

State Operations Manual

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

Interpretive Guidance

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(Rev. 200, Issued: 02-21-20)

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Introduction

(Rev. 186, Issued: 03-04-19, Effective: 03-04-2019, Implementation: 03-04-2019)

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. Planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others. All facilities must develop an all-hazards emergency preparedness program and plan.

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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.102, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12

The [facility, except for Transplant *Programs*] 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, §484.102, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12.

NOTE: This does not apply to Transplant *Programs*.

NOTE: The word comprehensive is not used in the language for ASCs.

Guidance is pending and will be updated in future release.

E-0002

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§482.78 Condition of participation: Emergency preparedness for transplant *programs*. A transplant *program* 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 *program* is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

Interpretive Guidelines for §482.78.

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

Transplant *programs* 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 *program*, hospital, and OPO's duties and responsibilities during an emergency.

Survey Procedures

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

E-0003

(Rev. 169, Issued: 06-09-17, Effective: 06-09-17, Implementation: 06-09-17)

§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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.102(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.

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 *every 2 years*. The plan must do all of the following:

* [For hospitals at §482.15 and CAHs at §485.625(a):] ***Emergency Plan.*** 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.

* [For LTC Facilities at §483.73(a):] ***Emergency Plan.*** *The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually.*

* [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 *every 2 years*.

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), §484.102(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 ***Programs***.

Guidance is pending and will be updated in future release.

E-0005

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

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

Survey Procedures

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

E-0006

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years*. 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.*

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

****[For LTC facilities at §483.73(a)(1):] Emergency Plan. The LTC 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, including missing residents.

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

*[For ICF/IIDs at §483.475(a)(1):] ***Emergency Plan. The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. 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, including missing clients.**
- (2) Include strategies for addressing emergency events identified by the risk assessment.***

* [For Hospices at §418.113(a)(2):] ***Emergency Plan. The Hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. 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.

(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), §484.102(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 *Programs*.
Guidance is pending and will be updated in future release.

E-0007

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years*. 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.**

**[For LTC facilities at §483.73(a)(3):] Emergency Plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually.*

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

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), §484.102(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 *Programs* and OPOs.

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

Guidance is pending and will be updated in future release.

E-0008

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*. 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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC facilities)*. 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. **

*** [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. 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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0010

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*. 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).

Guidance is pending and will be updated in future release.

E-0011

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*. 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 *every 2 years*. 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 *2-year* 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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§ 482.78 Condition of participation: Emergency preparedness for transplant *programs*. A transplant *program* 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 *program* is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) Standard: Policies and procedures.

A transplant *program* 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 *program* must develop and maintain 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 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 *programs* must include within their emergency planning and preparedness process one representative, at minimum, from the transplant *program*. If a hospital has multiple transplant *programs*, each *program* 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 *programs* in its emergency preparedness plan policies and procedures, communication plans, as well as the training and testing programs.

Both the hospital and the transplant *programs* 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 *programs* 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 *programs* 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 *programs* and the associated OPOs.

E-0013

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.102(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 *every 2 years*.

**[For LTC facilities at §483.73(b):] Policies and procedures. The LTC 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.*

*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 *every 2 years*.**

***[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 *every 2 years* 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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0014

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§482.78(b) Standard: Protocols with hospital and OPO. A transplant *program* must develop and maintain 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 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 *programs* 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 *programs* 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 *programs* 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 *program* is not individually responsible for the emergency preparedness requirements in §482.15.

The hospital in which a transplant *program* is located (i.e., a transplant hospital) would be responsible for ensuring that the transplant *program* is involved in the development of an emergency preparedness program. This requirement does not oblige a transplant *program* that agrees to care for another transplant *program*'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 *program* that is affected by an emergency will resume its normal operations within a short period of time. However, if a transplant *program* does arrange for its patients to be transferred to another transplant *program* during an emergency, both transplant *program* 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 *program* would be added to the receiving *transplant program's* waiting lists.

Survey Procedures

- Verify the transplant *program* has developed 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 designated OPO.
- Ask to see documentation of the protocols.

E-0015

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC)*. 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 *Programs*, HHA, CORFs, CMHCs, RHCs/FQHCs, ESRD facilities.

Guidance is pending and will be updated in future release.

E-0016

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*.] 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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§484.102(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 *every 2 years*.]

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 §484.102(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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC).*] 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 *Programs*, HHAs, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, RHCs/FQHCs.

Guidance is pending and will be updated in future release.

E-0019

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§418.113(b)(2), §460.84(b)(4), §484.102(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 *every 2 years*. 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 §484.102(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), §484.102(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.

Guidance is pending and will be updated in future release.

E-0020

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC)*. 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: This does not apply to HHAs, OPOs, and Transplant *Programs*.

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

Guidance is pending and will be updated in future release.

E-0021

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§484.102(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 *every 2 years*.] 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 §484.102(b)(3).

Guidance is pending and will be updated in future release.

E-0022

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC)*.] 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 *Programs*, HHAs or OPOs.

Guidance is pending and will be updated in future release.

