPs at §§482.1 through 482.57 (as set forth at §482.68(b)), and the hospitals in which they are located must meet the provisions of § 482.15, however, a transplant center is not individually responsible for the emergency preparedness requirements in §482.15.

The hospital in which a transplant center is located (i.e., a transplant hospital) would be responsible for ensuring that the transplant center is involved in the development of an emergency preparedness program. This requirement does not oblige a transplant center that agrees to care for another transplant center's patients during an emergency to put those patients on its waiting lists. We anticipate that most emergencies would be of short duration and that the transplant center that is affected by an emergency will resume its normal operations within a short period of time. However, if a transplant center does arrange for its patients to be transferred to another transplant center during an emergency, both transplant centers would need to determine what care would be provided to the transferring patients, including whether and under what circumstances the patients from the transferring transplant center would be added to the receiving center's waiting lists.

Survey Procedures

- Verify the transplant center has developed mutually agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is operated, and the designated OPO.
- Ask to see documentation of the protocols.

E-0015
(Issued XX-XX-17)

§403.748(b)(1), §418.113(b)(6)(iii), §441.184(b)(1), §460.84(b)(1), §482.15(b)(1), §483.73(b)(1), §483.475(b)(1), §485.625(b)(1)

[(b) Policies and procedures. [*Facilities*] 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:

(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 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.

*[*For Inpatient Hospice at §418.113(b)(6)(iii):*] **Policies and procedures.**
(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:
(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:
(A) Food, water, medical, and pharmaceutical supplies.
(B) Alternate sources of energy to maintain the following:
(1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.
(2) Emergency lighting.
(3) Fire detection, extinguishing, and alarm systems.
(C) Sewage and waste disposal.

Interpretive Guidelines applies to: §403.748(b)(1), §418.113(b)(6)(iii), §441.184(b)(1), §460.84(b)(1), §482.15(b)(1), §483.73(b)(1), §483.475(b)(1), §485.625(b)(1).

Note: This does not apply to ASCs, Outpatient Hospice Providers [applies to inpatient hospices], Transplant Centers, HHA, CORFs, CMHCs, RHCs/FQHCs, ESRD facilities.

Facilities must be able to provide for adequate subsistence for all patients and staff for the duration of an emergency or until all its patients have been evacuated and its operations cease. Facilities have flexibility in identifying their individual subsistence needs that would be required during an emergency. There are no set requirements or standards for the amount of provisions to be provided in facilities, Provisions include, but are not limited to, food, pharmaceuticals and medical supplies. Provisions should be stored in an area which is less likely to be affected by disaster, such as storing these resources above ground-level to protect from possible flooding. Additionally, when inpatient facilities determine their supply needs, they are expected to consider the possibility that volunteers, visitors, and individuals from the community may arrive at the facility to offer assistance or seek shelter.

Alternate sources of energy depend on the resources available to a facility, such as battery-operated lights, or heating and cooling, in order to meet the needs of a facility during an emergency. Facilities are not required to upgrade their electrical systems, but after review of their risk assessment, facilities may find it prudent to make any necessary adjustments to ensure that occupants health and safety needs are met, and that facilities maintain safe and sanitary storage areas for provisions.

This specific standard does not require facilities to have or install generators or any other specific type of energy source. (However, for hospitals at §482.15(e), CAHs at §485.625(e) and LTC facilities at §483.73(e) please also refer to Tag E-0041 for Emergency and Stand-by Power Systems.) It is up to each individual facility, based on its risk assessment, to determine the most appropriate alternate energy sources to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions, emergency lighting, fire detection, extinguishing, and alarm systems and sewage and waste disposal. Whatever alternate sources of energy a facility chooses to utilize must be in accordance with local and state laws as well as relevant LSC requirements.
Facilities must establish policies and procedures that determine how required heating and cooling of their facility will be maintained during an emergency situation, as necessary, if there were a loss of the primary power source.

If a facility determines the best way to maintain temperatures, emergency lighting, fire detection and extinguishing systems and sewage and waste disposal would be through the use of a portable generator, then the Life Safety Code (LSC) provisions, such as generator testing and fuel storage, etc. outlined under the NFPA guidelines would not be applicable. Portable generators should be operated, tested, and maintained in accordance with manufacturer, local and/or State requirements. If a facility, however, chooses to utilize a permanent generator to maintain emergency power, LSC provisions such as

generator testing and maintenance will apply and the facility may be subject to LSC surveys to ensure compliance is met.

As an example, some ESRD facilities have contracted services with companies who maintain portable emergency generators for the facilities off-site. In the event of an emergency where the facility is unable to reschedule patients or evacuate, the generators are brought to the location in advance to assist in the event of loss of power. Facilities who are not specifically required by the EP Final Rule to have a generator, but are required to meet provision for an alternate sources of energy, may consider this approach for their facility.

Facilities are encouraged to confer with local health department and emergency management officials, as well as and healthcare coalitions, where available, 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. As part of the risk assessment planning, facilities should determine the feasibility of relying on these sources and plan accordingly.

Facilities are not required to provide onsite treatment of sewage but must make provisions for maintaining necessary services. For example, LTC facilities are already required to meet Food Receiving and Storage provisions at §483.35(i) Sanitary Conditions, which contain requirements for keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents can also help maintain food quality and prevent contamination. Additionally, ESRD facilities under current CfCs at §494.40(a)(4) are also required to have policies and procedures for handling, storage and disposal of potentially infectious waste. We are not specifying any required provisions regarding treatment of sewage and necessary services under this tag; however, facilities are required to follow their current facility-type requirements (e.g., CoPs/CfCs, Requirements) which may address these areas. Additionally, we would expect facilities under this requirement to ensure current practices are followed, such as those outlined by the Environmental Protection Agency (EPA) and under State-specific laws. Maintaining necessary services may include, but are not limited to, access to medical gases; treatment of soiled linens; disposal of bio-hazard materials for different infectious diseases; and may require additional assistance from transportation companies for safe and appropriate disposal in accordance with nationally accepted industry guidelines for emergency preparedness.

Survey Procedures

- Verify the emergency plan includes policies and procedures for the provision of subsistence needs including, but not limited to, food, water and pharmaceutical supplies for patients and staff by reviewing the plan.
- Verify the emergency plan includes policies and procedures to ensure adequate alternate energy sources necessary to maintain:
    - Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;
    - Emergency lighting; and,

    - Fire detection, extinguishing, and alarm systems.
- Verify the emergency plan includes policies and procedures to provide for sewage and waste disposal.

E-0016
(Issued XX-XX-17)

§418.113(b)(1): Condition for Participation:
[(b) Policies and procedures. The hospice 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:

(1) Procedures to follow up with on duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The hospice must inform State and local officials of any on-duty staff or patients that they are unable to contact.

Interpretive Guidelines for §418.113(b)(1).

Hospices have the flexibility to determine how best to develop these policies and procedures. For administrative purposes, all hospices should already have some mechanism in place to keep track of patients and staff contact information. However, the information regarding patient services that are needed during or after an interruption in their services and on-duty staff and patients that were not able to be contacted must be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient.

Survey Procedures

- Review the emergency plan to verify it includes policies and procedures for following up with staff and patients.
- Interview a staff member or leadership and ask them to explain the procedures in place in the event they are unable to contact a staff member or patient.

E-0017
(Issued XX-XX-17)

§484.22(b)(1) Condition for Participation:
[(b) Policies and procedures. The HHA 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:]

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at §484.55.

Interpretive Guidelines for §484.22(b)(1).

HHAs must include policies and procedures in its emergency plan for ensuring all patients have an individualized plan in the event of an emergency. That plan must be included as part of the patient's comprehensive assessment.

For example, discussions to develop individualized emergency preparedness plans could include potential disasters that the patient may face within the home such as fire hazards, flooding, and tornados; and how and when a patient is to contact local emergency officials. Discussions may also include patient, care providers, patient representative, or any person involved in the clinical care aspects to educate them on steps that can be taken to improve the patient's safety. The individualized emergency plan should be in writing and could be as simple as a detailed emergency card to be kept with the patient. HHA personnel should document that these discussions occurred and also keep a copy of the individualized emergency plan in the patient's file as well as provide a copy to the patient and or their caregiver.

Survey Procedures

- Through record review, verify that each patient has an individualized emergency plan documented as part of the patient's comprehensive assessment.

E-0018

(Issued XX-XX-17)

§403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).

[(b) Policies and procedures. The [*facilities*] 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:]

[(2) or (1)] A system to track the location of on-duty staff and sheltered patients in the [*facility's*] care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the [*facility*] must document the specific name and location of the receiving facility or other location.

*[*For PRTFs at §441.184(b), LTC at §483.73(b), ICF/IIDs at §483.475(b), PACE at §460.84(b):*] **Policies and procedures. (2) A system to track the location of on-duty staff and sheltered residents in the [*PRTF's, LTC, ICF/IID or PACE*] care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the [*PRTF's, LTC, ICF/IID or PACE*] must document the specific name and location of the receiving facility or other location.**

*[*For Inpatient Hospice at §418.113(b)(6):*] **Policies and procedures.**
(ii) Safe evacuation from the hospice, 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.
(v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

*[*For CMHCs at §485.920(b):*] **Policies and procedures. (2) Safe evacuation from the CMHC, 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.**

*[*For OPOs at § 486.360(b):*] **Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.**

*[*For ESRD at § 494.62(b):*] **Policies and procedures. (2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.**

Interpretive Guidelines applies to: §403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).

Note: This does not apply to Transplant Centers, HHAs, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, RHCs/FQHCs.

