

Organ Procurement Organization Requirements

CMS Emergency Preparedness Final Rule

Updates Effective March 26, 2021

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 Interpretive Guidelines (as updated 3.6.19, 11.8.19, and 3.26.21) from CMS to provide a consolidated overview document for the Organ Procurement Organization Requirements. This document reflects final language as of the most recent Final Rule updates and Interpretive Guidance updates as of March 26, 2021. For a comparison of changes between past versions, please review the [Interpretive Guidelines published by CMS on March 26, 2021](#).

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.

Quick Links

[Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers Final Rule](#)

[Burden Reduction Final Rule](#) (effective November 29, 2019)

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Integrated Healthcare Systems
OPO Requirements as Written in the Interpretive Guidelines

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

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> 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.

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 every 2 years.

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.

(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 every 2 years. 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 every 2 years. 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 every 2 years.

- 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 every 2 years.
 - iii. Maintain documentation of all emergency preparedness training.
 - iv. Demonstrate staff knowledge of emergency procedures.
 - v. If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.
- 2) **Testing.** The OPO must conduct exercises to test the emergency plan. The OPO must do the following:
 - i. Conduct a paper-based, tabletop exercise or workshop at least annually. A tabletop exercise is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the emergency event.

- ii. Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the 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](#)

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

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			<p>The term “comprehensive” in this requirement is to ensure that facilities do not only choose one potential emergency that may occur in their area, but rather consider a multitude of events and be able to demonstrate that they have considered this during their development of the emergency preparedness plan. As emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive emergency preparedness program should include emerging infectious diseases and pandemics during a public health emergency (PHE). The comprehensive emergency preparedness program emerging infectious disease planning should encompass how facilities will plan, coordinate and respond to a localized and widespread pandemic, similar to what is occurring with the 2019 Novel Coronavirus (COVID-19) PHE. Facilities should ensure their emergency preparedness programs are aligned with their State and local emergency plans/pandemic plans.</p> <p>Documentation and Requirements</p> <p>The emergency preparedness program must be in writing. The requirements under the emergency preparedness Final Rule allow for documentation flexibility. While facilities are required to meet all of the provisions applicable to their provider/supplier type, how they document their efforts is subject to their discretion. We are not requiring a hard copy/paper, electronic or any particular system for meeting the requirements. It is up to each individual facility to be able to demonstrate in writing their emergency preparedness program. We would also recommend, but are not requiring, facilities to develop a crosswalk as applicable for where their documents are located. For instance, if their emergency plan is located in a binder, specify this for surveyors. If there are policies and procedures to specific standards/requirements, identify where these are located.</p> <p>Providers and suppliers are encouraged to keep documentation and their written emergency preparedness program based on the requirements for their provider type. Inpatient providers should maintain documentation and records for at least 2 years. Outpatient providers for at least four years. We are recommending this process due to the requirements related to training and testing exercises. Inpatient providers are required to have 2 exercises per year, therefore surveyors will review most recent two-years of documentation to determine compliance. For outpatient providers, testing exercises are required annually, alternating full-scale exercises</p>

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			<p>every other year, with the opposite years allowing for the exercise of choice. In order to determine compliance, surveyors will be required to review at least the past 2 cycles (generally 4 years) of emergency testing exercises.</p> <p>Additionally, we are not requiring approval of the Emergency Program or official “sign-off,” however, we do recommend facilities check with their State Agencies and local emergency planning coordinators (LEPCs) as some states require approval of the emergency preparedness plans as part of state licensure.</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.

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0004	Develop and Maintain EP Program	<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>The emergency preparedness program must include, but not be limited to, the following elements:]</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.</p>	<p>Emergency Plan-General</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 every 2 years, with the exception for LTC facilities which must review and update their plan on an annual basis. This periodic review must be documented to include the date of the review and any updates made to the emergency plan based on the review. The format of the emergency preparedness plan that a facility uses is at its discretion. While this 2-year review process (except for LTC facilities) provides more flexibilities for providers to update their program as they see fit, facilities are encouraged to continue to review and update their emergency preparedness plans and train their staff accordingly as the plan may change on a more frequent basis (84 FR at 51756).</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.</p> <p>Elements of the Emergency Plan</p> <p>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;

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			<ul style="list-style-type: none">○ Loss of all or portion of a facility; and○ Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).● Emerging infectious diseases (EIDs) such as Influenza, Ebola, Zika Virus and others.<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. <p>Emerging Infectious Diseases (EIDs)</p> <p>As facilities develop or make revisions to their emergency preparedness plans, EID’s are a potential threat which can impact the operations and continuity of care within a healthcare setting and should be considered. The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EID’s within a facility’s risk assessment ensures that facilities consider having infection prevention personnel involved in the planning, development and revisions to the emergency preparedness program, as these individuals would likely be coordinating activities within the facility during a potential surge of patients.</p> <p>Some examples of EID’s may include, but are not limited to:</p> <ul style="list-style-type: none">● Potentially infectious Bio-Hazardous Waste● Bioterrorism● Pandemic Flu● Highly Communicable Diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2) <p>EID’s may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential. Facilities should engage and coordinate with their local healthcare systems and healthcare coalitions, and</p>

