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Aspen Federal Regulation Set: E 1.02 Emergency Preparedness

FED - E0000 - Initial Comments

Title Initial Comments

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline

Unless otherwise indicated, the general use of the terms "facility" or "facilities" refers to all provider and suppliers affected by this regulation. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations.

FED - E0001 - Establishment of the Emergency Program (EP)

Title Establishment of the Emergency Program (EP)

Type Condition

CFR 403.748
416.54
418.113
441.184
482.15
483.73
483.475
485.68
485.625
485.727
485.920
486.360
491.12
484.102

Regulation Definition

Interpretive Guideline

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

Guidance is pending and will be updated in future release.

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

*[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:

FED - E0002 - Establishment of the EP Program Transplant

Title Establishment of the EP Program Transplant

Type Condition

CFR 482.78

Regulation Definition

§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 Guideline

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).

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

o 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.

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FED - E0003 - Establishment of the EP Program Dialysis

Title Establishment of the EP Program Dialysis

Type Condition

CFR 494.62

Regulation Definition

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 Guideline

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

o Ask to see written or electronic documentation of the program.

FED - E0004 - Develop EP Plan, Review and Update Annually

Title Develop EP Plan, Review and Update Annually

Type Standard

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CFR 403.748(a)
416.54(a)
418.113(a)
441.184(a)
482.15(a)
483.73(a)
483.475(a)
485.68(a)
485.625(a)
485.727(a)
485.920(a)
486.360(a)
491.12(a)
494.62(a)
484.102(a)

Regulation Definition

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

Interpretive Guideline

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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.

FED - E0005 - Transplant EP Policies Included in Hospital

Title Transplant EP Policies Included in Hospital

Type Standard

CFR 482.78(a)

Regulation Definition

§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 Guideline

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

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

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FED - E0006 - Plan Based on All Hazards Risk Assessment

Title Plan Based on All Hazards Risk Assessment

Type Standard

CFR 403.748(a)(1)-(2)
416.54(a)(1)-(2)
418.113(a)(1)-(2)
441.184(a)(1)-(2)
482.15(a)(1)-(2)
483.73(a)(1)-(2)
483.475(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)
484.102(a)(1)-(2)

Regulation Definition

(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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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.

FED - E0007 - EP Program Patient Population

Title EP Program Patient Population

Type Standard

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CFR 403.748(a)(3)
416.54(a)(3)
418.113(a)(3)
441.184(a)(3)
482.15(a)(3)
483.73(a)(3)
483.475(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)
484.102(a)(3)

Regulation Definition

[(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.

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

Interpretive Guideline

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FED - E0008 - OPO Agreement, Service, Operation, Succession

Title OPO Agreement, Service, Operation, Succession

Type Standard

CFR 486.360(a)(3)

Regulation Definition

§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 Guideline

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:

- o Services the OPO would be able to provide during an emergency;
- o How the OPO plans to continue operations during an emergency;
- o Delegations of authority and succession plans.
- o 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.

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FED - E0009 - Local, State, Tribal Collaboration Process

Title Local, State, Tribal Collaboration Process

Type Standard

CFR 403.748(a)(4)
416.54(a)(4)
418.113(a)(4)
441.184(a)(4)
482.15(a)(4)
483.73(a)(4)
483.475(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)
484.102(a)(4)

Regulation Definition

[(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 Guideline

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FED - E0010 - Clinic Location- Use of Alarms and Fire

Title Clinic Location- Use of Alarms and Fire

Type Standard

CFR 485.727(a)(4)

Regulation Definition

[(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 Guideline

The Organizations' emergency plan must address the location and use of alarm systems and signals. The plan must also include the methods used for containing fires, such as fire extinguishers, sprinkler systems and other current methods used. The National Fire Protection Association (NFPA) at section A.20.1.1.1.6, recognizes that certain functions necessary for the life safety of building occupants, such as the closing of corridor doors, the operation of manual fire alarm devices, and the removal of patients from the room of fire origin, require the intervention of facility staff. Therefore, the plan should follow guidelines set forth by the NFPA.

Survey Procedures

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

FED - E0011 - CORF/Clinic Development and Fire Safety

Title CORF/Clinic Development and Fire Safety

Type Standard

CFR 485.68(a)(5)
485.727(a)(6)

Regulation Definition

[(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,

Interpretive Guideline

Guidance is pending and will be updated in future release.