Facilities must develop a means to track patients and on-duty staff in the facility's care during an emergency event. In the event staff and patients are relocated, the facility must document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency.

CMHCs, PRTF's, LTC facilities, ICF/IIDs, PACE organizations and ESRD Facilities are required to track the location of sheltered patients and staff during and *after* an emergency.

We are not specifying which type of tracking system should be used; rather, a facility has the flexibility to determine how best to track patients and staff, whether it uses an electronic database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response systems as needed in the interest of the patient. It is recommended that a facility that is using an electronic database consider backing up its computer system with a secondary source, such as hard copy documentation in the event of power outages. The tracking systems set up by facilities may want to consider who is responsible for compiling/securing patient records and what information is needed during tracking a patient throughout an evacuation. A number of states already have such tracking systems in place or under development and the systems are available for use by health care providers and suppliers. Facilities are encouraged to leverage the support and resources available to them through local and national healthcare systems, healthcare coalitions, and healthcare organizations for resources and tools for tracking patients.

Facilities are not required to track the location of patients who have voluntarily left on their own, or have been appropriately discharged, since they are no longer in the facility's care. However, this information must be documented in the patient's medical record should any questions later arise as to the patient's whereabouts.

Note: If an ASC is able to cancel surgeries and close (meaning there are no patients or staff in the ASC), this requirement of tracking patients and staff would no longer be applicable. Similarly to ESRD standard practices, if an emergency was imminent and able to be predicted (i.e. inclement weather conditions, etc.) we would expect that ASCs cancel surgeries and cease operations, which would eliminate the need to track patients and staff.

Survey Procedures

- Ask staff to describe and/or demonstrate the tracking system used to document locations of patients and staff.
- Verify that the tracking system is documented as part of the facilities' emergency plan policies and procedures.

E-0019

(Issued XX-XX-17)

§418.113(b)(2), §460.84(b)(4), §484.22(b)(2)

[(b) Policies and procedures. The [*facilities*] 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:]

**[For homebound Hospice at §418.113(b)(2), PACE at §460.84(b)(4), and HHAs at §484.22(b)(2):]*

The procedures to inform State and local emergency preparedness officials about [*homebound Hospice, PACE or HHA*] patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

Interpretive Guidelines applies to: §418.113(b)(2), §460.84(b)(4), §484.22(b)(2).

Note: The regulatory language for hospices under §418.113(b)(2) does not include the terms "emergency preparedness" when describing officials.

Note: This only applies to homebound Hospice, PACE and HHAs.

Home bound hospices, HHAs and PACE organizations are required to inform State and local emergency preparedness officials of the need for patient evacuations. These policies and procedures must address when and how this information is communicated to emergency officials and also include the clinical care needed for these patients. For instance, in the event an in-home hospice, PACE organization or HHA patient requires evacuation, the responsible agency should provide emergency officials with the appropriate information to facilitate the patient's evacuation and transportation. This should include, but is not limited to, the following:

- Whether or not the patient is mobile.
- What type of life-saving equipment does the patient require?
- Is the life-saving equipment able to be transported? (E.g., Battery operated, transportable, condition of equipment, etc.)
- Does the patient have special needs? (E.g., Communication challenges, language barriers, intellectual disabilities, special dietary needs, etc.)

Since such policies and procedures include protected health information of patients, facilities must also ensure they are in compliance with applicable the Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR parts 160 and 164, as appropriate. See (81 FR 63879, Sept. 16, 2016).

Survey Procedures

- Review the emergency plan to verify it includes procedures to inform State and local emergency preparedness officials about patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

E-0020

(Issued XX-XX-17)

§403.748(b)(3), §416.54(b)(2), §418.113(b)(6)(ii), §441.184(b)(3), §460.84(b)(3), §482.15(b)(3), §483.73(b)(3), §483.475(b)(3), §485.68(b)(1), §485.625(b)(3), §485.727(b)(1), §485.920(b)(2), §491.12(b)(1), §494.62(b)(2)

[(b) Policies and procedures. The [*facilities*] 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:]

[(3) or (1), (2), (6)] Safe evacuation from the [*facility*], 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.

*[*For RNHCs at §403.748(b)(3) and ASCs at §416.54(b)(2):]*
Safe evacuation from the [*RNHCI or ASC*] which includes the following:

(i) Consideration of care needs of evacuees.
(ii) Staff responsibilities.
(iii) Transportation.
(iv) Identification of evacuation location(s).
(v) Primary and alternate means of communication with external sources of assistance.

* [*For CORFs at §485.68(b)(1), Clinics, Rehabilitation Agencies, OPT/Speech at §485.727(b)(1), and ESRD Facilities at §494.62(b)(2):*]
Safe evacuation from the [*CORF; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services; and ESRD Facilities*], which includes staff responsibilities, and needs of the patients.

* [*For RHCs/FQHCs at §491.12(b)(1):]* **Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients**.

Interpretive Guidelines applies to: §403.748(b)(3), §416.54(b)(2), §418.113(b)(6)(ii), §441.184(b)(3), §460.84(b)(3), §482.15(b)(3), §483.73(b)(3), §483.475(b)(3), §485.68(b)(1), §485.625(b)(3), §485.727(b)(1), §485.920(b)(2), §491.12(b)(1), §494.62(b)(2)

Note: Note this does not apply to HHAs, OPOs, and Transplant Centers.

Note: The requirements under §418.113(b)(6)(ii) is not a requirement for outpatient hospice providers.

Facilities must develop policies and procedures that provide for the safe evacuation of patients from the facility and include all of the requirements of this standard. RHCs and FQHCs must also place exit signs to guide patients and staff in the event of an evacuation from the facility.

Facilities must have policies and procedures which address the needs of evacuees. The facility should also consider in development of the policies and procedures, the evacuation protocols for not only the evacuees, but also staff members and families/patient representatives or other personnel who sought potential refuge at the facility. Additionally, the policies and procedures must address staff responsibilities during evacuations. Facilities must consider the patient population needs as well as their care and treatment. For example, if an evacuation is in progress and the facility must evacuate, leadership should consider the needs for critically ill patients to be evacuated and accompanied by staff who could provide care and treatment enroute to the designated relocation site, in the event trained medical professionals are unavailable by the transportation services.

Facilities must consider in their development of policies and procedures, the needs of their patient population and what designated transportation services would be most appropriate. For instance, if a facility primarily cares for critically ill patients with ventilation needs and life-saving equipment, the transportation services should be able to assist in evacuation of this special population and be equipped to do so. Additionally, facilities may also find it prudent to consider alternative methods for evacuation and patient care and treatment, such as mentioned above to have staff members evacuate with patients in given situations.

Additionally, facilities should consider their triaging system when coordinating the tracking and potential evacuation of patient/residents/clients. For instance, a triaging system for evacuation may consider the most critical patients first followed by those less critical and dependent on life-saving equipment. Considerations for prioritization may be based on, among other things, acuity, mobility status (stretch-bound/wheelchair/ambulatory), and location of the unit, availability of a known transfer destination or some combination thereof. Included within this system should be who (specifically) will be tasked with making triage decisions. Following the triaging system, staff should consider the communication of patient care requirements to the in-taking facility, such as attaching hard copy of standard abbreviated patient health condition/history, injuries, allergies, and treatment rendered. On the same method for communicating this information, a facility could consider color coordination of triage level (i.e. green folder with this information is for less critical patients; red folders for critical and urgent evacuated patients, etc.). Additionally, this hard copy could include family member/representative contact information.

Finally, facilities policies and procedures must outline primary and alternate means for communication with external sources for assistance. For instance, primarily methods may be considered via regular telephone services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials; whereas alternate means

account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance.

Survey Procedures

- Review the emergency plan to verify it includes policies and procedures for safe evacuation from the facility and that it includes all of the required elements.
- When surveying an RHC or FQHC, verify that exit signs are placed in the appropriate locations to facilitate a safe evacuation.

E-0021

(Issued XX-XX-17)

§484.22(b)(3) Condition of Participation:
[(b) Policies and procedures. The HHA 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:]

(3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.

Interpretive Guidelines for §484.22(b)(3).

HHAs must include in its emergency plan, procedures required of this standard. During an emergency, if a patient requires care that is beyond the capabilities of the HHA, there is an expectation that care of the patient would be rearranged or suspended for a period of time, as most HHAs in general would not necessarily transfer patients to other HHAs during an emergency.

HHAs policies and procedures should clearly outline what surrounding facilities, such as a hospital or a nursing home, it has a transfer arrangement with to ensure patient care is continued. Additionally, these policies and procedures should outline timelines for transferring patients or under what conditions patients would need to move. For instance, if the emergency is one which only is anticipated to have one or two days of disruption and does not pose immediate threat to patient health or safety (in which then the HHA should immediately transfer the patient); the HHA may rearrange services, whereas if a disaster is anticipated to last over one week or more, the HHA may need to initiate transfer of a patient as soon as possible. The policies and procedures should address these events. Additionally, the HHAs' policies and procedures must address what actions would be required due to the inability to make contact with staff or patients and reporting capabilities to the local and State emergency officials.

Survey Procedures

- Verify that the HHA has included in its emergency plan these procedures to follow-up with staff and patients and to inform state and local authorities when they are unable to contact any of them.
- Verify that the HHA has procedures in its emergency plan to follow up with on-duty staff and patients to determine the services that are needed, in the event that there is an interruption in services during or due to an emergency.
- Ask the HHA to describe the mechanism to inform State and local officials of any on-duty staff or patients that they are unable to contact.

E-0022

(Issued XX-XX-17)

§403.748(b)(4), §416.54(b)(3), §418.113(b)(6)(i), §441.184(b)(4), §460.84(b)(5), §482.15(b)(4), §483.73(b)(4), §483.475(b)(4), §485.68(b)(2), §485.625(b)(4), §485.727(b)(2), §485.920(b)(3), §491.12(b)(2), §494.62(b)(3).

(b) Policies and procedures. The [*facilities*] 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:]

[(4) or (2),(3),(5),(6)] A means to shelter in place for patients, staff, and volunteers who remain in the [*facility*].

*[*For Inpatient Hospices at §418.113(b):*] **Policies and procedures.**
(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

Interpretive Guidelines applies to: §403.748(b)(4), §416.54(b)(3), §418.113(b)(6)(i), §441.184(b)(4), §460.84(b)(5), §482.15(b)(4), §483.73(b)(4), §483.475(b)(4), §485.68(b)(2), §485.625(b)(4), §485.727(b)(2), §485.920(b)(3), §491.12(b)(2), §494.62(b)(3).

Note: This does not apply to Transplant Centers, HHAs or OPOs.

Emergency plans must include a means for sheltering all patients, staff, and volunteers who remain in the facility in the event that an evacuation cannot be executed. . In certain disaster situations (such as tornadoes) , sheltering in place may be more appropriate as opposed to evacuation and would require a facility to have a means to shelter in place for such emergencies. Therefore, facilities are required to have policies and procedures for sheltering in place which align with the facility's risk assessment.

Facilities are expected to include in their policies and procedures the criteria for determining which patients and staff that would be sheltered in place. When developing policies and procedures for sheltering in place, facilities should consider the ability of their building(s) to survive a disaster and what proactive steps they could take prior to an emergency to facilitate sheltering in place or transferring of patients to alternate settings if their facilities were affected by the emergency. For example, if it is dangerous to evacuate or the emergency affects available sites for transfer or discharge, then the patients would remain in the facility until it was safe to effectuate transfers or discharges. The plan should take into account the appropriate facilities in the community to which patients could be transferred in the event of an emergency. Facilities must determine their policies based on the type of emergency and the types of patients, staff, volunteers and visitors that may be present during an emergency. Based on its emergency plan, a facility could decide to have various approaches to sheltering some or all of its patients and staff.

Survey Procedures

- Verify the emergency plan includes policies and procedures for how it will provide a means to shelter in place for patients, staff and volunteers who remain in a facility.
- Review the policies and procedures for sheltering in place and evaluate if they aligned with the facility's emergency plan and risk assessment.

E-0023

(Issued XX-XX-17)

§403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.22(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360(b)(2), §491.12(b)(3), §494.62(b)(4).

[(b) Policies and procedures. The [*facilities*] 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:]

[(5) or (3),(4),(6)] A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.

*[*For RNHCIs at §403.748(b):*] **Policies and procedures. (5) A system of care documentation that does the following:**

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

*[*For OPOs at §486.360(b):*] **Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.**

Interpretive Guidelines applies to: §403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.22(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360 (b)(2), §491.12(b)(3), §494.62(b)(4).

Note: This does not apply to Transplant Centers.

In addition to any existing requirements for patient records found in existing laws, under this standard, facilities are required to ensure that patient records are secure and readily available to support continuity of care during emergency. This requirement does not supersede or take away any requirements found under the provider/supplier's medical records regulations, but rather, this standard adds to such policies and procedures. These policies and procedures must also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Privacy and Security Rules at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information.

Survey Procedures

- Ask to see a copy of the policies and procedures that documents the medical record documentation system the facility has developed to preserves patient (or potential and actual donor for OPOs) information, protects confidentiality of patient (or potential and actual donor for OPOs) information, and secures and maintains availability of records.

E-0024

(Issued XX-XX-17)

§403.748(b)(6), §416.54(b)(5), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.22(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

[(b) Policies and procedures. The [*facilities*] 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:]

(6) [*or (4), (5), or (7) as noted above*] The use of volunteers in an emergency or 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.

*[*For RNHCIs at §403.748(b):*] **Policies and procedures. (6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.**

Interpretive Guidelines applies to: §403.748(b)(6), §416.54(b)(5), §418.113(b)(4), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.22(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

Note: This does not apply to Hospices, Transplant Centers, or OPOs.

During an emergency, a facility may need to accept volunteer support from individuals with varying levels of skills and training. The facility must have policies and procedures in place to facilitate this support. In order for volunteering healthcare professionals to be able to perform services within their scope of practice and training, facilities must include any necessary privileging and credentialing processes in its emergency preparedness plan policies and procedures. Non-medical volunteers would perform non-medical tasks. Facilities have flexibility in determining how best to utilize volunteers during an emergency as long as such utilization is in accordance with State law, State scope of practice rules, and facility policy. These may also include federally designated health care professionals, such as Public Health Service (PHS) staff, National Disaster Medical System (NDMS) medical teams, Department of Defense (DOD) Nurse Corps, Medical Reserve Corps (MRC), or personnel such as those identified in federally designated Health Professional Shortage Areas (HPSAs) to include licensed primary care medical, dental, and mental/behavioral health professionals. Facilities are also encouraged to integrate State-established volunteer registries, and where possible, State-based Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP).

Facilities are expected to include in its emergency plan a method for contacting off-duty staff during an emergency and procedures to address other contingencies in the event staff are not able to report to duty which may include, but are not limited to, utilizing staff from other facilities and state or federally-designated health professionals.

Survey Procedures

- Verify the facility has included policies and procedures for the use of volunteers and other staffing strategies in its emergency plan.

E-0025

(Issued XX-XX-17)

§403.748(b)(7), §418.113(b)(5), §441.184(b)(7), §460.84(b)(8), §482.15(b)(7), §483.73(b)(7), §483.475(b)(7), §485.625(b)(7), §485.920(b)(6), §494.62(b)(6).

[(b) Policies and procedures. The [*facilities*] 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:]

*[*For Hospices at §418.113(b), PRFTs at §441.184,(b) Hospitals at §482.15(b), and LTC Facilities at §483.73(b):*] **Policies and procedures. (7) [or (5)] The development of arrangements with other [*facilities*] [and] other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.**

*[*For PACE at §460.84(b), ICF/IIDs at §483.475(b), CAHs at §486.625(b), CMHCs at §485.920(b) and ESRD Facilities at §494.62(b):*] **Policies and procedures. (7) [or (6), (8)] The development of arrangements with other [*facilities*] [or] other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.**

*[*For RNHCIs at §403.748(b):*] **Policies and procedures. (7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of non-medical services to RNHCI patients.**

Interpretive Guidelines applies to: §403.748(b)(7), §418.113(b)(5), §441.184(b)(7), §460.84(b)(8), §482.15(b)(7), §483.73(b)(7), §483.475(b)(7), §485.625(b)(7), §485.920(b)(6), §494.62(b)(6).

Note: The differences for some providers and suppliers between "and" and "or" are referenced above. Additionally, the there are differences between continuity of "operations" and "services" within the regulatory language.

Note: This does not apply to ASCs, Transplant Centers, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs.

Facilities are required to have policies and procedures which include prearranged transfer agreements, which may include written agreements or contracted arrangements with other facilities and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients. Facilities should consider all needed arrangements for the transfer of patients during an evacuation. For example, if a CAH is required to evacuate, policies and procedures should address what facilities are nearby and outside the area of disaster which could accept the CAH's patients. Additionally, the policies and procedures and facility agreements should include pre-arranged agreements for transportation between the

facilities. The arrangements should be in writing, such as Memorandums of Understanding (MOUs) and Transfer Agreements, in order to demonstrate compliance.

For RNHCIs, at § 403.748(b)(7), the term "non-medical" is added in order to accommodate the uniqueness of the RNHCI non-medical care.

Survey Procedures

- Ask to see copies of the arrangements and/or any agreements the facility has with other facilities to receive patients in the event the facility is not able to care for them during an emergency.
- Ask facility leadership to explain the arrangements in place for transportation in the event of an evacuation.

E-0026

(Issued XX-XX-17)

§403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7) §494.62(b)(7).

[(b) Policies and procedures. The [*facilities*] 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:]

(8) [(6), (6)(C)(iv), (7), or (9)] The role of the [*facility*] 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.

*[*For RNHCIs at §403.748(b):*] **Policies and procedures.** (**8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternative care site identified by emergency management officials.**

Interpretive Guidelines applies to: §403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7), §494.62(b)(7)

Note: This does not apply to Transplant Centers, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs.

Facilities must develop and implement policies and procedures that describe its role in providing care at alternate care sites during emergencies. It is expected that state or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.

Facility's policies and procedures must specifically address the facility's role in emergencies where the President declares a major disaster or emergency under the Stafford Act or an emergency under the National Emergencies Act, and the HHS Secretary declares a public health emergency Examples of 1135 waivers include some of the existing CoPs; Licensure for Physicians or others to provide services in the affected State; EMTALA; Medicare Advantage out of network providers and HIPAA.

Facilities policies and procedures should address what coordination efforts are required during a declared emergency in which a waiver of federal requirements under section 1135 of the Act has been granted by the Secretary. For example, if due to a mass casualty incident in a geographic location, an 1135 waiver may be granted to waive licensure for physicians in order for these individuals to assist at a specific facility where they do not normally practice, then the facility should have policies and procedures which outline the responsibilities during the duration of this waiver period. For instance, the policies may establish a lead person in charge for accountability and oversight of assisting physicians not usually under contract with the facility.

