

End Stage Renal Disease Facilities Requirements CMS Emergency Preparedness Final Rule

Updates Effective November 29, 2019

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 End Stage Renal Disease (ESRD) Facility 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 an updated [Interpretive Guidelines](#) (Appendix Z) on February 1, 2019). Changes in those 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:

ESRD Facility Requirements as Written in the Final Rule

Emergency Plan

Policies and Procedures

Communications Plan

Training and Testing

Integrated Healthcare Systems

ESRD Facility Requirements as Written in the Interpretive Guidelines

ESRD Facility Requirements as Written in the Final Rule and as amended by 2019 Burden Reduction (November 2019)

The following excerpt is taken from page 64042 of the Final Rule, accessible directly by this link: <https://www.federalregister.gov/d/2016-21404/p-amd-41> 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**).

PART 494—CONDITIONS FOR COVERAGE FOR ESRD FACILITIES

38. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 494.60[Amended]

39. Amend § 494.60 by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

40. Add § 494.62 to subpart B to read as follows:

§ 494.62

Emergency preparedness.

The ESRD facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The ESRD facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be evaluated 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 dialysis facility 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 dialysis facility's~~

~~efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts~~ **(effective 11.29.19)**. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least ~~annually~~ **every 2 years (effective 11.29.19)**. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

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

- 1) A system to track the location of on-duty staff and sheltered patients in the dialysis facility's care during and after an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.
- 2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.
- 3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.
- 4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
- 5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.
- 6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients.
- 7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.
- 8) How emergency medical system assistance can be obtained when needed.
- 9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) Communication plan. The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least ~~annually~~ **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 dialysis facilities.
 - v. Volunteers.
- 2) Contact information for the following:
 - i. Federal, State, tribal, regional, or local emergency preparedness staff.
 - ii. Other sources of assistance.
- 3) Primary and alternate means for communicating with the following:
 - i. Dialysis facility's staff.
 - ii. Federal, State, tribal, regional, or local emergency management agencies.
- 4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care 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).
- 6) 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).
- 7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least ~~annually~~ **every 2 years (effective 11.29.19)**.

- 1) **Training program.** The dialysis facility must do all of the following:
 - i. Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
 - ii. Provide emergency preparedness training at least ~~annually~~ **every 2 years (effective 11.29.19)**. Staff training must:
 - iii. Demonstrate staff knowledge of emergency procedures, including informing patients of—
 - a. What to do;
 - b. Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;
 - c. Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to

- receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and
- d. How to disconnect themselves from the dialysis machine if an emergency occurs.
 - iv. Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and
 - v. Properly train its nursing staff in the use of emergency equipment and emergency drugs.
 - vi. Maintain documentation of the training.
 - vii. ***If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures. (effective 11.29.19)***
- 2) **Testing.** The ESRD facility must conduct exercises to test the emergency plan at least annually. The ESRD facility 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 ESRD facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD facility 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:
 - (C) A second full-scale exercise that is community-based or individual, facility-based ***functional exercise; or***
 - (D) ***A mock disaster drill; or (effective 11.29.19)***
 - (E) 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 ESRD facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ESRD facility's emergency plan, as needed.

(e) Integrated healthcare systems. If a dialysis 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 dialysis 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 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 ESRD Facilities

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>

ESRD Facility 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:	<p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.

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.)
0003	Establishment of the EP Program Dialysis	<p>§494.62 Condition for Coverage: The dialysis facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p> <p>The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:</p>	<p>Under this condition, the ESRD facility is required to develop and update an emergency preparedness program that meets all of the standards contained within the condition. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health and safety needs of their patient population during an emergency; as well as the whole community during and surrounding an emergency event (natural or man-made).</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Ask to see written or electronic documentation of the program.

<p>0004</p>	<p>Develop and Maintain EP Program</p>	<p>[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.]</p> <p>* [For ESRD Facilities at §494.62(a):] Emergency Plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least every 2 years annually (effective 11.29.19).</p>	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • Natural disasters • Man-made disasters, • Facility-based disasters that include but are not limited to: <ul style="list-style-type: none"> ○ Care-related emergencies; ○ Equipment and utility failures, including but not limited to power, water, gas, etc.; ○ Interruptions in communication, including cyber-attacks; ○ Loss of all or portion of a facility; and ○ Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable). • EIDs such as Influenza, Ebola, Zika Virus and others. <ul style="list-style-type: none"> ○ 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) <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.
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0006	Maintain and Annual EP Updates	<p>[(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:]</p> <p>(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.*</p> <p>(2) Include strategies for addressing emergency events identified by the risk assessment.</p>	<p>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).</p> <p>“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.</p> <p>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.</p> <p>When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following:</p> <ul style="list-style-type: none"> • 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;
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			<ul style="list-style-type: none"> • 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. <p>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.</p> <p>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.</p> <p>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</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.
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0007	EP Program Patient Population	<p>[(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:]</p> <p>(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.**</p> <p>*Note: [“Persons at risk” does not apply to: ASC, hospice, PACE, HHA, CORF, CMCH, RHC, FQHC, or ESRD facilities.]</p>	<p>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.</p> <p>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.</p> <p>The emergency plan must also address the types of services that the facility would be able to provide in an emergency. The emergency plan must identify which staff would assume specific roles in another’s absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing internal people with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available. During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available. At a minimum, there should be a qualified person who "is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility."</p> <p>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</p>
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			<p>encouraged to refer to and utilize resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations.</p> <p>Survey Procedures</p> <ul style="list-style-type: none">• Interview leadership and ask them to describe the following:<ul style="list-style-type: none">○ The facility's patient populations that would be at risk during an emergency event;○ Strategies the facility (except for an ASC, hospice, PACE organization, HHA, CORF, CMHC, RHC, FQHC and ESRD facility) has put in place to address the needs of at-risk or vulnerable patient populations;○ Services the facility would be able to provide during an emergency;○ How the facility plans to continue operations during an emergency;○ Delegations of authority and succession plans.• Verify that all of the above are included in the written emergency plan.
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Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0009	Process for EP Collaboration	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>[(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:]</p> <p>(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)</p> <p>* [For ESRD facilities only at §494.62(a)(4)]: (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts (effective 11.29.19). The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.</p>	<p>(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.)</p> <p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.

<p>0013</p>	<p>Development of EP Policies and Procedures</p>	<p>*[For ESRD Facilities at §494.62(b):] Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years annually (effective 11.29.19). These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.</p>	<p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Review the written policies and procedures which address the facility's emergency plan and verify the following: <ul style="list-style-type: none"> ○ 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.
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<p>0018</p>	<p>Procedures for Tracking of Staff and Patients</p>	<p>[(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).]</p> <p>At a minimum, the policies and procedures must address the following:]</p> <p>(1) A system to track the location of on-duty staff and sheltered patients in the [facility's] care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the [facility] must document the specific name and location of the receiving facility or other location.</p> <p>*[For ESRD at § 494.62(b):] Policies and procedures. (2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.</p> <p>Interpretive Guidelines applies to: §403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).</p>	<p>Facilities must develop a means to track patients and on-duty staff in the facility's care during an emergency event. In the event staff and patients are relocated, the facility must document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency.</p> <p>CMHCs, PRTF's, LTC facilities, ICF/IIDs, PACE organizations and ESRD Facilities are required to track the location of sheltered patients and staff during and after an emergency.</p> <p>We are not specifying which type of tracking system should be used; rather, a facility has the flexibility to determine how best to track patients and staff, whether it uses an electronic database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response systems as needed in the interest of the patient. It is recommended that a facility that is using an electronic database consider backing up its computer system with a secondary source, such as hard copy documentation in the event of power outages. The tracking systems set up by facilities may want to consider who is responsible for compiling/securing patient records and what information is needed during tracking a patient throughout an evacuation. A number of states already have such tracking systems in place or under development and the systems are available for use by health care providers and suppliers. Facilities are encouraged to leverage the support and resources available to them through local and national healthcare systems, healthcare coalitions, and healthcare organizations for resources and tools for tracking patients.</p> <p>Facilities are not required to track the location of patients who have voluntarily left on their own, or have been appropriately discharged, since they are no longer in the facility's care. However, this information must be documented in the patient's medical record should any questions later arise as to the patient's whereabouts.</p> <p>We also recommend facilities ensure they follow their evacuation procedures as outlined under this section during disasters and emergencies. Facilities are required follow all state/local mandates or requirements under most CoPs/CfCs. If your local community, region, or state declares a state of emergency and is requiring a mandatory evacuation of the area, facilities should abide by these laws and mandates. (New 3.6.19)</p> <p>Note: If an ASC is able to cancel surgeries and close (meaning there are no patients or staff in the ASC), this requirement of tracking patients and staff would no longer be applicable. Similarly to ESRD standard practices, if an emergency was imminent and able to be predicted (i.e. inclement weather conditions, etc.) we would expect that ASCs cancel surgeries and cease operations, which would eliminate the need to track patients and</p>
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			<p>staff.</p> <p>Survey Procedures</p> <ul style="list-style-type: none">• Ask staff to describe and/or demonstrate the tracking system used to document locations of patients and staff.• Verify that the tracking system is documented as part of the facilities' emergency plan policies and procedures.
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<p>0020</p>	<p>Policies and Procedures including Evacuation</p>	<p>[(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:]</p> <p>* [For CORFs at §485.68(b)(1), Clinics, Rehabilitation Agencies, OPT/Speech at §485.727(b)(1), and ESRD Facilities at §494.62(b)(2):]</p> <p>Safe evacuation from the ESRD Facilities, which includes staff responsibilities, and needs of the patients.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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 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.</p> <p>Finally, facilities policies and procedures must outline primary and alternate means for communication with</p>
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			<p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none">• 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.
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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.)
0022	Policies and Procedures for Sheltering	<p>(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:]</p> <p>(4) A means to shelter in place for patients, staff, and volunteers who remain in the [facility].</p>	<p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0023	Policies and Procedures for Medical Docs.	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>[(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:]</p> <p>(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.</p>	<p>(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.)</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> 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.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0024	Policies and Procedures for Volunteers	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>[(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:]</p> <p>(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.</p>	<p>(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.)</p> <p>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).</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Verify the facility has included policies and procedures for the use of volunteers and other staffing strategies in its emergency plan.

0025	Arrangement with other Facilities	<p>[(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).]</p> <p>At a minimum, the policies and procedures must address the following:]</p> <p>*[For PACE at §460.84(b), ICF/IIDs at §483.475(b), CAHs at §486.625(b), CMHCs at §485.920(b) and ESRD Facilities at §494.62(b):] Policies and procedures. (7) [or (6), (8)] The development of arrangements with other [facilities] [or] other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.</p>	<p>Facilities are required to have policies and procedures which include prearranged transfer agreements, which may include written agreements or contracted arrangements with other facilities and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.</p> <p>Facilities should consider all needed arrangements for the transfer of patients during an evacuation. For example, if a CAH is required to evacuate, policies and procedures should address what facilities are nearby and outside the area of disaster which could accept the CAH’s patients. Additionally, the policies and procedures and facility agreements should include pre-arranged agreements for transportation between the facilities. The arrangements should be in writing, such as Memorandums of Understanding (MOUs) and Transfer Agreements, in order to demonstrate compliance.</p> <p>For RNHCIs, at § 403.748(b)(7), the term “non-medical” is added in order to accommodate the uniqueness of the RNHCI non-medical care.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Ask to see copies of the arrangements and/or any agreements the facility has with other facilities to receive patients in the event the facility is not able to care for them during an emergency. • Ask facility leadership to explain the arrangements in place for transportation in the event of an evacuation.
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<p>0026</p>	<p>Roles under a Waiver Declared by Secretary</p>	<p>[(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:]</p> <p>(8) [(6), (6)(C)(iv), (7), or (9)] The role of the [facility] under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.</p>	<p>Facilities must develop and implement policies and procedures that describe its role in providing care at alternate care sites during emergencies. It is expected that state or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.</p> <p>Facility's policies and procedures must specifically address the facility's role in emergencies where the President declares a major disaster or emergency under the Stafford Act or an emergency under the National Emergencies Act, and the HHS Secretary declares a public health emergency Examples of 1135 waivers include some of the existing CoPs; Licensure for Physicians or others to provide services in the affected State; EMTALA; Medicare Advantage out of network providers and HIPAA.</p> <p>Facilities policies and procedures should address what coordination efforts are required during a declared emergency in which a waiver of federal requirements under section 1135 of the Act has been granted by the Secretary. For example, if due to a mass casualty incident in a geographic location, an 1135 waiver may be granted to waive licensure for physicians in order for these individuals to assist at a specific facility where they do not normally practice, then the facility should have policies and procedures which outline the responsibilities during the duration of this waiver period. For instance, the policies may establish a lead person in charge for accountability and oversight of assisting physicians not usually under contract with the facility.</p> <p>Additionally, facilities should also have in place policies and procedures which address emergency situations in which a declaration was not made and where an 1135 waiver may not be applicable, such as during a disaster affecting the single facility. In this case, policies and procedures should address potential transfers of patients; timelines of patients at alternate facilities, etc.</p> <p>For additional 1135 Waiver information, the SCG Emergency Preparedness Website has resources.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Verify the facility has included policies and procedures in its emergency plan describing the facility's role in providing care and treatment (except for RNHCI, for care only) at alternate care sites under an 1135 waiver.
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Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0027	Dialysis Medical System Assistance	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>§494.62(b)(8) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years annually (effective 11.29.19).] At a minimum, the policies and procedures must address the following:]</p> <p>(8) How emergency medical system assistance can be obtained when needed.</p>	<p>(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.)</p> <p>ESRD facilities must include in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed. Medical system assistance can be considered but not limited to, outside assistance such as from a nearby hospital. Additionally, this can mean assistance from other ESRD facilities including personnel to assist during a single-facility disaster.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Verify the ESRD facility has included in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
		<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>§494.62(b)(9) Condition for Coverage: [(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years annually (effective 11.29.19).]</p> <p>At a minimum, the policies and procedures must address the following:]</p> <p>(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.</p>	<p>(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.)</p> <p>ESRD facilities must include policies and procedures in its emergency plan that address a process that confirms that the specific requirements listed under this standard are on the premises at all times and immediately available in the event of an emergency. The process must be in writing. It is the facilities responsibility to determine what equipment is should on the premises and available during an emergency to assist patients in an emergency. Additionally, it is the responsibility of the facility to ensure that all necessary equipment identified in this area, Should be in working order at all times in accordance with the manufacturer instructions. Emergency drugs should not be out of date and should be stored and maintained based on the manufacturer instructions. The facility is in the best position to determine what emergency equipment it needs to have available. In addition, dialysis facilities need to be able to manage care-related emergencies during an emergency when other assistance, emergency medical services systems, may not be immediately available to them.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Verify the dialysis facility has a process in place by which its staff can confirm that emergency equipment is on the premises and immediately available. • Verify that the process includes at least the listed emergency equipment within its emergency plan by asking to see a copy of the written processes/ policy on emergency equipment and medications. • Check to see that all of the above equipment is available and in working order. Ask to see procedures/checklist for ensuring equipment is checked. • Check to see that all emergency drugs are not out of date.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0029	Development of Communication Plan	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>(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).</p>	<p>(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.)</p> <p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.

