SUMMARY: This final rule establishes national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It will also assist providers and suppliers to adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. Despite some variations, our regulations will provide consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters.

DATES: Effective date: These regulations are effective on [insert date 60 days after date of publication in the Federal Register].

Implementation date: These regulations must be implemented by November 15, 2017.

I. Overview
   A. Executive Summary

   We have reviewed existing Medicare emergency regulatory preparedness requirements for both providers and suppliers. We found that many providers and suppliers have emergency preparedness requirements, but those requirements do not go far enough in ensuring that these providers and suppliers are equipped and prepared to help protect those they serve during emergencies and disasters. Hospitals, for example, are currently required to have emergency power and lighting in some specified areas and there must be facilities for emergency gas and water supply. We believe that these existing requirements are generally insufficient in the face of the needs of the patients, staff and communities, and do not address inconsistency in the level of emergency preparedness amongst healthcare providers. For example, while some accreditation organizations have standards that exceed CMS’ current requirements for hospitals by requiring them to conduct a risk assessment, there are other providers and suppliers who do not have any emergency preparedness requirements, such as Community Mental Health Centers (CMHCs) and Psychiatric Residential Treatment Facilities (PRTFs). We concluded that current emergency preparedness requirements are not comprehensive enough to address the complexities of the actual emergencies. Over the past several years, the United States has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, the 2009 H1N1 influenza pandemic, tornadoes and floods in the spring of 2011, and Hurricane Sandy in 2012, our nation's health security and readiness for public health emergencies have been on the national agenda. This final rule issues emergency preparedness requirements that establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness and response that incorporates the lessons learned from the past, combined with the proven best practices of the present. We recognize that central to this approach is to develop and guide emergency preparedness and response within the
framework of our national healthcare system. To this end, these requirements also encourage providers and suppliers to coordinate their preparedness efforts within their own communities and states as well as across state lines, as necessary, to achieve their goals.


We are issuing emergency preparedness requirements that will be consistent and enforceable for all affected Medicare and Medicaid providers and suppliers (referred to collectively as "facilities," throughout the remainder of this final rule where applicable). This final rule addresses the three key essentials we believe are necessary for maintaining access to healthcare services during emergencies: safeguarding human resources, maintaining business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

Based on our research and consultation with stakeholders, we have identified four core elements that are central to an effective and comprehensive framework of emergency preparedness requirements for the various Medicare- and Medicaid-participating providers and suppliers. The four elements of the emergency preparedness program are as follows:

- **Risk assessment and emergency planning:** We are requiring facilities to perform a risk assessment that uses an "all-hazards" approach prior to establishing an emergency plan. The all-hazards risk assessment will be used to identify the essential components to be integrated into the facility emergency plan. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider or supplier and considers the particular types of hazards most likely to occur in their areas. These may include, but are not limited to, care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. Additional information on the emergency preparedness cycle can be found at the Federal Emergency Management Agency (FEMA) National Preparedness System website located at: https://www.fema.gov/threat-and-hazard-identification-and-risk-assessment.

- **Policies and procedures:** We are requiring that facilities develop and implement policies and procedures that support the successful execution of the emergency plan and risks identified during the risk assessment process.

- **Communication plan:** We are requiring facilities to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across healthcare providers, and with state and local public health departments and emergency management agencies and systems to protect patient health and safety in the event of a disaster. The following link is to FEMA’s comprehensive preparedness guide to develop and maintain emergency operations plans: During an emergency, it is critical that hospitals, and all providers/suppliers, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely
manner to ensure continuation of patient care functions throughout the facilities and to ensure that these functions are carried out in a safe and effective manner.

- Training and testing: We are requiring that a facility develop and maintain an emergency preparedness training and testing program. A well-organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as annual refresher trainings. The facility must offer annual emergency preparedness training so that staff can demonstrate knowledge of emergency procedures. The facility must also conduct drills and exercises to test the emergency plan to identify gaps and areas for improvement.

Comments

J. Emergency Preparedness Requirements for Long Term Care (LTC) Facilities (§483.73)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to patients that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to patients: skilled nursing care and related services for patients who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who due to their mental or physical condition require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities must meet certain requirements located at part 483, Subpart B, Requirements for Long Term Care Facilities. SNFs must be certified as meeting the requirements of section 1819(a) through (d) of the Act. NFs must be certified as meeting section 1919(a) through (d) of the Act. A LTC facility may be both Medicare and Medicaid approved.

