Organ Procurement Organization Requirements
CMS Emergency Preparedness Final Rule

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

This document combines excerpts from the Final Rule and the recently released Interpretive Guidelines from CMS to provide a consolidated overview document for the Organ Procurement Organization (OPO) 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.

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OPO Requirements as Written in the Final Rule

The following excerpt is taken from page 64040 of the Final Rule, accessible directly by this link: https://www.federalregister.gov/d/2016-21404/p-amd-37.

34. Add § 486.360 to read as follows:
§ 486.360
Emergency preparedness.

The OPO must comply with all applicable Federal, State, and local emergency preparedness requirements. The OPO 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 OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

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 the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.
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 OPO's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

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

1) A system to track the location of on-duty staff during and after an emergency. If on-duty staff is relocated during the emergency, the OPO must document the specific name and location of the receiving facility or other location.
2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.

(c) Communication plan. The OPO must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed

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

1) Names and contact information for the following:
    i. Staff.
    ii. Entities providing services under arrangement.
    iii. Volunteers.
    iv. Other OPOs.
    v. Transplant and donor hospitals in the OPO's Donation Service Area (DSA).
2) Contact information for the following:
    i. Federal, State, tribal, regional, and local emergency preparedness staff.
    ii. Other sources of assistance.
3) Primary and alternate means for communicating with the following:
    i. OPO's staff.
    ii. Federal, State, tribal, regional, and local emergency management agencies.

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

1) **Training**. The OPO must do all of the following:
    i. Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
    ii. Provide emergency preparedness training at least annually.
    iii. Maintain documentation of the training.
    iv. Demonstrate staff knowledge of emergency procedures.
2) **Testing**. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:
    i. Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
    ii. Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

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

1) The OPO must develop and maintain in the protocols with transplant programs required under § 486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency.
2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have:

i. An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency;
ii. If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or
iii. A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.

(f) Integrated healthcare systems. If an OPO 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 OPO 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.
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 OPOs

Full text available at: Appendix Z – Emergency Preparedness for All Providers and Certified Supplier Types: Interpretive Guidelines

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

OPO References as Outlined in the Interpretive Guidance and the Surveyor Cheat Sheet

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
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: *[For hospitals at §482.15:] The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. *[For CAHs at §485.625:] The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach.	Under this condition/requirement, facilities are required to develop an emergency preparedness program that meets all of the standards specified within the condition/requirement. The emergency preparedness program must describe a facility's comprehensive approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation. The program must also address how the facility would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made, facility). The emergency preparedness program must be reviewed annually. A comprehensive approach to meeting the health and safety needs of a patient population should encompass the elements for emergency preparedness planning based on the "all-hazards" definition and specific to the location of the facility. For instance, a facility in a large flood zone, or tornado prone region, should have included these elements in their overall planning in order to meet the health, safety, and security needs of the staff and of the patient population. Additionally, if the patient population has limited mobility, facilities should have an approach to address these challenges during emergency events. The term "comprehensive" in this requirement is to ensure that facilities do not only choose one potential emergency that may occur in their area, but rather consider a multitude of events and be able to demonstrate that they have considered this during their development of the emergency preparedness plan. **Survey Procedures** • Interview the facility leadership and ask him/her/them to describe the facility's emergency preparedness program. • Ask to see the facility's written policy and documentation on the emergency preparedness program. • For hospitals and CAHs only: Verify the hospital's or CAH's program was developed based on an all-hazards approach by asking their leadership to describe how the facility used an all-hazards approach when developing its program.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0004	Develop and Maintain EP Program	[The [facility] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility] must develop establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section.] * [For hospitals at §482.15 and CAHs at §485.625(a):] The [hospital or CAH] must comply with all applicable Federal, State, and local emergency preparedness requirements. The [hospital or CAH] must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.] The emergency preparedness program must include, but not be limited to, the following elements:] (a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be [reviewed], and updated at least annually. * [For ESRD Facilities at §494.62(a):] Emergency Plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least annually.	Facilities are required to develop and maintain an emergency preparedness plan. The plan must include all of the required elements under the standard. The plan must be reviewed and updated at least annually. The annual review must be documented to include the date of the review and any updates made to the emergency plan based on the review. The format of the emergency preparedness plan that a facility uses is at its discretion. An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. This approach is specific to the location of the facility and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to: • Natural disasters • Man-made disasters, • Facility-based disasters that include but are not limited to: o Care-related emergencies; o Equipment and utility failures, including but not limited to power, water, gas, etc.; o Interruptions in communication, including cyber-attacks; o Loss of all or portion of a facility; and o Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable). When evaluating potential interruptions to the normal supply of essential services, the facility should take into account the likely durations of such interruptions. Arrangements or contracts to re-establish essential utility services during an emergency should describe the timeframe within which the contractor is required to initiate services after the start of the emergency, how they will be procured and delivered in the facility's local area, and that the contractor will continue to supply the essential items throughout and to the end of emergencies of varying duration. **Survey Procedures** • Verify the facility has an emergency preparedness plan by asking to see a copy of the plan. • Ask facility leadership to identify the hazards (e.g. natural, man-made, facility, geographic, etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted.

