Rural Health Clinic / Federally Qualified Health Center Requirements
CMS Emergency Preparedness Final Rule

The Centers for Medicare & Medicaid Services (CMS) issued the Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers Final Rule to establish consistent emergency preparedness requirements for healthcare providers participating in Medicare and Medicaid, increase patient safety during emergencies, and establish a more coordinated response to natural and human-caused disasters. The U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR) worked closely with CMS in the development of the rule.

This document combines excerpts from the Final Rule, the Interpretive Guidelines, and revisions (New 3.6.19) from CMS to provide a consolidated overview document for the Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Requirements.

This document is meant as a reference and is NOT intended to replace your review of the Final Rule or the Interpretive Guidance documents and speaking with your surveyor or accrediting body. This document may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a resource. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Note: CMS published updated Interpretive Guidelines (Appendix Z) on February 1, 2019. Changes in the interpretive guidelines are reflected in this document in red and noted as "New 3.6.19."

NOTE (11.8.19): CMS released updated regulatory language as a result of a Burden Reduction Rule published in the Federal Register on September 30, 2019 and are effective as of November 29, 2019. Changes to the regulatory text are noted as follows:
- All changes will be noted with the change date (effective 11.29.19)
- All language added to the original text is marked in ***red, bold italics***.
- All deletions to the original text have a ~~double strikethrough~~.

Quick Links
Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers Final Rule
Interpretive Guidelines and revisions (New 3.6.19)
Interpretive Guidelines Surveyor Cheat Sheet

In this document:

TRACIE
HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

RHC/FQHC Requirements as Written in the Final Rule and as amended by 2019 Burden Reduction (November 2019)

The following excerpt is taken from page 64041 of the Final Rule, accessible directly by this link: https://www.federalregister.gov/d/2016-21404/p-amd-40 and 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 published September 30, 2019 and effective November 29, 2019 *(effective 11.29.19).*

37. Add § 491.12 to read as follows:

§ 491.12
Emergency preparedness.
The RHC/FQHC must comply with all applicable Federal, State, and local emergency preparedness requirements. The RHC/FQHC 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:

(a) Emergency plan. The RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least ~~annually~~ *every 2 years (effective 11.29.19)*. The plan must do all of 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.
3) Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. ~~including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.~~ *(effective 11.29.19)*

(b) Policies and procedures. The RHC/FQHC 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~~ *every 2 years (effective 11.29.19)*. At a minimum, the policies and procedures must address the following:

1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.
2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.
3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
4) 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.

(c) Communication plan. The RHC/FQHC 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~~ *every 2 years (effective 11.29.19)*. 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 RHCs/FQHCs.
    v. Volunteers.
2) Contact information for the following:
    i. Federal, State, tribal, regional, and local emergency preparedness staff.
    ii. Other sources of assistance.
3) Primary and alternate means for communicating with the following:
    i. RHC/FQHC's staff.
    ii. Federal, State, tribal, regional, and local emergency management agencies.
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).
5) A means of providing information about the RHC/FQHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The RHC/FQHC 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~~ *every 2 years (effective 11.29.19)*.

1) **Training program.** The RHC/FQHC must do all of the following:
    i. Initial training in emergency preparedness policies and procedures to all new and existing staff,

individuals providing services under arrangement, and volunteers, consistent with their expected roles,

  ii. Provide emergency preparedness training at least ~~annually~~ *every 2 years (effective 11.29.19)*.

  iii. Maintain documentation of *all emergency preparedness (effective 11.29.19)* 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. (effective 11.29.19)

2) **Testing.** The RHC/FQHC must conduct exercises to test the emergency plan at least annually. The RHC/FQHC must:

  ***i. *** Participate in a full-scale exercise that is community-based *every 2 years; or (effective 11.29.19)*

    a. When a community-based exercise is not accessible, *conduct a facility-based functional exercise every 2 years;* or ~~an individual, facility-based.~~ *(effective 11.29.19)*

    b. If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in *its next required* ~~a~~ *(effective 11.29.19)* community-based or individual, facility-based ~~full-scale~~ *functional (effective 11.29.19)* exercise for 1 year 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, (effective 11.29.19)* 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 (effective 11.29.19)

    c. A tabletop exercise *or workshop (effective 11.29.19)* that is ~~includes a group discussion~~ *(effective 11.29.19)* led by a facilitator and *includes a group discussion (effective 11.29.19)*, 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 RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