E-0023

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC).*] 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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0024

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC).*] 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.**

***[For Hospice at §418.113(b):] Policies and procedures. (4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.**

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), §484.102(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 Transplant *Programs*, or OPOs.

Guidance is pending and will be updated in future release.

E-0025

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC)*.] 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, there are differences between continuity of “operations” and “services” within the regulatory language.

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

Guidance is pending and will be updated in future release.

E-0026

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years (annually for LTC)*.] 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 *Programs*, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs.

Guidance is pending and will be updated in future release.

E-0027

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*.] 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

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*.] 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.

PACE - NON-CITABLE (No assigned tags)

Reference Only (PACE)

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years.*]

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 *every 2 years*. 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).

Guidance is pending and will be updated in future release.

E-0029

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.102(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 *every 2 years (annually for LTC)*.

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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0030

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 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 *every 2 years (annually for LTC)*.] 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 HHAs at §484.102(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 OPOs at §486.360(c):] **The communication plan must include all of the following:**

(2) **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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0031

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC)*.] 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, 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.**

*[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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0032

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC)*.] 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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0033

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC)*.] 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 §484.102(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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0034

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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 *every 2 years (annually for LTC)*.] 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); §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0035

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§483.73(c)(8); §483.475(c)(8)

**[For ICF/IIDs at §483.475(c):]*

[(c) The 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 every 2 years.] The communication plan must include all of the following:

**[For LTC Facilities at §483.73(c):]*

[(c) The LTC 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:

(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.

Guidance is pending and will be updated in future release.

E-0036

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§403.748(d), §416.54(d), §418.113(d), §441.184(d), §460.84(d), §482.15(d), §483.73(d), §483.475(d), §484.102(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §486.360(d), §491.12(d), §494.62(d).

**[For RNCHIs at §403.748, ASCs at §416.54, Hospice at §418.113, PRTFs at §441.184, PACE at §460.84, Hospitals at §482.15, HHAs at §484.102, CORFs at §485.68, CAHs at §486.625, “Organizations” under 485.727, CMHCs at §485.920, OPOs at §486.360, RHC/FHQs at §491.12:]*

(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 every 2 years.

[For LTC at §483.73(d):]* **(d) Training and testing. The LTC 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 *every 2 years*. The

ICF/IID must meet the requirements for evacuation drills and training at §483.470(i).

*[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 *evaluated* and updated at *every 2 years*.

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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0037

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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).

**[For RNCHIs at §403.748, ASCs at §416.54, Hospitals at §482.15, ICF/IIDs at §483.475, HHAs at §484.102, “Organizations” under §485.727, OPOs at §486.360, RHC/FQHCs at §491.12:]*

(1) Training program. 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 roles.*
- (ii) Provide emergency preparedness training at least every 2 years.*
- (iii) Maintain documentation of all emergency preparedness training.*
- (iv) Demonstrate staff knowledge of emergency procedures.*
- (v) If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and 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 *every 2 years*.
- (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.
- (v) *Maintain documentation of all emergency preparedness training.*
- (vi) *If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.*

*[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 *every 2 years*.
- (iii) Demonstrate staff knowledge of emergency procedures.
- (iv) Maintain documentation of all emergency preparedness training.
- (v) *If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.*

*[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 *every 2 years*.
- (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.
- (v) *If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.*

**[For LTC Facilities at §483.73(d):] (1) Training Program. The LTC 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.*

*[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 *every 2 years*.**
- (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.**
- (v) If the emergency preparedness policies and procedures are significantly updated, the CORF must conduct training on the updated policies and procedures.*

*[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 *every 2 years*.**
- (iii) Maintain documentation of the training.**
- (iv) Demonstrate staff knowledge of emergency procedures.**
- (v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and 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 *every 2 years*.

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), §484.102(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 *Programs* or ESRD facilities.

Guidance is pending and will be updated in future release.

E-0038

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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 *every 2 years*.

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.

(vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.

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

Guidance is pending and will be updated in future release.

E-0039

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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), §484.102(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).

**[For RNCHI at §403.748, ASCs at §416.54, HHAs at §484.102, CORFs at §485.68, OPO, “Organizations” under §485.727, CMHC at §485.920, RHC/FQHC at §491.12, ESRD Facilities at §494.62]:*

(2) Testing. The **[facility]** must conduct exercises to test the emergency plan annually. The **[facility]** must do all of the following:

- (i) Participate in a full-scale exercise that is community-based *every 2 years*; or**
 - or***
 - (A) When a community-based exercise is not accessible, *conduct a facility-based functional exercise every 2 years*; or**
 - (B) 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 *its next required* community-based or individual, facility-based *functional* exercise following the onset of the actual event.**
- (ii) Conduct an additional exercise *at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted*, that may include, but is not limited to the following:**
 - (A) A second full-scale exercise that is community-based or individual, facility-based *functional exercise*; or**
 - (B) *A mock disaster drill*; or**
 - (C) A tabletop exercise *or workshop* that *is* led by a facilitator *and includes a group discussion* 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 Hospices at 418.113(d):]*