0030	Names and Contact Information	<p>[(c) The [facility, except RNHCIs, hospices, transplant centers, and HHAs] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years annually (effective 11.29.19).]</p> <p>The communication plan must include all of the following:]</p> <p>(1) Names and contact information for the following:</p> <p>(i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians (iv) Other [facilities]. (v) Volunteers.</p>	<p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.
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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.)
0031	Emergency Officials Contact Information	<p>[(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:</p> <p>(2) Contact information for the following:</p> <p>(i) Federal, State, tribal, regional, and local emergency preparedness staff.</p> <p>(ii) Other sources of assistance.</p>	<p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.

0032	Primary/Alternate Means for Communication	<p>[(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.)</p> <p>The communication plan must include all of the following:</p> <p>(3) Primary and alternate means for communicating with the following:</p> <p>(i) [Facility] staff.</p> <p>(ii) Federal, State, tribal, regional, and local emergency management agencies.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.
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<p>0033</p>	<p>Methods for Sharing Information</p>	<p>[(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:</p> <p>(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.</p> <p>(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).]</p> <p>(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).</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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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<p>0034</p>	<p>Sharing Information on Occupancy/Needs</p>	<p>[(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:</p> <p>(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.</p>	<p>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, RNHCs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, they must also have a means for providing information about their occupancy.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Note: As defined by the Federal Emergency Management Administration (FEMA), an Incident Command System (ICS) is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. (FEMA, 2016). The industry, as well as providers/suppliers, use various terms to refer to the same function and we have used the term "Incident Command Center" to mean "Emergency Operations Center" or "Incident Command Post." Local, State, Tribal and Federal emergency preparedness officials, as well as regional healthcare coalitions, can assist facilities in the identification of their Incident Command Centers and reporting requirements dependent on an emergency.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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, RNHCs, inpatient hospices, PRTFs, LTC facilities, and ICF/IIDs, also verify if the communication plan includes a means of providing information about their occupancy.
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0036	Emergency Prep Training and Testing	*[For ESRD Facilities at §494.62(d):] Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing and orientation program must be reviewed evaluated (effective 11.29.19) and updated at least every 2 years annually (effective 11.29.19).	<p>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.</p> <p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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).

