



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

Ref: QSO-21-15-ALL

DATE: March 26, 2021

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Updated Guidance for Emergency Preparedness-Appendix Z of the State Operations Manual (SOM)

Memorandum Summary

- **Burden Reduction Final Rule Interpretive Guidelines:** The Centers for Medicare & Medicaid Services (CMS) is releasing interpretive guidelines and updates to Appendix Z of the State Operations Manual (SOM) as a result of the revisions of the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (CMS 3346-F) Final Rule*.
- **Expanded Guidance related to Emerging Infectious Diseases (EIDs):** CMS is also providing additional guidance based on best practices, lessons learned and general recommendations for planning and preparedness for EID outbreaks.

Background

On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published two final rules with certain provisions effective November 29, 2019. The first rule was the [*Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction \(CoPs\) \(CMS 3346-F\)*](#) (referenced to as the Burden Reduction Final Rule 84 FR 51732) which revised requirements all providers and suppliers for Emergency Preparedness. The guidance within the SOM Appendix Z has now been updated to reflect the revisions made within this Final Rule.

Additionally, in February 2019, CMS added “emerging infectious diseases” to the definition of all-hazards approach in Appendix Z as 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.

In light of the coronavirus disease 2019 (COVID-19) public health emergency (PHE), CMS is expanding the Emergency Preparedness Interpretive Guidelines to further expand on best practices, lessons learned, and planning considerations for EIDs.

Discussion

While the primary changes to Appendix Z focused on the changes as a result of the Burden Reduction Final Rule, specifically adjustment of cycles of updates required for non-long term care providers and changes to the training and testing program; CMS has also updated the guidance to reflect some of the following changes:

- Expanded surveyor guidance to ensure Life Safety Code and health surveyors communicate/collaborate surrounding potential deficiencies for alternate source energy.
- Added new definitions based on Burden Reduction Final Rule expansion of acceptable testing exercises.
- Clarified expectations surrounding documentation of the emergency program.
- Added additional guidance/considerations for EID planning stages, to include personal protective equipment (PPE).
- Added additional guidance on risk assessment considerations, to include EIDs.
- Included planning considerations for surge and staffing.
- Expanded guidance for surge planning- to include recommendations for natural disaster surge planning and EID surge planning.
- Included recommendations during PHE's for facilities to monitor Centers for Disease Control and Prevention (CDC) and other public health agencies which may issue event-specific guidance and recommendations to healthcare workers.
- Clarified existing guidance surrounding use of portable generators and maintaining temperature controls.
- Added additional planning considerations for hospices during EIDs outbreaks.
- Expanded guidance and added clarifications related to alternate care sites and 1135 Waivers.
- Expanded guidance and best practices related to reporting of facility needs, facility's ability to provide assistance and occupancy reporting.
- Revised guidance related to training and testing program as the Burden Reduction Rule extensively changed these requirements, especially for outpatient providers.
- Provided clarifications related to testing exercise exemptions when a provider/supplier experiences an actual emergency event.

Training: CMS is currently working on updates to the Emergency Preparedness Basic Surveyor Training Course to reflect the new changes. We will communicate the updated course availability at a later time.

Contact: For questions or concerns, please contact QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment- Advanced Copy- Appendix Z, State Operations Manual

cc: Survey and Operations Group Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal-Advanced Copy

Date:

**SUBJECT: Revisions to the State Operations Manual (SOM) Appendix Z
Emergency Preparedness.**

I. SUMMARY OF CHANGES: This Transmittal includes revisions based on recent federal regulation changes via (CMS–3346–F) and is a follow up to memo QSO 20-07 released on December 20, 2019. In addition to updates on the interpretive guidelines, this update also provides additional guidance on emerging infectious diseases.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: 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/Survey Protocol
R	Appendix Z/Definitions
R	Appendix Z/E-0001
R	Appendix Z/E-0003
R	Appendix Z/E-0004
R	Appendix Z/E-0006
R	Appendix Z/E-0007
R	Appendix Z/E-0008
R	Appendix Z/E-0009
R	Appendix Z/E-0010 (Old guidance prior to February 2020 reinstated without change)
R	Appendix Z/E-0013
R	Appendix Z/E-0015
R	Appendix Z/E-0016
R	Appendix Z/E-0017
R	Appendix Z/E-0018

R	Appendix Z/E-0019
R	Appendix Z/E-0020
R	Appendix Z/E-0021
R	Appendix Z/E-0022 (Old guidance prior to February 2020 reinstated without change)
R	Appendix Z/E-0023 (Old guidance prior to February 2020 reinstated without change)
R	Appendix Z/E-0024
R	Appendix Z/E-0025
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R	Appendix Z/E-0038
R	Appendix Z/E-0039
R	Appendix Z/E-0041
R	Appendix Z/E-0042
R	Appendix Z/E-0044

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

Or

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

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

State Operations Manual

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

Interpretive Guidance

Table of Contents *(Rev.)*

Transmittals for Appendix Z

§403.748, Condition of Participation for Religious Nonmedical Health Care Institutions (RNHCIs)

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

§418.113, Condition of Participation for Hospices

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

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

§482.15, Condition of Participation for Hospitals

§482.78, Requirement for Transplant Programs

§483.73, Requirement for Long-Term Care (LTC) Facilities

§483.475, Condition of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)

§484.102, Condition of Participation for Home Health Agencies (HHAs)

§485.68, Condition of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs)

§485.625, Condition of Participation for Critical Access Hospitals (CAHs)

§485.727, Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech Language Pathology Services

§485.920, Condition of Participation for Community Mental Health Centers (CMHCs)

§486.360, Condition of Participation for Organ Procurement Organizations (OPOs)

§491.12, Conditions for Certification for Rural Health Clinics (RHCs) and Conditions for Coverage for Federally Qualified Health Centers (FQHCs)

§494.62, Condition for Coverage for End-Stage Renal Disease (ESRD) Facilities

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 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 *emergency preparedness* 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.

While the use of healthcare coalitions are encouraged, this may not always be feasible for all providers and suppliers. For facilities participating in coalitions, the “level” of participation is not specified. However, if facilities use healthcare coalitions to conduct exercises or assist in their efforts for compliance, these efforts should be documented. The 2016 Emergency Preparedness Final Rule emphasized that healthcare facilities should continue to engage their healthcare coalitions and state hospital preparedness program (HPP) coordinators for training and guidance. We encourage healthcare facilities, particularly those in neighboring geographic areas, to build relationships that will allow facilities to share and leverage resources. For additional information, please visit <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/State-resources>.

Applicability and Format of this Appendix

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 17 provider and suppliers, *specifically Ambulatory Surgical Centers (ASCs); Critical Access Hospitals (CAHs); Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech Language Pathology Services (OPT/OSP); Community Mental Health Centers (CMHCs); Comprehensive Outpatient Rehabilitation Facilities (CORFs); End-Stage Renal Disease (ESRD) Facilities; Home Health Agencies (HHAs); Hospices; Hospitals; Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID); Long-Term Care (LTC) Facilities; Organ Procurement Organizations (OPOs); Psychiatric Residential Treatment Facilities (PRTFs); Programs of All-Inclusive Care for the Elderly (PACE); Religious Nonmedical Health Care Institutions (RNHCIs); Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs); and, Transplant Programs.*

Additionally, the term “patient(s)” within this appendix includes patients, residents and clients unless otherwise stated.

Finally, as some specific citations between providers vary, *we have specified changes in regulatory language with an asterisks and the specific language, for example:*

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

Resources

Facilities can consider using the checklists developed by Assistant Secretary for Preparedness and Response’s (ASPR’s) Technical Resources and Assistance Center and Information Exchange (TRACIE) and identify the location for each of their requirements. ASPR TRACIE developed resources and checklists created from our guidance, under <https://asprtracie.s3.amazonaws.com/documents/aspr-tracie-cms-ep-rule-long-term-care.pdf>, or see all checklists under Facility-Specific Requirement Overviews at <https://asprtracie.hhs.gov/cmsrule>. These checklists can be used by providers and suppliers, as well as the surveyors in order to have a provider-specific checklist.

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 (**EP**) 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.

Additionally, Hospitals, CAHs, LTC Facilities, Inpatient Hospices, ASCs, ICF-IIDs, RNHCIs, and ESRD facilities all have life safety from fire protection regulations that require compliance with the LSC. The LSC typically requires an emergency power

system/generator to provide **limited** emergency power in Hospitals, CAHs, LTC Facilities, Inpatient Hospice facilities, ESRD facilities and ASCs. For surveys of Hospitals, CAHs, LTC Facilities, Inpatient Hospice facilities, ESRD facilities and ASCs, health surveyors should consult with LSC surveyors when concerns related to emergency power are identified to determine if a deficiency should be cited under EP standards or LSC standards. We note, there may be instances of overlap as emergency preparedness regulations require alternate source power (E-0015) for inpatient facilities and also requires emergency standby power systems for Hospitals, CAHs and LTC facilities (E-0041).

Please note, there may be instances in which the facility chooses, as part of their risk assessment and program, to install an emergency standby power systems with a generator that is not subject to LSC or Physical Environment regulations under their provider/supplier type. In this instance, the facility should consider the requirements under standard (e) (tag E-0041) of the EP regulations related to testing, inspection, fuel and generator location.

It is critical to understand that the response process to emergency incidents may be the same for multiple hazards or risks. Facilities have the flexibility to determine how to format the documentation of their program and are not required to have a separate policy and procedure for each type of hazard. As the EP program should be comprehensive and include all potential natural or man-made disasters or EIDs, it is not unusual for surveyors to find facilities with a large volume of documentation needing review. Facilities must address each type of hazard within the emergency preparedness program, but can consolidate these policies and procedures based on the designated response without duplication within their program.

The facility should identify within their policies and procedures under what circumstances the facility would invoke particular procedures (e.g. evacuate or shelter), and actions that may vary based on the type of hazard. Also, procedures should include who would initiate the emergency preparedness response. While the documentation formatting is left to the discretion of the facility, the facility should be prepared to provide CMS with written evidence of its emergency preparedness program at the time of the survey. We also note there is no particular method in which the facility must document its review and updates (refer to more information under E-0013).