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safety, and other appropriate experts.

[(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.

FED - E0012 - Transplant with OPO/Hospitals

Title Transplant with OPO/Hospitals

Type Standard

CFR 482.78(a) and 482.78(b)

Regulation Definition

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

Interpretive Guideline

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

o Verify the hospital has written documentation to demonstrate that a representative of each transplant programs participated in the development of the emergency program.

o Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the

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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.

transplant programs and the associated OPOs.

FED - E0013 - Development of EP Policies and Procedures

Title Development of EP Policies and Procedures

Type Standard

CFR 403.748(b)
416.54(b)
418.113(b)
441.184(b)
482.15(b)
483.73(b)
483.475(b)
485.68(b)
485.625(b)
485.727(b)
485.920(b)
486.360(b)
491.12(b)
494.62(b)
484.102(b)

Regulation Definition

(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

Interpretive Guideline

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plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.

*[For ESRD Facilities at §494.62(b):] Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least 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.

FED - E0014 - Hospital and OPO Mutual Policies

Title Hospital and OPO Mutual Policies

Type Standard

CFR 482.78(b)

Regulation Definition

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 Guideline

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.

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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

- o 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.
- o Ask to see documentation of the protocols.

FED - E0015 - Subsistence Needs for Staff and Patients

Title Subsistence Needs for Staff and Patients

Type Standard

CFR 403.748(b)(1)
418.113(b)(6)(iii)
441.184(b)(1)
482.15(b)(1)
483.73(b)(1)
483.475(b)(1)
485.625(b)(1)

Regulation Definition

[(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:

Interpretive Guideline

Guidance is pending and will be updated in future release.

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- (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.

FED - E0016 - Hospice Follow up for Staff

Title Hospice Follow up for Staff

Type Standard

CFR 418.113(b)(1)

Regulation Definition

(b) Policies and procedures. The hospice must develop and

Interpretive Guideline

Hospices have the flexibility to determine how best to develop these policies and procedures. For administrative

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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.

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

- o Review the emergency plan to verify it includes policies and procedures for following up with staff and patients.
- o 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.

FED - E0017 - HHA Comprehensive Assessment in Disaster

Title HHA Comprehensive Assessment in Disaster

Type Standard

CFR 484.102(b)(1)

Regulation Definition

[(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 Guideline

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

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

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FED - E0018 - Procedures for Tracking of Staff and Patients

Title Procedures for Tracking of Staff and Patients

Type Standard

CFR 403.748(b)(2)
416.54(b)(1)
418.113(b)(6)(ii) and (v)
441.184(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)

Regulation Definition

[(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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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.

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FED - E0019 - Homebound HHA/Hospice Inform EP Officials

Title Homebound HHA/Hospice Inform EP Officials

Type Standard

CFR 418.113(b)(2)
484.102(b)(2)

Regulation Definition

[(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 Guideline

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

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

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

Survey Procedures

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

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FED - E0020 - Policies for Evac. and Primary/Alt. Comm.

Title Policies for Evac. and Primary/Alt. Comm.

Type Standard

CFR 403.748(b)(3)
416.54(b)(2)
418.113(b)(6)(iii)
441.184(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)

Regulation Definition

[(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.

Interpretive Guideline

Guidance is pending and will be updated in future release.

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- (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.

FED - E0021 - HHA- Procedures for Follow up Staff/Pts.

Title HHA- Procedures for Follow up Staff/Pts.

Type Standard

CFR 484.102(b)(3)

Regulation Definition

[(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:]

Interpretive Guideline

HHAs must include in its emergency plan, procedures required of this standard.

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

HHAs policies and procedures should clearly outline what surrounding facilities, such as a hospital or a nursing home, it has a transfer arrangement with to ensure patient care is continued. Additionally, these policies and procedures should outline timelines for transferring patients or under what conditions patients would need to move. For instance, if the emergency is one which only is anticipated to have one or two days of disruption and does not

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(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.

pose immediate threat to patient health or safety (in which then the HHA should immediately transfer the patient); the HHA may rearrange services, whereas if a disaster is anticipated to last over one week or more, the HHA may need to initiate transfer of a patient as soon as possible. The policies and procedures should address these events. Additionally, the HHAs' policies and procedures must address what actions would be required due to the inability to make contact with staff or patients and reporting capabilities to the local and State emergency officials.

