



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO19-06-ALL

DATE: February 1, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Emergency Preparedness- Updates to Appendix Z of the State Operations Manual (SOM)

Memorandum Summary

- **Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers:** On September 16, 2016, the *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (Emergency Preparedness Rule) final rule was published in the Federal Register.
- Health care providers and suppliers affected by the rule were required comply and implement all regulations by November 15, 2017.
- We are updating Appendix Z of the SOM to reflect changes to add emerging infectious diseases to the definition of all-hazards approach, new Home Health Agency (HHA) citations and clarifications under alternate source power and emergency standby systems.

Background

The Emergency Preparedness Final Rule (81 Fed. Reg. 63860, September 16, 2016) sets out requirements for all providers and suppliers in regards to planning, preparing and training for emergency situations. The rule includes requirements for emergency plans, policies and procedures, communications and staff training. While there are minor variations based on the specific provider type, the rule is applicable to all providers and suppliers. The emergency preparedness requirement is a Condition of Participation/Condition for Coverage which covers the requirement for facilities to have an emergency preparedness program.

Discussion

CMS is adding “emerging infectious diseases” to the current definition of all-hazards approach. After review, CMS determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program. In light of events such as the Ebola Virus and Zika, we believe that facilities should consider preparedness and infection prevention within their all-hazards approach, which covers both natural and man-made disasters.

Additionally, since the release of the Interpretive Guidelines for Emergency Preparedness in 2017, stakeholders and providers have asked for additional clarifications related to portable/mobile generators. CMS has added guidance under Tag E0015- Alternate Source Power as well as clarifications under Tag E0042- Emergency Standby Power Systems. Facilities should use the most appropriate energy source or electrical system based on their review of their individual facility's all-hazards risks assessment and as required by existing regulations or state requirements. Regardless of the alternate sources of energy a facility chooses to utilize, it must be in accordance with local and state laws, manufacturer requirements, as well as applicable Life Safety Code (LSC) requirements.

If a facility risk assessment determines the best way to maintain temperatures, emergency lighting, fire detection and extinguishing systems and sewage and waste disposal would be through the use of a portable and mobile generator, rather than a permanent generator, then the LSC provisions such as generator testing, maintenance, etc. outlined under the National Fire Protection Association (NFPA) guidelines requirements would not be applicable, except for NFPA 70 - National Electrical Code. However, the revisions, as the provisions under emergency preparedness themselves, **do not take away existing requirements** under LSC, physical environment or any other Conditions of Participation that a provider type is subject to (for example to maintain safe and comfortable temperatures).

Finally, in addition to minor technical edits, CMS has also made the change to the HHA citations from 482.22 to reflect the regulatory citation 484.102.

Contact: For questions regarding the Emergency Preparedness Rule, please contact SCGEmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. The information provided in this memorandum should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Karen Tritz
Acting Director

Attachment- Advanced Copy- Revised Appendix Z State Operations Manual

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human
Services (DHHS)
Centers for Medicare & Medicaid
Services (CMS)

Transmittal 169

Date: Month XX, 2018

SUBJECT: Revisions to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types

I. SUMMARY OF CHANGES: We are making minor revisions to Appendix Z to correct errors and changes in citation numbers as reflected in the table below. We've also added areas of clarification to E-0015 related to use of alternate source power and changes to the citations for Home Health Agencies.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix Z/Introduction
R	Appendix Z/E0001
R	Appendix Z/E0004
R	Appendix Z/E0006
R	Appendix Z/E0009
R	Appendix Z/E0010
R	Appendix Z/E0013
R	Appendix Z/E0015
R	Appendix Z/E0017
R	Appendix Z/E0018
R	Appendix Z/E0019
R	Appendix Z/E0021
R	Appendix Z/E0024
R	Appendix Z/E0029
R	Appendix Z/E0030
R	Appendix Z/E0031
R	Appendix Z/E0032
R	Appendix Z/E0033
R	Appendix Z/E0034

R	Appendix Z/E0036
R	Appendix Z/E0037
R	Appendix Z/E0039
R	Appendix Z/E0041
R	Appendix Z/E0042

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2016 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual

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

Interpretive Guidance

Table of Contents

(Rev. Issued 06-09-2017)

Introduction

(Rev.)