*We would **recommend** the surveyor review the program with the responsible facility representative and ask this representative to facilitate this review by referring the surveyor to the specific documentation requested.*

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

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.

Community Partners: *Community partners are considered any emergency management officials (fire, police, emergency medical services, etc.) for full-scale and community-based exercises, however can also include community partners that assist in an emergency, such as surrounding providers and suppliers.*

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/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).

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.

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.

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). *Though there is no specific number of entities required to participate in a full-scale community-based exercise, it is recommended that it be a collaborative exercise which involves, at a minimum, local or state emergency officials to develop community-based responses to potential threats.*

Functional Exercise (FE): *The Department of Homeland Security’s (DHS’s) Homeland Security Exercise and Evaluation Program (HSEEP) explains that FEs are an operations-based exercise that is designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FEs are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions. For additional details, please visit HSEEP guidelines located at https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Apr13_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da*

Mock Disaster Drill: *A mock disaster drill is a coordinated, supervised activity usually employed to validate a specific function or capability in a single agency or organization. Mock disaster drills are commonly used to provide training on new equipment, validate procedures, or practice and maintain current skills. For example, mock disaster drills may be appropriate for establishing a community-designated disaster receiving center or shelter. Mock disaster drills can also be used to determine if plans can be executed as designed, to assess whether more training is required, or to reinforce best practices. A mock disaster drill is useful as a stand-alone tool, but a series of drills can be used to prepare several organizations to collaborate in an FSE.*

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.

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.

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.

Workshop: A workshop, for the purposes of this guidance, is a planning meeting, seminar or practice session, which establishes the strategy and structure for an exercise program. We are aligning our definitions with the HSEEP guidelines. For additional details, see HSEEP guidelines at https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Apr13_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da.

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

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

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

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

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

NOTE: This does not apply to Transplant Programs.

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

NOTE: The emergency preparedness program and its elements must be reviewed and updated annually for LTC facilities at §483.73(a) . We've identified the differences in regulatory text for LTC facilities.

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 *every two years for all providers and suppliers, with the exception of LTC providers who must review their emergency program annually. All facilities are expected to make the appropriate changes to their emergency program in the event changes are required more frequently outside of their update cycles. ("Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care" Final Rule, 84 FR 51732, 51735, Sept. 30, 2019) ("Burden Reduction Rule").*

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. *As emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive emergency preparedness program should include emerging infectious diseases and pandemics during a public health emergency (PHE). The comprehensive emergency preparedness program emerging infectious disease planning should encompass how facilities will plan, coordinate and respond to a localized and widespread pandemic, similar to what is occurring with the 2019 Novel Coronavirus (COVID-19) PHE. Facilities should ensure their emergency preparedness programs are aligned with their State and local emergency plans/pandemic plans.*

Documentation and Requirements

***The emergency preparedness program must be in writing.** The requirements under the emergency preparedness Final Rule allow for documentation flexibility. While facilities are required to meet all of the provisions applicable to their provider/supplier type, how they document their efforts is subject to their discretion. We are not requiring a hard copy/paper, electronic or any particular system for meeting the requirements. It is up to each individual facility to be able to demonstrate in writing their emergency preparedness program. We would also recommend, but are not requiring, facilities to develop a crosswalk as applicable for where their documents are located. For instance, if their emergency plan is located in a binder, specify this for surveyors. If there are policies and procedures to specific standards/requirements, identify where these are located.*

Providers and suppliers are encouraged to keep documentation and their written emergency preparedness program based on the requirements for their provider type. Inpatient providers should maintain documentation and records for at least 2 years. Outpatient providers for at least four years. We are recommending this process due to the requirements related to training and testing exercises. Inpatient providers are required to have 2 exercises per year, therefore surveyors will review most recent two-years of documentation to determine compliance. For outpatient providers, testing exercises are required annually, alternating full-scale exercises every other year, with the opposite years allowing for the exercise of choice. In order to determine compliance, surveyors will be required to review at least the past 2 cycles (generally 4 years) of emergency testing exercises.

Additionally, we are not requiring approval of the Emergency Program or official “sign-off,” however, we do recommend facilities check with their State Agencies and local emergency planning coordinators (LEPCs) as some states require approval of the emergency preparedness plans as part of state licensure.

Survey Procedures

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

E-0002

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

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

Interpretive Guidelines for §482.78.

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

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

Survey Procedures

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

E-0003

(Rev.)

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

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

Interpretive Guidelines for §494.62.

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

Survey Procedures

- Ask to see written or electronic documentation of the program.
- *Verify that the ESRD facility emergency preparedness program measures plan for emergencies including, but not limited to, emergencies of fire, equipment, or power failures, care-related emergencies, including emerging infectious diseases, water supply interruption, and natural disasters likely to occur in the facility's geographic area.*

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

(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be [reviewed], and updated at least every 2 years. The plan must do all of the following:

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

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

* [For ESRD Facilities at §494.62(a):] **Emergency Plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least every 2 years.**

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

NOTE: This does not apply to Transplant Programs.

Emergency Plan- General

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 *every 2 years, with the exception for LTC facilities which must review and update their plan on an annual basis*. This *periodic 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. *While this 2-year review process (except for LTC facilities) provides more flexibilities for providers to update their program as they see fit, facilities are encouraged to continue to review and update their emergency preparedness plans and train their staff accordingly as the plan may change on a more frequent basis (84 FR at 51756).*

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.

Elements of the Emergency Plan

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).
- **Emerging infectious diseases** (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.

Emerging Infectious Diseases (EIDs)

As facilities develop or make revisions to their emergency preparedness plans, EID's are a potential threat which can impact the operations and continuity of care within a healthcare setting and should be considered. The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EID's within a facility's risk assessment ensures that facilities consider having infection prevention personnel involved in the planning, development and revisions to the emergency preparedness program, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.

Some examples of EID's may include, but are not limited to:

- *Potentially infectious Bio-Hazardous Waste*
- *Bioterrorism*
- *Pandemic Flu*
- *Highly Communicable Diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2)*

EID's may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential. Facilities should engage and coordinate with their local healthcare systems and healthcare coalitions, and their state and local health departments when deciding on ways to meet surge needs in their community.

Understanding the Terminology

CMS recognizes that there are differences in terminology used within the emergency preparedness industry pertaining to "continuity of operations" and "business continuity." We consider "continuity of business" to incorporate all continuity operations and business continuity, which involves planning to ensure business operations will continue even during a disaster. The concept of continuity is the facility's ability to continue operations or services related to patient care and to ensure patient safety and quality of care is continued in an emergency event. The emergency 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 to services that are necessary during an actual emergency (81 FR 63875-63876). For additional information related to continuity of operations, please visit the Federal Emergency Management Agency's (FEMA's) Continuity Guidance Circular at https://www.fema.gov/sites/default/files/2020-07/Continuity-Guidance-Circular_031218.pdf.

Essential Services and Continuity of Care

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. *However, we recognize that contractors may be subject to the same hardships as the community they serve, and there are no guarantees in the event of a disaster that the contractor would be able to fulfill their duties.*

The emergency plan should take into account contingency planning, such as evacuation triggers in the event essential resources provided by the contractor cannot be fulfilled.

*Finally, facilities should also include in their planning and revisions of existing plans, contracts and inventory of supply needs; availability of personal protective equipment (PPE); critical care equipment; and transportation options/needs to be prepared for surge events. **NOTE:** This is also further delineated under the facility policies and procedures required by facilities under the emergency preparedness program.*

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 *every 2 years (annually for LTC facilities)* by looking for documentation of the date of the review and updates that were made to the plan based on the review

E-0005

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

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

Interpretive Guidelines for §482.78(a).

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

Survey Procedures

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

E-0006

(Rev.)

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

[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]

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

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

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

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

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice’s ability to provide care.

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

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

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

***[For ICF/IIDs at §483.475(a):] Emergency Plan. The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:**

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

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

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

NOTE: This does not apply to Transplant Programs.

Risk Assessments Using All-Hazards Approach

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.

Though a format is not specified, facilities must document the risk assessment. 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, *including pandemics and EIDs as noted under E-0004.* This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area, *but should also include unforeseen widespread communicable diseases.* 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.

Also, a risk assessment is facility-based, which, among other things, considers a facility's patient population and vulnerabilities. Facility-based and community-based risk assessments are intended to 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 (81 FR 63876). For instance, if a facility has a population which is primarily dependent on medical equipment the risk assessment would identify a higher impact for emergencies that lead to power failures. 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).

Understanding Community-Based

“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.

Development of Risk Assessments based on the Plan

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.

Risk Assessment Considerations:

Based on the community threat and hazard identification process, facilities should select a comprehensive risk assessment tool that evaluates their risk and potential for hazards.. The comprehensive risk assessment should include all risks that could disrupt the facility's operations and necessitate emergency response planning to address the risk mitigation requirements and ensure continuity of care.

Using an all-hazards approach helps facilities consider and prepare for a variety of risks which may impact their healthcare settings. Facilities should categorize the various probable risks and hazards identified by likelihood of occurrence and further create supplemental risk assessments based on the disaster or public health emergency. For example:

- ***For power loss and potential disruptions of services:*** Facilities can consider using a heat index or heat risk assessment to identify situations which present concerns related to patient care and safety. Facilities are required to maintain safe temperatures under (b) policies and procedures (see Tag E-0015), therefore a heat risk assessment can be considered as an additional risk assessment, but is not required. Facilities may find it helpful to refer to ASPR TRACIE for the Natural Disasters Topic Collection at <https://asprtracie.hhs.gov/technical-resources/36/natural-disasters/27>.