LTC facilities provide a substantial amount of care to Medicare and Medicaid beneficiaries, as well as "dually eligible individuals" who qualify for both Medicare and Medicaid. As of June 2016, there were 15,699 LTC facilities and these facilities provided care for about 1.7 million patients. The existing requirements for LTC facilities contain specific requirements for emergency preparedness, set out at §483.75(m)(1) and (2). Section 483.75(m)(1) states that a facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents. We proposed that this language be incorporated into proposed §483.73(a)(1). Existing §483.75(m)(2) states that a facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures. These requirements would be incorporated into proposed §483.73(d)(1) and (2). Section 483.75(m)(1) and (2) would be removed. Our proposed emergency preparedness requirements for LTC facilities are identical to those we proposed for hospitals at §482.15, with
two exceptions. Specifically, at §483.73(a)(1), we proposed that in an emergency situation, LTC facilities would have to account for missing residents.

Section 483.73(c) would require these facilities to develop an emergency preparedness communication plan, which would include, among other things, a means of providing information about the general condition and location of residents under the facility's care. We proposed to add an additional requirement at §483.73(c)(8) that read, "A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives." Also, we proposed at §483.73(e)(1)(i) that LTC facilities must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99, NFPA® 101, and NFPA® 110, we proposed that LTC facilities test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the LTC facility anticipates it would require during an emergency. However, we also solicited comments on whether there should be a specific requirement for "residents' power needs" in the LTC requirements. Comment: Some commenters recommended that LTC facilities be required to include patients, their families, and relevant stakeholders throughout the emergency preparedness planning and testing process. They recommended that the method of providing information from the emergency plan be clearly communicated with residents, representatives, and caregivers and that the LTC facilities follow a specific time frame to provide this communication. Some commenters recommended that PACE facilities and HHAs be required to include patients and their families in the emergency preparedness planning as well. A few commenters recommended that LTC facilities include their state Long-Term Care Ombudsman Program in this planning process. Some commenters also recommended that LTC facilities provide the Program with a completed emergency plan. Response: As we stated in the proposed rule, LTC facilities are unlike many of the inpatient care providers. Many of the residents have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the residents' homes. We believe this fact changes the nature of the relationship with the residents and their families or representatives.

We continue to believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its residents and their families or representatives and the most efficient manner in which to share that information. Therefore, we are finalizing our proposal at §483.73(c)(8) that LTC facilities develop and maintain a method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives. We note that we are not requiring that PACE and HHA providers share information from the emergency plan with families and their representatives. However, these providers can choose to share information with any appropriate party, so long as they comply with federal, state, and local laws.

We are not requiring LTC facilities to share information with stakeholders, or Long-Term Care Ombudsman Program representatives, because we believe such a requirement could be overly burdensome for the LTC facilities. We believe that facilities need the flexibility to develop their emergency plans and determine what portions of those plans and the parties with whom
those plans should be shared. If a facility determines that it is appropriate and timely to share either the complete emergency plan, or certain portions of it, with stakeholders or representatives from the Long-Term Care Ombudsman Program, we encourage them to do so. Therefore, we are finalizing our proposal at §483.73(c)(2)(iii) that LTC facilities maintain the contact information for the Office of the State Long-Term Care Ombudsman.

Comment: A majority of commenters expressed support for the proposal that requires LTC facilities to develop a communications plan. A few commenters also supported CMS' proposal to require LTC facilities to share information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives. A commenter recommended that LTC facilities follow a specific timeframe to provide this communication.

Response: We appreciate the commenters' support. We note that we are not requiring specific timeframes for LTC facility communications in these emergency preparedness requirements. We are allowing facilities the flexibility to make the determination on when emergency preparedness plans and information should be communicated with the relevant entities during an emergency or disaster.

Comment: A commenter specifically recommended that CMS issue guidance to facilities regarding steps to disseminate information about the emergency plan to the general public. These steps would include posting the plan on the facility's website, if available, making a hard copy available for review at the facility's front desk; providing a notice to residents upon entering a facility that they or their representative can receive a free electronic copy at any time by providing their email address, and proving a copy of the plan in electronic format to local entities that are a resource for families during a disaster. A commenter recommended that CMS require LTC facilities to make the plans available to residents and their representatives upon request. According to the commenter, information that the facility shares should be written in clear and concise language and the facility's website could be a place for current, updated information.