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

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

Survey Protocol

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

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

Definitions

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

Emergency: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. It requires a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) to meet the expected outcome, and commonly requires change from routine management methods to an incident command process to achieve the expected outcome (see “disaster” for important contrast between the two terms).

Reference: Assistant Secretary for Preparedness and Response (ASPR) 2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms) (November 2016).

Disaster: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. Despite a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) and change from routine management methods to an incident command/management process, the outcome is lower than expected compared with a smaller scale or lower magnitude impact (see “emergency” for important contrast between the two terms).

Reference: Assistant Secretary for Preparedness and Response (ASPR) 2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms) (November 2016).

Emergency Preparedness Program: The Emergency Preparedness Program describes a facility’s comprehensive approach to meeting the health, safety and security needs of the

facility, its staff, their patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan that is based on a Risk Assessment and incorporates an all hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

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

All-Hazards Approach: An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. *Planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others.* All facilities must develop an all-hazards emergency preparedness program and plan.

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

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

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

Table-top Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior

staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.

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

E-0001

(Rev.)

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

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

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

***[For hospitals at §482.15:] The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:**

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

Interpretive Guidelines applies to: §403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.102, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12.

NOTE: This does not apply to Transplant Centers.

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

Under this condition/requirement, facilities are required to develop an emergency preparedness program that meets all of the standards specified within the condition/requirement. The emergency preparedness program must describe a facility's

comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation. The program must also address how the facility would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made, facility). The emergency preparedness program must be reviewed annually.

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

Survey Procedures

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

E-0004

(Rev.)

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

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

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

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

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

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

Interpretive Guidelines applies to: §403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.102(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a).

NOTE: This does not apply to Transplant Centers.

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

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

- Natural disasters
- Man-made disasters,
- Facility-based disasters that include but are not limited to:
 - Care-related emergencies;
 - Equipment and utility failures, including but not limited to power, water, gas, etc.;
 - Interruptions in communication, including cyber-attacks;
 - Loss of all or portion of a facility; and
 - Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).
- *EIDs such as Influenza, Ebola, Zika Virus and others.*
 - *These EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures.*

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

Survey Procedures

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

E-0006

(Rev.)

§403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.102(a)(1)-(2), §485.68(a)(1)-(2), §485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §486.360(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2)

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

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

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

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

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

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

Interpretive Guidelines applies to: §403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.102(a)(1)-(2), §485.68(a)(1)-(2), §485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2).

NOTE: This does not apply to Transplant Centers.

Facilities are expected to develop an emergency preparedness plan that is based on the facility-based and community-based risk assessment using an “all-hazards” approach. Facilities must document both risk assessments. An example consideration may include, but is not limited to, natural disasters prevalent in a facility’s geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies. Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security’s Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ).

“Community” is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency.

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

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

- Identification of all business functions essential to the facility’s operations that should be continued during an emergency;

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

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

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

Facilities must develop strategies for addressing emergency events that were identified during the development of the facility- and community-based risk assessments. Examples of these strategies may include, but are not limited to, developing a staffing strategy if staff shortages were identified during the risk assessment or developing a surge capacity strategy if the facility has identified it would likely be requested to accept additional patients during an emergency. Facilities will also want to consider evacuation plans. For example, a facility in a large metropolitan city may plan to utilize the support of other large community facilities as alternate care sites for its patients if the facility needs to be evacuated. The facility is also expected to have a backup evacuation plan for instances in which nearby facilities are also affected by the emergency and are unable to receive patients

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

Survey Procedures

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

E-0007

(Rev.)