NOTE: 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 public health emergencies, such as EIDs or pandemics:*** Facilities should consider risk assessments to include the needs of the patient population they serve in relation to a communicable or emerging infectious disease outbreak. Planning should include a process to evaluate the facility's needs based on the specific characteristics of an EID that includes, but is not limited to:
 - *Influx in need for PPE;*
 - *Considerations for screening patients and visitors; which may also include testing considerations for staff, visitors and patients for infectious diseases;*
 - *Transfers and discharges of patients;*
 - *Home-based healthcare settings;*
 - *Physical Environment, including but not limited to changes needed for distancing, isolation, or capacity/surge.*

Planning for Staffing in Emergencies:

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

Additional Specific Requirements for LTC, ICF/IIDs and Hospice:

- 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.
- 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 *facility-based and community-based, and* based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards, *such as EIDs*.

***NOTE:** Surveyors are not expected to analyze a facility's risk assessment to determine whether the identified risks are appropriate. Surveyors may take into consideration the geographic location and review the remaining standards to determine that the facility has addressed the hazards within their risk assessment through their policies and procedures. However, the intent is that surveyors review the risk assessments to determine if the facility has a risk assessment which is **facility-based and also community-based**. The facility's risk assessment should describe a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population. The ranking of priority of the hazards and the format of the risk assessment is at the discretion and expertise of the facility.*

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 every 2 years. The plan must do the following:]

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

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

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

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

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

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

Patient Population

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. *At-risk populations, in the event of emerging infectious diseases*

and communicable diseases, may also include older adults and people of any age with underlying medical conditions or who are immunocompromised, in which exposure may place them at higher risk for severe illnesses.

Mobility & Transfers

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 plan should also address ways the facility will address identified patient needs that can't be addressed by in house services in an emergency, such as just in time contracts or emergency transfers. Ultimately, the delegations of authority and succession plans need to include plans on how the facility ensures patient safety is protected and patients will receive care at the facility or if transferred, under what circumstances transfers will occur.

Surge & Staffing

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." *This does not mean that the facility must have documentation which lists each role and the designee for those roles within the same policy. Facilities may have a general plan which outlines the roles and responsibilities of the different individuals (e.g. incident commander, public information officer, patient liaison, etc.) and refers to those individuals by their titles. For example, a Facility Incident Commander may be the Facility Administrator. Also, an Emergency Department Charge Nurse of the Day may be the facility's identified person as the Safety Officer. However, if the facility chooses to follow this process without individual name identification, the individual serving in the role during the time of the survey should be able to adequately describe their role and responsibility during an emergency.*

The emergency plan should also include ways the facility will respond to identified patient needs that cannot be addressed by in-house services in an emergency, such as use of just-in-time contracts or emergency transfers. As discussed under E-0001, CMS

recognizes the variability in terminology in continuity of operations, business continuity, and other terms used by the emergency management industry. The intent behind this requirement is to ensure continuity of operations, including emergency preparedness succession planning, ultimately to ensure the facility has plans in place to continue functioning during an emergency and provide care in a safe setting, which may require some/all evacuations.

Ultimately, the delegations of authority and succession plans, which are different from the “continuity” plans, are documented plans which outline the specific individuals and alternate/successors who can activate the facilities emergency plans to ensure patient safety is protected and patients will receive care at the facility or if transferred, under what circumstances transfers will occur.

General Considerations

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 *that* the facility would be able to provide during an emergency *and any plans to address services needed that cannot be provided by the facility during an emergency as part of continuity of operations and services.*
- 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.

- *If the facility has delegations and succession plans which identifies roles and responsibilities over individual facility staff names (e.g. Safety Officer = Emergency Department Charge Nurse or Pharmacy Department Lead), identify the individual who would be designated in one of the roles and interview the individual asking them to describe their role based on the facility’s emergency program.*

E-0008

(Rev.)

§486.360(a)(3) Condition for Participation:

[(a) Emergency Plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]

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

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

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

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

Survey Procedures

Interview leadership and ask them to describe the following:

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

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

E-0009

(Rev.)

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

[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years [annually for LTC facilities]. The plan must do the following:]

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. *

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

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

NOTE: This does not apply to Transplant Programs.

Cooperation and Collaboration

While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility *must have a process 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. *While every detail of the cooperation and collaboration process is not required to be documented in writing, it is expected that the facility has documented sufficient details to support verification of the process.*

When deciding on ways to meet public health emergency needs in their community, facilities are expected to engage and coordinate with their local healthcare systems (including any emergency-related Alternate Care Sites), and their local and state health departments, and federal agency staff and also encouraged to engage with their healthcare coalitions, as applicable. Facility awareness of the state’s emergency preparedness programs and pandemic plan ensures coordination occurs with the community. Coordination should be pre-planned and facility management should know the state and local emergency contacts (further defined within a facilities communication plan).

We also note that under state licensure or their accreditation requirements, facilities may still be required to document their collaboration with local, tribal, regional, State, and Federal emergency preparedness officials. We recommend facilities contact their State Survey Agency (SA) and/or accrediting organizations (AO) to determine if any additional requirements exist.

Additional Requirement for ESRD

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.
- For ESRD facilities, ask *facility leadership to describe their process for contacting* the local public health and emergency management agency public official at least to confirm that the agency is aware of the ESRD facility’s needs in the event of an emergency and know how to contact the agencies in the event of an emergency.

E-0010

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

§485.727(a)(4) Condition for Participation:

[(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]

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

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

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

Survey Procedures

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

E-0011

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

§485.68(a)(5) Condition for Participation:

[(a) Emergency Plan. The Comprehensive Outpatient Rehabilitation Facility (CORF) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]

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

§485.727(a)(6) Condition for Participation:

[(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]

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

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

The CORF and Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services must collaborate with fire, safety and other appropriate experts to develop and maintain its

emergency plan. They must document their collaboration with these experts and include them in the 2-year review of the plan.

Survey Procedures

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

E-0012

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

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

(a) Standard: Policies and procedures.

A transplant program must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

(b) Standard: Protocols with hospital and OPO. A transplant program must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

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

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

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

Survey Procedures

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

E-0013

(Rev.)

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

(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years.

***[For LTC facilities at §483.73(b):] Policies and procedures. The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.**

*Additional Requirements for PACE and ESRD Facilities:

***[For PACE at §460.84(b):] Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. The policies and procedures must be reviewed and updated at least every 2 years.**

***[For ESRD Facilities at §494.62(b):] Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.**

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

NOTE: This does not apply to Transplant Programs.

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 also recommend that facilities include strategies and succession planning, as well as contingencies which support their response to any disaster or public health emergency (also see requirements at E-0024).*

Facilities should also consider updates to their emergency preparedness policies and procedures during a disaster, including planning for an emergency event with a duration longer than expected. For instance, during public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue event-specific guidance and recommendations to healthcare workers. Facilities should ensure their programs have policies in place to update or provide additional emergency preparedness procedures to staff. This may include a policy delegating an individual to monitor guidance by public health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and, any other applicable guidance in a public health emergency.

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. *We are also not specifying the type of documentation- i.e. hard copy, electronic or other system-based emergency plans.*

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.

Furthermore, since the format of the documentation is at the discretion of the facility, surveyors can identify a facility's reviews and updates of the emergency program through meeting minutes (facilities need to be clear if the entire program or any specific policy was reviewed and updated); through electronic or hard copy signatures on the table of contents of the emergency program documentation; or another manner. Facilities should clearly document the date of review and update and what the update entailed.

For ESRD and PACE Organizations, the policies and procedures must align with the risk assessment and also include specific policies related to fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. Care related emergencies may be specific to the patient

population served within these healthcare entities; as a result, the facility should ensure that in the event of any EID, there are policies and procedures in place which protect the health and safety of patients, to include but not limited to disinfection of patient stations for ESRDs and notification of transportation considerations with local government and community providers. We would expect ESRD and PACE Organizations to encompass care related emergencies within their policies and procedures.

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 *at least every 2 years (annually for LTC facilities). Format is at the discretion of the facility.*

E-0014

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

482.78(b) Standard: Protocols with hospital and OPO. A transplant program must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

Interpretive Guidelines for §482.78(b).

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

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

The hospital in which a transplant program is located (i.e., a transplant hospital) would be responsible for ensuring that the transplant program is involved in the development of an emergency preparedness program. This requirement does not oblige a transplant program that agrees to care for another transplant program's patients during an emergency to put those patients on its waiting lists. We anticipate that most emergencies would be of short duration and that the transplant program that is affected by an emergency will resume its

normal operations within a short period of time. However, if a transplant program does arrange for its patients to be transferred to another transplant program during an emergency, both transplant program would need to determine what care would be provided to the transferring patients, including whether and under what circumstances the patients from the transferring transplant program would be added to the receiving transplant program's waiting lists.

Survey Procedures

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

E-0015

(Rev.)

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

[(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:

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

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

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

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

- (iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:**
 - (A) Food, water, medical, and pharmaceutical supplies.**
 - (B) Alternate sources of energy to maintain the following:**

- (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.
 - (2) Emergency lighting.
 - (3) Fire detection, extinguishing, and alarm systems.
- (C) Sewage and waste disposal.

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

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

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.

Provisions

There are no requirements or standards establishing a set amount of provisions to be provided in facilities. *However, some states laws or accrediting organization requirements do specify a set amount or duration of subsistence items to have on hand, therefore facilities should check with their state agencies and accrediting organizations to determine if any additional requirements exist. Facilities also are required to continue to meet existing health and safety standards, such as physical environment at §482.41(a)(1) for hospitals, which address requirements like the emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available..* 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. *Inpatient providers must ensure that they have policies and procedures that address food, water, medical/pharmaceutical needs for both staff and patients during an emergency, regardless of whether they evacuate or not. Evacuation efforts may be delayed, therefore facilities affected by this provision should account for patient and staff needs leading up to or during an evacuation.*

This standard does not apply to outpatient facilities such as ASCs, Outpatient Hospice providers, transplant programs, HHAs, CORFs, CMHCs, RHCs/FQHCs, and ESRD

facilities as it is expected that such outpatient providers would close and evacuate their patients to a safer setting during the emergency.