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			<p>their state and local health departments when deciding on ways to meet surge needs in their community.</p> <p>Understanding the Terminology</p> <p>CMS recognizes that there are differences in terminology used within the emergency preparedness industry pertaining to “continuity of operations” and “business continuity.” We consider “continuity of business” to incorporate all continuity operations and business continuity, which involves planning to ensure business operations will continue even during a disaster. The concept of continuity is the facility’s ability to continue operations or services related to patient care and to ensure patient safety and quality of care is continued in an emergency event. The emergency plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support to services that are necessary during an actual emergency (81 FR 63875-63876). For additional information related to continuity of operations, please visit the Federal Emergency Management Agency’s (FEMA’s) Continuity Guidance Circular at https://www.fema.gov/sites/default/files/2020-07/Continuity-Guidance-Circular_031218.pdf.</p> <p>Essential Services and Continuity of Care</p> <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. However, we recognize that contractors may be subject to the same hardships as the community they serve, and there are no guarantees in the event of a disaster that the contractor would be able to fulfill their duties.</p>

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			<p>The emergency plan should take into account contingency planning, such as evacuation triggers in the event essential resources provided by the contractor cannot be fulfilled.</p> <p>Finally, facilities should also include in their planning and revisions of existing plans, contracts and inventory of supply needs; availability of personal protective equipment (PPE); critical care equipment; and transportation options/needs to be prepared for surge events. NOTE: This is also further delineated under the facility policies and procedures required by facilities under the emergency preparedness program.</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 every 2 years (annually for LTC facilities) by looking for documentation of the date of the review and updates that were made to the plan based on the review.

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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. 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>Risk Assessments Using All-Hazards Approach</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. Though a format is not specified, facilities must document the risk assessment. An example consideration may include, but is not limited to, natural disasters prevalent in a facility’s geographic region such as wildfires, tornados, flooding, etc. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, including pandemics and EIDs as noted under E-0004. This approach is specific to the location of the facility considering the types of hazards most likely to occur in the area, but should also include unforeseen widespread communicable diseases. Thus, all-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies.</p> <p>Also, a risk assessment is facility-based, which, among other things, considers a facility’s patient population and vulnerabilities. Facility-based and community-based risk assessments are intended to assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency (81 FR 63876). For instance, if a facility has a population which is primarily dependent on medical equipment the risk assessment would identify a higher impact for emergencies that lead to power failures. Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security’s Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ).</p> <p>Understanding Community-Based</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</p>

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			<p>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>Development of Risk Assessments based on the Plan</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;• 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>Risk Assessment Considerations:</p> <p>Based on the community threat and hazard identification process, facilities should select a comprehensive risk assessment tool that evaluates their risk and potential for hazards. The comprehensive risk assessment should include all risks that could disrupt the facility’s operations</p>

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			<p>and necessitate emergency response planning to address the risk mitigation requirements and ensure continuity of care.</p> <p>Using an all-hazards approach helps facilities consider and prepare for a variety of risks which may impact their healthcare settings. Facilities should categorize the various probable risks and hazards identified by likelihood of occurrence and further create supplemental risk assessments based on the disaster or public health emergency. For example:</p> <ul style="list-style-type: none">• For power loss and potential disruptions of services: Facilities can consider using a heat index or heat risk assessment to identify situations which present concerns related to patient care and safety. Facilities are required to maintain safe temperatures under (b) policies and procedures (see Tag E-0015), therefore a heat risk assessment can be considered as an additional risk assessment, but is not required. Facilities may find it helpful to refer to ASPR TRACIE for the Natural Disasters Topic Collection at https://asprtracie.hhs.gov/technical-resources/36/natural-disasters/27. <p>NOTE: In situations where the facility does not own the structure(s) where care is provided, it is the facility's responsibility to discuss emergency preparedness concerns with the landlord to ensure continuation of care if the structure of the building and its utilities are impacted.</p> <ul style="list-style-type: none">• For public health emergencies, such as EIDs or pandemics: Facilities should consider risk assessments to include the needs of the patient population they serve in relation to a communicable or emerging infectious disease outbreak. Planning should include a process to evaluate the facility's needs based on the specific characteristics of an EID that includes, but is not limited to:<ul style="list-style-type: none">○ Influx in need for PPE;○ Considerations for screening patients and visitors; which may also include testing considerations for staff, visitors and patients for infectious diseases;○ Transfers and discharges of patients;○ Home-based healthcare settings;○ Physical Environment, including but not limited to changes needed for distancing, isolation, or capacity/surge. <p>Planning for Staffing in Emergencies:</p>

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

Tag #	Title	Tag Text (Regulatory Text)	Interpretive Guidelines
0008	Establishment of the EP Program OPO	<p>§486.360(a)(3) Condition for Participation:</p> <p>[(a) Emergency Plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:]</p> <p>(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.</p>	<p>The emergency plan must address the type of hospitals with which the OPO has agreements and the types of services that the OPO would be able to provide in an emergency. However, the emergency preparedness plan is not required to be included as a part of each agreement that the OPO has with their hospitals. The emergency plan must also identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing staff with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become necessary. During times of emergency, facilities must have internal employees who are capable of assuming various critical roles in the event that current staff and leaders are not available. At a minimum, facilities should designate a qualified person who is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility.</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 ASPR when developing strategies for ensuring continuity of operations.</p> <p>Survey Procedures</p> <p>Interview leadership and ask them to describe the following:</p> <ul style="list-style-type: none"> • Services the OPO would be able to provide during an emergency; • How the OPO plans to continue operations during an emergency; • Delegations of authority and succession plans. • How the OPO has included/addressed all of the hospitals with which it has agreements into its emergency plan. <p>Verify that all of the above are included in the written emergency plan.</p>