§403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.102(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

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

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

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

Interpretive Guidelines applies to: §403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.102(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

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

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

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

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

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

Survey Procedures

Interview leadership and ask them to describe the following:

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

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

E-0009

(Rev.)

§403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.102(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4)

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

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

* [For ESRD facilities only at §494.62(a)(4)]: **(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.**

Interpretive Guidelines applies to: §403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.102(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4).

NOTE: This does not apply to Transplant Centers.

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

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

Survey Procedures

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

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

E-0013

(Rev.)

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

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

*Additional Requirements for PACE and ESRD Facilities:

***[For PACE at §460.84(b):] Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. The policies and procedures must be reviewed and updated at least annually.**

***[For ESRD Facilities at §494.62(b):] Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.**

Interpretive Guidelines applies to: §403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.102(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §486.360(b), §491.12(b), §494.62(b).

NOTE: This does not apply to Transplant Centers.

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

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

Survey Procedures

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

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

E-0015

(Rev.)

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

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

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

(i) Food, water, medical and pharmaceutical supplies

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

***[For Inpatient Hospice at §418.113(b)(6)(iii):] Policies and procedures.**

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

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

- (A) Food, water, medical, and pharmaceutical supplies.**
- (B) Alternate sources of energy to maintain the following:**
 - (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.**
 - (2) Emergency lighting.**
 - (3) Fire detection, extinguishing, and alarm systems.**
- (C) Sewage and waste disposal.**

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

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

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

It is up to each individual facility, based on its risk assessment, to determine the most appropriate alternate energy sources to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions, emergency lighting, fire detection, extinguishing, and alarm systems, and sewage and waste disposal.

Facilities are not required to upgrade their alternate energy source or electrical systems, but after review of their risk assessment may find it prudent to make modifications.

Regardless of the alternate sources of energy a facility chooses to utilize, it must be in accordance with local and state laws, manufacturer requirements, as well as applicable LSC requirements (for example, hospitals are required to have an essential electric system with a generator that complies with NFPA 99 – Health Care Facilities Code and associate reference documents).

Facilities must establish policies and procedures that determine how required heating and cooling of their facility will be maintained during an emergency situation, as necessary, if there were a loss of the primary power source. *Facilities are not required to heat and cool the entire building evenly, but must ensure safe temperatures are maintained in those areas deemed necessary to protect patients, other people who are in the facility, and for provisions stored in the facility during the course of an emergency, as determined by the facility risk assessment. If unable to meet the temperature needs, a facility should have a relocation/evacuation plan (that may include internal relocation, relocation to other buildings on the campus or full evacuation). The relocation/evacuation should take place in a timely manner so as not to expose patients and residents to unsafe temperatures.*

Note: For LTC under 483.10(i)(6), there are additional requirements for facilities who were initially certified after October 1, 1990 who must maintain a temperature range of 71 to 81 °F.

If a facility risk assessment determines the best way to maintain temperatures, emergency lighting, fire detection and extinguishing systems and sewage and waste disposal would be through the use of a portable and mobile generator, rather than a permanent generator, then the LSC provisions such as generator testing, maintenance, etc. outlined under the NFPA guidelines requirements would not be applicable, except for NFPA 70 - National Electrical Code.

Per NFPA 70, portable and mobile generators should:

- Have all wiring to each unit installed in accordance with the requirements of any of the wiring methods in Chapter 3.*
- Be designed and located so as to minimize the hazards that might cause complete failure due to flooding, fires, icing, and vandalism.*
- Be located so that adequate ventilation is provided.*
- Be located or protected so that sparks cannot reach adjacent combustible material.*
- Be operated, tested and maintained in accordance with manufacturer, local and/or State requirements.*

For requirements regarding permanently installed generators, please refer to existing Life Safety Code and NFPA guidance.