Response: We agree with the commenter that transparency in communication is important. Therefore, we are requiring that LTC facilities have a method for sharing appropriate information with residents and their families or representatives. Consistent with our belief that these emergency preparedness requirements should afford facilities flexibility, we do not believe that it is appropriate to require that LTC facilities take specific steps or utilize specific strategies to share these documents with residents and their families or representatives.

Comment: A commenter stated that the communication plan requirement is broad and will lead to inconsistent approaches for facilities. Furthermore, the commenter noted that this will cause compliance and enforcement of the rule to be subjective.

Response: The proposed emergency preparedness regulations provide the minimum requirements that facilities must follow. This allows a variety of facilities, ranging from small rural providers to large facilities that are part of a franchise or chain, the flexibility to develop communication plans that are specific to the needs of their resident population and facility. Additionally, we have written these regulations with the intention to allow for flexibility in how facilities develop and maintain their emergency preparedness plans.
In addition to the CoPs/CfCs, interpretative guidelines (IGs) will be developed for each provider and supplier types. We also note that surveyors will be provided training on the emergency preparedness requirements, so that enforcement of the rule will be based on the regulations set forth here.

Comment: A commenter noted that the proposed requirements for a communication plan for LTC facilities do not mention a waiver that would allow for sharing of client information, which would create a potential violation of HIPAA. Furthermore, the commenter requested clarification in the final rule.

Response: As we stated previously in this final rule, HIPAA requirements are not suspended during a national or public health emergency. Thus, the communication plan is to be created consistent with the HIPAA Rules. See http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy. http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy-emergencysituations.

Comment: A commenter stated that LTC facilities should consider multiple options for transportation in planning for an evacuation. Another commenter recommended that there should be coordination between vendors that provide transportation services for LTC facility residents with other facilities and community groups to avoid having too many providers relying on a few vendors.

Response: We agree with the commenters that it is preferable for facilities to have multiple options for the provision of services, including transportation, and that those services be coordinated so that they are used efficiently. We also encourage facilities to coordinate with other facilities in their geographic area to determine if their arrangements with any service provider are realistic. For example, if two LTC facilities in the same city are depending upon the same transportation vendor to evacuate their residents, both facilities should ensure that the vendor has sufficient vehicles and personnel to evacuate both facilities. Also, we believe that the requirements for testing that are set forth in §483.73(d)(2), especially the full-scale exercise, should provide facilities with the opportunity to test their emergency plans and determine if they need to include multiple options for services and whether those services have been coordinated.

Comment: Due to the difficulty that the training requirement would place on smaller LTC facilities, a commenter suggested that we allow training by video demonstration, webinar, or by association-sponsored programs where regional training can be given to the staff of several facilities simultaneously. The commenter pointed out that group training would also bring about more in-depth discussion, questions, and comments.

Response: We agree that these training styles could be beneficial. Our proposed requirement for emergency preparedness training does not limit training types to within the facility only.

Comment: CMS solicited comments on whether LTC facilities should be required to provide the necessary electrical power to meet a resident's individualized power needs. Some organizations recommended that the regulation include specific requirements for a "resident's power needs." However, many commenters were opposed to this requirement. Opposing commenters stated that
in an emergency, based on the emergency and available resources, things such as medically sustaining life support equipment would be needed rather than a powered wheelchair and the individual facility would be best at making that determination. Some commenters recommended that the final regulation state that power needs would be managed by the providers based on priority to address critical equipment and systems both for individual needs as well as the needs of the entire facility.

Response: We appreciate the feedback that we received from commenters on this issue. We agree that the needs of the most vulnerable residents should be considered first and expect that facilities would take the needs of their most vulnerable population into consideration as part of their daily operations. At §483.73(a)(3) we require that the facility's emergency plan address their resident population to include persons at-risk, the type of services the facility has the ability to provide in an emergency, and continuity of their operations. We agree with commenters, and want facilities to have the flexibility to conduct their risk assessment, individually assess their population, and determine in their plans how they will meet the individual needs of their residents. We believe that the individual power needs of the residents are encompassed within the requirement that the facility assess its resident population. Therefore, we are not adding a specific requirement for LTC facilities to provide the necessary power for a resident's individualized power needs. However, we encourage facilities to establish policies and procedures in their emergency preparedness plan that would address providing auxiliary electrical power to power dependent residents during an emergency or evacuating such residents to alternate facilities. If a power outage occurs during an emergency or disaster, power dependent residents will require continued electrical power for ventilators, speech generator devices, dialysis machines, power mobility devices, certain types of durable medical equipment, and other types of equipment that are necessary for the residents' health and well-being. We therefore reiterate the importance of protecting the needs of this vulnerable population during an emergency.