Alternate Energy Sources & Temperatures

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 *and continuity of treatments.*

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 *facilities* 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 (*min*) to 81 °F (*max*). *Facilities should include their Medicare [and Medicaid, as applicable] certification date[s] in the front of their plan.*

If used, portable generators should be connected to a facility's electrical circuits via a power transfer system, as recommended by the generators' manufacturer. A power transfer system typically consists of a transfer switch, generator power cord and power inlet box. In accordance with manufacturer instructions and NFPA 70, Article 400.8, individual extension cords should not be run from portable generator outlet receptacles to electrical appliances. If a facility's 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 to minimize the hazards that might cause complete failure due to flooding, fires, icing, and vandalism.
- Be located so that adequate ventilation is provided. *Typically, this may be accomplished by locating a portable or mobile generator outside of the building.*
- 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 *applicable NFPA Codes and Standards*. *If a health surveyor is unclear whether the facility is complying with the alternate sources of energy and temperature requirements, the health surveyor must consult with their LSC surveyors.*

Extension cords or other temporary wiring devices may not be used to connect electrical *equipment* in the facility to a portable and mobile generator due to the potential for shock, fire, and tripping hazards when using such devices. *For portable generators, they must be connected and provide emergency power to a facility's electrical system circuits via a power transfer system as recommended by the generator manufacturer. A power transfer system typically consists of a generator power supply cord, power inlet box mounted outside, and transfer switch connected to the facility electrical panel.*

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 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.

Sewage & Waste Disposal

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.

Additional General Guidance

As part of the cooperation and collaboration with emergency preparedness officials required *under* subsection (a) (*for example, §482.15(a)(4)*), facilities should also confer with health department and emergency management officials, 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.

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-0016

(Rev.)

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

[(b) Policies and procedures. The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

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

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

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

Hospices must develop policies and procedures that address the use of hospice employees in an emergency and the hospices' potential surge needs; accordingly, hospices should give consideration to their roles during a natural disasters and emerging infectious diseases outbreaks or pandemics. Depending on the type of emergency, hospice staff must develop policies and procedures to maintain the continuity of services to hospice patients and should account for variability in the services which they provide- including planning considerations for inpatient versus outpatient hospices and that in a given emergency either setting may need to transfer patients to different healthcare settings based on needs.

Hospices must develop policies and procedures which address the requirement 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. These policies and procedures should include considerations such as but not limited to:

- *Staffing shortages;*
- *Staff ability to provide safe care, to include any potential needs such as PPE;*
- *Care needs of the patients- inpatient or in home-based settings and potential equipment needs;*
- *Screening phone calls prior to arrival and screening questions prior to entry into a home*
- *Ways to decontaminate equipment and procedures to limit equipment taken into homes*

Additionally, since hospices must inform local and state officials of any on-duty staff or patients that they are unable to contact, the policies and procedures should align with the facility's communication plans outlined under §418.113(c). These policies and procedures should outline the timeframes for check-in with the facility's designated individual (e.g. staff check-in's every 2 or 4 hours while on shift, and every 8 while off-duty).

A level of pre-coordination activities with state and local emergency officials may be needed. Hospices should work with their state and local officials to determine how to coordinate the reporting of staff or patients who cannot be contacted. Hospices should also account for contingency planning in the event that some staff are unaccounted for and how this relates to providing patient care.

Survey Procedures

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

E-0017

(Rev.)

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

[(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years.

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

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

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

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

For example, discussions to develop individualized emergency preparedness plans could include potential disasters that the patient may face within the home such as fire hazards, flooding, tornados, *and EIDs*; 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.

Additionally, HHAs should consider potential contingency operations within their policies. For example, how will the HHA ensure the appropriate discipline/staff perform the required initial and comprehensive assessments when access to residences may be hindered due to an emergency? While some contingency plans may include requests for Section 1135(b) emergency waiver flexibility during a declared public health emergency (requiring CMS pre-approval prior to use), HHAs are encouraged to plan ahead for the potential use of alternative staffing options/professions, acting in accordance with their state scope of practice laws.

For additional information on 1135 Waivers, please visit: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities> and also the CMS Frequently Asked Questions, Emergency-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers, at https://www.cms.gov/about-cms/agency-information/emergency/downloads/consolidated_medicare_ffs_emergency_qsas.pdf

Survey Procedures

- Through record review, verify that each patient has an individualized emergency plan documented as part of the patient's comprehensive assessment.
- *Does the HHA have a process related to how to continue to meet the requirements for individualized care plans?*

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 every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:]

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

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

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

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.

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

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

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

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

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

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

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. *Additionally, tracking of staff can often be more challenging based on the mechanism used for signing in and out for payment of staff based on hours worked, especially in the event of a power failure. Facilities can consider implementing a staff tracking system such as designating an area or protocol to check in with a designated person(s) during the emergency.*

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. *While collaboration with healthcare coalitions is encouraged, it is not a requirement. Though the precise details of the actual collaboration with state and local emergency officials is not required to be documented, it is expected that sufficient information is documented to support verification of the process as part of the investigation.*

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 every 2 years. At a minimum, the policies and procedures must address the following:]

***[For homebound Hospice at §418.113(b)(2), PACE at §460.84(b)(4), and HHAs at §484.102(b)(2):] The procedures to inform State and local emergency preparedness officials about [homebound Hospice, PACE or HHA] patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.**

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

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

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

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., *electricity-dependent*, communication challenges, language barriers, intellectual disabilities, special dietary needs, etc.)
- *Is the patient a person under investigation (PUI), suspected exposure to or a confirmed case for any communicable diseases?*

Since such policies and procedures include protected health information of patients, facilities must also ensure they are in compliance with, *as 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).

A level of pre-coordination activity with state and local emergency officials may be needed. Facilities should work with their state and local officials to determine how to coordinate the reporting of staff or patients who cannot be contacted. Emergency officials may include but are not limited to, emergency management departments/agencies (such as local FEMA or ASPR representatives), the state health department, CMS State Survey Agency or local response public emergency officials. (For additional information, please see standard (c)(2) [Tag E-0031] under the Communications Plan).

Facilities should also account for contingency planning in the event that some staff are unaccounted for and how this relates to providing patient care.

Finally, a facility's policies and procedures should outline a contingency plan in the event patients require evacuation but are unable to be transferred due to a community-wide impacted emergency. See also, tag E-0022 for policy and procedure requirements addressing shelter in place.

Survey Procedures

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

E-0020

(Rev.)

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

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set

forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years *annually for LTC facilities*. At a minimum, the policies and procedures must address the following:]

[(3) or (1), (2), (6)] Safe evacuation from the [facility], which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

*[For RNHCs at §403.748(b)(3) and ASCs at §416.54(b)(2):]

Safe evacuation from the [RNHCI or ASC] which includes the following:

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

* [For CORFs at §485.68(b)(1), Clinics, Rehabilitation Agencies, OPT/Speech at §485.727(b)(1), and ESRD Facilities at §494.62(b)(2):]

Safe evacuation from the [CORF; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services; and ESRD Facilities], which includes staff responsibilities, and needs of the patients.

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

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

NOTE: This does not apply to HHAs, OPOs, and Transplant Programs.

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

Evacuations & Patient Population Considerations

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

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

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

Triaging Considerations

Additionally, facilities should consider their triaging system when coordinating the tracking and potential evacuation of patient/residents/clients. For instance, a triaging system for evacuation may consider the most critical patients first followed by those less critical and not dependent on life-saving equipment. Considerations for prioritization may be based on, among other things, acuity, mobility status (stretch-bound/wheelchair/ambulatory), and location of the unit, availability of a known transfer destination or some combination thereof. Included within this system should be who (specifically) will be tasked with making triage decisions.

Following the triaging system, staff should consider the communication of patient care requirements to the in-taking facility, such as attaching a hard copy of a standard abbreviated patient health condition/history, injuries, allergies, and treatment rendered. Another method for communicating this information, a facility could consider color coordination of triage levels (i.e. green folder with this information is for less critical patients; red folders for critical and urgent evacuated patients, etc.). Additionally, this hard copy could include family member/representative contact information.

Patient safety should be the number one priority and it is expected that facilities provide care in a safe setting, therefore any existing guidance on patient rights and safe setting (e.g. §482.13(c)(2) for hospitals) should be continued. It would be prudent for facilities to consider how they would address a situation where a patient/resident refuses to evacuate, therefore leaving a patient in an unsafe environment is not acceptable.

The facilities policies and procedures must outline primary and alternate means for communication with external sources for assistance. For instance, primary methods may be via regular telephone services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials; whereas alternate means account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance.

Triage and coordination of evacuation requires planning and communication of plans within the facility and with entities that assist in providing services such as transportation and life-saving equipment.

Survey Procedures

- Review the emergency plan to verify it includes policies and procedures for safe evacuation from the facility and that it includes all of the required elements.
- When surveying an RHC or FQHC, verify that exit signs are placed in the appropriate locations to facilitate a safe evacuation.
- *Ask staff to describe how they would handle a situation in which a patient refused to evacuate.*

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 every 2 years. At a minimum, the policies and procedures must address the following:]

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

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

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.

Since HHAs must inform local and state officials of any on-duty staff or patients that they are unable to contact, the policies and procedures should align with the facility's communication plans outlined under §418.113(c). These policies and procedures should outline the timeframes for check-in with the facility's designated individual (e.g. staff check-in's every 2 or 4 hours while on shift, and every 8 while off-duty).

A level of pre-coordination activity with state and local emergency officials may be needed. HHAs should work with their state and local officials to determine how to coordinate the reporting of staff or patients who cannot be contacted. HHAs should also accordingly account for contingency planning in the event that some staff are unaccounted for and how this relates to providing patient care.

Survey Procedures

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

E-0022

(Rev.)

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

(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and

the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:]

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

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

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

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

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

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

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

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

Survey Procedures

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

E-0023

(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 every 2 years *[annually for LTC facilities]*. At a minimum, the policies and procedures must address the following:]

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

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

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

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

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

NOTE: This does not apply to Transplant Programs.