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0009	Process for EP Collaboration	<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. 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. **</p>	<p>Cooperation and Collaboration</p> <p>While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility must have a process to engage in collaborative planning for an integrated emergency response. The facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. While every detail of the cooperation and collaboration process is not required to be documented in writing, it is expected that the facility has documented sufficient details to support verification of the process.</p> <p>When deciding on ways to meet public health emergency needs in their community, facilities are expected to engage and coordinate with their local healthcare systems (including any emergency-related Alternate Care Sites), and their local and state health departments, and federal agency staff and also encouraged to engage with their healthcare coalitions, as applicable. Facility awareness of the state's emergency preparedness programs and pandemic plan ensures coordination occurs with the community. Coordination should be pre-planned and facility management should know the state and local emergency contacts (further defined within a facilities communication plan).</p> <p>We also note that under state licensure or their accreditation requirements, facilities may still be required to document their collaboration with local, tribal, regional, State, and Federal emergency preparedness officials. We recommend facilities contact their State Survey Agency (SA) and/or accrediting organizations (AO) to determine if any additional requirements exist.</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.

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0013	Development of EP Policies and Procedures	(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years.	<p>NOTE: This does not apply to Transplant Programs.</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. We also recommend that facilities include strategies and succession planning, as well as contingencies which support their response to any disaster or public health emergency (also see requirements at E-0024).</p> <p>Facilities should also consider updates to their emergency preparedness policies and procedures during a disaster, including planning for an emergency event with a duration longer than expected. For instance, during public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue event-specific guidance and recommendations to healthcare workers. Facilities should ensure their programs have policies in place to update or provide additional emergency preparedness procedures to staff. This may include a policy delegating an individual to monitor guidance by public health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and, any other applicable guidance in a public health emergency.</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. We are also not specifying the type of documentation-i.e. hard copy, electronic or other system-based emergency plans. However, the facility must be able to demonstrate compliance upon survey, therefore we recommend that facilities have a central place to house the emergency preparedness program documents (to include all policies and procedures) to facilitate review. Furthermore, since the format of the documentation is at the discretion of the facility, surveyors can identify a facility's reviews and updates of the emergency program through meeting minutes (facilities need to be clear if the entire program or any specific policy was reviewed and updated); through electronic or hard copy signatures on the table of</p>

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			<p>contents of the emergency program documentation; or another manner. Facilities should clearly document the date of review and update and what the update entailed.</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 at least every 2 years (annually for LTC facilities). Format is at the discretion of the facility.

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0018	Procedures for Tracking of Staff and Patients	<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. At a minimum, the policies and procedures must address the following:]</p> <p>*[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.</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. Additionally, tracking of staff can often be more challenging based on the mechanism used for signing in and out for payment of staff based on hours worked, especially in the event of a power failure. Facilities can consider implementing a staff tracking system such as designating an area or protocol to check in with a designated person(s) during the emergency.</p> <p>Facilities are encouraged to leverage the support and resources available to them through local and national healthcare systems, healthcare coalitions, and healthcare organizations for resources and tools for tracking patients. While collaboration with healthcare coalitions is encouraged, it is not a requirement. Though the precise details of the actual collaboration with state and local emergency officials is not required to be documented, it is expected that sufficient information is documented to support verification of the process as part of the investigation.</p>

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			<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.</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 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.
0020	Policies and Procedures including Evacuation	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:]	<p>Evacuations & Patient Population Considerations</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</p>

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		[(3) or (1), (2), (6)] Safe evacuation from the [facility], which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.	<p>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>Triaging Considerations</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 not dependent on life-saving equipment. Considerations for prioritization may be based on, among other things, acuity, mobility status (stretcher-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.</p> <p>Following the triaging system, staff should consider the communication of patient care requirements to the in-taking facility, such as attaching a hard copy of a standard abbreviated patient health condition/history, injuries, allergies, and treatment rendered. Another method for communicating this information, a facility could consider color coordination of triage levels (i.e. green folder with this information is for less critical patients; red folders for critical and urgent</p>

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			<p>evacuated patients, etc.). Additionally, this hard copy could include family member/representative contact information.</p> <p>Patient safety should be the number one priority and it is expected that facilities provide care in a safe setting, therefore any existing guidance on patient rights and safe setting (e.g. §482.13(c)(2) for hospitals) should be continued. It would be prudent for facilities to consider how they would address a situation where a patient/resident refuses to evacuate, therefore leaving a patient in an unsafe environment is not acceptable.</p> <p>The facilities policies and procedures must outline primary and alternate means for communication with external sources for assistance. For instance, primary methods may be via regular telephone services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials; whereas alternate means account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance.</p> <p>Triage and coordination of evacuation requires planning and communication of plans within the facility and with entities that assist in providing services such as transportation and life-saving equipment.</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.• Ask staff to describe how they would handle a situation in which a patient refused to evacuate.