Comment: A commenter objected to our proposal to require LTC facilities to have policies and procedures that addressed alternate sources of energy to maintain sewage and waste disposal. The commenter indicated that the provision and restoration of sewage and waste disposal systems may well be beyond the operational control of some providers.

Response: We agree with the commenter that the provision and restoration of sewage and waste disposal systems could be beyond the operational control of some providers. However, we are not requiring LTC facilities to have onsite treatment of sewage or to be responsible for public services. LTC facilities would only be required to make provisions for maintaining the necessary services.

Comment: A commenter noted that the proposed requirements do not address the issue of regional evacuation. This commenter believed that this was an essential part of an emergency plan and that the plan must address transportation and accommodations for people with physical, intellectual, or cognitive impairments. The commenter also recommended that the regional evacuation plan account for long-term sheltering and that there be specific standards for sheltering-in-place. Also, they believed that LTC facilities should be required to adopt the 2007 EP checklist that was issued by CMS.
Response: We agree with the commenter that the emergency plans for LTC facilities should address regional as well as local evacuations and long-term as well as short-term sheltering-in-place. However, we are finalizing the requirement for the emergency plan to be based upon a facility-based and community-based risk assessment, utilizing an all-hazards approach (§483.73(a)(1)). The "all-hazards" approach includes emergencies that could affect only the facility as well as the community in which it is located and beyond. It also includes emergencies that are both short-term and long-term. When facilities are developing their risk assessments, they should be considering all of those possibilities. We disagree about the recommendation that we propose more specific standards on sheltering-in-place. We believe that each facility needs the flexibility to develop its own plans for sheltering-in-place for both short and long-term use. We also disagree about requiring adoption of the 2007 CMS EP checklist. That checklist is a resource that facilities may use. In addition, over time CMS may publish updates or other checklists or facilities may choose to use tools from other resources.

Comment: A commenter agreed with us that LTC facilities should have plans concerning missing residents. The current LTC requirements require LTC facilities to have plans for emergencies, including missing residents (§483.75(m)). However, the commenter also believed that this requirement could be confusing and that we should clarify that facilities should have plans to account for missing residents in both emergency and non-emergency situations.

Response: We agree with the commenter that LTC facilities must have plans concerning missing residents that can be activated regardless of whether the facility must activate its emergency plan. A missing resident is an emergency and LTC facilities must have a plan to account for or locate the missing resident.

Comment: Some commenters wanted more clarification on the requirements for LTC facilities to have policies and procedures that address subsistence needs for staff and residents, particularly related to medical supplies and temperature to protect resident health and safety and for safe and sanitary storage of provisions. A commenter requested additional guidance and clarification on medical supplies. They questioned whether "supplies" would include individual residents' medications and, if it did, how that affected prescribing limits, payment systems, access, etc. Furthermore, a commenter wanted clarification on power requirements for temperatures. Another commenter recommended we specify a minimum for all needed supplies and provisions.

Response: We have not required minimums for these types of requirements because they would vary greatly between facilities. Each facility is required to conduct a facility-based and community-based assessment that addresses, among other things, its resident population. From that assessment, each facility should be able to identify what it needs for its resident population, including what medical/pharmaceutical supplies it needs to maintain and its temperature needs for both its resident population and its necessary provisions. As to minimum time periods, each facility would need to determine those based on its assessment and any other applicable requirements.

Comment: A commenter recommended that we require specific types of medical documentation in proposed §483.73(b)(5). The commenter specifically recommended the inclusion of resident
Response: We appreciate the commenter’s suggestion. Proposed §483.73(b)(5) required that the facility have policies and procedures that address “A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available.” While the types of documentation the commenter identified will probably be included in that documentation, we believe that facilities need the flexibility to determine what will be included in the medical documentation and how they will develop these systems.
Thus, we are finalizing this provision as proposed. After consideration of the comments we received on the proposals, and the general comments we received on the proposed rule, as discussed earlier in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for LTC facilities with the following modifications:

- Revising the introductory text of §483.73 by adding the term "local" to clarify that LTC facilities must also comply with local emergency preparedness requirements.

- Revising §483.73(a) to change the term "ensure" to "maintain."
- Revising §483.73(b)(1)(i) to state that LTC facilities must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.

- Revising §483.73(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered residents. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered residents are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.

- Revising §483.73(b)(5) to replace the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."