(e) Integrated healthcare systems. If a RHC/FQHC 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 RHC/FQHC 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:

T R A C I E
HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

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 all of 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 References for RHC/FQHC

Full text available at: Appendix Z – Emergency Preparedness for All Providers and Certified Supplier Types: Interpretive Guidelines and revisions (New 3.6.19)

Full Surveyor Cheat Sheet Spreadsheet available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Surveyor-Tool-EP-Tags.xlsx

T R A C I E

RHC/FQHC References as Outlined in the Interpretive Guidance and the Surveyor Cheat Sheet

Tag #	Title	Tag Text (Regulatory Text) (This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)	Interpretive Guidelines (These Interpretive Guidelines have NOT been updated to reflect the Burden Reduction Final Rule Issued on September 30, 2019. Once CMS has issued updated Interpretive Guidelines, this section will be updated to reflect the new language.)
0001	Establishment of the Emergency Program (EP)	The [facility, except for Transplant Center] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility] must establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section. * The emergency preparedness program must include, but not be limited to, the following elements:	Under this condition/requirement, facilities are required to develop an emergency preparedness program that meets all of the standards specified within the condition/requirement. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation. The program must also address how the facility would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made, facility). The emergency preparedness program must be reviewed annually. A comprehensive approach to meeting the health and safety needs of a patient population should encompass the elements for emergency preparedness planning based on the "all-hazards" definition and specific to the location of the facility. For instance, a facility in a large flood zone, or tornado prone region, should have included these elements in their overall planning in order to meet the health, safety, and security needs of the staff and of the patient population. Additionally, if the patient population has limited mobility, facilities should have an approach to address these challenges during emergency events. The term "comprehensive" in this requirement is to ensure that facilities do not only choose one potential emergency that may occur in their area, but rather consider a multitude of events and be able to demonstrate that they have considered this during their development of the emergency preparedness plan. **Survey Procedures** • Interview the facility leadership and ask him/her/them to describe the facility's emergency preparedness program. • Ask to see the facility's written policy and documentation on the emergency preparedness program. For hospitals and CAHs only: Verify the hospital's or CAH's program was developed based on an all-hazards approach by asking their leadership to describe how the facility used an all-hazards approach when developing its program.

T R A C I E

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0004	Develop and Maintain EP Program	[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* annually (effective 11.29.19).
			Facilities are required to develop and maintain an emergency preparedness plan. The plan must include all of the required elements under the standard. The plan must be reviewed and updated at least annually. The annual review must be documented to include the date of the review and any updates made to the emergency plan based on the review. The format of the emergency preparedness plan that a facility uses is at its discretion.
			
			An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. This approach is specific to the location of the facility and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to:
			• Natural disasters
			• Man-made disasters,
			• Facility-based disasters that include but are not limited to:
			   o Care-related emergencies;
			   o Equipment and utility failures, including but not limited to power, water, gas, etc.;
			   o Interruptions in communication, including cyber-attacks;
			   o Loss of all or portion of a facility; and
			   o Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).
			• EIDs such as Influenza, Ebola, Zika Virus and others.
			   o 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. (New 3.6.19)

TRACIE

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			When evaluating potential interruptions to the normal supply of essential services, the facility should take into account the likely durations of such interruptions. Arrangements or contracts to re-establish essential utility services during an emergency should describe the timeframe within which the contractor is required to initiate services after the start of the emergency, how they will be procured and delivered in the facility's local area, and that the contractor will continue to supply the essential items throughout and to the end of emergencies of varying duration. **Survey Procedures** • Verify the facility has an emergency preparedness plan by asking to see a copy of the plan. • Ask facility leadership to identify the hazards (e.g. natural, man-made, facility, geographic, etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted. • Review the plan to verify it contains all of the required elements. • Verify that the plan is reviewed and updated annually by looking for documentation of the date of the review and updates that were made to the plan based on the review.