Survey Procedures

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

FED - E0022 - Policies/Procedures for Sheltering in Place

Title Policies/Procedures for Sheltering in Place

Type Standard

CFR 403.748(b)(4)
416.54(b)(3)
418.113(b)(6)(i)
441.184(b)(4)
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)

Regulation Definition

(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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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.

FED - E0023 - Policies/Procedures for Medical Documentation

Title Policies/Procedures for Medical Documentation

Type Standard

CFR 403.748(b)(5)
416.54(b)(4)
418.113(b)(3)
441.184(b)(5)
482.15(b)(5)
483.73(b)(5)
483.475(b)(5)
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)
484.102(b)(4)

Regulation Definition

[(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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(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.

FED - E0024 - Policies/Procedures-Volunteers and Staffing

Title Policies/Procedures-Volunteers and Staffing

Type Standard

CFR 403.748(b)(6)
416.54(b)(5)
441.184(b)(6)
482.15(b)(6)
483.73(b)(6)
483.475(b)(6)
485.68(b)(4)
485.625(b)(6)
485.727(b)(4)
485.920(b)(5)
491.12(b)(4)
494.62(b)(5)
418.113(b)(4)
484.102(b)(5)

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Regulation Definition

[(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 Guideline

Guidance is pending and will be updated in future release.

FED - E0025 - Arrangement with Other Facilities

Title Arrangement with Other Facilities

Type Standard

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CFR 403.748(b)(7)
418.113(b)(5)
441.184(b)(7)
482.15(b)(7)
483.73(b)(7)
483.475(b)(7)
485.625(b)(7)
485.920(b)(6)
494.62(b)(6)

Regulation Definition

[(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) 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

Interpretive Guideline

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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.

FED - E0026 - Roles Under a Waiver Declared by Secretary

Title Roles Under a Waiver Declared by Secretary

Type Standard

CFR 403.748(b)(8)
416.54(b)(6)
418.113(b)(6)(C)(iv)
441.184(b)(8)
482.15(b)(8)
483.73(b)(8)
483.475(b)(8)
485.625(b)(8)
485.920(b)(7)
494.62(b)(7)

Regulation Definition

[(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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Secretary, in accordance with section 1135 of Act, in the provision of care at an alternative care site identified by emergency management officials.

FED - E0027 - Dialysis Emergency Medical System Assistance

Title Dialysis Emergency Medical System Assistance

Type Standard

CFR 494.62(b)(8)

Regulation Definition

[(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 Guideline

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

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

FED - E0028 - Dialysis Emergency Equipment

Title Dialysis Emergency Equipment

Type Standard

CFR 494.62(b)(9)

Regulation Definition

[(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in

Interpretive Guideline

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

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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.

should be 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

- o 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.
- o 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.
- o 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
- o Check to see that all emergency drugs are not out of date.

FED - E0029 - Development of Communication Plan

Title Development of Communication Plan

Type Standard

CFR 403.748(c)
416.54(c)
418.113(c)
441.184(c)
482.15(c)
483.73(c)
483.475(c)
485.68(c)
485.625(c)
485.727(c)
485.920(c)
486.360(c)
491.12(c)
494.62(c)
484.102(c)

Regulation Definition

(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal,

Interpretive Guideline

Guidance is pending and will be updated in future release.

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State and local laws and must be reviewed and updated at least every 2 years (annually for LTC).

FED - E0030 - Names and Contact Information

Title Names and Contact Information

Type Standard

CFR 403.748(c)(1)
416.54(c)(1)
418.113(c)(1)
441.184(c)(1)
482.15(c)(1)
483.73(c)(1)
483.475(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)
484.102(c)(1)

Regulation Definition

[(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.

Interpretive Guideline

Guidance is pending and will be updated in future release.

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- (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.

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- (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).

FED - E0031 - Emergency Officials Contact Information

Title Emergency Officials Contact Information

Type Standard

CFR 403.748(c)(2)
416.54(c)(2)
418.113(c)(2)
441.184(c)(2)
482.15(c)(2)
483.73(c)(2)
483.475(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)
484.102(c)(2)

Regulation Definition

[(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:

Interpretive Guideline

Guidance is pending and will be updated in future release.