- Revising §483.73(b)(7) to replace the term "ensure" with "maintain."

- Revising §483.73(c) by adding the term "local" to clarify that the LTC facility must develop and maintain an emergency preparedness communication plan that also complies with local laws.

- Revising §483.73(c)(5) to clarify that the LTC facility must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).

- Revising §483.73(d) by adding that each LTC facility's training and testing program must be based on the LTC facility's emergency plan, risk assessment, policies and procedures, and communication plan.

- Revising §483.73(d)(1)(iv) to replace the phrase "Ensure that staff can demonstrate knowledge" with "Demonstrate staff knowledge."

- Revising §483.73(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."

- Revising §483.73(d)(2)(ii) to allow a LTC facility to choose the type of exercise it will conduct to meet the second annual testing requirement.

- Revising §483.73(e)(1) and (2) by removing the requirement for additional generator testing.
• Revising §483.73(e)(2)(i) by removing the requirement for an additional 4 hours of generator testing and by clarifying that LTC facilities must meet the requirements of NFPA® 99, 2012 edition and NFPA® 110, 2010 edition.

• Revising §483.73(e)(3) by removing the requirement that LTC facilities maintain fuel quantities onsite and clarify that LTC facilities must have a plan to maintain operations unless the LTC facility evacuates.

• Adding §483.73(f) to allow a separately certified LTC facility within a healthcare system to elect to be a part of the healthcare system’s emergency preparedness program.

• Adding a new §483.73(g) to incorporate by reference the requirements of 2012 NFPA® 99, 2012 NFPA® 101, and 2010 NFPA® 110.
K. Emergency Preparedness Regulations for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) ($483.475)

Section 1905(d) of the Act created the ICF/IID benefit to fund "institutions" with four or more beds to serve people with [intellectual disability] or other related conditions. To qualify for Medicaid reimbursement, ICFs/IID must be certified and comply with CoPs at 42 CFR part 483, subpart I, §§483.400 through 483.480. As of June 2016, there were 6,237 ICFs/IID, serving approximately 129,000 clients, and all clients receiving ICF/IID services must qualify financially for Medicaid assistance under their applicable state plan. Clients with intellectual disabilities who receive care provided by ICF/IIDs may have additional emergency planning and preparedness requirements. For example, some care recipients are non-ambulatory, or may experience additional mobility or sensory disabilities or impairments, seizure disorders, behavioral challenges, or mental health challenges.

Because ICF/IIDs vary widely in size and the services they provide, we expect that the risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. However, we believe each of them has the capability to comply fully with the requirements so that the health and safety of its clients are protected in the event of an emergency situation or disaster.

Thus, we proposed to require that ICF/IIDs meet the same requirements we proposed for hospitals, with two exceptions. At §483.475(a)(1), we proposed that ICF/IIDs utilize an all-hazards approach, including plans for locating missing clients. We believe that in the event of a natural or man-made disaster, ICF/IIDs would maintain responsibility for care of their own client population but would not receive patients from the community. Also, because we recognize that all ICF/IIDs clients have unique needs, we proposed to require ICF/IIDs to "address the unique needs of its client population …" at §483.475(a)(3).

In addressing the unique needs of their client population, we believe that ICF/IIDs should consider their individual clients' power needs. For example, some clients could have motorized wheelchairs that they need for mobility, or require a continuous positive airway pressure or CPAP machine, due to sleep apnea. We believe that the proposed requirements at §483.475(a) (a risk assessment utilizing an all-hazards approach and that the facility address the unique needs of its client population) encompass consideration of individual clients' power needs and should be included in ICF/IIDs risk assessments and emergency plans.

As we stated earlier, the purpose of this final rule is to establish requirements to ensure that Medicare and Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during more widespread local, state, and national emergencies. We do not believe the existing requirements for ICF/IIDs are sufficiently comprehensive to protect clients during an emergency that impacts the larger community. However, we have been careful not to remove emergency preparedness requirements that are more rigorous than the additional requirements we proposed.
For example, our current regulations for ICF/IIDs include requirements for emergency preparedness. Specifically, §483.430(c)(2) and (3) contain specific requirements to ensure that direct care givers are available at all times to respond to illness, injury, fire, and other emergencies. However, we did not propose to relocate these existing facility staffing requirements at §483.430(c)(2) and (3) because they address staffing issues based on the number of clients per building and client behaviors, such as aggression. Such requirements, while related to emergency preparedness tangentially, are not within the scope of the emergency preparedness requirements for ICF/IIDs.

Current §483.470, Physical environment, includes a standard for emergency plan and procedures at §483.470(h) and a standard for evacuation drills at §483.470(i). The standard for emergency plan and procedures at current §483.470(h)(1) requires facilities to develop and implement detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing clients. This requirement will be relocated to proposed §483.475(a)(1). Existing §483.470(h)(1) will be removed.

Currently §483.470(h)(2) states, with regard to a facility's emergency plan, that the facility must communicate, periodically review the plan, make the plan available, and provide training to the staff. These requirements are covered in proposed §483.475(d). Current §483.470(h)(2) will be removed. ICF/IIDs are unlike many of the inpatient care providers. Many of the clients can be expected to have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the clients' residences or homes. Section 483.475(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of clients under the facility's care. We did not indicate what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its clients and their families or representatives and the most efficient manner in which to share that information. Therefore, we proposed to add an additional requirement at §483.475(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives."

The standard for disaster drills set forth at existing §483.470(i)(1) specifies that facilities must hold evacuation drills at least quarterly for each shift of personnel under varied conditions to ensure that all personnel on all shifts are trained to perform assigned tasks; ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and evaluate the effectiveness of their emergency and disaster plans and procedures. Currently §483.470(i)(2) further specifies that facilities must evacuate clients during at least one drill each year on each shift; make special provisions for the evacuation of clients with physical disabilities; file a report and evaluation on each evacuation drill; and investigate all problems with evacuation drills, including accidents, and take corrective action. Furthermore, during fire drills, facilities may evacuate clients to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code. Finally, at existing §483.470(i)(3), facilities must meet the requirements of §483.470(i)(1) and (2) for any live-in and relief staff they utilize.
Because these existing requirements are so extensive, we proposed cross referencing §483.470(i) (redesignated as §483.470(h)) at proposed §483.475(d).

Comment: A commenter recommended that CMS include language that would exclude community-based residential services servicing three or fewer residents. The commenter noted that implementing the same emergency preparedness requirements as ICF/IID facilities for community based residential services would be cost prohibitive.

Response: A community-based residential facility with less than 4 beds would not meet the definition of an ICF/IID and would not be covered under this regulation. We encourage facilities that are concerned about the implementation of emergency preparedness requirements to refer to the various resources noted in the proposed and final rules, and participate in healthcare coalitions within their community for support in implementing these requirements.

Comment: A commenter agreed with CMS’ proposal that ICF/IID providers’ communication plans be shared with the families of their clients. The commenter noted that an annual correspondence to families, with intermediate updates as changes or additions are made, should not be burdensome to facilities.

Response: We appreciate the commenter's support. We have not set specific requirements for when or how often ICF/IID facilities should correspond with families and their representatives. However, facilities can choose to correspond with clients' families and their representatives as frequently as they deem appropriate.

Comment: Multiple commenters expressed their opposition to the requirement for ICF/IIDs to hold evacuation drills at least quarterly for each shift for personnel under varied conditions. Each commenter stated that quarterly evacuation drills are costly and will require the unnecessary movement of clients which could result in liability issues as well as disrupt operations.

Response: The requirement for quarterly evacuation drills is one of the requirements in the existing regulations for ICF/IIDs at §483.470(i) (proposed to be redesignated to §483.470(h)). We stated in the proposed rule that the purpose of the rule was to establish requirements to ensure that Medicare and Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during a widespread emergency. While we did not believe that the existing requirements for ICF/IIDs are sufficiently comprehensive enough to protect clients during an emergency that impacts the larger community, we were careful not to remove emergency preparedness requirements that are more rigorous than those additional requirements we proposed. Therefore, we proposed to retain this requirement. We believe that, unlike many of the inpatient care providers due to the long term nature of their clients stays, ICF/IIDs have a heightened responsibility to ensure the safety of their clients given that these facilities essentially become the clients' residences or homes.

Comment: A commenter expressed their support for the emphasis that the proposed rule placed on drills and testing for this vulnerable population and pointed out that many accrediting organizations require ICF/IIDs to test their emergency management plans each year.
Response: We thank the commenter for their support and agree that drills and testing are an important aspect of developing a comprehensive emergency preparedness program.

Comment: A commenter stated that the proposed requirement to place a generator in each home and to test it annually would be extremely costly.