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 preserve 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 every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:]

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

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

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

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

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

Surge Planning

Emergencies, whether natural disasters, man-made disasters or infectious disease outbreaks, stress our healthcare systems through challenges with capacity and capability. While it is not possible to predict every scenario which could result in surge situations, healthcare facilities must have policies and procedures which include emergency staffing strategies and plan for emergencies. These strategies encompass procedures to preserve the healthcare system while continuing to provide care for all patients, at the appropriate level (e.g., home-based care, outpatient, urgent care, emergency room, or hospitalization).

Facilities must have policies which address their ability to respond to a surge in patients. As required, these policies and procedures must be aligned with a facility's risk assessment, and should include planning for EIDs. Concentrated efforts will be required to mobilize all aspects of the healthcare system to reduce transmission of disease, direct people to the right level of care, and decrease the burden on the healthcare system.

Surge Planning During Natural Disasters

In most circumstances, staffing strategies and surge planning surrounding natural disasters, such as hurricanes, are generally event-specific and focus on evacuations, transfers, and staffing assistance from areas which are not impacted by the emergency.

Surge Planning for Infectious Diseases/Pandemics

Infectious diseases may rise to the level of pandemic, causing severe impact on response and staffing strategies within the healthcare system. The primary goals in planning for infectious disease pandemics are to:

- *Reduce morbidity and mortality*
- *Minimize disease transmission*
- *Protect healthcare personnel*
- *Preserve healthcare system functioning*

Surge Planning Considerations

Facilities are encouraged to consider development of policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility, such as:

- *Instructing patients to use available advice lines, patient portals, and/or on-line self-assessment tools;*
- *Call options to speak to an office/clinic staff and identification of staff to conduct telephonic interactions with patients;*
- *Development of protocols so that staff can triage and assess patients quickly;*

- *Determine algorithms to identify which patients can be managed by telephone and advised to stay home, and which patients will need to be sent for emergency care or come to your facility.*

***NOTE:** Facilities are required to have a risk assessment in accordance with E-0004, however we recommend that facilities also consider implications or evaluation of staffing needs. For instance, if a facility identifies a particular hazard, the facility should consider what staffing needs are required to ensure patients continue to receive care.*

Volunteers- Medical and Non-Medical

During an emergency, a facility may *also* 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.

While not required to use volunteers as part of their plans to supplement or increase staffing during an emergency, the facility must have policies and procedures to address plans for emergency staffing needs. This could include the types of healthcare professionals they would use to assist during an emergency.

If facilities use volunteers as part of their emergency staffing strategy, policies and procedures should clearly outline what type of volunteers would be accepted during an emergency and what role these volunteers might play. For example, a facility might decide to use Red Cross Volunteers to assist in directing incoming patients during a surge situation.

Emergency staffing strategy policies and procedures should outline how the facility would ensure healthcare professionals used for emergency staffing are credentialed, licensed (as applicable) or able to provide medical support within the facility in accordance with any state and federal laws.

Resources

Facilities are recommended to review the tools available related to planning for surge. ASPR TRACIE has developed multiple documents which could provide additional assistance during the development of policies and procedures, which include but are not limited to <https://asprtracie.s3.amazonaws.com/documents/aspr-tracie-considerations-for-the-use-of-temporary-care-locations-for-managing-seasonal-patient-surge.pdf>

Survey Procedures

- *Ask facility leadership to explain their staffing strategies. Do they use volunteers? If, no volunteers are used, does the facility have other emergency staffing strategies?*
- Verify the facility has included policies and procedures for the use of volunteers and other emergency staffing strategies in its emergency plan.
- *Verify that the facility's program includes a policy and procedure which addresses surge needs during an emergency.*

E-0025

(Rev.)

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

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:]

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

***[For PACE at §460.84(b), ICF/IIDs at §483.475(b), CAHs at §486.625(b), CMHCs at §485.920(b) and ESRD Facilities at §494.62(b):] Policies and procedures. (7) [or (6), (8)] The development of arrangements with other [facilities] [or] other providers to**

receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.

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

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

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

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

Facilities are required to have policies and procedures which include prearranged transfer agreements, which may include written agreements or contracted arrangements with other facilities and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients. Facilities should consider all needed arrangements for the transfer of patients during an evacuation. For example, if a CAH is required to evacuate, policies and procedures should address what facilities are nearby and outside the area of disaster which could accept the CAH’s patients. Additionally, the policies and procedures and facility agreements should include pre-arranged agreements for transportation between the facilities. The arrangements should be in writing, such as Memorandums of Understanding (MOUs) and Transfer Agreements, in order to demonstrate compliance.

When developing transfer agreements, facilities should take into account the patient population and the ability for the receiving facility to provide continuity of services. For example, if facility X has a transfer arrangement with facility Y, however facility Y is not able to accommodate and provide continuity of care due to the nature of the emergency, lack of resources, etc., contingency plans should be implemented. Facility X should have to plan accordingly to have the patient receive services at another facility, not facility Y. For ICFs/IID and LTC facilities, the facility is also responsible for the tracking of residents, therefore any written arrangements should account for the patient population, number of patients and the ability for the receiving facility or facilities to continue care to the residents/patients.

Finally, as the regulation requires policies and procedures to be reviewed every 2 years (annually for LTC), facilities should also consider reviewing their developed arrangements on the same scheduled review timeframe to ensure the

contract/agreement/MOU is still applicable and able to be fulfilled to provide continuity of care.

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

Survey Procedures

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

E-0026

(Rev.)

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

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:]

(8) [(6), (6)(C)(iv), (7), or (9)] The role of the [facility] under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

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

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

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

General

The facility's emergency preparedness program must include policies and procedures which outline the facility's role in the provision of care and treatment under section 1135 waivers during a declared public health emergency in alternate care sites. Facilities should also be aware of what flexibilities are available with or without an 1135 waiver.

Alternate Care Site (ACS)

ACS is a broad term for any building or structure that is temporarily converted for healthcare use. An ACS is one of several alternate care strategies that can be used in a disaster. A facility's individual ACS structure and process may include several different models and require different planning considerations based on the type of emergency. Models for a facility's ACS may be dependent on factors such as: emergency/disaster spread across a community; anticipated longevity of operating in the ACS setting; level of capacity the ACS can provide and how this correlates with the need for transfers and discharge, among many other considerations.

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

Planning related to the development of an ACS is a proactive step to ensuring continuity of services. While the establishment and use of an ACS are generally acceptable only during an emergency and require CMS approval, the facility's program must address the facility's ability to provide care in an alternate setting. Considerations may include patient population, supplies, equipment, and staffing as well as physical environment. Planning considerations also include the capabilities of an ACS if authorized during a declared public health emergency.

Section 1135 Emergency Waiver

Policies and procedures must specifically address the facility's role in emergencies where the Secretary waives or modifies certain statutory and regulatory requirements for healthcare facilities in response to emergencies under section 1135 of the Act related to the provision of care at an alternate care site identified by emergency officials. The Secretary is authorized to issue a section 1135 waiver only when both the President declares a disaster or emergency under the Stafford Act or the National Emergencies Act, and the HHS Secretary declares a Public Health Emergency under section 319 of the Public Health Services Act. Examples of 1135 waivers issued during prior emergencies

have included *waivers of various* CoPs *and CfCs*; Licensure for Physicians or others to provide services in the affected State; EMTALA *requirements*; *and* Medicare Advantage out of network providers and HIPAA.

Facilities' policies and procedures should address what coordination efforts are required during a declared emergency in which a waiver of federal requirements under section 1135 of the Act has been *issued* by the Secretary *related to alternate care sites*. For example, due to a mass casualty incident in a geographic location, *the Secretary* may waive *federal* licensure *requirements* for physicians in order for these individuals to assist at a specific facility where they do not normally practice. *In such cases, the provider or supplier should have policies and procedures which address the responsibilities of these physicians during this waiver period. The policies may establish, for example, a lead person in charge for accountability and oversight of assisting physicians not usually under contract with the facility.*

Waivers issued under section 1135 of the Act are time-limited, and only waive federal requirements, not state requirements under their licensure authority. The purpose of section 1135 waivers are to ensure that sufficient health care items and services are available to meet the needs of the individuals in such areas. They are also intended to ensure healthcare providers (defined in section 1135(g)(2) of the Act) that can furnish such items or services in good faith, but are unable to comply with federal requirements, are allowed reimbursement during an emergency or disaster even if providers can't comply with certain requirements that would under normal circumstances bar Medicare, Medicaid or CHIP payment. Section 1135 waivers typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

Facilities should also have in place policies and procedures which address emergency situations in which a declaration was not made and where an 1135 waiver may not be applicable, such as during a disaster affecting the single facility. In this case, policies and procedures should address potential transfers of patients; timelines of patients at alternate facilities, etc. We would expect that state or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies. This requirement encourages providers to collaborate with their local emergency officials in proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted. Health department and emergency management officials, in collaboration with facility staff, would be responsible for determining the need to establish an alternate care site as part of the delivery of care during an emergency. The alternate care site staff would be expected to function in the capacity of their individual licensure and best practice requirements and laws. Decisions regarding staff responsibilities would be determined based on the facility- and community based assessments and the type of services staff could provide (81 FR at 63882). These elements should be included in the facilities policy and procedure under this standard.

During emergencies such as a widespread pandemic, a PHE may continue for a longer period of time than initially anticipated. In the event a facility is operating under a Section 1135 Waiver, including a potential blanket waiver, facilities should also consider their policies and procedures related to the use of the waiver flexibility and timeframe. While facilities are authorized to use a Section 1135 waiver during the duration of the PHE, in accordance with state emergency and pandemic plans, it may be prudent for facilities to consider how to continue operations when the 1135 Waiver has expired (end of the declared PHE) as facilities are expected to come back into full compliance at the end of the declared emergency. For instance, in the event a pandemic PHE or EID has decreased in a specific community (as generally outlined by CDC), the facility may no longer need the flexibility provided in an 1135 waiver. Therefore, the facility should consider not using or forgoing the waiver and ensuring it is back in substantial compliance with the specific requirement(s) waived even while the PHE may continue. The intent behind an 1135 waiver is to provide relief and flexibilities while the facility is directly impacted or challenged with meeting the Medicare requirement(s).