TRACIE

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0006	Maintain and Annual EP Updates	[(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~~ **(effective 11.29.19).** 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.	Facilities are expected to develop an emergency preparedness plan that is based on the facility-based and community-based risk assessment using an "all-hazards" approach. Facilities must document both risk assessments. An example consideration may include, but is not limited to, natural disasters prevalent in a facility's geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies. Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security's Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ). "Community" is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency. Facilities may rely on a community-based risk assessment developed by other entities, such as public health agencies, emergency management agencies, and regional health care coalitions or in conjunction with conducting its own facility-based assessment. If this approach is used, facilities are expected to have a copy of the community-based risk assessment and to work with the entity that developed it to ensure that the facility's emergency plan is in alignment. When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following:

TRACIE

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			• Identification of all business functions essential to the facility's operations that should be continued during an emergency; • Identification of all risks or emergencies that the facility may reasonably expect to confront; • Identification of all contingencies for which the facility should plan; • Consideration of the facility's location; • Assessment of the extent to which natural or man-made emergencies may cause the facility to cease or limit operations; and, • Determination of what arrangements may be necessary with other health care facilities, or other entities that might be needed to ensure that essential services could be provided during an emergency. In situations where the facility does not own the structure(s) where care is provided, it is the facility's responsibility to discuss emergency preparedness concerns with the landlord to ensure continuation of care if the structure of the building and its utilities are impacted. For LTC facilities and ICF/IIDs, written plans and the procedures are required to also include missing residents and clients, respectively, within their emergency plans. Facilities must develop strategies for addressing emergency events that were identified during the development of the facility- and community-based risk assessments. Examples of these strategies may include, but are not limited to, developing a staffing strategy if staff shortages were identified during the risk assessment or developing a surge capacity strategy if the facility has identified it would likely be requested to accept additional patients during an emergency. Facilities will also want to consider evacuation plans. For example, a facility in a large metropolitan city may plan to utilize the support of other large community facilities as alternate care sites for its patients if the facility needs to be evacuated. The facility is also expected to have a backup evacuation plan for instances in which nearby facilities are also affected by the emergency and are unable to receive patients

TRACIE

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			Hospices must include contingencies for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. **Survey Procedures** - Ask to see the written documentation of the facility's risk assessments and associated strategies. - Interview the facility leadership and ask which hazards (e.g. natural, man-made, facility, geographic) were included in the facility's risk assessment, why they were included and how the risk assessment was conducted. - Verify the risk-assessment is based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards.

TRACIE

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0007	EP Program Patient Population	[(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 **(effective 11.29.19).** The plan must do the following:] (3) Address patient/client population, including, but not limited to, persons at-risk; the type of services the [facility] has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.** *Note: ["Persons at risk" does not apply to: ASC, hospice, PACE, HHA, CORF, CMCH, RHC, FQHC, or ESRD facilities.]	The emergency plan must specify the population served within the facility, such as inpatients and/or outpatients, and their unique vulnerabilities in the event of an emergency or disaster. A facility's emergency plan must also address persons at-risk, except for plans of ASCs, hospices, PACE organizations, HHAs, CORFs, CMHCs, RHCs, FQHCs and ESRD facilities. As defined by the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision, and medical care. In addition to those individuals specifically recognized as at-risk in the PAHPA (children, senior citizens, and pregnant women), "at-risk populations" are also individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures and racial and ethnic backgrounds, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. At-risk populations would also include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities as well as others with access and functional needs, and infants and children. Mobility is an important part in effective and timely evacuations, and therefore facilities are expected to properly plan to identify patients who would require additional assistance, ensure that means for transport are accessible and available and that those involved in transport, as well as the patients and residents are made aware of the procedures to evacuate. For outpatient facilities, such as Home Health Agencies (HHAs), the emergency plan is required to ensure that patients with limited mobility are addressed within the plan. The emergency plan must also address the types of services that the facility would be able to provide in an emergency. The emergency plan must identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing internal people with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available. During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available. At

TRACIE

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			a minimum, there should be a qualified person who "is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility." In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and Assistant Secretary for Preparedness and Response (ASPR) when developing strategies for ensuring continuity of operations. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations. **Survey Procedures** • Interview leadership and ask them to describe the following: 　o The facility's patient populations that would be at risk during an emergency event; 　o 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; 　o Services the facility would be able to provide during an emergency; 　o How the facility plans to continue operations during an emergency; 　o Delegations of authority and succession plans. • Verify that all of the above are included in the written emergency plan.