Response: We would like to clarify that we did not propose a requirement for generators to be placed in each ICF/IID facility. We proposed additional testing requirements for hospitals, CAHs, and LTC facilities. However, due to the numbers of comments we received stating that the requirement for additional testing would be overly burdensome and unnecessary. We have removed this requirement in the final rule.
After consideration of the comments we received on these provisions of the proposed rule, and the general comments we received, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for ICF/IIDs with the following modifications:

• Revising the introductory text of §483.475, by adding the term "local" to clarify that ICF/IIDs must also comply with local emergency preparedness requirements.

• Revising §483.475(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."

• Adding at §483.475(b)(1)(i) that ICF/IIDs must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.

• Revising §483.47(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered clients. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered residents are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.

• Revising §483.475(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records;" also revising paragraph (b)(7) to change the term "ensure" to "maintain."

• Revising §483.475(b)(1), (b)(1)(ii)(A), and (b)(2) to replace the term "residents" to "clients." Throughout the preamble discussion, the terms "patients and residents" have been deleted and replaced with the term "client."

• Revising §483.475(c) by adding the term "local" to clarify that ICF/IIDs must develop and maintain an emergency preparedness communication plan that also complies with local laws.

• Revising §483.475(c)(5) to clarify that ICF/IIDs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).

• Revising §483.475(d) by adding that each ICF/IID's training and testing program must be based on the ICF/IID's emergency plan, risk assessment, policies and procedures, and communication plan.

• Revising §483.475(d)(1)(iv) to replace the phrase "Ensure that staff can demonstrate knowledge" to "Demonstrate staff knowledge."

• Revising §483.475(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."

• Revising §483.475(d)(2)(ii) to allow an ICF/IIDs to choose the type of exercise it will conduct to meet the second annual testing requirement.
• Adding §483.475(e) to allow a separately certified ICF/IID within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.
3. Provisions of the Final Regulations

A. Changes Included in the Final Rule

In this final rule, we are adopting the provisions of the December 27, 2013 proposed rule (78 FR 79082) with the following revisions:

- For all provider and supplier types, we are making a technical revision to clarify that facilities must also coordinate with local emergency preparedness systems.

- For ESRD facilities, CMHCs, LTC facilities, ICF/IIDs, PACE organizations, PRTFs, and OPOs we are clarifying that tracking during and after the emergency applies to on-duty staff and sheltered patients. We have also revised the regulations to provide that if on-duty staff and sheltered patients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.

- For all provider and supplier types, we are making a technical revision to clarify that facilities must develop and maintain an emergency preparedness communication plan that also complies with local law.

- For RNHCIs, ASCs, hospices, PRTFs, PACE organizations, hospitals, LTC facilities, ICF/IIDs, CAHs, CMHCs, and dialysis facilities, we are clarifying that these provider and supplier types must have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

- For all provider and supplier types with the exception of RNHCIs, OPOs, and transplant centers, we are revising testing requirements by replacing the term "community mock disaster drill" with "full-scale exercise."

- For all provider and supplier types with the exception of RNHCIs, OPOs, and transplant centers, we are revising testing requirements to allow each facility to choose the type of exercise they must conduct to meet the second annual testing requirement.

- For hospitals, CAHs, and LTC facilities, we are revising emergency and standby power system requirements by removing the requirement for an additional 4 hours of generator testing and clarifying that a facility must meet the requirements of NFPA® 99 2012 edition and NFPA® 110, 2010 edition.

- For hospitals, CAHs, and LTC facilities, we are revising emergency and standby power system requirements by removing the requirement that a facility must maintain fuel onsite and clarifying that facilities must have a plan to maintain operations unless the facility evacuates.

- For all provider and supplier types, we are adding a separate standard to the regulations text that will allow a separately certified healthcare facility within a healthcare system to elect to be a part of the healthcare systems unified emergency preparedness program.
B. Incorporation by Reference

In this final rule, we are incorporating by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Tentative Interim Amendments issued prior to April 16, 2014; the NFPA 99® 2012 edition of the Health Care Facilities Code, issued August 11, 2011, and all Tentative Interim Amendments issued prior to April 16, 2014; and the NFPA 110 ® 2010 edition of the Standard for Emergency and Standby Power Systems(including Tentative Interim Amendments to chapter 7), issued August 6, 2009.

  ++ TIA 12-2 to NFPA® 99, issued August 11, 2011.
  ++ TIA 12-3 to NFPA® 99, issued August 9, 2012.
  ++ TIA 12-4 to NFPA® 99, issued March 7, 2013.
  ++ TIA 12-5 to NFPA® 99, issued August 1, 2013.