For additional information on 1135 waivers and process for submission please visit the Quality, Safety & Oversight Group Emergency Preparedness Website <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers> . We also recommend providers and suppliers review the ACS Toolkit developed by ASPR which can be found at: <https://files.asprtracie.hhs.gov/documents/acs-toolkit-ed1-20200330-1022.pdf>.

Survey Procedures

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

***NOTE:** This policy and procedure requirement does not require a facility to have an 1135 waiver on hand at the time of the survey as such waivers are established or granted by CMS only during a declared emergency period. Section 1135 waivers by nature are time limited.*

E-0027

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

§494.62(b)(8) Condition for Coverage:

[(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]

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

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

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

Survey Procedures

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

E-0028

(Rev.)

§494.62(b)(9) Condition for Coverage:

[(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]

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

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

ESRD facilities must include policies and procedures in its emergency plan that address a process that confirms that the specific requirements listed under this standard are on the premises at all times and immediately available in the event of an emergency. The process must be in writing. It is the facilities' responsibility to determine what equipment *in addition to oxygen, airways, suction, defibrillator or automated external defibrillators, artificial resuscitators, and emergency drugs* should *be* on the premises and available during an emergency to assist patients in an emergency. *ESRD facilities may find that additional emergency equipment should be maintained on the premises as well, such as additional potable water for treatment; water treatment equipment (carbon filtration and either reverse osmosis or deionization); or supplies (dialyzers, blood lines, saline, medications, etc.)* Additionally, it is the responsibility of the facility to ensure that all necessary equipment identified in this *standard* should-be in working order at all times in accordance with the manufacturer instructions. Emergency drugs should not be out of

date and should be stored and maintained based on the manufacturer instructions, *however, in certain emergencies which may present shortages, such as during a pandemic, the facility should monitor FDA's website for Emergency Use Authorizations which may include extensions on shelf life for medications and other equipment and supplies to help address shortages.* The facility is in the best position to determine what emergency equipment it needs to have available. In addition, dialysis facilities need to be able to manage care-related emergencies during an emergency when other assistance, emergency medical services systems, may not be immediately available to them.

ESRD facilities should also consider supply chain challenges and other planning considerations in the event of large-scale emergencies, such as pandemics. During these emergencies, timely and immediately available additional equipment may be dependent on receipt through an agreement with a vendor, an alternate arrangement, or the state. In the event of supply shortages, we recommend facilities have policies and procedures in place for reviewing recommendations provided by the state and federal government to procure supplies, or transfer patients to different care settings to provide continuity of care based on the patient's needs.

ESRD facilities experiencing a shortage should have a set process on how to engage their local and state health and emergency management departments for assistance, including processes on how to engage with the ESRD Networks. For additional information on local health departments supporting preparedness and response activities, visit the National Association for County and City Health Officials Directory of Local Health Departments. ESRD facilities should also monitor the Food and Drug Administration Emergency Use Authorization website (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>) that may list current and terminated Emergency Use Authorizations that make available diagnostic and therapeutic medical devices to diagnose and respond during declared public health emergencies.

Survey Procedures

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

PACE - NON-CITABLE (No assigned tags)

Reference Only (PACE)

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

§460.84(b)(10) Requirement:

[(b) Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years.]

The policies and procedures must address management of medical and non-medical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at every 2 years. At a minimum, the policies and procedures must address the following:

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

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

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

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 every 2 years *[annually for LTC facilities]*.

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

NOTE: This does not apply to Transplant Programs.

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. Although *the requirement for documentation of collaboration with state and local officials was removed (see 84 FR 51817, Sept. 30, 2019), facilities should continue to collaborate with state and local emergency officials. During the creation process for communication plans, facilities should also consult their applicable state and local emergency and pandemic plans.*

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 *should* 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) *at least every 2 years (annually for LTC facilities).*
- *Ask facility leadership or the designee responsible for the emergency program to verbally explain how they are to collaborate with Federal, State and local officials to ensure their communication plan complies with the Federal, State and local requirements.*

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 must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years [annually for LTC facilities]. 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:**

1) Names and contact information for the following:

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

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

NOTE: This does not apply to Transplant Programs.

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, *at a minimum, to the individual(s) designated as the emergency preparedness coordinator or person(s) responsible for the facility's emergency preparedness program and management during an emergency event*, 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 *every 2 years, annually for LTC facilities*. 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 *programs* should be included in the development of the hospitals communication plans. In the case of a Medicare-approved transplant *program*, 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 *program* 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.

***NOTE:** For Home Health Agencies, contact information should also include patient’s physicians or allowed practitioners. Section 484.60 requires that each patient’s written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Accordingly, additional practitioners at HHAs should also be notified to reflect the interdisciplinary, coordinated approach to home health care delivery consistent with the HHA regulations.*

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 *every 2 years (annually for LTC facilities)* by asking to see evidence of the 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 every 2 years [annually for LTC facilities]. The communication plan must include all of the following:

(2) Contact information for the following:

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

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

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

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

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

- (iii) The State Licensing and Certification Agency.
- (iv) The State Protection and Advocacy Agency.

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

NOTE: This does not apply to Transplant Programs.

A facility must have the contact information for those individuals and entities outlined within the standard. *Emergency management officials may include, but are not limited to, emergency management agencies which may be local to the community as well as local officials who support the Incident Command System depending on the nature of the disaster (e.g. fire, police, public health, etc.). Additionally, emergency management officials also include the state public health departments and State Survey Agencies as well as federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.) and tribal emergency officials, as applicable.*

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

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 the facility has contact information for the State Survey Agency and/or public health departments.*
- Verify that all contact information has been reviewed and updated at least *in the past 2 years (annually for LTC facilities)* by asking to see evidence of the review.

NOTE: *Even though the communications plan must include contact information, it does not specifically require the facility to have an individual contact for emergency management agencies. For instance, a state emergency management agency may have a specific phone line or contact method and not a specific individual person.*

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 every 2 years [annually for LTC *facilities*]. The communication plan must include all of the following:

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

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

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

NOTE: This does not apply to Transplant Programs.

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 should identify their primary and alternate means of communication in their*

emergency preparedness communication plan. For instance, a primary means of communication may be cellular phones, hard wire lines and the facilities intercom system, whereas the facilities alternate means (given interruption of primary means) may be the SHARED RESOURCES.

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 every 2 years [annually for LTC facilities]. The communication plan must include all of the following:

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

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

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

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

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

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

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

NOTE: This does not apply to Transplant Programs.

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 every 2 years [annually for LTC *facilities*]. The communication plan must include all of the following:

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

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

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

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

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

Facilities, except for transplant *programs*, 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).

Reporting of a Facility's Needs

Generally, in small community emergency disasters, reporting the facility's needs will be coordinated through established processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to: shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and, staffing shortages.

In large scale emergency disasters or pandemics, reporting of needs specific to a facility may be altered by local, state and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume. It is recommended that facilities verify their reporting requirements with their local Incident Command Structures or State Agencies.

Dependent on the emergency event and the anticipated longevity, facilities may need to report select criteria such as in an EID outbreak or the number of patients' positive or persons under investigation (PUI). The facility's process should include monitoring by the facility's emergency management coordinator or designee of reporting requirements issued by CMS or other agencies with jurisdiction. Additional monitoring and reporting may be required by local and state public health agencies due to contact tracing requirements for extended periods of time or for time specific intervals. Facilities should identify local and state policies for reporting and contract tracing to ensure they have appropriate information to address requirements.

Facilities should actively engage with their healthcare coalitions, associations, accrediting organizations and other stakeholders during the onset of any wide-spread emergency. As state and federal emergency organizations may become overwhelmed with requests, these stakeholders may be able to reconcile needs-requests for specific providers and suppliers. In situations in which a Presidential Declaration and a Public Health Emergency (PHE) have been declared, and Section 1135 Waivers may be granted, these stakeholders (healthcare coalitions, associations, accrediting organizations and others) may have the ability to request and streamline 1135 waiver requests for their members, dependent on the severity of the emergency.

Reporting of a Facility's Ability to Provide Assistance

During widespread disasters, reporting a facility's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an emergency to determine what assistance may be necessary directly supports surge planning within a community. For instance, in preparation for a natural disaster such as a hurricane, pre-planning reporting criteria such as the facility's response-- e.g. closing the outpatient services in a forecasted natural disaster-- may facilitate the Incident Command as they would be aware of the operating status of the facility. Reporting the ability to provide assistance would also include pre-planning with public health and emergency officials in the local community to make them aware of what capabilities are available within the specific facility, e.g. number of beds, critical care equipment, staffing, etc.

During widespread disasters, facilities may be required to report the following to local officials:

- Ability to care for patients requiring transfer from different healthcare settings;*
- Availability of PPE;*
- Availability of staff who may be able to assist in a mass casualty incident;*
- Availability of electricity-dependent medical and assistive equipment, such as ventilators and other oxygen equipment (BiPAP, CPAP, etc.), renal replacement therapy machines (e.g., home and facility-based hemodialysis, peritoneal dialysis, continuous renal replacement therapy and other machines, etc.), and wheelchairs and beds.*

Occupancy Reporting

For hospitals, CAHs, RNHCIs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, they must also have a means for providing information about their occupancy.

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

but is not limited to, shortage of provisions such as food, water, medical supplies, assistance with evacuation and transfers, etc.

NOTE: The authority having jurisdiction varies by local, state and federal emergency management structures as well as the type of disaster. For example, in the event of a multi-state wildfire, the jurisdictional authority who would take over the Incident Command Center or state-wide coordination of the disaster would likely be a fire-related agency.

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

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

Survey Procedures

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

E-0035

(Rev.)

§483.73(c)(8); §483.475(c)(8)

*[For LTC Facilities at §483.73(c):]

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

*[For ICF/IIDs at §483.475(c):]

[(c) The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:]

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

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

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

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

Survey Procedures

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

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).