Additionally, facilities should also have in place policies and procedures which address emergency situations in which a declaration was not made and where an 1135 waiver may not be applicable, such as during a disaster affecting the single facility. In this case, policies and procedures should address potential transfers of patients; timelines of patients at alternate facilities, etc.

For additional 1135 Waiver information, the SCG Emergency Preparedness Website has resources.

Survey Procedures

- Verify the facility has included policies and procedures in its emergency plan describing the facility's role in providing care and treatment (except for RNHCI, for care only) at alternate care sites under an 1135 waiver.

E-0027

(Issued XX-XX-17)

§494.62(b)(8) Condition for Coverage:
[(b) Policies and procedures. The dialysis facility 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:]

(8) How emergency medical system assistance can be obtained when needed.

Interpretive Guidelines for §494.62(b)(8).

ESRD facilities must include in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed. Medical system assistance can be considered but not limited to, outside assistance such as from a nearby hospital. Additionally, this can mean assistance from other ESRD facilities including personnel to assist during a single-facility disaster.

Survey Procedures

- Verify the ESRD facility has included in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed.

E-0028

(Issued XX-XX-17)

§494.62(b)(9) Condition for Coverage:
[(b) Policies and procedures. The dialysis facility 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:]

(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

Interpretive Guidelines for §494.62(b)(9).

ESRD facilities must include policies and procedures in its emergency plan that address a process that confirms that the specific requirements listed under this standard are on the premises at all times and immediately available in the event of an emergency. The process must be in writing. It is the facilities responsibility to determine what equipment is should on the premises and available during an emergency to assist patients in an emergency. Additionally, it is the responsibility of the facility to ensure that all necessary equipment identified in this area, should be in working order at all times in accordance with the manufacturer instructions. Emergency drugs should not be out of date and should be stored and maintained based on the manufacturer instructions. The facility is in

the best position to determine what emergency equipment it needs to have available. In addition, dialysis facilities need to be able to manage care-related emergencies during an emergency when other assistance, emergency medical services systems, may not be immediately available to them.

Survey Procedures

- Verify the dialysis facility has a process in place by which its staff can confirm that emergency equipment is on the premises and immediately available.
- Verify that the process includes at least the listed emergency equipment within its emergency plan by asking to see a copy of the written processes/ policy on emergency equipment and medications.
- Check to see that all of the above equipment is available and in working order. Ask to see procedures/checklist for ensuring equipment is checked
- Check to see that all emergency drugs are not out of date.

E-TAG NON-CITABLE (No assigned tags)
Reference Only (PACE)
(Issued XX-XX-17)

§460.84(b)(10) Requirement:
[(b) Policies and procedures. The PACE organization 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.] The policies and procedures must address management of medical and non-medical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(10)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.
(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.
(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

Interpretive Guidelines for §460.84(b)(10).

PACE organizations must include policies and procedures in its emergency plan to address the requirements of this standard.

E-0029

(Issued XX-XX-17)

§403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.22(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §486.360(c), §491.12(c), §494.62(c).

(c) The [*facility*] 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.

Interpretive Guidelines applies to: §403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.22(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §486.360(c), §491.12(c), §494.62(c).

Note: This does not apply to Transplant Centers.

Facilities must have a written emergency communication plan that contains how the facility coordinates patient care within the facility, across healthcare providers, and with state and local public health departments. The communication plan should include how the facility interacts and coordinates with emergency management agencies and systems to protect patient health and safety in the event of a disaster. The development of a communication plan will support the coordination of care. The plan must be reviewed annually and updated as necessary. We are allowing facilities flexibility in how they formulate and operationalize the requirements of the communication plan.

Facilities in rural or remote areas with limited connectivity to communication methodologies such as the Internet, World Wide Web, or cellular capabilities need to ensure their communication plan addresses how they would communicate and comply with this requirement in the absence of these communication methodologies. For example, if a facility is located in a rural area, which has limited or no Internet and phone connectivity during an emergency, it must address what alternate means are available to alert local and State emergency officials. Optional communication methods facilities may consider include satellite phones, radios and short wave radios.

Survey Procedures

- Verify that the facility has a written communication plan by asking to see the plan.
- Ask to see evidence that the plan has been reviewed (and updated as necessary) on an annual basis.

E-0030

(Issued XX-XX-17)

§403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.22(c)(1), §485.68(c)(1),

§485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

[(c) The [*facility,* except RNHCIs, hospices, transplant centers, and HHAs] 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:
- **(i) Staff.**
- **(ii) Entities providing services under arrangement.**
- **(iii) Patients' physicians**
- **(iv) Other [facilities].**
- **(v) Volunteers.**

*[*For Hospitals at §482.15(c) and CAHs at §485.625(c)]* **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.**

*[*For RNHCIs at §403.748(c):*] **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) Next of kin, guardian, or custodian.**
- **(iv) Other RNHCIs.**
- **(v) Volunteers.**

*[*For ASCs at §416.45(c):*] **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) Volunteers.**

*[*For Hospices at §418.113(c):*] **The communication plan must include all of the following:**
(1) Names and contact information for the following:
- **(i) Hospice employees.**
- **(ii) Entities providing services under arrangement.**

(iii) Patients' physicians.
(iv) Other hospices.

*[*For OPOs at §486.360(c):*] **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) Volunteers.
(iv) Other OPOs.
(v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

Interpretive Guidelines applies to: §403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.22(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

Note: This does not apply to Transplant Centers.

A facility must have the contact information for those individuals and entities outlined within the standard. The requirement to have contact information for "other facilities" requires a provider or supplier to have the contact information for another provider or supplier of the same type as itself. For instance, hospitals should have contact information for other hospitals and CORFs should have contact information for other CORFs, etc. While not required, facilities may also find it prudent to have contact information for other facilities not of the same type. For instance a hospital may find it appropriate to have the contact information of LTC facilities within a reasonable geographic area, which could assist in facilitating patient transfers. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership and staff during an emergency event. Facilities which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information must be reviewed and updated as necessary at least annually. Contact information contained in the communication plan must be accurate and current. Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list.

Transplant Centers should be included in the development of the hospitals communication plans. In the case of a Medicare-approved transplant center, a communication plan needs to be developed and disseminated between the hospitals, OPO, and transplant patients. For example, if the transplant program is planning to transfer patients to another transplant center due to an emergency, the communication plan between the hospitals, the OPO, and the patient should include the responsibilities of each of the facility types to ensure continuity of care. During an emergency, should an

organ offer become available at the time the patient is at the "transferred hospital," the OPO's emergency preparedness communication plan should address how this information will be communicated to both the OPO and the patient of where their care will be continued.

Survey Procedures

- Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information.
- Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

E-0031

(Issued XX-XX-17)

§403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.22(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

[(c) The [*facility*] 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:

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

*[*For LTC Facilities at §483.73(c):*] **(2) Contact information for the following:**

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

*[*For ICF/IIDs at §483.475(c):*] **(2) Contact information for the following:**

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

Interpretive Guidelines applies to: §403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.22(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

Note: This does not apply to Transplant Centers.

A facility must have the contact information for those individuals and entities outlined within the standard. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Facilities are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information must be reviewed and updated at least annually.

Survey Procedures

- Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information.
- Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

E-0032

(Issued XX-XX-17)

§403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.22(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

[(c) The [*facility*] 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:

(3) Primary and alternate means for communicating with the following:

(i) [*Facility*] staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

*[*For ICF/IIDs at §483.475(c):*] **(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.**

Interpretive Guidelines applies to: §403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.22(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

Note: This does not apply to Transplant Centers.

Facilities are required to have primary and alternate means of communicating with staff, Federal, State, tribal, regional, and local emergency management agencies. Facilities

have the discretion to utilize alternate communication systems that best meets their needs. However, it is expected that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. We recognize that some facilities, especially in remote areas, may have difficulty using some communication systems, such as cellular phones, even in non-emergency situations, which should be outlined within their risk assessment and addressed within the communications plan. It is expected these facilities would address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency.

The communication plan should include procedures regarding when and how alternate communication methods are used, and who uses them. In addition the facility should ensure that its selected alternative means of communication is compatible with communication systems of other facilities, agencies and state and local officials it plans to communicate with during emergencies. For example, if State X local emergency officials use the SHAred RESources (SHARES) High Frequency (HF) Radio program and facility Y is trying to communicate with RACES, it may be prudent to consider if these two alternate communication systems can communicate on the same frequencies.

Facilities may seek information about the National Communication System (NCS), which offers a wide range of National Security and Emergency Preparedness communications services, the Government Emergency Telecommunications Services (GETS), the Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and SHARES. Other communication methods could include, but are not limited to, satellite phones, radio, and short wave radio. The Radio Amateur Civil Emergency Services (RACES) is an integral part of emergency management operations.

Survey Procedures

- Verify the communication plan includes primary and alternate means for communicating with facility staff, Federal, State, tribal, regional and local emergency management agencies by reviewing the communication plan.
- Ask to see the communications equipment or communication systems listed in the plan.

E-0033

(Issued XX-XX-17)

§403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6), §483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.22(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

[(c) The [*facility*] 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:

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

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). [*This provision is not required for HHAs under §484.22(c), CORFs under §485.68(c)*]

(6) [(4) or (5)]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).

*[*For RNHCIs at §403.748(c):*] **(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative.**

*[For *RHCs/FQHCs at §491.12(c):*] **(4) 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).**

Interpretive Guidelines applies to: §403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.22(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

Note: For RHCs/FQHC's the regulatory language differs under (c)(4). Additionally, a method for sharing information and medical documentation for patients under the RHC/FQHC's care, as necessary, with other health providers to maintain the continuity of care and a means of providing information about the general condition and location of patients does not apply.