  ++ TIA 12-1 to NFPA® 101, issued August 11, 2011.
  ++ TIA 12-3 to NFPA® 101, issued October 22, 2013.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

§ 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal, State and local emergency preparedness requirements. The LTC facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(1) Emergency plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

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

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

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

   (4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(2) Policies and procedures. The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph

(3) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

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

      i. Food, water, medical, and pharmaceutical supplies.

      ii. Alternate sources of energy to maintain--

         1. Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;
2. Emergency lighting;
3. Fire detection, extinguishing, and alarm systems; and
4. Sewage and waste disposal.

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

(3) Safe evacuation from the LTC 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.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

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

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to LTC residents.

(8) The role of the LTC facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

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

1. Names and contact information for the following:
   i. Staff.
   ii. Entities providing services under arrangement.
   iii. Residents' physicians.
   iv. Other LTC facilities.
   v. Volunteers.
(2) Contact information for the following:
   i. Federal, State, tribal, regional, or local emergency preparedness staff.
   ii. The State Licensing and Certification Agency.
   iii. The Office of the State Long-Term Care Ombudsman.
   iv. Other sources of assistance.

(3) Primary and alternate means for communicating with the following:
   i. LTC facility's staff.
   ii. Federal, State, tribal, regional, or local emergency management agencies.

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

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

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

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

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

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

(1) Training program. The LTC facility must do all of the following:
   i. Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
   ii. Provide emergency preparedness training at least annually.
   iii. Maintain documentation of the training.
   iv. Demonstrate staff knowledge of emergency procedures.
(2) Testing. The LTC facility must conduct exercises to test the emergency plan at least annually, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

1. (i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

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

      1. A second full-scale exercise that is community-based or individual, facility-based.

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

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

(6) Emergency and standby power systems. The LTC facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) Emergency generator inspection and testing. The LTC facility must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) Emergency generator fuel. LTC facilities that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates. (f) Integrated healthcare systems. If a LTC 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 LTC 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:

(4) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(7) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(8) 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.

(9) 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—

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.

(2) 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.

(10) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below.

(13) (iii) TIA 12-3 to NFPA 99, issued August 9, 2012.
(14) (iv) TIA 12-4 to NFPA 99, issued March 7, 2013.
(15) (v) TIA 12-5 to NFPA 99, issued August 1, 2013.
(18) (viii) TIA 12-1 to NFPA 101, issued August 11, 2011.
(20) (x) TIA 12-3 to NFPA 101, issued October 22, 2013.
(21) (xi) TIA 12-4 to NFPA 101, issued October 22, 2013.
(22) (xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including

(23) TIAs to chapter 7, issued August 6, 2009.
§483.475 Condition of participation: Emergency preparedness.

1. The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal, State, and local emergency preparedness requirements.

2. The ICF/IID 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 ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

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

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

      (3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

   (b) Policies and procedures. The ICF/IID 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 602 paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

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

         (i) Food, water, medical, and pharmaceutical supplies.

         (ii) Alternate sources of energy to maintain the following:

            (A) Temperatures to protect client health and safety and for the safe and sanitary storage of provisions.

            (B) Emergency lighting.

            (C) Fire detection, extinguishing, and alarm systems.

            (D) Sewage and waste disposal.
(2) A system to track the location of on-duty staff and sheltered clients in the ICF/IID’s care during and after an emergency. If on-duty staff and sheltered clients are relocated during the emergency, the ICF/IID must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the ICF/IID, 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.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and secures and maintains the availability of records.

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

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to maintain the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include the following:

(1) Names and contact information for the following:
   (i) Staff.
   (ii) Entities providing services under arrangement.
   (iii) Clients’ physicians.
   (iv) Other ICF/IIDs.
   (v) Volunteers.

(2) Contact information for the following:
(i) Federal, State, tribal, regional, and local emergency preparedness staff.
(ii) Other sources of assistance.
(iii) The State Licensing and Certification Agency.
(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510(b)(1)(ii).

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

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

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

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

(1) Training program. The ICF/IID must do all the following:
   (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
   (ii) Provide emergency preparedness training at least annually.
   (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures.

(2) Testing. The ICF/IID must conduct exercises to test the emergency plan at least annually. The ICF/IID must do the following:
   (i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an
individual, facility-based. If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

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

(A) A second full-scale exercise that is community-based or individual, facility-based.
(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

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

3. Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
4. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
5. 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.
6. 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:
   (a) A documented community–based risk assessment, utilizing an all-hazards approach.
   (b) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
7. 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.