TRACIE

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0009	Process for EP Collaboration	[(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 **(effective 11.29.19).**The plan must do the following:] (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. including documentation of the facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. *(effective 11.29.19)*	While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility must document its efforts to contact these officials to engage in collaborative planning for an integrated emergency response. The facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. For ESRD facilities, §494.120(c)(2) of the ESRD Conditions for Coverage on Special Purpose Dialysis Facilities describes the requirements for ESRD facilities that are set up in an emergency (i.e., an emergency circumstance facility) which are issued a unique CMS Certification Number (CCN). ESRD facilities must incorporate these specific provisions into the coordination requirements under this standard. **Survey Procedures** • Interview facility leadership and ask them to describe their process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation. • Ask for documentation of the facility's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. • For ESRD facilities, ask to see documentation that the ESRD facility contacted the local public health and emergency management agency public official at least annually to confirm that the agency is aware of the ESRD facility's needs in the event of an emergency and know how to contact the agencies in the event of an emergency.

TRACIE

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0013	Development of EP Policies and Procedures	(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* annually **(effective 11.29.19).**	Facilities must develop and implement policies and procedures per the requirements of this standard. The policies and procedures are expected to align with the identified hazards within the facility's risk assessment and the facility's overall emergency preparedness program. We are not specifying where the facility must have the emergency preparedness policies and procedures. A facility may choose whether to incorporate the emergency policies and procedures within their emergency plan or to be part of the facility's Standard Operating Procedures or Operating Manual. However, the facility must be able to demonstrate compliance upon survey, therefore we recommend that facilities have a central place to house the emergency preparedness program documents (to include all policies and procedures) to facilitate review. **Survey Procedures** • Review the written policies and procedures which address the facility's emergency plan and verify the following: o Policies and procedures were developed based on the facility- and community-based risk assessment and communication plan, utilizing an all-hazards approach. • Ask to see documentation that verifies the policies and procedures have been reviewed and updated on an annual basis.

TRACIE

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0020	Policies and Procedures including Evacuation	[(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 (effective 11.29.19). At a minimum, the policies and procedures must address the following:] * [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.	Facilities must develop policies and procedures that provide for the safe evacuation of patients from the facility and include all of the requirements of this standard. RHCs and FQHCs must also place exit signs to guide patients and staff in the event of an evacuation from the facility. Facilities must have policies and procedures which address the needs of evacuees. The facility should also consider in development of the policies and procedures, the evacuation protocols for not only the evacuees, but also staff members and families/patient representatives or other personnel who sought potential refuge at the facility. Additionally, the policies and procedures must address staff responsibilities during evacuations. Facilities must consider the patient population needs as well as their care and treatment. For example, if an evacuation is in progress and the facility must evacuate, leadership should consider the needs for critically ill patients to be evacuated and accompanied by staff who could provide care and treatment enroute to the designated relocation site, in the event trained medical professionals are unavailable by the transportation services. Facilities must consider in their development of policies and procedures, the needs of their patient population and what designated transportation services would be most appropriate. For instance, if a facility primarily cares for critically ill patients with ventilation needs and life-saving equipment, the transportation services should be able to assist in evacuation of this special population and be equipped to do so. Additionally, facilities may also find it prudent to consider alternative methods for evacuation and patient care and treatment, such as mentioned above to have staff members evacuate with patients in given situations. Additionally, facilities should consider their triaging system when coordinating the tracking and potential evacuation of patient/residents/clients. For instance, a triaging system for evacuation may consider the most critical patients first followed by those less critical and dependent on life-saving equipment. Considerations for prioritization may be based on, among other things, acuity, mobility status (stretch-bound/wheelchair/ambulatory), and location of the unit, availability of a known transfer destination or some combination thereof. Included within this system should be who (specifically) will be tasked with making triage decisions. Following the triaging system, staff should consider the communication of patient care requirements

TRACIE

| Tag # | Title | Tag Text (Regulatory Text)

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

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

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

TRACIE

| 0022 | Policies and Procedures for Sheltering | (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~~ **(effective 11.29.19).]** At a minimum, the policies and procedures must address the following:]

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

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

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

TRACIE

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0023	Policies and Procedures for Medical Docs.	[(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~~ **(effective 11.29.19).**] At a minimum, the policies and procedures must address the following:] (5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.	In addition to any existing requirements for patient records found in existing laws, under this standard, facilities are required to ensure that patient records are secure and readily available to support continuity of care during emergency. This requirement does not supersede or take away any requirements found under the provider/supplier's medical records regulations, but rather, this standard adds to such policies and procedures. These policies and procedures must also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Privacy and Security Rules at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information. **Survey Procedures** • Ask to see a copy of the policies and procedures that documents the medical record documentation system the facility has developed to preserves patient (or potential and actual donor for OPOs) information, protects confidentiality of patient (or potential and actual donor for OPOs) information, and secures and maintains availability of records.