*[For RNCHIs at §403.748, ASCs at §416.54, Hospice at §418.113, PRTFs at §441.184, PACE at §460.84, Hospitals at §482.15, HHAs at §484.102, CORFs at §485.68, CAHs at

§486.625, “Organizations” under 485.727, CMHCs at §485.920, OPOs at §486.360, *and* RHC/FHQs at §491.12:] **(d) Training and testing.** The [facility] must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

*[For LTC facilities at §483.73(d):] **(d) Training and testing.** The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

*[For ICF/IIDs at §483.475(d):] **Training and testing.** The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. The ICF/IID must meet the requirements for evacuation drills and training at §483.470(i).

*[For ESRD Facilities at §494.62(d):] **Training, testing, and orientation.** The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing and orientation program must be evaluated and updated at every 2 years.

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

NOTE: This does not apply to Transplant Programs.

Training and Testing Program- General

An emergency preparedness training and testing program as specified in this requirement must be documented, reviewed and updated. 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 Component

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. For training requirements, the facility must have a process outlined within its emergency preparedness program which encompasses staff and volunteer training complementing the risk assessment. The training for staff should at a minimum include training related to the facility's policies and procedures. Facilities must maintain documentation of the training so that surveyors are able to clearly identify staff training and testing conducted. For example, facilities may have a sign-in roster of training conducted within their training files or inclusion of this training in their training program, or individual training certificates of completion within personnel records. A surveyor should be able to ask for a list of employees and to verify training on the emergency preparedness requirements as required under E-0037 (subsection (d)(1)(iii)).

Testing Component

Testing requirements vary based on the provider type. Inpatient providers are required to conduct two testing exercises annually. Outpatient providers are required to conduct one testing exercise annually (that at least every two years their exercise must be a full-scale exercise)- Refer to E-0039 (subsection (d)(2)).

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. *Additionally, facilities should establish a process which includes participation of all staff in testing exercises over a period of time. Facilities are encouraged to consider their scheduled exercises and the appropriate departments to be included. For instance, if a clinically-relevant testing exercise is not necessarily applicable to some other departments or staff, then the staff which did not participate in one year should participate in the next testing exercise to ensure that over a period of time all shifts are incorporated. Additionally, we are not specifying a facility to utilize all required equipment in the testing (drills) or a percentage of the patients/residents that would be included in these drills, however facilities should test their exercises according to how they would respond to the emergency would it be an actual real emergency.*

Under this standard, surveyors are to assess whether or not the facility has a training and testing program based on the facility's risk assessment and has incorporated its policies and procedures, as well as its communication plan within training required for staff and its testing exercises.

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.
- *Refer back to the facility's risk assessment to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.*
- Verify the program has been reviewed and updated at least *every 2 years (annually for LTC facilities)* 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).

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

(1) Training program. The [facility] must do all of the following:

- (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least every 2 years.**
- (iii) Maintain documentation of all emergency preparedness training.**
- (iv) Demonstrate staff knowledge of emergency procedures.**
- (v) If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.**

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

- (i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.**
- (ii) Demonstrate staff knowledge of emergency procedures.**
- (iii) Provide emergency preparedness training at least every 2 years.**

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(vi) If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.

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

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

(ii) After initial training, provide emergency preparedness training every 2 years.

(iii) Demonstrate staff knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

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

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

(ii) Provide emergency preparedness training at least every 2 years.

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

(iv) Maintain documentation of all training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

***[For LTC Facilities at §483.73(d):] (1) Training Program. The LTC facility must do all of the following:**

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

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

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

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

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

- (i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least every 2 years.**
- (iii) Maintain documentation of the training.**
- (iv) Demonstrate staff knowledge of emergency procedures.**
- (v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.**

***[For CMHCs at §485.920(d):] (1) Training. The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least every 2 years.**

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

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

Training Program- General

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.

The training provided by the facility must be based on the facility's risk assessment policies and procedures as well as the communication plan. The intent is that staff, volunteers and individuals providing services at the facility are familiar and trained on the facility's processes for responding to an emergency. Training should include individual-based response activities in the event of a natural disasters, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate. Training should include how the facility manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events.

Furthermore, the facility must train staff based on the facility's risk assessment. Training for staff should mirror the facility's emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID's this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members.

Facilities should provide **initial emergency training during orientation** (or shortly thereafter) to ensure initial training is not delayed.

Continued Training

*After the initial training has been conducted for staff, facilities must provide training on their facility's emergency plan at least every 2 years (except for LTC facilities which will still be required to provide training annually). Facilities have the flexibility to determine the focus of their **initial and 2-year** training, as long as it aligns with the emergency plan and risk assessment. **Initial and subsequent** training should be modified *as needed and if the facility updates the policies and procedures to include but not limited to* incorporating any lessons learned from the most recent exercises *and* real-life emergencies that occurred in and during the review of the facility's emergency program, *we would expect the facility be able to demonstrate how they have updated the training as well.* For example, *the 2 year subsequent* 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 review.*

While facilities are required to provide *initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually)* training

to all staff, it is up to the facility to decide what level of training each staff member will be required to complete 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 training requirements. For example, staff who work with radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical emergencies. It is up to the facility to decide if the external training meets the facility's requirements.

Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. Facilities which may have changed their emergency plan should plan to conduct initial training to all staff on the new or revised sections of the plan. If a facility determines the need to add additional policies and procedures based on a new risk identified in the facility's risk assessment, the facility must train all staff on the new policies and procedures and the staff responsibilities. Facilities are not required to re-train staff on the entire emergency plan, but can choose to train staff on the new or revised element of the emergency preparedness program. For example, a facility identifies during an influenza outbreak that additional policies and procedures and adjustments to the risk assessment are needed to address a significant influx of patients/clients/residents. The facility identifies clinical locations in which contagious patients can be triaged in a manner to minimize exposure to non-infected individuals. The training for this new or revised policy can be done without needing to re-train staff on the entire program.

Variance by Provider/Supplier Type

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.

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.

LTC facilities must continue to provide initial and continued training on an annual basis.

Training of Volunteers and Contracted Staff

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.

Documentation Requirements

Facilities must maintain documentation of the *initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually)* 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 *and subsequent (at least every 2 years or annual for LTC)* emergency preparedness trainings and annual emergency preparedness training offerings.
- Interview various staff and ask questions regarding the facility's initial and *subsequent (at least every 2 years or annual for LTC)* training course to verify staff knowledge of emergency procedures.
- Review a sample of staff training files to verify staff have received initial and *subsequent (at least every 2 years or annual for LTC)*, emergency preparedness training.

***NOTE:** For ease of demonstrating compliance that the facility has updated its training program at least every 2 years, we recommend that facilities retain at a minimum, the past 2 cycles (generally 4 years) of emergency training documentation for both training and exercises for surveyor verification.*

E-0038

(Rev.)

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

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

- (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least every 2 years.**

Staff training must:

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

- (A) What to do;**
- (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;**
- (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and**
- (D) How to disconnect themselves from the dialysis machine if an emergency occurs.**

(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and

(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.

(vi) Maintain documentation of the training.

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

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

Training Program- General

ESRD 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.

The training provided by the facility must be based on the facility's risk assessment, policies and procedures as well as the communication plan. The intent is that staff, volunteers and individuals providing services at the facility are familiar and trained on the facility's processes for responding to an emergency. Training should include

individual-based response activities in the event of a natural disaster, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate if the natural disaster was not able to be forecasted. Training should include how the facility manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events.

Furthermore, the ESRD facility must train staff based on the facility's risk assessment. Training for staff should mirror the facility's emergency plan and should include training staff and focus on procedures are relevant to the hazards identified. For example, for EIDs, this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities.

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

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

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

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

Survey Procedures

- Verify the facility has an emergency preparedness training program and that it is updated *at least every 2 years*.
- Interview staff and ask them to describe the evacuation procedures and plan.
- Verify current copies of CPR certifications for all patient care staff are on file.

E-0039

(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).

**[For ASCs at §416.54, CORFs at §485.68, OPO, “Organizations” under §485.727, CMHCs at §485.920, RHCs/FQHCs at §491.12, and ESRD Facilities at §494.62]:*

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

- (i) Participate in a full-scale exercise that is community-based every 2 years; or**
 - (A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or**
 - (B) If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.**
- (ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:**
 - (A) A second full-scale exercise that is community-based or individual, facility-based functional exercise; or**
 - (B) A mock disaster drill; or**
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.**
- (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.**

**[For Hospices at 418.113(d):]*

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

- (i) Participate in a full-scale exercise that is community based every 2 years; or**
 - (A) When a community based exercise is not accessible, conduct an individual facility based functional exercise every 2 years; or**
 - (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from**

engaging in its next required full scale community-based exercise or individual facility-based functional exercise following the onset of the emergency event.

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

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

(B) A mock disaster drill; or

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

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

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

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

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

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

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

(B) A mock disaster drill; or

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

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

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

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

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

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

(B) If the [PRTF, Hospital, CAH] experiences an actual natural or man-made emergency that requires activation of the emergency plan,

the [facility] is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event.

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

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

(B) A mock disaster drill; or

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

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

*[For PACE at §460.84(d):]

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

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

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

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

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

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

(B) A mock disaster drill; or

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

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

*[For LTC Facilities at §483.73(d):]

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

- (i) Participate in an annual full-scale exercise that is community-based; or**
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise.**
 - (B) If the [LTC facility] facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.**
- (ii) Conduct an additional annual exercise that may include, but is not limited to the following:**
 - (A) A second full-scale exercise that is community-based or an individual, facility based functional exercise; or**
 - (B) A mock disaster drill; or**
 - (C) A tabletop exercise or workshop that is led by a facilitator includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.**
- (iii) Analyze the [LTC facility] facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [LTC facility] facility's emergency plan, as needed.**

***[For ICF/IIDs at §483.475(d)]:**

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

- (i) Participate in an annual full-scale exercise that is community-based; or**
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.**
 - (B) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.**
- (ii) Conduct an additional annual exercise that may include, but is not limited to the following:**
 - (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or**
 - (B) A mock disaster drill; or**
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.**

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

**[For HHAs at §484.102]*

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

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

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

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

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

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

(B) A mock disaster drill; or

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

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

**[For OPOs at §486.360]*

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

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

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

**[RNCHIs at §403.748]:*

(d)(2) Testing. The RNHCI must conduct exercises to test the emergency plan. The RNHCI 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 response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.***

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

NOTE: This does not apply to Transplant Programs.