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			• 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	[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:] (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.* *[For LTC facilities at §483.73(a)(1):] (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents. *[For ICF/IIDs at §483.475(a)(1):] (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients. (2) Include strategies for addressing emergency events identified by the risk assessment. * [For Hospices at §418.113(a)(2):] (2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.	Facilities are expected to develop an emergency preparedness plan that is based on the facility-based and community-based risk assessment using an "all-hazards" approach. Facilities must document both risk assessments. An example consideration may include, but is not limited to, natural disasters prevalent in a facility's geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies. Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security's Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ). "Community" is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency. Facilities may rely on a community-based risk assessment developed by other entities, such as public health agencies, emergency management agencies, and regional health care coalitions or in conjunction with conducting its own facility-based assessment. If this approach is used, facilities are expected to have a copy of the community-based risk assessment and to work with the entity that developed it to ensure that the facility's emergency plan is in alignment. When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following: • Identification of all business functions essential to the facility's operations that should be continued during an emergency; • Identification of all risks or emergencies that the facility may reasonably expect to confront; • Identification of all contingencies for which the facility should plan; • Consideration of the facility's location; • Assessment of the extent to which natural or man-made emergencies may cause the facility to cease or limit operations; and,

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			• Determination of what arrangements may be necessary with other health care facilities, or other entities that might be needed to ensure that essential services could be provided during an emergency. In situations where the facility does not own the structure(s) where care is provided, it is the facility's responsibility to discuss emergency preparedness concerns with the landlord to ensure continuation of care if the structure of the building and its utilities are impacted. For LTC facilities and ICF/IIDs, written plans and the procedures are required to also include missing residents and clients, respectively, within their emergency plans. Facilities must develop strategies for addressing emergency events that were identified during the development of the facility- and community-based risk assessments. Examples of these strategies may include, but are not limited to, developing a staffing strategy if staff shortages were identified during the risk assessment or developing a surge capacity strategy if the facility has identified it would likely be requested to accept additional patients during an emergency. Facilities will also want to consider evacuation plans. For example, a facility in a large metropolitan city may plan to utilize the support of other large community facilities as alternate care sites for its patients if the facility needs to be evacuated. The facility is also expected to have a backup evacuation plan for instances in which nearby facilities are also affected by the emergency and are unable to receive patients Hospices must include contingencies for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. **Survey Procedures** • Ask to see the written documentation of the facility's risk assessments and associated strategies. • Interview the facility leadership and ask which hazards (e.g. natural, man-made, facility, geographic) were included in the facility's risk assessment, why they were included and how the risk assessment was conducted. • Verify the risk-assessment is based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0008	Establishment of the EP Program OPO	§486.360(a)(3) Condition for Participation: [(a) Emergency Plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:] (3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.	The emergency plan must address the type of hospitals with which the OPO has agreements and the types of services that the OPO would be able to provide in an emergency. The emergency plan must also identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing staff with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become necessary. During times of emergency, facilities must have internal employees who are capable of assuming various critical roles in the event that current staff and leaders are not available. At a minimum, facilities should designate a qualified person who is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility. In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations. **Survey Procedures** • Interview leadership and ask them to describe the following: o Services the OPO would be able to provide during an emergency; o How the OPO plans to continue operations during an emergency; o Delegations of authority and succession plans. o How the OPO has included/addressed all of the hospitals with which it has agreements into its emergency plan. • Verify that all of the above are included in the written emergency plan.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0009	Process for EP Collaboration	[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:] (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. ** * [For ESRD facilities only at §494.62(a)(4)]: (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.	