TRACIE

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0024	Policies and Procedures for Volunteers	[(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~~ **(effective 11.29.19).**] 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.	During an emergency, a facility may need to accept volunteer support from individuals with varying levels of skills and training. The facility must have policies and procedures in place to facilitate this support. In order for volunteering healthcare professionals to be able to perform services within their scope of practice and training, facilities must include any necessary privileging and credentialing processes in its emergency preparedness plan policies and procedures. Non-medical volunteers would perform non-medical tasks. Facilities have flexibility in determining how best to utilize volunteers during an emergency as long as such utilization is in accordance with State law, State scope of practice rules, and facility policy. These may also include federally designated health care professionals, such as Public Health Service (PHS) staff, National Disaster Medical System (NDMS) medical teams, Department of Defense (DOD) Nurse Corps, Medical Reserve Corps (MRC), or personnel such as those identified in federally designated Health Professional Shortage Areas (HPSAs) to include licensed primary care medical, dental, and mental/behavioral health professionals. Facilities are also encouraged to integrate State-established volunteer registries, and where possible, State-based Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP). Facilities are expected to include in its emergency plan a method for contacting off-duty staff during an emergency and procedures to address other contingencies in the event staff are not able to report to duty which may include, but are not limited to, utilizing staff from other facilities and state or federally-designated health professionals. **Survey Procedures** • Verify the facility has included policies and procedures for the use of volunteers and other staffing strategies in its emergency plan.

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0029	Development of Communication Plan	(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~~ (effective 11.29.19).	Facilities must have a written emergency communication plan that contains how the facility coordinates patient care within the facility, across healthcare providers, and with state and local public health departments. The communication plan should include how the facility interacts and coordinates with emergency management agencies and systems to protect patient health and safety in the event of a disaster. The development of a communication plan will support the coordination of care. The plan must be reviewed annually and updated as necessary. We are allowing facilities flexibility in how they formulate and operationalize the requirements of the communication plan. Facilities in rural or remote areas with limited connectivity to communication methodologies such as the Internet, World Wide Web, or cellular capabilities need to ensure their communication plan addresses how they would communicate and comply with this requirement in the absence of these communication methodologies. For example, if a facility is located in a rural area, which has limited or no Internet and phone connectivity during an emergency, it must address what alternate means are available to alert local and State emergency officials. Optional communication methods facilities may consider include satellite phones, radios and short wave radios. **Survey Procedures** - Verify that the facility has a written communication plan by asking to see the plan. - Ask to see evidence that the plan has been reviewed (and updated as necessary) on an annual basis.

TRACIE

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0030	Names and Contact Information	[(c) The facility (New 3.6.19) 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 (effective 11.29.19).] 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.	A facility must have the contact information for those individuals and entities outlined within the standard. The requirement to have contact information for "other facilities" requires a provider or supplier to have the contact information for another provider or supplier of the same type as itself. For instance, hospitals should have contact information for other hospitals and CORFs should have contact information for other CORFs, etc. While not required, facilities may also find it prudent to have contact information for other facilities not of the same type. For instance a hospital may find it appropriate to have the contact information of LTC facilities within a reasonable geographic area, which could assist in facilitating patient transfers. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership and staff during an emergency event. Facilities which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information must be reviewed and updated as necessary at least annually. Contact information contained in the communication plan must be accurate and current. Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list. Transplant Centers should be included in the development of the hospitals communication plans. In the case of a Medicare-approved transplant center, a communication plan needs to be developed and disseminated between the hospitals, OPO, and transplant patients. For example, if the transplant program is planning to transfer patients to another transplant center due to an emergency, the communication plan between the hospitals, the OPO, and the patient should include the responsibilities of each of the facility types to ensure continuity of care. During an emergency, should an organ offer become available at the time the patient is at the "transferred hospital," the OPO's emergency preparedness communication plan should address how this information will be communicated to both the OPO and the patient of where their care will be continued. **Survey Procedures** • Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information.