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(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.

FED - E0032 - Primary/Alternate Means for Communication

Title Primary/Alternate Means for Communication

Type Standard

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CFR 403.748(c)(3)
416.54(c)(3)
418.113(c)(3)
441.184(c)(3)
482.15(c)(3)
483.73(c)(3)
483.475(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)
484.102(c)(3)

Regulation Definition

[(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 Guideline

Guidance is pending and will be updated in future release.

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FED - E0033 - Methods for Sharing Information

Title Methods for Sharing Information

Type Standard

CFR 403.748(c)(4)-(6)
416.54(c)(4)-(6)
418.113(c)(4)-(6)
441.184(c)(4)-(6)
482.15(c)(4)-(6)
483.73(c)(4)-(6)
483.475(c)(4)-(6)
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)
484.102(c)(4)-(5)

Regulation Definition

(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]

Interpretive Guideline

Facilities are required to develop a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

Facilities (with the exception of HHAs, RHCs, FQHCs, and CORFs) are also required to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 and a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). Thus, facilities must have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted under 45 CFR 164.510(b)(4), to family members and others.

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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 RNHCT'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).

Facilities have the flexibility to develop and maintain their own system in a manner that best meets its needs.

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

Survey Procedures

o Verify the communication plan includes a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health (or care for RNHCIs) providers to maintain the continuity of care by reviewing the communication plan.

- For RNHCIs, verify that the method for sharing patient information is based on a requirement for the written election statement made by the patient or his or her legal representative.

o Verify the facility has developed policies and procedures that address the means the facility will use to release patient information to include the general condition and location of patients, by reviewing the communication plan

FED - E0034 - Information on Occupancy/Needs

Title Information on Occupancy/Needs

Type Standard

CFR 403.748(c)(7)
416.54(c)(7)
418.113(c)(7)
441.184(c)(7)
482.15(c)(7)
483.73(c)(7)
483.475(c)(7)
485.68(c)(5)
485.625(c)(7)
485.727(c)(5)
485.920(c)(7)
491.12(c)(5)
494.62(c)(7)
484.102(c)(6)

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Regulation Definition

[(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 Guideline

Guidance is pending and will be updated in future release.

FED - E0035 - LTC and ICF/IID Sharing Plan with Patients

Title LTC and ICF/IID Sharing Plan with Patients

Type Standard

CFR 483.73(c)(8)
483.475(c)(8)

Regulation Definition

*[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

Interpretive Guideline

LTC facilities [and ICF/IIDs are required to share emergency preparedness plans and policies with family members and resident representative s or client representatives, respectively. Facilities have flexibility in deciding what information from the emergency plan should be shared, as well as the timing and manner in which it should be disseminated. While we are not requiring facilities take specific steps or utilize specific strategies to share this

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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.

information with residents or clients and their families or representatives, we would recommend that facilities provide a quick "Fact Sheet" or informational brochure to the family members and resident or client representatives which may highlight the major sections of the emergency plan and policies and procedures deemed appropriate by the facility. Other options include providing instructions on how to contact the facility in the event of an emergency on the public website or to include the information as part of the facility's check-in procedures. The facility may provide this information to the surveyor during the survey to demonstrate compliance with the requirement.

Survey Procedures

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

FED - E0036 - EP Training and Testing

Title EP Training and Testing

Type Standard

CFR 403.748(d)
416.54(d)
418.113(d)
441.184(d)
482.15(d)
483.73(d)
483.475(d)
485.68(d)
485.625(d)
485.727(d)
485.920(d)
486.360(d)
491.12(d)
494.62(d)
484.102(d)

Regulation Definition

*[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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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§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

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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.

FED - E0037 - EP Training Program

Title EP Training Program

Type Standard

CFR 403.748(d)(1)
416.54(d)(1)
418.113(d)(1)
441.184(d)(1)
482.15(d)(1)
483.73(d)(1)
483.475(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)
484.102(d)(1)

Regulation Definition

*[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

Interpretive Guideline

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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

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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 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

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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.

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FED - E0038 - ESRD EP Training Program

Title ESRD EP Training Program

Type Standard

CFR 494.62(d)(1)

Regulation Definition

(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

Interpretive Guideline

Guidance is pending and will be updated in future release.