While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility must document its efforts to contact these officials to engage in collaborative planning for an integrated emergency response. The facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. For ESRD facilities, §494.120(c)(2) of the ESRD Conditions for Coverage on Special Purpose Dialysis Facilities describes the requirements for ESRD facilities that are set up in an emergency (i.e., an emergency circumstance facility) which are issued a unique CMS Certification Number (CCN). ESRD facilities must incorporate these specific provisions into the coordination requirements under this standard. **Survey Procedures** • Interview facility leadership and ask them to describe their process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation. • Ask for documentation of the facility's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. • For ESRD facilities, ask to see documentation that the ESRD facility contacted the local public health and emergency management agency public official at least annually to confirm that the agency is aware of the ESRD facility's needs in the event of an emergency and know how to contact the agencies in the event of an emergency.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0013	Development of EP Policies and Procedures	(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. *Additional Requirements for PACE and ESRD Facilities:*[For PACE at §460.84(b):] Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. The policies and procedures must be reviewed and updated at least annually. *[For ESRD Facilities at §494.62(b):] Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.	Facilities must develop and implement policies and procedures per the requirements of this standard. The policies and procedures are expected to align with the identified hazards within the facility's risk assessment and the facility's overall emergency preparedness program. We are not specifying where the facility must have the emergency preparedness policies and procedures. A facility may choose whether to incorporate the emergency policies and procedures within their emergency plan or to be part of the facility's Standard Operating Procedures or Operating Manual. However, the facility must be able to demonstrate compliance upon survey, therefore we recommend that facilities have a central place to house the emergency preparedness program documents (to include all policies and procedures) to facilitate review. **Survey Procedures** • Review the written policies and procedures which address the facility's emergency plan and verify the following: o Policies and procedures were developed based on the facility- and community-based risk assessment and communication plan, utilizing an all-hazards approach. o Ask to see documentation that verifies the policies and procedures have been reviewed and updated on an annual basis.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0018	Procedures for Tracking of Staff and Patients	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.] At a minimum, the policies and procedures must address the following:] (2) A system to track the location of on-duty staff and sheltered patients in the [facility's] care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the [facility] must document the specific name and location of the receiving facility or other location. *[For PRTFs at §441.184(b), LTC at §483.73(b), ICF/IIDs at §483.475(b), PACE at §460.84(b):] Policies and procedures. (2) A system to track the location of on-duty staff and sheltered residents in the [PRTF's, LTC, ICF/IID or PACE] care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the [PRTF's, LTC, ICF/IID or PACE] must document the specific name and location of the receiving facility or other location. *[For Inpatient Hospice at §418.113(b)(6):] Policies and procedures. (ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance. (v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific	Facilities must develop a means to track patients and on-duty staff in the facility's care during an emergency event. In the event staff and patients are relocated, the facility must document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency. CMHCs, PRTF's, LTC facilities, ICF/IIDs, PACE organizations and ESRD Facilities are required to track the location of sheltered patients and staff during and after an emergency. We are not specifying which type of tracking system should be used; rather, a facility has the flexibility to determine how best to track patients and staff, whether it uses an electronic database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response systems as needed in the interest of the patient. It is recommended that a facility that is using an electronic database consider backing up its computer system with a secondary source, such as hard copy documentation in the event of power outages. The tracking systems set up by facilities may want to consider who is responsible for compiling/securing patient records and what information is needed during tracking a patient throughout an evacuation. A number of states already have such tracking systems in place or under development and the systems are available for use by health care providers and suppliers. Facilities are encouraged to leverage the support and resources available to them through local and national healthcare systems, healthcare coalitions, and healthcare organizations for resources and tools for tracking patients. Facilities are not required to track the location of patients who have voluntarily left on their own, or have been appropriately discharged, since they are no longer in the facility's care. However, this information must be documented in the patient's medical record should any questions later arise as to the patient's whereabouts. Note: If an ASC is able to cancel surgeries and close (meaning there are no patients or staff in the ASC), this requirement of tracking patients and staff would no longer be applicable. Similarly to ESRD standard practices, if an emergency was imminent and able to be predicted (i.e. inclement weather conditions, etc.) we would expect that ASCs cancel surgeries and cease operations, which would eliminate the need to track patients and staff. **Survey Procedures** • Ask staff to describe and/or demonstrate the tracking system used to document locations of patients and staff.

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		name and location of the receiving facility or other location. *[For CMHCs at §485.920(b):] Policies and procedures. (2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. *[For OPOs at § 486.360(b):] Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records. *[For ESRD at § 494.62(b):] Policies and procedures. (2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients. Interpretive Guidelines applies to: §403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).	• Verify that the tracking system is documented as part of the facilities' emergency plan policies and procedures.

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0020	Policies and Procedures including Evacuation	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:] Safe evacuation from the [facility], which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. *[For RNHCs at §403.748(b)(3) and ASCs at §416.54(b)(2):] Safe evacuation from the [RNHCI or ASC] which includes the following: (i) Consideration of care needs of evacuees. (ii) Staff responsibilities. (iii) Transportation. (iv) Identification of evacuation location(s). (v) Primary and alternate means of communication with external sources of assistance. * [For CORFs at §485.68(b)(1), Clinics, Rehabilitation Agencies, OPT/Speech at §485.727(b)(1), and ESRD Facilities at §494.62(b)(2):] Safe evacuation from the [CORF; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services; and ESRD Facilities], which includes staff responsibilities, and needs of the patients. * [For RHCs/FQHCs at §491.12(b)(1):] Safe evacuation from the	Facilities must develop policies and procedures that provide for the safe evacuation of patients from the facility and include all of the requirements of this standard. RHCs and FQHCs must also place exit signs to guide patients and staff in the event of an evacuation from the facility. Facilities must have policies and procedures which address the needs of evacuees. The facility should also consider in development of the policies and procedures, the evacuation protocols for not only the evacuees, but also staff members and families/patient representatives or other personnel who sought potential refuge at the facility. Additionally, the policies and procedures must address staff responsibilities during evacuations. Facilities must consider the patient population needs as well as their care and treatment. For example, if an evacuation is in progress and the facility must evacuate, leadership should consider the needs for critically ill patients to be evacuated and accompanied by staff who could provide care and treatment enroute to the designated relocation site, in the event trained medical professionals are unavailable by the transportation services. Facilities must consider in their development of policies and procedures, the needs of their patient population and what designated transportation services would be most appropriate. For instance, if a facility primarily cares for critically ill patients with ventilation needs and life-saving equipment, the transportation services should be able to assist in evacuation of this special population and be equipped to do so. Additionally, facilities may also find it prudent to consider alternative methods for evacuation and patient care and treatment, such as mentioned above to have staff members evacuate with patients in given situations. Additionally, facilities should consider their triaging system when coordinating the tracking and potential evacuation of patient/residents/clients. For instance, a triaging system for evacuation may consider the most critical patients first followed by those less critical and dependent on life-saving equipment. Considerations for prioritization may be based on, among other things, acuity, mobility status (stretch-bound/wheelchair/ambulatory), and location of the unit, availability of a known transfer destination or some combination thereof. Included within this system should be who (specifically) will be tasked with making triage decisions. Following the triaging system, staff should consider the communication of patient care requirements 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.

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		RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.	Finally, facilities policies and procedures must outline primary and alternate means for communication with external sources for assistance. For instance, primarily methods may be considered via regular telephone services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials; whereas alternate means account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance. **Survey Procedures** • Review the emergency plan to verify it includes policies and procedures for safe evacuation from the facility and that it includes all of the required elements. • When surveying an RHC or FQHC, verify that exit signs are placed in the appropriate locations to facilitate a safe evacuation.