Extension cords or other temporary wiring devices may not be used to connect electrical devices in the facility to a portable and mobile generator due to the potential for shock, fire, and tripping hazards when using such devices.

The type of protection needed for the fuel stored by the facility for use by the portable and mobile generator will depend on the amount of fuel stored and the location of the storage, as per the appropriate NFPA standard.

If a facility, has a permanent generator to maintain emergency power, LSC and NFPA 110 provisions such as generator location, testing, fuel storage and maintenance, etc.

will apply and the facility may be subject to LSC surveys to ensure compliance is met. Please also refer to Tag E0041 Emergency and Standby Power Systems for additional requirements for LTC facilities, CAHs and Hospitals.

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

As part of the cooperation and collaboration with emergency preparedness officials required by subsection (a), facilities should also confer with health department and emergency management officials, as well as healthcare coalitions, where available, to determine the types and duration of energy sources that could be available to assist them in providing care to their patient population during an emergency. As part of the risk assessment planning, facilities should determine the feasibility of relying on these sources and plan accordingly.

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

Survey Procedures

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

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

E-0017

(Rev.)

§484.102(b)(1) Condition for Participation:

[(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.]

At a minimum, the policies and procedures must address the following:]

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

Interpretive Guidelines for §484.102(b)(1).

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

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

Survey Procedures

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

E-0018

(Rev.)

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

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

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

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

***[For Inpatient Hospice at §418.113(b)(6):] Policies and procedures.**
(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.
(v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

***[For CMHCs at §485.920(b):] Policies and procedures. (2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.**

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

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

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

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

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

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

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

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

We also recommend facilities ensure they follow their evacuation procedures as outlined under this section during disasters and emergencies. Facilities are required follow all state/local mandates or requirements under most CoPs/CfCs. If your local community, region, or state declares a state of emergency and is requiring a mandatory evacuation of the area, facilities should abide by these laws and mandates.

NOTE: If an ASC is able to cancel surgeries and close (meaning there are no patients or staff in the ASC), this requirement of tracking patients and staff would no longer be applicable. Similarly to ESRD standard practices, if an emergency was imminent and

able to be predicted (i.e. inclement weather conditions, etc.) we would expect that ASCs cancel surgeries and cease operations, which would eliminate the need to track patients and staff.

Survey Procedures

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

E-0019

(Rev.)

§418.113(b)(2), §460.84(b)(4), §484.102(b)(2)

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

*[For homebound Hospice at §418.113(b)(2), PACE at §460.84(b)(4), and HHAs at §484.102(b)(2):]

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

Interpretive Guidelines applies to: §418.113(b)(2), §460.84(b)(4), §484.102(b)(2).

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

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

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

- Whether or not the patient is mobile.
- What type of life-saving equipment does the patient require?

- Is the life-saving equipment able to be transported? (E.g., Battery operated, transportable, condition of equipment, etc.)
- Does the patient have special needs? (E.g., Communication challenges, language barriers, intellectual disabilities, special dietary needs, etc.)

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

Survey Procedures

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

E-0021

(Rev.)

§484.102(b)(3) Condition of Participation:

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

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

Interpretive Guidelines for §484.102(b)(3).

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

HHAs policies and procedures should clearly outline what surrounding facilities, such as a hospital or a nursing home, it has a transfer arrangement with to ensure patient care is continued. Additionally, these policies and procedures should outline timelines for transferring patients and under what conditions patients would need to move. For instance, if the emergency is anticipated to have one or two days of disruption and does

not pose an immediate threat to patient health or safety (in which then the HHA should immediately transfer the patient); the HHA may rearrange services, whereas if a disaster is anticipated to last over one week or more, the HHA may need to initiate transfer of a patient as soon as possible. The policies and procedures should address these events. Additionally, the HHAs' policies and procedures must address what actions would be required due to the inability to make contact with staff or patients and reporting capabilities to the local and State emergency officials.

Survey Procedures

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

E-0023

(Rev.)