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0023	Policies and Procedures for Medical Docs.	<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. At a minimum, the policies and procedures must address the following:]</p> <p>*[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.</p>	<p>NOTE: This does not apply to Transplant Programs.</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.

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0029	Development of Communication Plan	(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years.	<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. Although the requirement for documentation of collaboration with state and local officials was removed (see 84 FR 51817, Sept. 30, 2019), facilities should continue to collaborate with state and local emergency officials. During the creation process for communication plans, facilities should also consult their applicable state and local emergency and pandemic plans.</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 should address what alternate means are available to alert local and State emergency officials. Optional communication methods facilities may consider include satellite phones, radios and short wave radios.</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) at least every 2 years (annually for LTC facilities). • Ask facility leadership or the designee responsible for the emergency program to verbally explain how they are to collaborate with Federal, State and local officials to ensure their communication plan complies with the Federal, State and local requirements.

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0030	Names and 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. The communication plan must include all of the following:</p> <p>*[For OPOs at §486.360(c):] The communication plan must include all of the following:</p> <p>(1) Names and contact information for the following:</p> <p>(i) Staff.</p> <p>(ii) Entities providing services under arrangement.</p> <p>(iii) Volunteers.</p> <p>(iv) Other OPOs.</p> <p>(v) Transplant and donor hospitals in the OPO’s Donation Service Area (DSA).</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, at a minimum, to the individual(s) designated as the emergency preparedness coordinator or person(s) responsible for the facility’s emergency preparedness program and management during an emergency event, during an emergency event.</p> <p>Facilities which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information must be reviewed and updated as necessary at least every 2 years, annually for LTC facilities. Contact information contained in the communication plan must be accurate and current. Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list.</p> <p>Transplant programs should be included in the development of the hospitals communication plans. In the case of a Medicare-approved transplant program, a communication plan needs to be developed and disseminated between the hospitals, OPO, and transplant patients. For example, if the transplant program is planning to transfer patients to another transplant program due to an emergency, the communication plan between the hospitals, the OPO, and the patient should include the responsibilities of each of the facility types to ensure continuity of care. During an emergency, should an organ offer become available at the time the patient is at the “transferred hospital,” the OPO’s emergency preparedness communication plan should address how this information will be communicated to both the OPO and the patient of where their care will be continued.</p>

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			<p>NOTE: For Home Health Agencies, contact information should also include patient’s physicians or allowed practitioners. Section 484.60 requires that each patient’s written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Accordingly, additional practitioners at HHAs should also be notified to reflect the interdisciplinary, coordinated approach to home health care delivery consistent with the HHA regulations.</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 every 2 years (annually for LTC facilities) by asking to see evidence of the review.

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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. 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. Emergency management officials may include, but are not limited to, emergency management agencies which may be local to the community as well as local officials who support the Incident Command System depending on the nature of the disaster (e.g. fire, police, public health, etc.). Additionally, emergency management officials also include the state public health departments and State Survey Agencies as well as federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.) and tribal emergency officials, as applicable.</p> <p>Facilities have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Facilities are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information must be reviewed and updated at least every 2 years (annually, for LTC facilities).</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 the facility has contact information for the State Survey Agency and/or public health departments. • Verify that all contact information has been reviewed and updated at least in the past 2 years (annually for LTC facilities) by asking to see evidence of the review. <p>NOTE: Even though the communications plan must include contact information, it does not specifically require the facility to have an individual contact for emergency management agencies. For instance, a state emergency management agency may have a specific phone line or contact method and not a specific individual person.</p>

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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. 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 should identify their primary and alternate means of communication in their emergency preparedness communication plan. For instance, a primary means of communication may be cellular phones, hard wire lines and the facilities intercom system, whereas the facilities alternate means (given interruption of primary means) may be the SHARed RESources.</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</p>

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			<p>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.
0033	Methods for Sharing 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.] 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>Note: In the event of an evacuation, a means to release patient information as permitted under HIPAA is not required</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>

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		for HHAs under §484.22(c), CORFs under §485.68(c), and RHCs/FQHCs under §491.12(c).	<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.
0036	Emergency Prep Training and Testing	(d) Training and testing. The [facility] must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.	<p>Training and Testing Program-General</p> <p>An emergency preparedness training and testing program as specified in this requirement must be documented, reviewed and updated. The training and testing program must reflect the risks identified in the facility’s risk assessment and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking</p>