Variability in Requirements

For inpatient providers (inpatient hospice facilities, PRTFs, hospitals, LTC facilities*, ICFs/IID, and CAHs): The types of acceptable testing exercises are expanded. Inpatient providers can choose one of the two annually required testing exercises to be an exercise of their choice, which may include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

****NOTE: For LTC facilities, while the types of acceptable testing exercises was expanded, LTC facilities must continue to conduct their exercises on an annual basis. Facilities must conduct exercises to test the emergency plan, which for LTC facilities also includes unannounced staff drills using the emergency procedures***

For outpatient providers (ASCs, freestanding/home-based hospice, PACE, HHAs, CORFs, Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), CMHCs, OPOs, RHCs, FQHCs, and ESRD facilities): Facilities are required to only conduct one testing exercise on an annual basis, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise. The opposite years (every other year opposite of the full-scale exercises), these providers may choose the testing exercise of their choice, which can include either another full-scale, individual facility-based, a mock disaster drill (using mock patients), tabletop exercise or workshop which includes a facilitator.

For OPOs and RNCHIs, these providers must at a minimum conduct either a paper-based, tabletop exercise or workshop every year, however can elect to also participate in full-scale, individual facility-based exercise.

Understanding Exercises and Terminology

Similar to the training expectations outlined under E-0037 or (d)(1), such as hospitals at 482.15(d)(1), a facility's testing exercises require they be based on the individual facility's risk assessment, policies and procedures, and communication plan and support the patient population it serves. Testing exercises should vary, based on the facility's requirements, by cycles and frequency of testing. The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners. Testing exercises must be based on the facility's identified hazards, to include natural or man-made disasters. This should include EID outbreaks.

Facilities are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test the same scenario year after year or the same response processes. The intent is to identify gaps in the facility's emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility's program. In the event gaps are identified, facilities should update their emergency programs as outlined within the requirements for After-Action Report (AAR).

Full-Scale and Community Based Exercises

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. *Full-scale exercises in the industry setting are large exercises in which multiple agencies participate and may only be available every three to five years; while functional exercises are similar in nature, but may not involve as many participants and in which each agency can choose its priorities to test within the confines of the exercise. Therefore, full-scale can include what is known as a "functional" exercise or drill in the industry and according to HSEEP.* 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. 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 which determine that a full-scale community-based exercise will be planned for the facility's exercise requirement must also ensure that the exercise scenario developed is identified within the facility's risk assessment. While generally local and state emergency officials plan emergency exercises which could occur within the geographic location or community, facilities must ensure that participation in the exercise would adequately test the facility's emergency program (specifically its policies and procedures and communication plan). For instance, in the event the local or state full-scale exercise is testing the response to a major multiple car accident requiring airlift transfers of

patients, a LTC facility or ESRD facility may not be impacted by this type of disaster or require activation of its emergency program, therefore the exercise may not be as appropriate. In this case, the facility could document that the scenario offered in this full-scale community based exercise and that the facility conducted an individual facility-based exercise to test its emergency program instead. However, if the state or local exercise is testing an EID outbreak, all facilities in the community may be impacted, therefore participation would be strongly recommended.

The intent behind full-scale and community based exercises is to ensure the facility's emergency program and response capabilities complement the local and state emergency plans and support an integrated response while protecting the health and safety of patients.

Individual Facility-Based Exercises

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. *Community partners are considered any emergency management officials (fire, police, emergency medical services, etc.) for full-scale and community-based exercises, however can also mean community partners that assist in an emergency, such as surrounding providers and suppliers.*

Participation

While the regulations do not specify a minimum number of staff, or the roles of staff in the exercises, it is strongly encouraged that facility leadership and department heads participate in exercises. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities. Additionally, facilities can review which members of staff participated in the previous exercise, and include those who did not participate in the subsequent exercises to ensure all staff members have an opportunity to participate and gain insight and knowledge.

Facilities can use a sign-in roster for the exercise to substantiate staff participation. A sufficient number of staff should participate in the exercise to test the scenario and thoroughly assess the risk, policy, procedure, or plan being tested.

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. *If the facility uses fire drills based on their risk assessment (e.g. wild fires) as a full-scale community based exercise in one given year (which is also a requirement for some providers/suppliers under Life Safety Code), the facility is encouraged to choose in the following year a different hazard in their risk assessment to conduct an exercise in order to ensure variability in the training and testing program. The intent of the requirements under the emergency preparedness condition for participation/condition for coverage, or requirement for LTC, is to test the facility’s ability to respond to any emergency outlined within their risk assessment. The purpose of testing the facility’s emergency program is to identify gaps in response which could result in adverse events for patients and staff and to adjust plans, policies and procedures to ensure patient and staff safety is maintained regardless of the type of emergency which occurs.*

Table-Top Exercise and Workshops

Facilities are also required to conduct an “exercise of choice” or, for some, only conduct a table-top exercise (TTX) or workshop. Please refer back to the definition section above. TTX’s or workshops are expected to be group discussions led by a facilitator. We are not defining whether or not the facilitator must be a staff member or contracted service. Some facilities may find that a specific department lead may be best suited dependent on the scenario being tested, while other facilities may find an outside facilitator may be more appropriate to facilitate.

The intent behind TTX’s or workshops is to test an exercise based on the facility’s risk assessment. Some facilities may find it prudent to conduct a TTX or workshop prior to a full-scale or individual-facility based exercise in order to identify potential gaps or challenges and then update the policies and procedures accordingly to resolve the potential issue. This would allow for facilities to test their adjustments during a full-scale or individual facility-based exercise to determine if the corrective action was appropriate.

After-Action Reviews

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.

Exemption based on Actual Emergency

Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the *full-scale* exercise requirement and exempts the facility for engaging in *their next required community-based full-scale exercise or individual, facility-based exercise* for following the actual event; and facilities must be able to demonstrate this through written documentation. *With the changed requirements as a result of the 2019 Burden Reduction final rule (81 FR 63859) for outpatient providers required to conduct full-scale exercises only every other year, opposite of their exercises of choice, these facilities are exempt from their next required full-scale or individual facility-based exercise. For inpatient providers, the full-scale exercise would be annually. The intent is to ensure that facilities conduct at least one exercise per year.*

For example, in the event an outpatient provider conducts a required full-scale community based exercise in January 2019, and completed the optional exercise of its choice in January 2020, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2021. If the outpatient provider conducts a required full-scale community based exercise in January 2020, and has the optional exercise of its choice scheduled for January 2021, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2022, but must still conduct the required exercise of choice in January 2021. The exemption is based on the facility's required full-scale exercise, not the exercise of choice, therefore the exemption may not be applicable until two years following the activation of the emergency plan, dependent on the cycle the facility has determined and the actual emergency event.

For inpatient providers, the exemption would apply for the next required full-scale exercise as well, however, it may be the same year or following year, as inpatient providers are required to perform two exercises per year. If an inpatient provider completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020, but experiences an actual emergency in March 2020 which required activation of its emergency plan, the inpatient provider is exempt from the next required full-scale exercise in January 2021, but must complete the exercise of choice. If the inpatient provider conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the inpatient provider would be exempt from that full-scale exercise as it would not be the exercise of choice.

The exercises of choice, which allow facilities to choose one (e.g., another full-scale/individual facility based; mock disaster drill; or table top exercises) are not considered as the required full-scale community based or individual facility based exercises. Facilities which may have schedule full-scale exercises annually as part of their licensure or accrediting organizations requirements, would be exempt from their next required annual full-scale exercise. Facilities which have a full-scale exercise scheduled as part of their exercise of choice for the opposite years would be exempt from their next scheduled exercise following an emergency, which would still be July 2021 (using the above example).

Facilities must document that they had activated their emergency program based on an actual emergency. Documentation may include, but is not limited to: a section 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event specific information. The facility must also complete an after action review and integrated corrective actions into their emergency preparedness program.

Resources

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

Survey Procedures

- *Ask facility leadership to explain the participation of management and staff during scheduled exercises.*
- Ask to see documentation of the 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). *Documentation must demonstrate the facility has conducted the exercises described in the standard.*
- 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.

NOTE: We recommend facilities to retain, at a minimum, the past 2 cycles (generally 2 years for inpatient providers and 4 years for outpatient providers of emergency testing exercise documentation. This would allow surveyors to assess compliance on the cycle of testing required for outpatient providers.

E-0040

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

§494.62(d)(3) Condition for Coverage:

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

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

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

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

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

Survey Procedures

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

E-0041

(Rev.)

§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.

For information regarding permanently installed generators, please refer to applicable NFPA Codes and Standards as discussed under Tag E-0015. In the event a health surveyor is unclear whether the facility is complying with these requirements, the health surveyor must consult with their LSC surveyors. Generally, tag E-0041 should be reviewed by a LSC surveyor.

Survey Procedures

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

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

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

E-0042

(Rev.)

§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 *Programs*.

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 *every 2 years (annually for LTC facilities)* 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 reviews of the program requirements and any program updates.
- Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program).
- Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.

E-0043

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

§482.15(g)

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

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

(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant program, and the OPO for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

Interpretive Guidelines for §482.15(g).

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

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

Both the hospital and the transplant *program* are required to demonstrate during a survey that they have collaborated in the planning and development of the emergency program. Both are required to have written documentation of the emergency preparedness plans. However, the transplant *program* is not individually responsible for the emergency preparedness requirements under §482.15 (see Tag E-005 at §482.78).

Survey Procedures

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

E-044

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

§486.360(e)

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

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

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

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

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

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

Interpretive Guidelines for §486.360(e).

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

Survey Procedures

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