§403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.102(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360(b)(2), §491.12(b)(3), §494.62(b)(4).

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

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

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

- (i) Preserves patient information.**
- (ii) Protects confidentiality of patient information.**
- (iii) Secures and maintains the availability of records.**

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

confidentiality of potential and actual donor information, and secures and maintains the availability of records.

Interpretive Guidelines applies to: §403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.102(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360 (b)(2), §491.12(b)(3), §494.62(b)(4).

NOTE: This does not apply to Transplant Centers.

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

Survey Procedures

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

E-0024

(Rev.)

§403.748(b)(6), §416.54(b)(5), §418.113(b)(4), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.102(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

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

(6) [or (4), (5), or (7) as noted above] The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

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

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

Interpretive Guidelines applies to: §403.748(b)(6), §416.54(b)(5), §418.113(b)(4), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.102(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

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

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

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

Survey Procedures

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

E-0029

(Rev.)

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

(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.

Interpretive Guidelines applies to: §403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.102(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §486.360(c), §491.12(c), §494.62(c).

NOTE: This does not apply to Transplant Centers.

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

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

Survey Procedures

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

E-0030

(Rev.)

§403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

(c) The [facility, ~~except RNHCIs, hospices, transplant centers, and HHAs~~] must develop and maintain an emergency preparedness communication plan that

complies with Federal, State and local laws and must be reviewed and updated at least annually.] The communication plan must include all of the following:]

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

***[For Hospitals at §482.15(c) and CAHs at §485.625(c)] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians**
 - (iv) Other [hospitals and CAHs].**
 - (v) Volunteers.**

***[For RNHCIs at §403.748(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Next of kin, guardian, or custodian.**
 - (iv) Other RNHCIs.**
 - (v) Volunteers.**

***[For ASCs at §416.45(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians.**
 - (iv) Volunteers.**

***[For Hospices at §418.113(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Hospice employees.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians.**
 - (iv) Other hospices.**

****[For HHAs at §484.102(c):] The communication plan must include all of the following:***

- (1) Names and contact information for the following:***
- (i) Staff.***
 - (ii) Entities providing services under arrangement.***
 - (iii) Patients' physicians.***
 - (iv) Volunteers.***

***[For OPOs at §486.360(c):] The communication plan must include all of the following:**

- (2) Names and contact information for the following:**
- (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Volunteers.**
 - (iv) Other OPOs.**
 - (v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).**

Interpretive Guidelines applies to: §403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

NOTE: This does not apply to Transplant Centers.

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

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

plan between the hospitals, the OPO, and the patient should include the responsibilities of each of the facility types to ensure continuity of care. During an emergency, should an organ offer become available at the time the patient is at the “transferred hospital,” the OPO’s emergency preparedness communication plan should address how this information will be communicated to both the OPO and the patient of where their care will be continued.

Survey Procedures

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

E-0031

(Rev.)

§403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.102(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

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

(2) Contact information for the following:

- (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
- (ii) Other sources of assistance.**

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

- (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
- (ii) The State Licensing and Certification Agency.**
- (iii) The Office of the State Long-Term Care Ombudsman.**
- (iv) Other sources of assistance.**

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

- (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
- (ii) Other sources of assistance.**
- (iii) The State Licensing and Certification Agency.**
- (iv) The State Protection and Advocacy Agency.**

Interpretive Guidelines applies to: §403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.102(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

NOTE: This does not apply to Transplant Centers.

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

Survey Procedures

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

E-0032

(Rev.)

§403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.102(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

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

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

- (i) [Facility] staff.**
- (ii) Federal, State, tribal, regional, and local emergency management agencies.**

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

Interpretive Guidelines applies to: §403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.102(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

NOTE: This does not apply to Transplant Centers.

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

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

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

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

Survey Procedures

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

E-0033

(Rev.)

§403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6), §483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.102(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

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

reviewed and updated at least annually.] The communication plan must include all of the following:

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

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). [This provision is not required for HHAs under §484.102(c), CORFs under §485.68(c)]

(6) [(4) or (5)]A means of providing information about the general condition and location of patients under the [facility's] care as permitted under 45 CFR 164.510(b)(4).

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

*[For RHCs/FQHCs at §491.12(c):] **(4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).**

Interpretive Guidelines applies to: §403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.102(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

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

NOTE: This does not apply to Transplant Centers.

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

emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

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

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

Survey Procedures

- Verify the communication plan includes a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health (or care for RNHCIs) providers to maintain the continuity of care by reviewing the communication plan.
 - For 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.
- Verify the facility has developed policies and procedures that address the means the facility will use to release patient information to include the general condition and location of patients, by reviewing the communication plan

E-0034 **(Rev.)**

§403.748(c)(7), §416.54(c)(7), §418.113(c)(7) §441.184(c)(7), §482.15(c)(7), §460.84(c)(7), §483.73(c)(7), §483.475(c)(7), §484.102(c)(6), §485.68(c)(5),

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

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

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

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

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

Interpretive Guidelines applies to: §403.748(c)(7), §416.54(c)(7), §418.113(c)(7), §441.184(c)(7), §460.84(c)(7), §482.15(c)(7), §483.73(c)(7); §483.475(c)(7); §484.102(c)(6); §485.68(c)(5), §485.625(c)(7); §485.727(c)(5); §485.920(c)(7); §491.12 (c)(5), §494.62(c)(7).

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

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

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

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

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

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

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

Survey Procedures

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

E-0036

(Rev.)

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

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

***[For ICF/IIDs at §483.475(d):] Training and testing. The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this**

section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at §483.470(h).

***[For ESRD Facilities at §494.62(d):] Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing and orientation program must be reviewed and updated at least annually.**

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

NOTE: This does not apply to Transplant Centers.

NOTE: The citation to §483.470(h) referenced in §483.475(d) for ICF/IIDs requirements is incorrect as this was a technical error made within the Final Rule. An emergency preparedness training and testing program as specified in this requirement must be documented and reviewed and updated on at least an annual basis. The training and testing program must reflect the risks identified in the facility's risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location.

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

Survey Procedures

- Verify that the facility has a written training and testing (and for ESRD facilities, a patient orientation) program that meets the requirements of the regulation.
- Verify the program has been reviewed and updated on, at least, an annual basis by asking for documentation of the annual review as well as any updates made.

- Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

E-0037

(Rev.)

§403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §**484.102**(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1).

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

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

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

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

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

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

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

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

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

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

- (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least annually.**
- (iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.**
- (iv) Maintain documentation of all training.**

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

- (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least annually.**
- (iii) Maintain documentation of the training.**
- (iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment.**

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

- (i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least annually.**
- (iii) Maintain documentation of the training.**
- (iv) Demonstrate staff knowledge of emergency procedures.**

***[For CMHCs at §485.920(d):] (1) Training. The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.**

Interpretive Guidelines applies to: §403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §484.102(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1)

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

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

PACE organizations and CAHs have additional requirements. PACE organizations must also provide initial training to contractors and PACE participants. CAHs must also include initial training on the following: prompt reporting and extinguishing of fires; protection; and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities.

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

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

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

facility may determine that documented external training is sufficient to meet some or all of the facility's annual training requirements. For example, staff who work with radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical emergencies. It is up to the facility to decide if the external training meets the facility's requirements.

Facilities may contract with individuals providing services who also provide services in multiple surrounding areas. For instance, an ICF/IID may contract a nutritionist who also provides services in other locations. Given that these contracted individuals may provide services at multiple facilities, it may not be feasible for them to receive formal training for each of the facilities for emergency preparedness programs. The expectation is that each individual knows the facility's emergency program and their role during emergencies, however the delivery of such training is left to the facility to determine. Facilities in which these individuals provide services may develop some type of training documentation- i.e. the facility's emergency plan, important contact information, and the facility's expectation for those individuals during an emergency etc. which documents that the individual received the information/training. Furthermore, if a surveyor asks one of these individuals what their role is during a disaster, or any relevant questions, then the expectation is that the individual can describe the emergency plans/their role.