Note: This does not apply to Transplant Centers.

Facilities are required to develop a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient

treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

Facilities (with the exception of HHAs, RHCs/FQHCs, and CORFs) are also required to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 and 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). Thus, facilities must have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted under 45 CFR 164.510(b)(4), to family members and others. Facilities have the flexibility to develop and maintain their own system in a manner that best meets its needs.

HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes. Section 164.510 ‘‘Uses and disclosures requiring an opportunity for the individual to agree to or to object,’’ is part of the ‘‘Standards for Privacy of Individually Identifiable Health Information,’’ commonly known as ‘‘The Privacy Rule.’’ HIPAA Privacy Regulations at 45 CFR 164.510(b)(4), ‘‘Use and disclosures for disaster relief purposes,’’ establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient’s location or general condition.

Survey Procedures

- Verify the communication plan includes a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health (or care for RNHCIs) providers to maintain the continuity of care by reviewing the communication plan.
  - For RNCHIs, verify that the method for sharing patient information is based on a requirement for the written election statement made by the patient or his or her legal representative.
- Verify the facility has developed policies and procedures that address the means the facility will use to release patient information to include the general condition and location of patients, by reviewing the communication plan

E-0034

(Issued XX-XX-17)

§403.748(c)(7), §416.54(c)(7), §418.113(c)(7) §441.184(c)(7), §482.15(c)(7), §460.84(c)(7), §483.73(c)(7), §483.475(c)(7), §484.22(c)(6), §485.68(c)(5),

§485.68(c)(5), §485.727(c)(5), §485.625(c)(7), §485.920(c)(7), §491.12(c)(5), §494.62(c)(7).

[(c) The [*facility*] 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:

(7) [(5) or (6)] A means of providing information about the [*facility's*] occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

*[*For ASCs at 416.54(c)*]: **(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.**

*[*For Inpatient Hospice at §418.113(c):*] **(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee**.

Interpretive Guidelines applies to: §403.748(c)(7), §416.54(c)(7), §418.113(c)(7), §441.184(c)(7), §460.84(c)(7), §482.15(c)(7), §483.73(c)(7); §483.475(c)(7); §484.22(c)(6); §485.68(c)(5), §485.625(c)(7); §485.727(c)(5); §485.920(c)(7); §491.12 (c)(5), §494.62(c)(7).

Note: This does not apply to outpatient hospices or Transplant Centers.

Facilities, except for transplant centers, must have a means of providing information about the facility's needs and its ability to provide assistance to the authority having jurisdiction (local and State emergency management agencies, local and state public health departments, the Incident Command Center, the Emergency Operations Center, or designee). For hospitals, CAHs, RNHCIs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, they must also have a means for providing information about their occupancy.

Occupancy reporting is considered, but not limited to, reporting the number of patients currently at the facility receiving treatment and care or the facility's occupancy percentage. The facility should consider how its occupancy affects its ability to provide assistance. For example, if the facility's occupancy is close to 100% the facility may not be able to accept patients from nearby facilities. The types of "needs" a facility may have during an emergency and should communicate to the appropriate authority would include but is not limited to, shortage of provisions such as food, water, medical supplies, assistance with evacuation and transfers, etc.

Note: The authority having jurisdiction varies by local, state and federal emergency management structures as well as the type of disaster. For example, in the event of a multi-state wildfire, the jurisdictional authority who would take over the Incident

Command Center or state-wide coordination of the disaster would likely be a fire-related agency.

We are not prescribing the means that facilities must use in disseminating the required information. However, facilities should include in its communication plan, a process to communicate the required information.

Note: As defined by the Federal Emergency Management Administration (FEMA), an Incident Command System (ICS) is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. (FEMA, 2016). The industry, as well as providers/suppliers, use various terms to refer to the same function and we have used the term ''Incident Command Center'' to mean ''Emergency Operations Center'' or ''Incident Command Post.'' Local, State, Tribal and Federal emergency preparedness officials, as well as regional healthcare coalitions, can assist facilities in the identification of their Incident Command Centers and reporting requirements dependent on an emergency.

Survey Procedures

- Verify the communication plan includes a means of providing information about the facility's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee by reviewing the communication plan.
- For hospitals, CAHs, RNHCIs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, also verify if the communication plan includes a means of providing information about their occupancy.

E-0035

(Issued XX-XX-17)

§483.73(c)(8); §483.475(c)(8)

*[*For LTC Facilities at §483.73(c) and ICF/IIDs at §483.475(c) :*]
[(c) The [*LTC facility and ICF/IID*] 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:

(8) A method for sharing information from the emergency plan, that the facility has determined is appropriate, with residents [*or clients*] and their families or representatives.

Interpretive Guidelines for §483.73(c)(8) and §483.475(c)(8).

Note: This ONLY applies to LTC Facilities and ICF/IIDs.

LTC facilities and ICF/IIDs are required to share emergency preparedness plans and policies with family members and resident representative s or client representatives, respectively. Facilities have flexibility in deciding what information from the emergency plan should be shared, as well as the timing and manner in which it should be disseminated. While we are not requiring facilities take specific steps or utilize specific strategies to share this information with residents or clients and their families or representatives, we would recommend that facilities provide a quick "Fact Sheet" or informational brochure to the family members and resident or client representatives which may highlight the major sections of the emergency plan and policies and procedures deemed appropriate by the facility. Other options include providing instructions on how to contact the facility in the event of an emergency on the public website or to include the information as part of the facility's check-in procedures. The facility may provide this information to the surveyor during the survey to demonstrate compliance with the requirement.

Survey Procedures

- Ask staff to demonstrate the method the facility has developed for sharing the emergency plan with residents or clients and their families or representatives.
- Interview residents or clients and their families or representatives and ask them if they have been given information regarding the facility's emergency plan.
- Verify the communication plan includes a method for sharing information from the emergency plan, and that the facility has determined it is appropriate with residents or clients and their families or representatives by reviewing the plan.

E-0036

(Issued XX-XX-17)

§403.748(d), §416.54(d), §418.113(d), §441.184(d), §460.84(d), §482.15(d), §483.73(d), §483.475(d), §484.22(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §486.360(d), §491.12(d), §494.62(d).

(d) Training and testing. The [*facility*] 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.

*[*For ICF/IIDs at §483.475(d):*] **Training and testing. The ICF/IID 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. The ICF/IID must meet the requirements for evacuation drills and training at §483.470(h).**

*[*For ESRD Facilities at §494.62(d):*] **Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation 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, testing and orientation program must be reviewed and updated at least annually.**

Interpretive Guidelines applies to: §403.748(d), §416.54(d), §418.113(d), §441.184(d), §482.15(d), §460.84(d), §483.73(d), §483.475(d), §484.22(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §486.360(d), §491.12(d), §494.62(d).

Note: This does not apply to Transplant Centers.

Note: The citation to §483.470(h) referenced in §483.475(d) for ICF/IIDs requirements is incorrect as this was a technical error made within the Final Rule.

An emergency preparedness training and testing program as specified in this requirement must be documented and reviewed and updated on at least an annual basis. The training and testing program must reflect the risks identified in the facility's risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location.

Training refers to a facility's responsibility to provide education and instruction to staff, contractors, and facility volunteers to ensure all individuals are aware of the emergency preparedness program. Testing is the concept in which training is operationalized and the facility is able to evaluate the effectiveness of the training as well as the overall emergency preparedness program. Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement.

Survey Procedures

- Verify that the facility has a written training and testing (and for ESRD facilities, a patient orientation) program that meets the requirements of the regulation.
- Verify the program has been reviewed and updated on, at least, an annual basis by asking for documentation of the annual review as well as any updates made.
- Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

E-0037

(Issued XX-XX-17)

§403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §484.22(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1).

(1) *Training program.* The [*facility*, except Hospices, PRTFs, PACE organizations, Hospitals, CAHs, RHCs/ FQHCs, and dialysis facilities] must do all of the following:

(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.
(ii) Provide emergency preparedness training at least annually.
(iii) Maintain documentation of all emergency preparedness training.
(iv) Demonstrate staff knowledge of emergency procedures.

*[*For Hospitals at §482.15(d) and RHCs/FQHCs at §491.12:*] **(1) Training program. The [Hospital or RHC/FQHC] must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.
(ii) Provide emergency preparedness training at least annually.
(iii) Maintain documentation of the training.
(iv) Demonstrate staff knowledge of emergency procedures.

*[*For Hospices at §418.113(d):*] **(1) Training. The hospice must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.
(ii) Demonstrate staff knowledge of emergency procedures.
(iii) Provide emergency preparedness training at least annually.
(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

*[*For PRTFs at §441.184(d):*] **(1) Training program. The PRTF must do all of the following:**

(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 roles.
(ii) After initial training, provide emergency preparedness training at least annually.
(iii) Demonstrate staff knowledge of emergency procedures.
(iv) Maintain documentation of all emergency preparedness training.

*[*For PACE at §460.84(d):*] **(1) The PACE organization must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

[For CORFs at §485.68(d):]***(1) Training. The CORF must do all of the following:**

(i) Provide 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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment.

*[*For CAHs at §485.625(d):*] **(1) Training program. The CAH must do all of the following:**

(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 roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

*[*For CMHCs at §485.920(d):*] **(1) Training. The CMHC must provide 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 roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually**.

Interpretive Guidelines applies to: §403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1),

§484.22(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1)

Note: This does not apply to Transplant Centers or ESRD facilities.