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			<p>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 Component</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. For training requirements, the facility must have a process outlined within its emergency preparedness program which encompasses staff and volunteer training complementing the risk assessment. The training for staff should at a minimum include training related to the facility’s policies and procedures. Facilities must maintain documentation of the training so that surveyors are able to clearly identify staff training and testing conducted. For example, facilities may have a sign-in roster of training conducted within their training files or inclusion of this training in their training program, or individual training certificates of completion within personnel records. A surveyor should be able to ask for a list of employees and to verify training on the emergency preparedness requirements as required under E-0037 (subsection (d)(1)(iii)).</p> <p>Testing Component</p> <p>Testing requirements vary based on the provider type. Inpatient providers are required to conduct two testing exercises annually. Outpatient providers are required to conduct one testing exercise annually (that at least every two years their exercise must be a full-scale exercise)-Refer to E-0039 (subsection (d)(2)).</p> <p>Testing is the concept in which training is operationalized and the facility is able to evaluate the effectiveness of the training as well as the overall emergency preparedness program. Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement. Additionally, facilities should establish a process which includes participation of all staff in testing exercises over a period of time. Facilities are encouraged to consider their</p>

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			<p>scheduled exercises and the appropriate departments to be included. For instance, if a clinically-relevant testing exercise is not necessarily applicable to some other departments or staff, then the staff which did not participate in one year should participate in the next testing exercise to ensure that over a period of time all shifts are incorporated. Additionally, we are not specifying a facility to utilize all required equipment in the testing (drills) or a percentage of the patients/residents that would be included in these drills, however facilities should test their exercises according to how they would respond to the emergency would it be an actual real emergency.</p> <p>Under this standard, surveyors are to assess whether or not the facility has a training and testing program based on the facility's risk assessment and has incorporated its policies and procedures, as well as its communication plan within training required for staff and its testing exercises.</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.• Refer back to the facility's risk assessment to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.• Verify the program has been reviewed and updated at least every 2 years (annually for LTC facilities) by asking for documentation of the annual review as well as any updates made.• Verify that ICF/IID emergency plans also meet the requirements for evacuation drills and training at §483.470(i).

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0037	Emergency Prep Training Program	<p>(1) Training program. The [facility, except CAHs, ASCs, PACE organizations, PRTFs, Hospices, and dialysis facilities] must do all of the following:</p> <p>(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.</p> <p>(ii) Provide emergency preparedness training at least every 2 years.</p> <p>(iii) Maintain documentation of all emergency preparedness training.</p> <p>(iv) Demonstrate staff knowledge of emergency procedures.</p> <p>(v) If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.</p>	<p>Training Program-General</p> <p>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.</p> <p>The training provided by the facility must be based on the facility's risk assessment policies and procedures as well as the communication plan. The intent is that staff, volunteers and individuals providing services at the facility are familiar and trained on the facility's processes for responding to an emergency. Training should include individual-based response activities in the event of a natural disasters, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate. Training should include how the facility manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events.</p> <p>Furthermore, the facility must train staff based on the facility's risk assessment. Training for staff should mirror the facility's emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID's this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members.</p> <p>Facilities should provide initial emergency training during orientation (or shortly thereafter) to ensure initial training is not delayed.</p> <p>Continued Training</p> <p>After the initial training has been conducted for staff, facilities must provide training on their facility's emergency plan at least every 2 years (except for LTC facilities which will still be required to provide training annually). Facilities have the flexibility to determine the focus of their initial</p>

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			<p>and 2-year training, as long as it aligns with the emergency plan and risk assessment. Initial and subsequent training should be modified as needed and if the facility updates the policies and procedures to include but not limited to incorporating any lessons learned from the most recent exercises and real-life emergencies that occurred in and during the review of the facility's emergency program, we would expect the facility be able to demonstrate how they have updated the training as well. For example, the 2 year subsequent training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's review.</p> <p>While facilities are required to provide initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually) training to all staff, it is up to the facility to decide what level of training each staff member will be required to complete based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain clinical staff may require additional topics. For example, dietary staff who prepare meals may not need to complete annual training that is focused on patient evacuation procedures. Instead, the facility may provide training that focuses on the proper preparation and storage of food in an emergency. In addition, depending on specific staff duties during an emergency, a facility may determine that documented external training is sufficient to meet some or all of the facility's training requirements. For example, staff who work with radiopharmaceuticals may attend external training that teach staff how to handle radiopharmaceutical emergencies. It is up to the facility to decide if the external training meets the facility's requirements.</p> <p>Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. Facilities which may have changed their emergency plan should plan to conduct initial training to all staff on the new or revised sections of the plan. If a facility determines the need to add additional policies and procedures based on a new risk identified in the facility's risk assessment, the facility must train all staff on the new policies and procedures and the staff responsibilities. Facilities are not required to retrain staff on the entire emergency plan, but can choose to train staff on the new or revised element of the emergency preparedness program. For example, a facility identifies during an influenza outbreak that additional policies</p>

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			<p>and procedures and adjustments to the risk assessment are needed to address a significant influx of patients/clients/residents. The facility identifies clinical locations in which contagious patients can be triaged in a manner to minimize exposure to non-infected individuals. The training for this new or revised policy can be done without needing to re-train staff on the entire program.</p> <p>Variance by Provider/Supplier Type</p> <p>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.</p> <p>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.</p> <p>LTC facilities must continue to provide initial and continued training on an annual basis.</p> <p>Training of Volunteers and Contracted Staff</p> <p>Facilities may contract with individuals providing services who also provide services in multiple surrounding areas. For instance, an ICF/IID may contract a nutritionist who also provides services in other locations. Given that these contracted individuals may provide services at multiple facilities, it may not be feasible for them to receive formal training for each of the facilities for emergency preparedness programs. The expectation is that each individual knows the facility's emergency program and their role during emergencies, however the delivery of such training is left to the facility to determine. Facilities in which these individuals provide services may develop some type of training documentation-i.e. the facility's emergency plan, important contact</p>