0038	ESRD EP Training Program	<p>§494.62(d)(1): Condition for Coverage:</p> <p>(d)(1) Training program. The dialysis facility must do all of the following:</p> <p>(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.</p> <p>(ii) Provide emergency preparedness training at least every 2 years annually (effective 11.29.19).</p> <p>Staff training must:</p> <p>(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of—</p> <p>(A) What to do;</p> <p>(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;</p> <p>(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and</p> <p>(D) How to disconnect themselves from the dialysis machine if an emergency occurs.</p> <p>(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and</p> <p>(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.</p> <p>(vi) Maintain documentation of the training.</p> <p><i>(vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures. (effective 11.29.19).</i></p>	
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<p>0039</p>	<p>Emergency Prep Testing Requirements</p>	<p>2) Testing. The ESRD facility must conduct exercises to test the emergency plan at least annually. The ESRD facility must:</p> <ul style="list-style-type: none"> i. Participate in a full-scale exercise that is community-based every 2 years; or (effective 11.29.19) <ul style="list-style-type: none"> (F) 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) (G) If the ESRD facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD facility is exempt from engaging in its next required (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: <ul style="list-style-type: none"> (H) A second full-scale exercise that is community-based or individual, facility-based functional exercise; or (I) A mock disaster drill; or (effective 11.29.19) (J) A tabletop exercise or workshop (effective 11.29.19) that includes 	<p>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.</p> <p>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.</p> <p>Facilities are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement. In doing so, they are expected to document the date, the personnel and the agency or healthcare coalition that they contacted. It is also important to note that agencies and or healthcare coalitions conducting these exercises will not have the resources to fulfill individual facility requirements and thus will only serve as a conduit for broader community engagement and coordination prior to, during and after the full-scale community-based exercise. Facilities are responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement.</p>
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| | | | <ul style="list-style-type: none">• 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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040	ESRD Patient Orientation Training	<p>§494.62(d)(3) Condition for Coverage: Patient orientation: Emergency preparedness patient training. The dialysis facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.</p>	<p>ESRD facilities are required to implement an orientation and training program which educates patients on the emergency preparedness policies and procedures of the facility, including the requirements of the ESRD facility’s emergency preparedness training program under §494.62(d)(1). For instance, the orientation and training program should include how patients would be notified of an emergency; what particular procedures they are expected to follow; communication protocols for contacting the ESRD facility and identifying an alternate location for their treatment in the event of a facility closure as well as shelter-in place.</p> <p>Additionally, patients should be oriented to how they would evacuate the facility (if required) and the location of potential transfer sites or services. For instance, if an emergency situation required evacuation during a dialysis treatment, the facility must train the patient on how to safely disconnect from the machine. Additionally, in this example, if the patient was disconnected, the patient should be informed that he or she will be transferred to another facility or hospital to complete the dialysis (if required).</p> <p>Ultimately, the emergency preparedness orientation and training for patients should adequately address scenarios which were identified in the ESRD facility’s risk assessment and address specific actions required for the emergency situation. The orientation and training program is intended to ensure patients are informed, ready to assist themselves, and are aware of the facility procedures and resources (e.g. KCER) that can provide up to date information during and after an emergency.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Verify the ESRD facility has implemented their policies and procedures and are actively providing orientation and training of all their patients for the emergency preparedness program. • Interview a patient and ask them to describe their orientation to the facility in terms of emergency protocols and procedures.

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0042	Integrated Health Systems	<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>(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.</p> <p>If elected, the unified and integrated emergency preparedness program must- [do all of the following:]</p> <p>(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.</p> <p>(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.</p> <p>(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].</p> <p>(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:</p> <p>(i) A documented community-based risk assessment, utilizing an all-hazards approach.</p>	<p>(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.)</p> <p>Healthcare systems that include multiple facilities that are each separately certified as a Medicare-participating provider or supplier have the option of developing a unified and integrated emergency preparedness program that includes all of the facilities within the healthcare system instead of each facility developing a separate emergency preparedness program. If an integrated healthcare system chooses this option, each certified facility in the system may elect to participate in the system's unified and integrated emergency program or develop its own separate emergency preparedness program. It is important to understand that healthcare systems are not required to develop a unified and integrated emergency program. Rather it is a permissible option. In addition, the separately certified facilities within the healthcare system are not required to participate in the unified and integrated emergency preparedness program. It is simply an option for each facility. If this option is taken, the healthcare system's unified emergency preparedness program should be updated each time a facility enters or leaves the healthcare system's program.</p> <p>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.</p> <p>A unified program must be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into consideration the difference in services that are provided at a LTC facility and a hospital. The unique</p>

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		<p>(This language HAS been updated to reflect the Burden Reduction requirements. Effective 11.29.19)</p> <p>(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.</p> <p>(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.</p> <p>Interpretive Guidelines Applies to: §482.15(f), §416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.78(f), §483.73(f), §483.475(e), §484.22(e), §485.68(e), §485.625(f), §485.727(e), §485.920(e), §486.360(f), §491.12(e), §494.62(e).</p>	<p>(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.)</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The training and testing program in a unified emergency preparedness program must be developed considering all of the requirements of each facility type. For example, if a healthcare system includes, hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs must meet all of the specific regulatory requirements for each of these facility types.</p>

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			<p>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.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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). <p>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.</p>