Facilities are required to provide initial training in emergency preparedness policies and procedures that are consistent with their roles in an emergency to all new and existing staff, individuals providing services under arrangement, and volunteers. This includes individuals who provide services on a per diem basis such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency.

PACE organizations and CAHs have additional requirements. PACE organizations must also provide initial training to contractors and PACE participants. CAHs must also include initial training on the following: 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.

Facilities should provide initial emergency training during orientation (or shortly thereafter) to ensure initial training is not delayed. With the exception of CORFs which must complete initial training within the first two weeks of employment, we recommend initial training be completed by the time the staff has completed the facility's new hire orientation program. Additionally, in the case of facilities with multiple locations, such as multi-campus hospitals, staff, individuals providing services under arrangement, or volunteers should be provided initial training at their specific location and when they are assigned to a new location.

Facilities have the flexibility to determine the focus of their annual training, as long as it aligns with the emergency plan and risk assessment. Ideally, annual training should be modified each year, incorporating any lessons learned from the most recent exercises, real-life emergencies that occurred in the last year and during the annual review of the facility's emergency program. For example, annual training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's annual review.

While facilities are required to provide annual training to all staff, it is up to the facility to decide what level of training each staff member will be required to complete each year based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain clinical staff may require additional topics. For example, dietary staff who prepare meals may not need to complete annual training that is focused on patient evacuation procedures. Instead, the facility may provide training that focuses on the proper preparation and storage of food in an emergency. In addition, depending on specific staff duties during an emergency, a facility may determine that documented external training is sufficient to meet some or all of the facility's annual training requirements. For example, staff who work with

radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical emergencies. It is up to the facility to decide if the external training meets the facility's requirements.

Facilities must maintain documentation of the annual training for all staff. The documentation must include the specific training completed as well as the methods used for demonstrating knowledge of the training program. Facilities have flexibility in ways to demonstrate staff knowledge of emergency procedures. The method chosen is likely based on the training delivery method. For example: computer-based or printed self-learning packets may contain a test to demonstrate knowledge. If facilities choose instructor-led training, a question and answer session could follow the training. Regardless of the method, facilities must maintain documentation that training was completed and that staff are knowledgeable of emergency procedures.

Survey Procedures

- Ask for copies of the facility's initial emergency preparedness training and annual emergency preparedness training offerings.
- Interview various staff and ask questions regarding the facility's initial and annual training course, to verify staff knowledge of emergency procedures.
- Review a sample of staff training files to verify staff have received initial and annual emergency preparedness training.

E-0038

(Issued XX-XX-17)

§494.62(d)(1): Condition for Coverage:

(d)(1) *Training program.* The dialysis facility must do all of the following:

(i) Provide 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 roles.

(ii) Provide emergency preparedness training at least annually. Staff training must:

(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and
(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.
(vi) Maintain documentation of the training.

Interpretive Guidelines for §494.62(d)(1).

The ESRD facility is required to train new and existing staff on their emergency preparedness policies and procedures on an annual basis. Additionally, individuals providing services under arrangement and volunteers are required to undergo the training as applicable to their roles and responsibilities within the facility.

Many large ESRD Networks already implement trainings for staff regarding evacuation procedures of the facilities. Through this requirement, all facilities are required to demonstrate upon survey that that staff know the current evacuation plans, alternate locations as well as their emergency contacts. Among the training, ESRD staff must be able to demonstrate knowledge on procedures for informing patients on how to disconnect themselves from a dialysis machine in the event of a disaster.

The ESRD facility must train staff on informing patients on whom to contact if the facility is closed and cannot provide treatment due to an emergency situation and how they can locate an alternate dialysis facility (e.g. Kidney Community Emergency Response Program (KCER)) or hospital that can assist them.

The ESRD facilities are expected to rearrange patient appointments if a disaster or emergency is forecasted through emergency notification channels, such as national weather forecasts. For instance, for inclement weather such as a snow storm which could cause community-wide closures and dangerous road conditions, we would expect the facility to make the appropriate arrangements for patients to receive their dialysis or be transferred into an inpatient setting to be provided with the appropriate care. Therefore, ESRD facilities may gear their training and testing program to include evacuation procedures in the event the facility is unable to close prior to an emergency.

All ESRD facility patient care staff are required to maintain current CPR certifications and all nursing staff are required to be properly trained in clinical emergency protocols that include the use of emergency equipment and emergency drugs. The training and CPR certifications must be documented and maintained on file.

Survey Procedures

- Verify the facility has an emergency preparedness training program and that it is updated annually.
- Interview staff and ask them to describe the evacuation procedures and plan.
- Verify current copies of CPR certifications for all patient care staff are on file.

E-0039

(Issued XX-XX-17)

§416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.22(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §491.12(d)(2), §494.62(d)(2).

(2) *Testing.* The [*facility*, except for LTC facilities, RNHCIs and OPOs] must conduct exercises to test the emergency plan at least annually. The [*facility*, except for RNHCIs and OPOs] must do all of the following:

****[For LTC Facilities at §483.73(d):]* (2) Testing. The LTC facility must conduct exercises to test the emergency plan at least annually, including unannounced staff drills using the emergency procedures. The LTC facility must do all of the following:]**

(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 [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [*facility*] 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.

(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.

(iii) Analyze the [*facility's*] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.

*[*For RNHCIs at §403.748 and OPOs at §486.360*] **(d)(2) Testing. The [*RNHCI and OPO*] must conduct exercises to test the emergency plan. The [*RNHCI and OPO*] must do the following:**

(i) 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.

(ii) Analyze the [*RNHCI's and OPO's*] response to and maintain documentation of all tabletop exercises, and emergency events, and revise the [*RNHCI's and OPO's*] emergency plan, as needed.

Interpretive Guidelines applies to: §403.748(d)(2), §416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2),

§484.22(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §486.360(d)(2)§491.12(d)(2), §494.62(d)(2)

Note: This does not apply to Transplant Centers.

Note: RNHCIs and OPOs are only required to annually conduct paper-based tabletop exercises to test the emergency plan. They are not required to conduct individual facility based and full-scale community-based exercises.

Facilities must on an annual basis conduct exercises to test the emergency plan, which for LTC facilities also includes unannounced staff drills using the emergency procedures. Specifically, facilities are required to conduct a tabletop exercise and participate in a full-scale community-based exercise or conduct an individual facility exercise if a community-based exercise is not available. As the term full-scale exercise may vary by sector, facilities are not required to conduct a full-scale exercise as defined by FEMA or DHS's Homeland Security Exercise and Evaluation Program (HSEEP). For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility's functional capabilities by simulating a response to an emergency that would impact the facility's operations and their given community. A full-scale exercise is also an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements. There is also definition for "community" as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so, facilities have the flexibility to participate in and conduct exercises that more realistically reflect the risks and composition of their communities. Facilities are expected to consider their physical location, agency and other facility responsibilities and needs of the community when planning or participating in their exercises. The term could, however, mean entities within a state or multi-state region.

In many areas of the country, State and local agencies (emergency management agencies and health departments) and some regional entities, such as healthcare coalitions may conduct an annual full-scale, community-based exercise in an effort to more broadly assess community-wide emergency planning, potential gaps, and the integration of response capabilities in an emergency. Facilities should actively engage these entities to identify potential opportunities, as appropriate, as they offer the facility the opportunity to not only assess their emergency plan but also better understand how they can contribute to, coordinate with, and integrate into the broader community's response during an emergency. They also provide a collective forum for assessing their communications plans to ensure they have the appropriate contacts and understand how best to engage and communicate with their state and local public health and emergency management agencies and other relevant partners, such as a local healthcare coalition, during an emergency.

Facilities are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. In doing so, they are expected to document the date, the personnel and the agency or healthcare coalition that they contacted. It is also important to note that agencies and or healthcare coalitions conducting these exercises will not have the resources to fulfill individual facility requirements and thus will only serve as a conduit for broader community engagement and coordination prior to, during and after the full-scale community-based exercise. Facilities are responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement.

Facilities are encouraged to engage with their area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. Health Care Coalitions (HCCs) are groups of individual health care and response organizations who collaborate to ensure each member has what it needs to respond to emergencies and planned events. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness. There is value in participating in HCCs for participating in strategic planning, information sharing and resource coordination. HCC's do not coordinate individual facility exercises, but rather serve as a conduit to provide an opportunity for other provider types to participate in an exercise. HCCs should communicate exercise plans with local and state emergency preparedness agencies and HCCs will benefit the entire community's preparedness. In addition, CMS does not regulate state and local government disaster planning agencies. It is the sole responsibility of the facility to be in compliance.

Facilities that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities. Facilities that elect to develop a small community-based exercise have the opportunity to not only assess their own emergency preparedness plans but also better understand the whole community's needs, identify critical interdependencies and or gaps and potentially minimize the financial impact of this requirement. For example, a LTC facility, a hospital, an ESRD facility, and a home health agency, all within a given area, could conduct a small community-based exercise to assess their individual facility plans and identify interdependencies that may impact facility evacuations and or address potential surge scenarios due to a prolonged disruption in dialysis and home health care services. Those that elect to conduct a community-based exercise should make an effort to contact their local/state emergency officials and healthcare coalitions, where appropriate, and offer them the opportunity to attend as they can provide valuable insight into the broader emergency planning and response activities in their given area.

Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe "shelter-in-place" location (e.g. foyer,

cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient's continuity of care.