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

Survey Procedures

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

E-0039

(Rev.)

§416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §491.12(d)(2), §494.62(d)(2).

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

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

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event:

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

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

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

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

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

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

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

Interpretive Guidelines applies to: §403.748(d)(2), §416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §486.360(d)(2), §491.12(d)(2), §494.62(d)(2)

NOTE: This does not apply to Transplant Centers.

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

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

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

Facilities are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. In doing so, they are expected to document the date, the personnel and the agency or healthcare coalition that they contacted. It is also important to note that agencies and or healthcare coalitions conducting these exercises will not have the resources to fulfill individual facility requirements and thus

will only serve as a conduit for broader community engagement and coordination prior to, during and after the full-scale community-based exercise. Facilities are responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement.

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

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

Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe "shelter-in-place" location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital

admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient's continuity of care.

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

Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the annual exercise requirement and exempts the facility for engaging *in a community-based full-scale exercise or individual, facility-based mock disaster drill* for one year following the actual event; and facilities must be able to demonstrate this through written documentation. *If a facility activates its emergency plan twice in one year, then the facility would be exempt from both exercises (community-based full-scale exercise and the secondary exercise- individual, facility-based mock disaster drill, table top exercise) for one year following the actual events.*

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

Survey Procedures

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

E-0041

(Rev.)

§482.15(e) Condition for Participation:

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

§483.73(e), §485.625(e)

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

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

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

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

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

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

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

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

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

If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

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

- (i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.
- (ii) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.
- (iii) TIA 12–3 to NFPA 99, issued August 9, 2012.
- (iv) TIA 12–4 to NFPA 99, issued March 7, 2013.
- (v) TIA 12–5 to NFPA 99, issued August 1, 2013.
- (vi) TIA 12–6 to NFPA 99, issued March 3, 2014.
- (vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.
- (viii) TIA 12–1 to NFPA 101, issued August 11, 2011.
- (ix) TIA 12–2 to NFPA 101, issued October 30, 2012.
- (x) TIA 12–3 to NFPA 101, issued October 22, 2013.
- (xi) TIA 12–4 to NFPA 101, issued October 22, 2013.
- (xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

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

NOTE: For CAHs under §485.625(e)(2) “maintenance” is not included in the regulatory language.

NOTE: *Hospitals, CAHs and LTC facilities are required to base their emergency power and stand-by systems on their emergency plans and risk assessments, and including the policies and procedures for hospitals. The determination of the appropriate alternate energy source should be made through the development of the facility’s risk assessment and emergency plan. If these facilities determine that a permanent generator is not required to meet the emergency power and stand-by systems requirements for this emergency preparedness regulation, then §§482.15(e)(1) and (2), §483.73(e)(1) and (2), §485.625(e)(1) and (2), would not apply. However, these facility types must continue to meet the existing emergency power provisions and requirements for their provider/supplier types under physical environment CoPs or any existing LSC guidance.*

Emergency and standby power systems

CMS requires Hospitals, CAHs and LTC facilities to comply with the 2012 edition of the National Fire Protection Association (NFPA) 101 – Life Safety Code (LSC) and the 2012 edition of the NFPA 99 – Health Care Facilities Code in accordance with the Final Rule (CMS–3277–F). NFPA 99 requires Hospitals, CAHs and certain LTC facilities to install, maintain, inspect and test an Essential Electric System (EES) in areas of a building where the failure of equipment or systems is likely to cause the injury or death of patients or caregivers. An EES is a system which includes an alternate source of power, distribution system, and associated equipment that is designed to ensure continuity of electricity to elected areas and functions during the interruption of normal electrical service. The EES alternate source of power for these facility types is typically a generator. (**NOTE:** LTC facilities are also expected to meet the requirements under Life Safety Code and NFPA

99 as outlined within the LTC Appendix of the SOM). In addition, NFPA 99 identifies the 2010 edition of NFPA 110 – Standard for Emergency and Standby Power Systems as a mandatory reference, which addresses the performance requirements for emergency and standby power systems and includes installation, maintenance, operation, and testing requirements.