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0023	Policies and Procedures for Medical Docs.	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.] At a minimum, the policies and procedures must address the following:] (5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records. *[For RNHCIs at §403.748(b):] Policies and procedures. (5) A system of care documentation that does the following: (i) Preserves patient information. (ii) Protects confidentiality of patient information. (iii) Secures and maintains the availability of records. *[For OPOs at §486.360(b):] Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.	In addition to any existing requirements for patient records found in existing laws, under this standard, facilities are required to ensure that patient records are secure and readily available to support continuity of care during emergency. This requirement does not supersede or take away any requirements found under the provider/supplier's medical records regulations, but rather, this standard adds to such policies and procedures. These policies and procedures must also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Privacy and Security Rules at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information. **Survey Procedures** • Ask to see a copy of the policies and procedures that documents the medical record documentation system the facility has developed to preserves patient (or potential and actual donor for OPOs) information, protects confidentiality of patient (or potential and actual donor for OPOs) information, and secures and maintains availability of records.

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

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0030	Names and Contact Information	[(c) The [facility, except RNHCIs, hospices, transplant centers, and HHAs] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.] The communication plan must include all of the following:] (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians (iv) Other [facilities]. (v) Volunteers. *[For RNHCIs at §403.748(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Next of kin, guardian, or custodian. (iv) Other RNHCIs. (v) Volunteers. *[For ASCs at §416.45(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians. (iv) Volunteers. *[For Hospices at §418.113(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Hospice employees. (ii) Entities providing services under arrangement.	A facility must have the contact information for those individuals and entities outlined within the standard. The requirement to have contact information for "other facilities" requires a provider or supplier to have the contact information for another provider or supplier of the same type as itself. For instance, hospitals should have contact information for other hospitals and CORFs should have contact information for other CORFs, etc. While not required, facilities may also find it prudent to have contact information for other facilities not of the same type. For instance a hospital may find it appropriate to have the contact information of LTC facilities within a reasonable geographic area, which could assist in facilitating patient transfers. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership and staff during an emergency event. Facilities which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information must be reviewed and updated as necessary at least annually. Contact information contained in the communication plan must be accurate and current. Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list. Transplant Centers should be included in the development of the hospitals communication plans. In the case of a Medicare-approved transplant center, a communication plan needs to be developed and disseminated between the hospitals, OPO, and transplant patients. For example, if the transplant program is planning to transfer patients to another transplant center due to an emergency, the communication plan between the hospitals, the OPO, and the patient should include the responsibilities of each of the facility types to ensure continuity of care. During an emergency, should an organ offer become available at the time the patient is at the "transferred hospital," the OPO's emergency preparedness communication plan should address how this information will be communicated to both the OPO and the patient of where their care will be continued. **Survey Procedures** • Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information. • Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

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		(iii) Patients' physicians. (iv) Other hospices. *[For OPOs at §486.360(c):] The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Volunteers. (iv) Other OPOs. (v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).	

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0031	Emergency Officials Contact Information	[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually] The communication plan must include all of the following: (2) Contact information for the following: (i) Federal, State, tribal, regional, and local emergency preparedness staff. (ii) Other sources of assistance. *[For LTC Facilities at §483.73(c):] (2) Contact information for the following: (i) Federal, State, tribal, regional, or local emergency preparedness staff. (ii) The State Licensing and Certification Agency. (iii) The Office of the State Long-Term Care Ombudsman. (iv) Other sources of assistance. *[For ICF/IIDs at §483.475(c):] (2) Contact information for the following: (i) Federal, State, tribal, regional, and local emergency preparedness staff. (ii) Other sources of assistance. (iii) The State Licensing and Certification Agency. (iv) The State Protection and Advocacy Agency.	A facility must have the contact information for those individuals and entities outlined within the standard. Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Facilities are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information must be reviewed and updated at least annually. **Survey Procedures** • Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information. • Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the annual review.