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			• Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

TRACIE

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0031	Emergency Officials Contact Information	[(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~~ **(effective 11.29.19).**] 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.	A facility must have the contact information for those individuals and entities outlined within the standard. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Facilities are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information must be reviewed and updated at least annually. **Survey Procedures** • Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information. • Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

TRACIE

| 0032 | Primary/Alternate Means for Communication | [(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~~ **(effective 11.29.19).**] 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. | Facilities are required to have primary and alternate means of communicating with staff, Federal, State, tribal, regional, and local emergency management agencies. Facilities have the discretion to utilize alternate communication systems that best meets their needs. However, it is expected that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. We recognize that some facilities, especially in remote areas, may have difficulty using some communication systems, such as cellular phones, even in non-emergency situations, which should be outlined within their risk assessment and addressed within the communications plan. It is expected these facilities would address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency.

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

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

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

| 0033 | Methods for Sharing Information | [(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~~ **(effective 11.29.19).**] The communication plan must include all of the following:

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

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). [This provision is not required for HHAs under §484.22(c), CORFs under §485.68(c), and RHCs/FQHCs under §491.12(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).

Note: In the event of an evacuation, a means to release patient information as permitted under HIPAA is not required for HHAs under §484.22(c), CORFs under §485.68(c), and RHCs/FQHCs under §491.12(c). | Facilities are required to develop a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

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

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

Survey Procedures |

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

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0034	Sharing Information on Occupancy/Needs	[(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~~ **(effective 11.29.19).**] 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.	Facilities, except for transplant centers, must have a means of providing information about the facility's needs and its ability to provide assistance to the authority having jurisdiction (local and State emergency management agencies, local and state public health departments, the Incident Command Center, the Emergency Operations Center, or designee). For hospitals, CAHs, RNHCIs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, they must also have a means for providing information about their occupancy. Occupancy reporting is considered, but not limited to, reporting the number of patients currently at the facility receiving treatment and care or the facility's occupancy percentage. The facility should consider how its occupancy affects its ability to provide assistance. For example, if the facility's occupancy is close to 100% the facility may not be able to accept patients from nearby facilities. The types of "needs" a facility may have during an emergency and should communicate to the appropriate authority would include but is not limited to, shortage of provisions such as food, water, medical supplies, assistance with evacuation and transfers, etc. Note: The authority having jurisdiction varies by local, state and federal emergency management structures as well as the type of disaster. For example, in the event of a multi-state wildfire, the jurisdictional authority who would take over the Incident Command Center or state-wide coordination of the disaster would likely be a fire-related agency. We are not prescribing the means that facilities must use in disseminating the required information. However, facilities should include in its communication plan, a process to communicate the required information. Note: As defined by the Federal Emergency Management Administration (FEMA), an Incident Command System (ICS) is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. (FEMA, 2016). The industry, as well as providers/suppliers, use various terms to refer to the same function and we have used the term ''Incident Command Center'' to mean ''Emergency Operations Center'' or ''Incident Command Post.'' Local, State, Tribal and Federal emergency preparedness officials, as well as regional healthcare coalitions, can assist facilities in

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			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.

TRACIE

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0036	Emergency Prep Training and Testing	(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* annually **(effective 11.29.19).**	An emergency preparedness training and testing program as specified in this requirement must be documented and reviewed and updated on at least an annual basis. The training and testing program must reflect the risks identified in the facility's risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location. Training refers to a facility's responsibility to provide education and instruction to staff, contractors, and facility volunteers to ensure all individuals are aware of the emergency preparedness program. Testing is the concept in which training is operationalized and the facility is able to evaluate the effectiveness of the training as well as the overall emergency preparedness program. Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement. **Survey Procedures** • Verify that the facility has a written training and testing (and for ESRD facilities, a patient orientation) program that meets the requirements of the regulation. • Verify the program has been reviewed and updated on, at least, an annual basis by asking for documentation of the annual review as well as any updates made. • Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