Each facility is responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years. Facilities should also document the lessons learned following their tabletop and full-scale exercises and real-life emergencies and demonstrate that they have incorporated any necessary improvements in their emergency preparedness program. Facilities may complete an after action review process to help them develop an actionable after action report (AAR). The process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR. The AAR, at a minimum, should determine 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement. Lastly, facilities that are a part of a healthcare system, can elect to participate in their system's integrated and unified emergency preparedness program and exercises. However, those that do will still be responsible for documenting and demonstrating their individual facility's compliance with the exercise and training requirements.

Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the annual exercise requirements and exempts the facility for engaging in the required exercises for one year following the actual event; and facility's must be able to demonstrate this through written documentation.

For additional information and tools, please visit the CMS Survey & Certification Emergency Preparedness website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html or ASPR TRACIE.

Survey Procedures

- Ask to see documentation of the annual tabletop and full scale exercises (which may include, but is not limited to, the exercise plan, the AAR, and any additional documentation used by the facility to support the exercise.
- Ask to see the documentation of the facility's efforts to identify a full-scale community based exercise if they did not participate in one (i.e. date and personnel and agencies contacted and the reasons for the inability to participate in a community based exercise).
- Request documentation of the facility's analysis and response and how the facility updated its emergency program based on this analysis.

E-0040
(Issued XX-XX-17)

§494.62(d)(3) Condition for Coverage:
Patient orientation: Emergency preparedness patient training. The dialysis facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

Interpretive Guidelines for §494.62(d)(3).

ESRD facilities are required to implement an orientation and training program which educates patients on the emergency preparedness policies and procedures of the facility, including the requirements of the ESRD facility's emergency preparedness training program under §494.62(d)(1). For instance, the orientation and training program should include how patients would be notified of an emergency; what particular procedures they are expected to follow; communication protocols for contacting the ESRD facility and identifying an alternate location for their treatment in the event of a facility closure as well as shelter-in place.

Additionally, patients should be oriented to how they would evacuate the facility (if required) and the location of potential transfer sites or services. For instance, if an emergency situation required evacuation during a dialysis treatment, the facility must train the patient on how to safely disconnect from the machine. Additionally, in this example, if the patient was disconnected, the patient should be informed that he or she will be transferred to another facility or hospital to complete the dialysis (if required).

Ultimately, the emergency preparedness orientation and training for patients should adequately address scenarios which were identified in the ESRD facility's risk assessment and address specific actions required for the emergency situation. The orientation and training program is intended to ensure patients are informed, ready to assist themselves, and are aware of the facility procedures and resources (e.g. KCER) that can provide up to date information during and after an emergency.

Survey Procedures

- Verify the ESRD facility has implemented their policies and procedures and are actively providing orientation and training of all their patients for the emergency preparedness program.
- Interview a patient and ask them to describe their orientation to the facility in terms of emergency protocols and procedures.

E-0041
(Issued XX-XX-17)

§482.15(e) Condition for Participation:
(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)(1)(i) and (ii) of this section.

§483.73(e), §485.625(e)
(e) *Emergency and standby power systems.* The [*LTC facility and the CAH*] must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

§482.15(e)(1), §483.73(e)(1), §485.625(e)(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.**

482.15(e)(2), §483.73(e)(2), §485.625(e)(2)
***Emergency generator inspection and testing.* The [*hospital, CAH and LTC facility*] must implement the emergency power system inspection, testing, and [maintenance] requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.**

482.15(e)(3), §483.73(e)(3), §485.625(e)(3)
***Emergency generator fuel.* [*Hospitals, CAHs and LTC facilities*] 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.**

*[*For hospitals at §482.15(h), LTC at §483.73(g), and CAHs §485.625(g):]*
The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.
(v) TIA 12–5 to NFPA 99, issued August 1, 2013.
(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.
(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.
(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.
(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.
(x) TIA 12–3 to NFPA 101, issued October 22, 2013.
(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.
(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

Interpretive Guidelines applies to: 482.15(e), §485.625(e), §483.73(e).

Note: For CAHs under §485.625(e)(2) "maintenance" is not included in the regulatory language.

Note: This provision for hospitals, CAHs and LTC facilities requires these facility types to base their emergency power and stand-by systems on their emergency plan, risk assessment and policies and procedures. The determination for a generator should be made through the development of the facility's risk assessment and policies and procedures. If these facilities determine that no generator is required to meet the emergency power and stand-by systems requirements, then §§482.15(e)(1) and (2), §483.73(e)(1) and (2), §485.625(e)(1) and (2), would not apply.
However, these facility types are must continue to meet the existing provisions and requirements for their provider/supplier types under physical environment CoPs or any existing LSC guidance.

Emergency and standby power systems

CMS requires Hospitals, CAHs and LTC facilities to comply with the 2012 edition of the National Fire Protection Association (NFPA) 101 – *Life Safety Code* (LSC) and the 2012 edition of the NFPA 99 – *Health Care Facilities Code* in accordance with the Final Rule (CMS–3277–F**)**. NFPA 99 requires Hospitals, CAHs and certain LTC facilities to install, maintain, inspect and test an Essential Electric System (EES) in areas of a building where the failure of equipment or systems is likely to cause the injury or death of patients or caregivers. An EES is a system which includes an alternate source of power, distribution system, and associated equipment that is designed to ensure continuity of electricity to elected areas and functions during the interruption of normal electrical service. The EES alternate source of power for these facility types is typically a generator. (Note: LTC facilities are also expected to meet the requirements under Life Safety Code and NFPA 99 as outlined within the LTC Appendix of the SOM). In addition, NFPA 99 identifies the 2010 edition of NFPA 110 – *Standard for Emergency and Standby Power Systems* as a mandatory reference, which addresses the performance requirements for emergency and standby power systems and includes installation, maintenance, operation, and testing requirements.

In addition to the LSC, NFPA 99 and NFPA 110 requirements, the Emergency Preparedness regulation requires all Hospitals, CAHs, and LTC facilities to implement emergency and standby power systems based upon a facility's established emergency plan, policies, and procedures. Emergency preparedness policies and procedures (substandard (b) of the emergency preparedness requirements) are required to address the subsistence needs of staff and residents, whether the facility decides to evacuate or shelter in place. Subsistence needs include, but are not limited to, food, water, medical, and pharmaceutical supplies, and alternate sources of energy to maintain: temperatures to protect patient/resident health and safety and sanitary storage of provisions; emergency lighting; fire detection, extinguishing, and alarm systems; and sewage and waste disposal.

NFPA 99 contains emergency power requirements for emergency lighting, fire detection systems, extinguishing systems, and alarm systems. But, NFPA 99 does not specify emergency power requirements for maintaining supplies, and facility temperature requirements are limited to heating equipment for operating, delivery, labor, recovery, intensive care, coronary care, nurseries, infection/isolation rooms, emergency treatment spaces, and general patient/resident rooms. In addition, NFPA 99 does not require heating in general patient rooms during the disruption of normal power where the outside design temperature is higher than 20 degrees Fahrenheit or where a selected room(s) is provided for the needs of all patients (where patients would be internally relocated), then only that room(s) needs to be heated. Therefore, EES in Hospitals, CAHs and LTC facilities should include consideration for design to accommodate any additional electrical loads the facility determines to be necessary to meet all subsistence needs required by emergency preparedness plans, policies and procedures, unless the facility's emergency plans, policies and procedures required under paragraph (a) and paragraph (b)(1)(i) and (ii) of this section determine that the hospital, CAH or LTC facility will relocate patients internally or evacuate in the event of an emergency. Facilities may plan to evacuate all patients, or choose to relocate internally only patients located in certain locations of the facility based on the ability to meet emergency power requirements in certain locations. For example, a hospital that has the ability to maintain temperature requirements in 50 percent of the inpatient locations during a power outage, may develop an emergency plan that includes bringing in alternate power, heating and/or cooling capabilities, and the partial relocation or evacuation of patients during a power outage instead of installing additional power sources to maintain temperatures in all inpatient locations. Or a LTC facility may decide to relocate residents to a part of the facility, such as a dining or activities room, where the facility can maintain the proper temperature requirements rather than the maintaining temperature within the entire facility. It is up to each facility to make emergency power system decisions based on its risk assessment and emergency plan.

Emergency generator location

NFPA 110 contains minimum requirements and considerations for the installation and environmental conditions that may have an effect on Emergency Power Supply System (EPSS) equipment, including, building type, classification of occupancy, hazard of contents, and geographic location. NFPA 110 requires that EPSS equipment, including

generators, to be designed and located to minimize damage (e.g., flooding). NFPA 110 requires emergency power supply systems to be permanently attached, therefore portable and mobile generators would not be permitted as an option to provide or supplement emergency power to Hospitals, CAHs or LTC facilities.

Under emergency preparedness, the regulations require that the generator and its associated equipment be located in accordance with the LSC, NFPA 99, and NFPA 110 when a new structure is built or an existing structure or building is renovated. Therefore, new structures or building renovations that occur after November 15, 2016, the effective date of the Emergency Preparedness Final Rule must consider NFPA requirements to ensure that the EPSS equipment is in a location to minimize damage.

Emergency generator inspection and testing

NFPA 110 contains routine maintenance and operational testing requirements for emergency and standby power systems, including generators. Emergency generators required by NFPA 99 and the Emergency Preparedness Final Rule must be maintained and tested in accordance with NFPA 110 requirements, which are based on manufacture recommendations, instruction manuals, and the minimum requirements of NFPA 110, Chapter 8.