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0032	Primary/Alternate Means for Communication	[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.] The communication plan must include all of the following: (3) Primary and alternate means for communicating with the following: (i) [Facility] staff. (ii) Federal, State, tribal, regional, and local emergency management agencies. *[For ICF/IIDs at §483.475(c):] (3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.	Facilities are required to have primary and alternate means of communicating with staff, Federal, State, tribal, regional, and local emergency management agencies. Facilities have the discretion to utilize alternate communication systems that best meets their needs. However, it is expected that facilities would consider pagers, cellular telephones, radio transceivers (that is, walkie-talkies), and various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (HAM Radio) systems, as well as satellite telephone communications systems. We recognize that some facilities, especially in remote areas, may have difficulty using some communication systems, such as cellular phones, even in non-emergency situations, which should be outlined within their risk assessment and addressed within the communications plan. It is expected these facilities would address such challenges when establishing and maintaining a well-designed communication system that will function during an emergency. The communication plan should include procedures regarding when and how alternate communication methods are used, and who uses them. In addition the facility should ensure that its selected alternative means of communication is compatible with communication systems of other facilities, agencies and state and local officials it plans to communicate with during emergencies. For example, if State X local emergency officials use the SHAred RESources (SHARES) High Frequency (HF) Radio program and facility Y is trying to communicate with RACES, it may be prudent to consider if these two alternate communication systems can communicate on the same frequencies. Facilities may seek information about the National Communication System (NCS), which offers a wide range of National Security and Emergency Preparedness communications services, the Government Emergency Telecommunications Services (GETS), the Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and SHARES. Other communication methods could include, but are not limited to, satellite phones, radio, and short wave radio. The Radio Amateur Civil Emergency Services (RACES) is an integral part of emergency management operations. **Survey Procedures** • Verify the communication plan includes primary and alternate means for communicating with facility staff, Federal, State, tribal, regional and local emergency management agencies by reviewing the communication plan. • Ask to see the communications equipment or communication systems listed in the plan.

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0033	Methods for Sharing Information	[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.] The communication plan must include all of the following: (4) A method for sharing information and medical documentation for patients under the [facility's] care, as necessary, with other health providers to maintain the continuity of care. (5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). [This provision is not required for HHAs under §484.22(c), CORFs under §485.68(c), and RHCs/FQHCs under §491.12(c).] (6) [(4) or (5)]A means of providing information about the general condition and location of patients under the [facility's] care as permitted under 45 CFR 164.510(b)(4). *[For RNHCIs at §403.748(c):] (4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative. Note: In the event of an evacuation, a means to release patient information as permitted under HIPAA is not required for HHAs under §484.22(c), CORFs under §485.68(c), and RHCs/FQHCs under §491.12(c).	Facilities are required to develop a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information. Facilities (with the exception of HHAs, RHCs, FQHCs, and CORFs) are also required to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 and a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). Thus, facilities must have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted under 45 CFR 164.510(b)(4), to family members and others. Facilities have the flexibility to develop and maintain their own system in a manner that best meets its needs. HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes. Section 164.510 ''Uses and disclosures requiring an opportunity for the individual to agree to or to object,'' is part of the ''Standards for Privacy of Individually Identifiable Health Information,'' commonly known as ''The Privacy Rule.'' HIPAA Privacy Regulations at 45 CFR 164.510(b)(4), ''Use and disclosures for disaster relief purposes,'' establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient's location or general condition. **Survey Procedures** • Verify the communication plan includes a method for sharing information and medical (or for RNHCIs only, care) documentation for patients under the facility's care, as necessary, with other

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			health (or care for RNHCIs) providers to maintain the continuity of care by reviewing the communication plan. o 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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0036	Emergency Prep Training and Testing	(d) Training and testing. The [facility] must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually. *[For ICF/IIDs at §483.475(d):] Training and testing. The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at §483.470(h). *[For ESRD Facilities at §494.62(d):] Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing and orientation program must be reviewed and updated at least annually.	An emergency preparedness training and testing program as specified in this requirement must be documented and reviewed and updated on at least an annual basis. The training and testing program must reflect the risks identified in the facility's risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location. Training refers to a facility's responsibility to provide education and instruction to staff, contractors, and facility volunteers to ensure all individuals are aware of the emergency preparedness program. Testing is the concept in which training is operationalized and the facility is able to evaluate the effectiveness of the training as well as the overall emergency preparedness program. Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement. **Survey Procedures** • Verify that the facility has a written training and testing (and for ESRD facilities, a patient orientation) program that meets the requirements of the regulation. • Verify the program has been reviewed and updated on, at least, an annual basis by asking for documentation of the annual review as well as any updates made. • Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