TRACIE

0037	Emergency Prep Training Program	(1) Training program. The [facility, except CAHs, ASCs, PACE organizations, PRTFs, Hospices, and dialysis facilities] must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role. (ii) Provide emergency preparedness training at least *every 2 years* ~~annually~~ *(effective 11.29.19).* (iii) Maintain documentation of *all emergency preparedness (effective 11.29.19)* 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. (effective 11.29.19)*	Facilities are required to provide initial training in emergency preparedness policies and procedures that are consistent with their roles in an emergency to all new and existing staff, individuals providing services under arrangement, and volunteers. This includes individuals who provide services on a per diem basis such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency. PACE organizations and CAHs have additional requirements. PACE organizations must also provide initial training to contractors and PACE participants. CAHs must also include initial training on the following: prompt reporting and extinguishing of fires; protection; and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities. Facilities should provide initial emergency training during orientation (or shortly thereafter) to ensure initial training is not delayed. With the exception of CORFs which must complete initial training within the first two weeks of employment, we recommend initial training be completed by the time the staff has completed the facility's new hire orientation program. Additionally, in the case of facilities with multiple locations, such as multi-campus hospitals, staff, individuals providing services under arrangement, or volunteers should be provided initial training at their specific location and when they are assigned to a new location. Facilities have the flexibility to determine the focus of their annual training, as long as it aligns with the emergency plan and risk assessment. Ideally, annual training should be modified each year, incorporating any lessons learned from the most recent exercises, real-life emergencies that occurred in the last year and during the annual review of the facility's emergency program. For example, annual training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's annual review. While facilities are required to provide annual training to all staff, it is up to the facility to decide what level of training each staff member will be required to complete each year based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain clinical staff may require additional topics. For example, dietary staff who prepare meals may not need to complete annual training that is focused on patient evacuation procedures. Instead, the facility may provide training that focuses on the proper preparation and storage of food in an emergency. In addition, depending on specific staff duties during an emergency, a facility may determine that documented external training is sufficient to meet some or all of the facility's annual training requirements. For example, staff who work with

TRACIE

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

Facilities may contract with individuals providing services who also provide services in multiple surrounding areas. For instance, an ICF/IID may contract a nutritionist who also provides services in other locations. Given that these contracted individuals may provide services at multiple facilities, it may not be feasible for them to receive formal training for each of the facilities for emergency preparedness programs. The expectation is that each individual knows the facility's emergency program and their role during emergencies, however the delivery of such training is left to the facility to determine. Facilities in which these individuals provide services may develop some type of training documentation- i.e. the facility's emergency plan, important contact information, and the facility's expectation for those individuals during an emergency etc. which documents that the individual received the information/training. Furthermore, if a surveyor asks one of these individuals what their role is during a disaster, or any relevant questions, then the expectation is that the individual can describe the emergency plans/their role. (New 3.6.19)

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

Survey Procedures
- Ask for copies of the facility's initial emergency preparedness training and annual emergency preparedness training offerings.
- Interview various staff and ask questions regarding the facility's initial and annual training course, to verify staff knowledge of emergency procedures.
- Review a sample of staff training files to verify staff have received initial and annual emergency preparedness training. |
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| 0039 | Emergency Prep Testing Requirements | 2) **Testing.** The RHC/FQHC must conduct exercises to test the emergency plan at least annually. The RHC/FQHC must:

   i. Participate in a full-scale exercise that is community-based ***every 2 years; or (effective 11.29.19)***
      a. When a community-based exercise is not accessible, ***conduct a facility-based functional exercise every 2 years;*** or ~~an individual, facility-based.~~ ***(effective 11.29.19)***
      b. If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in ***its next required*** ~~a~~ ***(effective 11.29.19)*** community-based or individual, facility-based ~~full-scale~~ ***functional (effective 11.29.19)*** exercise for 1 year 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, (effective 11.29.19)*** 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 (effective 11.29.19)*** | Facilities must on an annual basis conduct exercises to test the emergency plan, which for LTC facilities also includes unannounced staff drills using the emergency procedures. Specifically, facilities are required to conduct a tabletop exercise and participate in a full-scale community-based exercise or conduct an individual facility exercise if a community-based exercise is not available. As the term full-scale exercise may vary by sector, facilities are not required to conduct a full-scale exercise as defined by FEMA or DHS's Homeland Security Exercise and Evaluation Program (HSEEP). For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility's functional capabilities by simulating a response to an emergency that would impact the facility's operations and their given community. There is also definition for "community" as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so, facilities have the flexibility to participate in and conduct exercises that more realistically reflect the risks and composition of their communities. Facilities are expected to consider their physical location, agency and other facility responsibilities and needs of the community when planning or participating in their exercises. The term could, however, mean entities within a state or multi-state region.