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			<p>information, and the facility’s expectation for those individuals during an emergency etc. which documents that the individual received the information/training. Furthermore, if a surveyor asks one of these individuals what their role is during a disaster, or any relevant questions, then the expectation is that the individual can describe the emergency plans/their role.</p> <p>Documentation Requirements</p> <p>Facilities must maintain documentation of the initial and subsequent (at least every 2 years except for LTC facilities which will still be required to provide training annually) training for all staff. The documentation must include the specific training completed as well as the methods used for demonstrating knowledge of the training program. Facilities have flexibility in ways to demonstrate staff knowledge of emergency procedures. The method chosen is likely based on the training delivery method. For example: computer-based or printed self-learning packets may contain a test to demonstrate knowledge. If facilities choose instructor-led training, a question and answer session could follow the training. Regardless of the method, facilities must maintain documentation that training was completed and that staff are knowledgeable of emergency procedures.</p> <p>Survey Procedures</p> <ul style="list-style-type: none">• Ask for copies of the facility’s initial and subsequent (at least every 2 years or annual for LTC) emergency preparedness trainings and annual emergency preparedness training offerings.• Interview various staff and ask questions regarding the facility’s initial and subsequent (at least every 2 years or annual for LTC) training course to verify staff knowledge of emergency procedures.• Review a sample of staff training files to verify staff have received initial and subsequent (at least every 2 years or annual for LTC), emergency preparedness training. <p>NOTE: For ease of demonstrating compliance that the facility has updated its training program at least every 2 years, we recommend that facilities retain at a minimum, the past 2 cycles (generally 4 years) of emergency training documentation for both training and exercises for surveyor verification.</p>

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0039	Emergency Prep Testing Requirements	<p>2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:</p> <ul style="list-style-type: none"> i. Conduct a paper-based, tabletop exercise or workshop at least. A tabletop exercise is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the emergency event. ii. Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed. 	<p>Variability in Requirements</p> <p>For inpatient providers (inpatient hospice facilities, PRTFs, hospitals, LTC facilities*, ICFs/IID, and CAHs): The types of acceptable testing exercises are expanded. Inpatient providers can choose one of the two annually required testing exercises to be an exercise of their choice, which may include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.</p> <p>*NOTE: For LTC facilities, while the types of acceptable testing exercises was expanded, LTC facilities must continue to conduct their exercises on an annual basis. Facilities must conduct exercises to test the emergency plan, which for LTC facilities also includes unannounced staff drills using the emergency procedures.</p> <p>For outpatient providers (ASCs, freestanding/home-based hospice, PACE, HHAs, CORFs, Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), CMHCs, OPOs, RHCs, FQHCs, and ESRD facilities): Facilities are required to only conduct one testing exercise on an annual basis, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise. The opposite years (every other year opposite of the full-scale exercises), these providers may choose the testing exercise of their choice, which can include either another full-scale, individual facility-based, a mock disaster drill (using mock patients), tabletop exercise or workshop which includes a facilitator.</p> <p>For OPOs and RNCHIs, these providers must at a minimum conduct either a paper-based, tabletop exercise or workshop every year, however can elect to also participate in full-scale, individual facility-based exercise.</p> <p>Understanding Exercises and Terminology</p> <p>Similar to the training expectations outlined under E-0037 or (d)(1), such as hospitals at 482.15(d)(1), a facility's testing exercises require they be based on the individual facility's risk</p>

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			<p>assessment, policies and procedures, and communication plan and support the patient population it serves. Testing exercises should vary, based on the facility’s requirements, by cycles and frequency of testing. The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners. Testing exercises must be based on the facility’s identified hazards, to include natural or man-made disasters. This should include EID outbreaks.</p> <p>Facilities are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test the same scenario year after year or the same response processes. The intent is to identify gaps in the facility’s emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the facility’s program. In the event gaps are identified, facilities should update their emergency programs as outlined within the requirements for After-Action Report (AAR).</p> <p>Full-Scale and Community Based Exercises</p> <p>As the term full-scale exercise may vary by sector, facilities are not required to conduct a full-scale exercise as defined by FEMA or DHS’s Homeland Security Exercise and Evaluation Program (HSEEP). For the purposes of this requirement, a full scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses a facility’s functional capabilities by simulating a response to an emergency that would impact the facility’s operations and their given community. Full-scale exercises in the industry setting are large exercises in which multiple agencies participate and may only be available every three to five years; while functional exercises are similar in nature, but may not involve as many participants and in which each agency can choose its priorities to test within the confines of the exercise. Therefore, full-scale can include what is known as a “functional” exercise or drill in the industry and according to HSEEP. A full-scale exercise is also an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional or operational elements. There is also definition for “community” as it is subject to variation based on geographic setting, (e.g. rural, suburban, urban, etc.), state and local agency roles and responsibilities, types of providers in a given area in addition to other factors. In doing so,</p>

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			<p>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. 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> <p>Facilities are encouraged to engage with their area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. Health Care Coalitions (HCCs) are groups of individual health care and response organizations who collaborate to ensure each member has what it needs to respond to</p>

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			<p>emergencies and planned events. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness. There is value in participating in HCCs for participating in strategic planning, information sharing and resource coordination. HCC's do not coordinate individual facility exercises, but rather serve as a conduit to provide an opportunity for other provider types to participate in an exercise. HCCs should communicate exercise plans with local and state emergency preparedness agencies and HCCs will benefit the entire community's preparedness. In addition, CMS does not regulate state and local government disaster planning agencies. It is the sole responsibility of the facility to be in compliance.</p> <p>Facilities which determine that a full-scale community-based exercise will be planned for the facility's exercise requirement must also ensure that the exercise scenario developed is identified within the facility's risk assessment. While generally local and state emergency officials plan emergency exercises which could occur within the geographic location or community, facilities must ensure that participation in the exercise would adequately test the facility's emergency program (specifically its policies and procedures and communication plan). For instance, in the event the local or state full-scale exercise is testing the response to a major multiple car accident requiring airlift transfers of patients, a LTC facility or ESRD facility may not be impacted by this type of disaster or require activation of its emergency program, therefore the exercise may not be as appropriate. In this case, the facility could document that the scenario offered in this full-scale community based exercise and that the facility conducted an individual facility-based exercise to test its emergency program instead. However, if the state or local exercise is testing an EID outbreak, all facilities in the community may be impacted, therefore participation would be strongly recommended.</p> <p>The intent behind full-scale and community based exercises is to ensure the facility's emergency program and response capabilities complement the local and state emergency plans and support an integrated response while protecting the health and safety of patients.</p> <p>Individual Facility-Based Exercises</p> <p>Facilities that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise,</p>

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			<p>documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities. Facilities that elect to develop a small community-based exercise have the opportunity to not only assess their own emergency preparedness plans but also better understand the whole community’s needs, identify critical interdependencies and or gaps and potentially minimize the financial impact of this requirement. For example, a LTC facility, a hospital, an ESRD facility, and a home health agency, all within a given area, could conduct a small community-based exercise to assess their individual facility plans and identify interdependencies that may impact facility evacuations and or address potential surge scenarios due to a prolonged disruption in dialysis and home health care services. Those that elect to conduct a community-based exercise should make an effort to contact their local/state emergency officials and healthcare coalitions, where appropriate, and offer them the opportunity to attend as they can provide valuable insight into the broader emergency planning and response activities in their given area. Community partners are considered any emergency management officials (fire, police, emergency medical services, etc.) for full-scale and community-based exercises, however can also mean community partners that assist in an emergency, such as surrounding providers and suppliers.</p> <p>Participation</p> <p>While the regulations do not specify a minimum number of staff, or the roles of staff in the exercises, it is strongly encouraged that facility leadership and department heads participate in exercises. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities. Additionally, facilities can review which members of staff participated in the previous exercise, and include those who did not participate in the subsequent exercises to ensure all staff members have an opportunity to participate and gain insight and knowledge.</p> <p>Facilities can use a sign-in roster for the exercise to substantiate staff participation. A sufficient number of staff should participate in the exercise to test the scenario and thoroughly assess the risk, policy, procedure, or plan being tested.</p>

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			<p>Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe “shelter-in-place” location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient’s continuity of care. If the facility uses fire drills based on their risk assessment (e.g. wild fires) as a full-scale community based exercise in one given year (which is also a requirement for some providers/suppliers under Life Safety Code), the facility is encouraged to choose in the following year a different hazard in their risk assessment to conduct an exercise in order to ensure variability in the training and testing program. The intent of the requirements under the emergency preparedness condition for participation/condition for coverage, or requirement for LTC, is to test the facility’s ability to respond to any emergency outlined within their risk assessment. The purpose of testing the facility’s emergency program is to identify gaps in response which could result in adverse events for patients and staff and to adjust plans, policies and procedures to ensure patient and staff safety is maintained regardless of the type of emergency which occurs.</p> <p>Table-Top Exercise and Workshops</p> <p>Facilities are also required to conduct an “exercise of choice” or, for some, only conduct a table-top exercise (TTX) or workshop. Please refer back to the definition section above. TTX’s or workshops are expected to be group discussions led by a facilitator. We are not defining whether or not the facilitator must be a staff member or contracted service. Some facilities may find that a specific department lead may be best suited dependent on the scenario being tested, while other facilities may find an outside facilitator may be more appropriate to facilitate.</p> <p>The intent behind TTX’s or workshops is to test an exercise based on the facility’s risk assessment. Some facilities may find it prudent to conduct a TTX or workshop prior to a full-scale</p>