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0037	Emergency Prep Training Program	(1) Training program. The [facility, except CAHs, ASCs, PACE organizations, PRTFs, Hospices, and dialysis facilities] must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role. (ii) Provide emergency preparedness training at least annually. (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures. *[For ASCs at §416.54(d):] (1) Training program. The ASC must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least annually. (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures. *[For Hospices at §418.113(d):] (1) Training. The hospice must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles. (ii) Demonstrate staff knowledge of emergency procedures. (iii) Provide emergency preparedness training at least annually. (iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.	Facilities are required to provide initial training in emergency preparedness policies and procedures that are consistent with their roles in an emergency to all new and existing staff, individuals providing services under arrangement, and volunteers. This includes individuals who provide services on a per diem basis such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency. PACE organizations and CAHs have additional requirements. PACE organizations must also provide initial training to contractors and PACE participants. CAHs must also include initial training on the following: prompt reporting and extinguishing of fires; protection; and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities. Facilities should provide initial emergency training during orientation (or shortly thereafter) to ensure initial training is not delayed. With the exception of CORFs which must complete initial training within the first two weeks of employment, we recommend initial training be completed by the time the staff has completed the facility's new hire orientation program. Additionally, in the case of facilities with multiple locations, such as multi-campus hospitals, staff, individuals providing services under arrangement, or volunteers should be provided initial training at their specific location and when they are assigned to a new location. Facilities have the flexibility to determine the focus of their annual training, as long as it aligns with the emergency plan and risk assessment. Ideally, annual training should be modified each year, incorporating any lessons learned from the most recent exercises, real-life emergencies that occurred in the last year and during the annual review of the facility's emergency program. For example, annual training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's annual review. While facilities are required to provide annual training to all staff, it is up to the facility to decide what level of training each staff member will be required to complete each year based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain clinical staff may require additional topics. For example, dietary staff who prepare meals may not need to complete annual training that is focused on patient evacuation procedures. Instead, the facility may provide training that focuses on the proper preparation and storage of food in an emergency. In addition, depending on specific staff duties during an emergency, a facility may determine that documented external training is sufficient to meet some or all of the facility's annual training requirements. For example, staff who work with radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical

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		*[For PRTFs at §441.184(d):] (1) Training program. The PRTF must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (ii) After initial training, provide emergency preparedness training at least annually. (iii) Demonstrate staff knowledge of emergency procedures. (iv) Maintain documentation of all emergency preparedness training. *[For PACE at §460.84(d):] (1) The PACE organization must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least annually. (iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency. (iv) Maintain documentation of all training. *[For CORFs at §485.68(d):](1) Training. The CORF must do all of the following: (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least annually. (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific	emergencies. It is up to the facility to decide if the external training meets the facility's requirements. Facilities must maintain documentation of the annual training for all staff. The documentation must include the specific training completed as well as the methods used for demonstrating knowledge of the training program. Facilities have flexibility in ways to demonstrate staff knowledge of emergency procedures. The method chosen is likely based on the training delivery method. For example: computer-based or printed self-learning packets may contain a test to demonstrate knowledge. If facilities choose instructor-led training, a question and answer session could follow the training. Regardless of the method, facilities must maintain documentation that training was completed and that staff are knowledgeable of emergency procedures. **Survey Procedures** • Ask for copies of the facility's initial emergency preparedness training and annual emergency preparedness training offerings. • Interview various staff and ask questions regarding the facility's initial and annual training course, to verify staff knowledge of emergency procedures. • Review a sample of staff training files to verify staff have received initial and annual emergency preparedness training.

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		responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment. *[For CAHs at §485.625(d):] (1) Training program. The CAH must do all of the following: (i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least annually. (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures. *[For CMHCs at §485.920(d):] (1) Training. The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.	