Emergency generator fuel

NFPA 110 permits fuel sources for generators to be liquid petroleum products (e.g., gas, diesel), liquefied petroleum gas (e.g., propane) and natural or synthetic gas (e.g., natural gas). Generators required by NFPA 99 are designated by Class, which defines the minimum time, in hours, that an EES is designed to operate at its rated load without having to be refueled. Generators required by NFPA 99 for Hospitals, CAHs and LTC facilities are designated Class X, which defines the minimum run time as being "other time, in hours, as required by application, code or user." However, NFPA 110 does require facilities considering seismic events to maintain a minimum 96 hour fuel supply. NFPA 110 also requires that generator installations in locations where the probability of interruption of off-site (e.g., natural gas) fuel supplies is high to maintain onsite storage of an alternate fuel source sufficient to allow full output of the ESS for the specified class.

The Emergency Preparedness Final Rule requires Hospitals, CAHs and LTC facilities that maintain onsite fuel sources (e.g., gas, diesel, propane) to have a plan to keep the EES operational for the duration of emergencies as defined by the facilities emergency plan, policy and procedures, unless it evacuates. This would include maintaining fuel onsite to maintain generator operation or it could include making arrangements for fuel delivery for an emergency event. If fuel is to be delivered during an emergency event, planning should consider limitations and delays that may impact fuel delivery during an event. In addition, planning should ensure that arranged fuel supply sources will not be limited by other community demands during the same emergency event. In instances when a facility maintains onsite fuel sources and plans to evacuate during an emergency,

a sufficient amount of onsite fuel should be maintained to keep the EES operational until such time the building is evacuated.

Survey Procedures

- Verify that the hospital, CAH and LTC facility has the required emergency and standby power systems to meet the requirements of the facility's emergency plan and corresponding policies and procedures
- Review the emergency plan for "shelter in place" and evacuation plans. Based on those plans, does the facility have emergency power systems or plans in place to maintain safe operations while sheltering in place?
- For hospitals, CAHs and LTC facilities which are under construction or have existing buildings being renovated, verify the facility has a written plan to relocate the EPSS by the time construction is completed

For hospitals, CAHs and LTC facilities with generators:

- For new construction that takes place between November 15, 2016 and is completed by November 15, 2017, verify the generator is located and installed in accordance with NFPA 110 and NFPA 99 when a new structure is built or when an existing structure or building is renovated. The applicability of both NFPA 110 and NFPA 99 addresses only new, altered, renovated or modified generator locations.
- Verify that the hospitals, CAHs and LTC facilities with an onsite fuel source maintains it in accordance with NFPA 110 for their generator, and have a plan for how to keep the generator operational during an emergency, unless they plan to evacuate.

E-0042

(Issued XX-XX-17)

§416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.15(f), §483.73(f), §483.475(e), §484.22(e), §485.68(e), §485.625(f), §485.727(e), §485.920(e), §486.360(f), §491.12(e), §494.62(e).

(e) [or (f)]Integrated healthcare systems. If a [*facility*] 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 [*facility*] 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 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 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.

Interpretive Guidelines Applies to: §482.15(f), §416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.78(f), §483.73(f), §483.475(e), §484.22(e), §485.68(e), §485.625(f), §485.727(e), §485.920(e), §486.360(f), §491.12(e), §494.62(e).

***** *[For ASCs at §416.54, PRTFs at §418.113, PACE organizations at §460.84, ICF/IIDs at §483.475, HHAs at §484.22, CORFs at §485.68, Clinics and Rehab facilities at §485.727, CMHCs at §485.920, RHCs/FQHCs at §491.12, and ESRD facilities at §494.62],* the requirements for **Integrated health systems are cited as substandard (e), not (f).**

Note: This does not apply to Transplant Centers.

Healthcare systems that include multiple facilities that are each separately certified as a Medicare-participating provider or supplier have the option of developing a unified and integrated emergency preparedness program that includes all of the facilities within the healthcare system instead of each facility developing a separate emergency preparedness program. If an integrated healthcare system chooses this option, each certified facility in the system may elect to participate in the system's unified and integrated emergency program or develop its own separate emergency preparedness program. It is important to understand that healthcare systems are not required to develop a unified and integrated emergency program. Rather it is a permissible option. In addition, the separately certified facilities within the healthcare system are not required to participate in the

unified and integrated emergency preparedness program. It is simply an option for each facility. If this option is taken, the healthcare system's unified emergency preparedness program should be updated each time a facility enters or leaves the healthcare system's program.

If a healthcare system elects to have a unified emergency preparedness program, the integrated program must demonstrate that each separately certified facility within the system that elected to participate in the system's integrated program actively participated in the development of the program. Therefore, each facility should designate personnel who will collaborate with the healthcare system to develop the plan. The unified and integrated plan should include documentation that verifies each facility participated in the development of the plan. This could include the names of personnel at each facility who assisted in the development of the plan and the minutes from planning meetings. All components of the emergency preparedness program that are required to be reviewed and updated at least annually must include all participating facilities. Again, each facility must be able to prove that it was involved in the annual reviews and updates of the program. The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable.

A unified program must be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into consideration the difference in services that are provided at a LTC facility and a hospital. The unique circumstances that should be addressed at each facility would include anything that would impact operations during an emergency, such as the location of the facility, resources such as the availability of staffing, medical supplies, subsistence, patients' and residents' varying acuity and mobility at the different types of facilities in a unified healthcare system, etc.

Each separately certified facility must be capable of demonstrating during a survey that it can effectively implement the emergency preparedness program and demonstrate compliance with all emergency preparedness requirements at the individual facility level. Compliance with the emergency preparedness requirements is the individual responsibility of each separately certified facility.

The unified emergency preparedness program must include a documented community–based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. This is especially important if the facilities in a healthcare system are located across a large geographic area with differing weather conditions.

Lastly, the unified program must have a coordinated communication plan and training and testing program. For example, if the unified emergency program incorporates a central point of contact at the "system" level who assists in coordination and

communication, such as during an evacuation, each facility must have this information outlined within its individual plan.

This type of integrated healthcare system emergency program should focus the training and exercises to ensure communication plans and reporting mechanisms are seamless to the emergency management officials at state and local levels to avoid potential miscommunications between the system and the multiple facilities under its control.

The training and testing program in a unified emergency preparedness program must be developed considering all of the requirements of each facility type. For example, if a healthcare system includes, hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs must meet all of the specific regulatory requirements for each of these facility types.

Because of the many different configurations of healthcare systems, from the different types of facilities in the system, to the varied locations of the facilities, it is not possible to specify how unified training and testing programs should be developed. There is no "one size fits all" model that can be prescribed. However, if the system decides to develop a unified and integrated training and testing program, the training and testing must be developed based on the community and facility based hazards assessments at each facility that is participating in the unified emergency preparedness program. Each facility must maintain individual training records of staff and records of all required training exercises.

Survey Procedures

- Verify whether or not the facility has opted to be part of its healthcare system's unified and integrated emergency preparedness program. Verify that they are by asking to see documentation of its inclusion in the program.
- Ask to see documentation that verifies the facility within the system was actively involved in the development of the unified emergency preparedness program.
- Ask to see documentation that verifies the facility was actively involved in the annual reviews of the program requirements and any program updates.
- Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program).
- Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.

EP-043
(Issued XX-XX-17)

§482.15(g)
(g) *Transplant hospitals.* If a hospital has one or more transplant centers (as defined in § 482.70)—

(1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program; and

(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.

Interpretive Guidelines for §482.15(g).

Hospitals which have transplant centers must include within their emergency planning and preparedness process one representative, at minimum, from the transplant center. If a hospital has multiple transplant centers, each center must have at least one representative who is involved in the development and maintenance of the hospital's emergency preparedness process. The hospital must include the transplant center in its emergency plan's policies and procedures, communication plans, as well is the training and testing programs.

The hospital must also collaborate with each OPO in its designated service area (DSA) or other OPO if the hospital was granted a waiver to develop policies and procedures (protocols) that address the duties and responsibilities of each entity during an emergency.

Both the hospital and the transplant center are required to demonstrate during a survey that they have collaborated in the planning and development of the emergency program. Both are required to have written documentation of the emergency preparedness plans. However, the transplant center is not individually responsible for the emergency preparedness requirements under §482.15 (see tag [INSERT] at §482.78).

Survey Procedures

- Verify the hospital has written documentation to demonstrate that a representative of each transplant center participated in the development of the emergency program.
- Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the transplant center and the associated OPOs.

EP-044

(Issued: 09-16-16; Effective Date 11-15-16; Implementation Date: 11-15-17)

§486.360(e)

(e) *Continuity of OPO operations during an emergency.* Each OPO must have a plan to continue operations during an emergency.

(1) The OPO must develop and maintain in the protocols with transplant programs required under § 486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency.

(2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have:

(i) An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency;

(ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or

(iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.

Interpretive Guidelines for §486.360(e).

An OPO may choose to relocate to an alternate location within its DSA. For instance, if a tornado threat or major flooding was anticipated within one area, however there is another location 20 miles away for the OPO to relocate to, we would anticipate the OPO would address this within its emergency plan. Additionally, OPOs must develop mutually-agreed upon protocols that address the duties and responsibilities of the hospital, transplant center and OPO during emergencies as previously outlined (Reference Tags: 0002, 0012, 0014, 0042). Therefore, these three facility types must work together to develop and maintain policies and programs which address emergency preparedness.

Survey Procedures

- Verify that the OPO has mutually-agreed upon protocols with every certified transplant program it is associated with which includes the duties and responsibilities of the hospital, transplant program and OPO during emergencies.
- Verify that the OPO has a plan in place to ensure continuity of its operation from an alternate location during an emergency.