(2) Testing for hospices that provide care in the patient’s home. The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

- (i) Participate in a full-scale exercise that is community based every 2 years; or**
 - (A) When a community based exercise is not accessible, conduct an individual facility based functional exercise every 2 years; or**
 - (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full scale community-based exercise or individual facility-based functional exercise following the onset of the emergency event.**
- (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:**

- (A) A second full-scale exercise that is community-based or a facility based functional exercise; or*
- (B) A mock disaster drill; or*
- (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*

(3) Testing for hospices that provide inpatient care directly. The hospice must conduct exercises to test the emergency plan twice per year. The hospice must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual facility-based functional exercise; or*
 - (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community based or facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an additional annual exercise that may include, but is not limited to the following:*

- (A) A second full-scale exercise that is community-based or a facility based functional exercise; or*
- (B) A mock disaster drill; or*
- (C) A tabletop exercise or workshop led by a facilitator that includes a group discussion 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 hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed.

**[For PRFTs at §441.184(d), Hospitals at §482.15(d), CAHs at §485.625(d):]*

(2) Testing. The [PRTF, Hospital, CAH] must conduct exercises to test the emergency plan twice per year. The [PRTF, Hospital, CAH] must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or*
 - (B) If the [PRTF, Hospital, CAH] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an [additional] annual exercise or and that may include, but is not limited to the following:*
 - (A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or*
 - (B) A mock disaster drill; or*

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 PACE at §460.84(d):]*

(2) Testing. The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

(B) If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

**[For LTC Facilities at §483.73(d):]*

(2) The [LTC facility] must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The [LTC facility, ICF/IID] must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise.

(B) If the [LTC facility] facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator includes a group discussion, 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 [LTC facility] facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [LTC facility] facility's emergency plan, as needed.

**[For ICF/IIDs at §483.475(d)]:*

(2) Testing. The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

(B) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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 ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

**[For OPOs at §486.360]*

(d)(2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise *or workshop* at least annually. A tabletop exercise is led by a facilitator *and includes a group discussion*, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. *If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt*

from engaging in its next required testing exercise following the onset of the emergency event.

(ii) Analyze the 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), §484.102(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 *Programs*.

Guidance is pending and will be updated in future release.

E-0040

(Rev. 169, Issued: 06-09-17, Effective: 06-09-17, Implementation: 06-09-17)

§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

(Rev. 186, Issued: 03-04-19, Effective: 03-04-2019, Implementation: 03-04-2019)

§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](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: Hospitals, CAHs and LTC facilities are required to base their emergency power and stand-by systems on their emergency plans and risk assessments, and including the policies and procedures for hospitals. The determination of the appropriate alternate energy source should be made through the development of the facility’s risk assessment and emergency plan. If these facilities determine that a permanent generator is not required to meet the emergency power and stand-by systems requirements for this emergency preparedness regulation, 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 must continue to meet the existing emergency power 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.

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.

If a Hospital, CAH or LTC facility determines that the use of a portable and mobile generator would be the best way to accommodate for additional electrical loads necessary to meet subsistence needs required by emergency preparedness plans, policies and procedures, then NFPA requirements on emergency and standby power systems such as generator installation, location, inspection and testing, and fuel would not be applicable to the portable generator and associated distribution system, except for NFPA 70 - National Electrical Code. (See E-0015 for Interpretive Guidance on portable generators.)

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). The NFPA 110 generator location requirements apply to EPSS (e.g. generators) that are permanently attached and do not apply to portable and mobile generators used to provide or supplement emergency power to Hospitals, CAHs and LTC facilities. (See E-0015 for Interpretive Guidance on portable generators.)

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 be in compliance with NFPA 110 generator location requirements to be determined as being in compliance with the Emergency Preparedness regulations.

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 manufacturer 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.” The 2010 edition of 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 permanently attached 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

(Rev. 186, Issued: 03-04-19, Effective: 03-04-2019, Implementation: 03-04-2019)

§416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.15(f), §483.73(f), §483.475(e), §484.102(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), §484.102(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 §484.102, 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.

E-043

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§482.15(g)

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

(1) A representative from each transplant *program* 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 *program*, 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 *programs* must include within their emergency planning and preparedness process one representative, at minimum, from the transplant *program*. If a hospital has multiple transplant *programs*, 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 *program* in its emergency plan's policies and procedures, communication plans, as well as 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 *program* 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 *program* is not individually responsible for the emergency preparedness requirements under §482.15 (see Tag E-005 at §482.78).

Survey Procedures

- Verify the hospital has written documentation to demonstrate that a representative of each transplant *program* 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 *program* and the associated OPOs.

E-044

(Rev. 169, Issued: 06-09-17, Effective: 06-09-17, Implementation: 06-09-17)

§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.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R200SOMA</u>	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
<u>R186SOMA</u>	03/04/2019	Revisions to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types	03/04/2019	N/A
<u>R169SOM</u>	06/09/2017	New to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types	06/09/2017	N/A