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0042	Integrated Health Systems	(e) [or (f)]Integrated healthcare systems. If a [facility] is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the [facility] may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must- [do all of the following:] (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance [with the program]. (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following: (i) A documented community-based risk assessment, utilizing an all-hazards approach. (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. (5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a	Healthcare systems that include multiple facilities that are each separately certified as a Medicare-participating provider or supplier have the option of developing a unified and integrated emergency preparedness program that includes all of the facilities within the healthcare system instead of each facility developing a separate emergency preparedness program. If an integrated healthcare system chooses this option, each certified facility in the system may elect to participate in the system's unified and integrated emergency program or develop its own separate emergency preparedness program. It is important to understand that healthcare systems are not required to develop a unified and integrated emergency program. Rather it is a permissible option. In addition, the separately certified facilities within the healthcare system are not required to participate in the unified and integrated emergency preparedness program. It is simply an option for each facility. If this option is taken, the healthcare system's unified emergency preparedness program should be updated each time a facility enters or leaves the healthcare system's program. If a healthcare system elects to have a unified emergency preparedness program, the integrated program must demonstrate that each separately certified facility within the system that elected to participate in the system's integrated program actively participated in the development of the program. Therefore, each facility should designate personnel who will collaborate with the healthcare system to develop the plan. The unified and integrated plan should include documentation that verifies each facility participated in the development of the plan. This could include the names of personnel at each facility who assisted in the development of the plan and the minutes from planning meetings. All components of the emergency preparedness program that are required to be reviewed and updated at least annually must include all participating facilities. Again, each facility must be able to prove that it was involved in the annual reviews and updates of the program. The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable. A unified program must be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into consideration the difference in services that are provided at a LTC facility and a hospital. The unique circumstances that should be addressed at each facility would include anything that would impact operations during an emergency, such as the location of the facility, resources such as the availability of staffing, medical supplies, subsistence, patients' and residents' varying acuity and mobility at the different types of facilities in a unified healthcare system, etc.

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
		coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively. Interpretive Guidelines Applies to: §482.15(f), §416.54(e), §418.113(e), §441.184(e), §460.84(e), §482.78(f), §483.73(f), §483.475(e), §484.22(e), §485.68(e), §485.625(f), §485.727(e), §485.920(e), §486.360(f), §491.12(e), §494.62(e).	Each separately certified facility must be capable of demonstrating during a survey that it can effectively implement the emergency preparedness program and demonstrate compliance with all emergency preparedness requirements at the individual facility level. Compliance with the emergency preparedness requirements is the individual responsibility of each separately certified facility. The unified emergency preparedness program must include a documented community–based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. This is especially important if the facilities in a healthcare system are located across a large geographic area with differing weather conditions. Lastly, the unified program must have a coordinated communication plan and training and testing program. For example, if the unified emergency program incorporates a central point of contact at the "system" level who assists in coordination and communication, such as during an evacuation, each facility must have this information outlined within its individual plan. This type of integrated healthcare system emergency program should focus the training and exercises to ensure communication plans and reporting mechanisms are seamless to the emergency management officials at state and local levels to avoid potential miscommunications between the system and the multiple facilities under its control. The training and testing program in a unified emergency preparedness program must be developed considering all of the requirements of each facility type. For example, if a healthcare system includes, hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs must meet all of the specific regulatory requirements for each of these facility types. Because of the many different configurations of healthcare systems, from the different types of facilities in the system, to the varied locations of the facilities, it is not possible to specify how unified training and testing programs should be developed. There is no "one size fits all" model that can be prescribed. However, if the system decides to develop a unified and integrated training and testing program, the training and testing must be developed based on the community and facility based hazards assessments at each facility that is participating in the unified emergency preparedness program. Each facility must maintain individual training records of staff and records of all required training exercises. **Survey Procedures**

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

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0044	OPO Continuity of Operations	(e) Continuity of OPO operations during an emergency. Each OPO must have a plan to continue operations during an emergency. (1) The OPO must develop and maintain in the protocols with transplant programs required under § 486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency. (2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have: (i) An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency; (ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or (iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.	An OPO may choose to relocate to an alternate location within its DSA. For instance, if a tornado threat or major flooding was anticipated within one area, however there is another location 20 miles away for the OPO to relocate to, we would anticipate the OPO would address this within its emergency plan. Additionally, OPOs must develop mutually-agreed upon protocols that address the duties and responsibilities of the hospital, transplant center and OPO during emergencies as previously outlined (Reference Tags: 0002, 0012, 0014, 0042). Therefore, these three facility types must work together to develop and maintain policies and programs which address emergency preparedness. **Survey Procedures** • Verify that the OPO has mutually-agreed upon protocols with every certified transplant program it is associated with which includes the duties and responsibilities of the hospital, transplant program and OPO during emergencies. • Verify that the OPO has a plan in place to ensure continuity of its operation from an alternate location during an emergency.