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

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

Emergency generator location

NFPA 110 contains minimum requirements and considerations for the installation and environmental conditions that may have an effect on Emergency Power Supply System (EPSS) equipment, including, building type, classification of occupancy, hazard of contents, and geographic location. NFPA 110 requires that EPSS equipment, including generators, to be designed and located to minimize damage (e.g., flooding). *The NFPA 110 generator location requirements apply to EPSS (e.g. generators) that are permanently attached and do not apply to portable and mobile generators used to provide or supplement emergency power to Hospitals, CAHs and LTC facilities. (See E-0015 for Interpretive Guidance on portable generators.)*

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

Emergency generator inspection and testing

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

Emergency generator fuel

NFPA 110 permits fuel sources for generators to be liquid petroleum products (e.g., gas, diesel), liquefied petroleum gas (e.g., propane) and natural or synthetic gas (e.g., natural gas). Generators required by NFPA 99 are designated by Class, which defines the minimum time, in hours, that an EES is designed to operate at its rated load without having to be refueled. Generators required by NFPA 99 for Hospitals, CAHs and LTC facilities are designated Class X, which defines the minimum run time as being “other time, in hours, as required by application, code or user.” *The 2010 edition of NFPA 110* also requires that generator installations in locations where the probability of interruption of off-site (e.g., natural gas) fuel supplies is high to maintain onsite storage of an alternate fuel source sufficient to allow full output of the ESS for the specified class.

The Emergency Preparedness Final Rule requires Hospitals, CAHs and LTC facilities that maintain onsite fuel sources (e.g., gas, diesel, propane) to have a plan to keep the EES operational for the duration of emergencies as defined by the facilities emergency plan, policy and procedures, unless it evacuates. This would include maintaining fuel onsite to maintain generator operation or it could include making arrangements for fuel delivery for an emergency event. If fuel is to be delivered during an emergency event,

planning should consider limitations and delays that may impact fuel delivery during an event. In addition, planning should ensure that arranged fuel supply sources will not be limited by other community demands during the same emergency event. In instances when a facility maintains onsite fuel sources and plans to evacuate during an emergency, a sufficient amount of onsite fuel should be maintained to keep the EES operational until such time the building is evacuated.

Survey Procedures

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

For hospitals, CAHs and LTC facilities with *permanently attached* generators:

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

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

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

If elected, the unified and integrated emergency preparedness program must- [do all of the following:]

- (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.**
- (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.**
- (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance [with the program].**
- (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:**
 - (i) A documented community-based risk assessment, utilizing an all-hazards approach.**
 - (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.**
- (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.**

Interpretive Guidelines Applies to: §482.15(f), §416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.78(f), §483.73(f), §483.475(e), §484.102(e), §485.68(e), §485.625(f), §485.727(e), §485.920(e), §486.360(f), §491.12(e), §494.62(e).

* [For ASCs at §416.54, PRTFs at §418.113, PACE organizations at §460.84, ICF/IIDs at §483.475, HHAs at §484.102, CORFs at §485.68, Clinics and Rehab facilities at §485.727, CMHCs at §485.920, RHCs/FQHCs at §491.12, and ESRD facilities at §494.62], the requirements for **Integrated health systems are cited as substandard (e), not (f).**

NOTE: This does not apply to Transplant Centers.

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

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

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

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

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

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

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

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

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

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

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

Survey Procedures

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