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

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

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		c. A tabletop exercise ***or workshop (effective 11.29.19)*** that is ~~includes a group discussion~~ ***(effective 11.29.19)*** led by a facilitator and ***includes a group discussion (effective 11.29.19)***, 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 RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.	requisite documentation is developed and available to demonstrate their compliance with this requirement. Facilities are encouraged to engage with their area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. Health Care Coalitions (HCCs) are groups of individual health care and response organizations who collaborate to ensure each member has what it needs to respond to emergencies and planned events. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness. There is value in participating in HCCs for participating in strategic planning, information sharing and resource coordination. HCC's do not coordinate individual facility exercises, but rather serve as a conduit to provide an opportunity for other provider types to participate in an exercise. HCCs should communicate exercise plans with local and state emergency preparedness agencies and HCCs will benefit the entire community's preparedness. In addition, CMS does not regulate state and local government disaster planning agencies. It is the sole responsibility of the facility to be in compliance. Facilities that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities. Facilities that elect to develop a small community-based exercise have the opportunity to not only assess their own emergency preparedness plans but also better understand the whole community's needs, identify critical interdependencies and or gaps and potentially minimize the financial impact of this requirement. For example, a LTC facility, a hospital, an ESRD facility, and a home health agency, all within a given area, could conduct a small community-based exercise to assess their individual facility plans and identify interdependencies that may impact facility evacuations and or address potential surge scenarios due to a prolonged disruption in dialysis and home health care services. Those that elect to conduct a community-based exercise should make an effort to contact their local/state emergency officials and healthcare coalitions, where appropriate, and offer them the opportunity to attend as they can provide valuable insight into the broader emergency planning and response activities in their given area. Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe "shelter-in-place" location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may

| | | | require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient's continuity of care.

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

Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the annual exercise requirement and exempts the facility for engaging in a community-based full-scale exercise or individual, facility-based mock disaster drill for one year following the actual event; and facilities must be able to demonstrate this through written documentation. If a facility activates its emergency plan twice in one year, then the facility would be exempt from both exercises (community-based full-scale exercise and the secondary exercise- individual, facility- based mock disaster drill, table top exercise) for one year following the actual events. (New 3.9.16)

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

Survey Procedures |

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

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Tag #	Title	Tag Text (Regulatory Text) (This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)	Interpretive Guidelines (These Interpretive Guidelines have NOT been updated to reflect the Burden Reduction Final Rule Issued on September 30, 2019. Once CMS has issued updated Interpretive Guidelines, this section will be updated to reflect the new language.)
0042	Integrated Health Systems	(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	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 preparedness program. Rather it is a permissible option. In addition, the separately certified facilities within the healthcare system are not required to participate in the unified and integrated emergency preparedness program. It is simply an option for each facility. If this option is taken, the healthcare system's unified emergency preparedness program should be updated each time a facility enters or leaves the healthcare system's program. If a healthcare system elects to have a unified emergency preparedness program, the integrated program must demonstrate that each separately certified facility within the system that elected to participate in the system's integrated program actively participated in the development of the program. Therefore, each facility should designate personnel who will collaborate with the healthcare system to develop the plan. The unified and integrated plan should include documentation that verifies each facility participated in the development of the plan. This could include the names of personnel at each facility who assisted in the development of the plan and the minutes from planning meetings. All components of the emergency preparedness program that are required to be reviewed and updated at least annually must include all participating facilities. Again, each facility must be able to prove that it was involved in the annual reviews and updates of the program. The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable. A unified program must be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into

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

TRACIE

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			hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs must meet all of the specific regulatory requirements for each of these facility types. Because of the many different configurations of healthcare systems, from the different types of facilities in the system, to the varied locations of the facilities, it is not possible to specify how unified training and testing programs should be developed. There is no "one size fits all" model that can be prescribed. However, if the system decides to develop a unified and integrated training and testing program, the training and testing must be developed based on the community and facility based hazards assessments at each facility that is participating in the unified emergency preparedness program. Each facility must maintain individual training records of staff and records of all required training exercises. **Survey Procedures** • Verify whether or not the facility has opted to be part of its healthcare system's unified and integrated emergency preparedness program. Verify that they are by asking to see documentation of its inclusion in the program. • Ask to see documentation that verifies the facility within the system was actively involved in the development of the unified emergency preparedness program. • Ask to see documentation that verifies the facility was actively involved in the annual reviews of the program requirements and any program updates. • Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program). • Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.

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