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			<p>or individual-facility based exercise in order to identify potential gaps or challenges and then update the policies and procedures accordingly to resolve the potential issue. This would allow for facilities to test their adjustments during a full-scale or individual facility-based exercise to determine if the corrective action was appropriate.</p> <p>After-Action Reviews</p> <p>Each facility is responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years. Facilities should also document the lessons learned following their tabletop and full-scale exercises and real-life emergencies and demonstrate that they have incorporated any necessary improvements in their emergency preparedness program. Facilities may complete an after action review process to help them develop an actionable after action report (AAR). The process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR. The AAR, at a minimum, should determine</p> <p>1)what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement. Lastly, facilities that are a part of a healthcare system, can elect to participate in their system’s integrated and unified emergency preparedness program and exercises. However, those that do will still be responsible for documenting and demonstrating their individual facility’s compliance with the exercise and training requirements.</p> <p>Exemption based on Actual Emergency</p> <p>Finally, an actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the facility for engaging in their next required community-based full-scale exercise or individual, facility-based exercise for following the actual event; and facilities must be able to demonstrate this through written documentation. With the changed requirements as a result of the 2019 Burden Reduction final rule (81 FR 63859) for outpatient providers required to conduct full-scale exercises only every other year, opposite of their exercises of choice, these facilities are exempt</p>

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			<p>from their next required full-scale or individual facility-based exercise. For inpatient providers, the full-scale exercise would be annually. The intent is to ensure that facilities conduct at least one exercise per year.</p> <p>For example, in the event an outpatient provider conducts a required full-scale community based exercise in January 2019, and completed the optional exercise of its choice in January 2020, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2021. If the outpatient provider conducts a required full-scale community based exercise in January 2020, and has the optional exercise of its choice scheduled for January 2021, and experiences an actual emergency in March 2020, the outpatient provider is exempt from next required full-scale community based or individual facility based exercise in January 2022, but must still conduct the required exercise of choice in January 2021. The exemption is based on the facility's required full-scale exercise, not the exercise of choice, therefore the exemption may not be applicable until two years following the activation of the emergency plan, dependent on the cycle the facility has determined and the actual emergency event.</p> <p>For inpatient providers, the exemption would apply for the next required full-scale exercise as well, however, it may be the same year or following year, as inpatient providers are required to perform two exercises per year. If an inpatient provider completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020, but experiences an actual emergency in March 2020 which required activation of its emergency plan, the inpatient provider is exempt from the next required full-scale exercise in January 2021, but must complete the exercise of choice. If the inpatient provider conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the inpatient provider would be exempt from that full-scale exercise as it would not be the exercise of choice.</p> <p>The exercises of choice, which allow facilities to choose one (e.g., another full-scale/individual facility based; mock disaster drill; or table top exercises) are not considered as the required full-scale community based or individual facility based exercises. Facilities which may have schedule full-scale exercises annually as part of their licensure or accrediting organizations requirements,</p>

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			<p>would be exempt from their next required annual full-scale exercise. Facilities which have a full-scale exercise scheduled as part of their exercise of choice for the opposite years would be exempt from their next scheduled exercise following an emergency, which would still be July 2021 (using the above example).</p> <p>Facilities must document that they had activated their emergency program based on an actual emergency. Documentation may include, but is not limited to: a section 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event specific information. The facility must also complete an after action review and integrated corrective actions into their emergency preparedness program.</p> <p>Resources</p> <p>For additional information and tools, please visit the CMS Quality, Safety & Oversight Group Emergency Preparedness website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html or ASPR TRACIE.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • Ask facility leadership to explain the participation of management and staff during scheduled exercises. • Ask to see documentation of the annual tabletop and full scale exercises (which may include, but is not limited to, the exercise plan, the AAR, and any additional documentation used by the facility to support the exercise). Documentation must demonstrate the facility has conducted the exercises described in the standard. • Ask to see the documentation of the facility's efforts to identify a full-scale community based exercise if they did not participate in one (i.e. date and personnel and agencies contacted and the reasons for the inability to participate in a community based exercise). • Request documentation of the facility's analysis and response and how the facility updated its emergency program based on this analysis.

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			NOTE: We recommend facilities to retain, at a minimum, the past 2 cycles (generally 2 years for inpatient providers and 4 years for outpatient providers of emergency testing exercise documentation. This would allow surveyors to assess compliance on the cycle of testing required for outpatient providers.
0042	Integrated Health Systems	<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. 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>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 every 2 years (annually for LTC facilities) must include all participating facilities. Again, each facility must be able to prove that it was involved in the annual reviews and updates of the program. The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable.</p>

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		<p>(i) A documented community-based risk assessment, utilizing an all-hazards approach.</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>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.</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</p>

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			<p>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> <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).• Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.

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0044	OPO Continuity of Operations	<p>(e) Continuity of OPO operations during an emergency. Each OPO must have a plan to continue operations during an emergency.</p> <p>(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.</p> <p>(2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have:</p> <p>(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;</p> <p>(ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or</p> <p>(iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.</p>	<p>An OPO may choose to relocate to an alternate location within its DSA. For instance, if a tornado threat or major flooding was anticipated within one area, however there is another location 20 miles away for the OPO to relocate to, we would anticipate the OPO would address this within its emergency plan. Additionally, OPOs must develop mutually-agreed upon protocols that address the duties and responsibilities of the hospital, transplant programs and OPO during emergencies as previously outlined (Reference Tags: 0002, 0012, 0014, 0042). Therefore, these three facility types must work together to develop and maintain policies and programs which address emergency preparedness.</p> <p>Survey Procedures</p> <ul style="list-style-type: none"> • 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.