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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.

FED - E0039 - EP Testing Requirements

Title EP Testing Requirements

Type Standard

CFR 403.748(d)(2)
416.54(d)(2)
418.113(d)(2)
441.184(d)(2)
482.15(d)(2)
483.73(d)(2)
483.475(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)
484.102(d)(2)

Regulation Definition

*[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

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

Interpretive Guideline

Guidance is pending and will be updated in future release.

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(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

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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

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(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 PRTFs 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

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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 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

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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

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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.

FED - E0040 - ESRD Patient Orientation Training

Title ESRD Patient Orientation Training

Type Standard

CFR 494.62(d)(3)

Regulation Definition

The dialysis facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

Interpretive Guideline

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).

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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

- o 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.
- o Interview a patient and ask them to describe their orientation to the facility in terms of emergency protocols and procedures.

FED - E0041 - Hospital CAH and LTC Emergency Power

Title Hospital CAH and LTC Emergency Power

Type Standard

CFR 482.15(e)
483.73(e)
485.625(e)

Regulation Definition

(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

Interpretive Guideline

NOTE: This provision for hospitals, CAHs and LTC facilities requires these facility types to base their emergency power and stand-by systems on their emergency plan, risk assessment and policies and procedures. The determination 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

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Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

482.15(e)(2), §483.73(e)(2), §485.625(e)(2)

Emergency generator inspection and testing. The [hospital, CAH and LTC facility] must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

482.15(e)(3), §483.73(e)(3), §485.625(e)(3)

Emergency generator fuel. [Hospitals, CAHs and LTC facilities] that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

*[For hospitals at §482.15(h), LTC at §483.73(g), and CAHs §485.625(g):]

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

If any changes in this edition of the Code are incorporated by

equipment or systems is likely to cause the injury or death of patients or caregivers. An EES is a system which includes an alternate source of power, distribution system, and associated equipment that is designed to ensure continuity of electricity to elected areas and functions during the interruption of normal electrical service. The EES alternate source of power for these facility types is typically a generator. (Note: LTC facilities are also expected to meet the requirements under Life Safety Code and NFPA 99 as outlined within the LTC Appendix of the SOM). In addition, NFPA 99 identifies the 2010 edition of NFPA 110 - Standard for Emergency and Standby Power Systems as a mandatory reference, which addresses the performance requirements for emergency and standby power systems and includes installation, maintenance, operation, and testing requirements.

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

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

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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.

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 best way to accommodate for additional electrical loads necessary to meet subsistence needs required by emergency preparedness plans, policies and procedures would be through the use of a portable and mobile generator, 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 does 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 in compliance with the Emergency Preparedness regulation.

Emergency generator inspection and testing

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

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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." Current guidance 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

- o 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
 - o 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?
 - o 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 permanent generators:
- o 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.
 - o 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.

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FED - E0042 - Integrated EP Program

Title Integrated EP Program

Type Standard

CFR 416.54(e)
418.113(e)
441.184(e)
482.15(f)
483.73(f)
483.475(e)
485.68(e)
485.625(f)
485.727(e)
485.920(e)
486.360(f)
491.12(e)
494.62(e)
484.102(e)

Regulation Definition

(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

Interpretive Guideline

* [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).

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

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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.

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

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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

- o 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.
- o Ask to see documentation that verifies the facility within the system was actively involved in the development of the unified emergency preparedness program.
- o Ask to see documentation that verifies the facility was actively involved in the annual reviews of the program requirements and any program updates.
- o 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).
- o 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.

FED - E0043 - Transplant/Hospital Mutual Policies

Title Transplant/Hospital Mutual Policies

Type Standard

CFR 482.15(g)

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Regulation Definition

(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 Guideline

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

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

FED - E0044 - OPO Continuity of Operations

Title OPO Continuity of Operations

Type Standard

CFR 486.360(e)

Regulation Definition

(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

Interpretive Guideline

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

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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.

types must work together to develop and maintain policies and programs which address emergency preparedness.

Survey Procedures

o 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.

o Verify that the OPO has a plan in place to ensure continuity of its operation from an alternate location during an emergency.

FED - E9999 - Final Observations

Title Final Observations

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline