



EMERGENCY PREPAREDNESS REGULATIONS FOR HOSPICE

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45CFR §418.113

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

Establishment of the EP Program §418.113

- Develop an emergency preparedness program that describes the hospice's *comprehensive* approach to meeting the health, safety, and security needs of their staff and patient population during an emergency or disaster situation.
 - Must address how the hospice would coordinate with other healthcare facilities, as well as the whole community during an emergency or disaster (natural, man-made, facility).
 - Must be reviewed annually.
 - Should encompass elements based on the "all-hazards" definition and specific to the location of the hospice. For instance, a hospice operating in a large flood zone, or tornado prone region, should have included these elements in their overall planning.
 - Hospices should have an approach to address patient limited mobility during emergency events.
 - Must consider a multitude of events, vs one potential event. emergency preparedness plan.

Develop and maintain EP Program §418.113(a)

- The annual review must be documented to include the date of the review and any updates made to the emergency plan based on the review.
- An emergency plan is one part of a facility's emergency preparedness program. The plan:
 - Provides the framework, including 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.
 - Supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials.

- Is specific to the hospice location and considers particular hazards most likely to occur in the area, such as:
 - Natural disasters
 - Man-made disasters
 - Facility-based disasters that include but are not limited to:
 - Care-related emergencies
 - Equipment and utility failures, such as power, water, gas, etc.
 - Interruptions in communication, including cyber-attacks;
 - Loss of all or portion of a facility; and
 - Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).
- 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.

Maintain and Annual EP Updates §418.113(a)(1)-(2)

Facilities must document both the facility-based and community-based risk assessments.

- All-hazards planning does not specifically address every possible threat or risk but ensures the facility will have the capacity to address a broad range of related emergencies.
- Facilities are encouraged to utilize the concepts outlined in the National Preparedness System, published by the United States Department of Homeland Security’s Federal Emergency Management Agency (FEMA), as well as guidance provided by the Agency for Healthcare Research and Quality (AHRQ).

“Community” is not defined in order to afford facilities the flexibility in deciding which healthcare facilities and agencies it considers to be part of its community for emergency planning purposes.

- Facilities may rely on a community-based risk assessment developed by other entities. If this approach is used, facilities are expected to have a copy of the community-based risk assessment and to work with the entity that developed it to ensure that the facility’s emergency plan is in alignment.

When developing an emergency preparedness plan, facilities are expected to consider, among other things, the following:

- Identification of all business functions essential to the facility's operations that should be continued during an emergency;
- Identification of all risks or emergencies that the facility may reasonably expect to confront;
- Identification of all contingencies for which the facility should plan;
- Consideration of the facility's location;
- Assessment of the extent to which natural or man-made emergencies may cause the facility to cease or limit operations; and,
- 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.

EP Program Patient Population §418.113(a)(3)

At-risk populations" are individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures and racial and ethnic backgrounds, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. At-risk populations would also include, but are not limited to, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities as well as others with access and functional needs, and infants and children.

Mobility is an important part in effective and timely evacuations, and therefore facilities are expected to

- properly plan to identify patients who would require additional assistance,
- ensure that means for transport are accessible and available and
- ensure that those involved in transport, as well as the patients, are made aware of the procedures to evacuate.

For outpatient facilities, such as Home Health Agencies (HHAs), the emergency plan is required to ensure that patients with limited mobility are addressed within the plan.

The emergency plan must also address

- the types of services that the facility would be able to provide in an emergency,
- which staff would assume specific roles in another's absence through succession planning and delegations of authority.

Process for EP Collaboration §418.113(a)(4)

EP Plan must 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. 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.

Development of EP Policies and Procedures (P&P) §418.113(b)

A facility may choose whether to incorporate the emergency P&P within their emergency plan or to be part of the facility's Standard Operating Procedures or Operating Manual.

Subsistence Needs for Staff and Patients §418.113(b)(6)(iii)

Hospices' emergency preparedness P&P must address the following:

- The provision of subsistence needs for staff and patients whether they evacuate or shelter in place, including, but are not limited to the following:
 - Food, water, medical and pharmaceutical supplies
 - Alternate sources of energy to maintain temperatures, emergency lighting, fire detection, extinguishing, and alarm systems, and sewage and waste disposal.

Procedures for Followups §418.113(b)(1)

P&P must include procedures to follow up with on duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The information must be readily available, accurate, and shareable among officials within and across the emergency response system, as needed. The hospice must inform State and local officials of any on-duty staff or patients that they are unable to contact.

Procedures for Tracking of Staff and Patients §418.113(b)(6)(ii) and (v)

P&P must address a system to track the location of on-duty staff and sheltered patients in the hospice's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

*[For Inpatient Hospices:

- Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.

P&P of Risk Assessment §418.113(b)(2)

Home bound hospices are required to inform State and local emergency preparedness officials of the need for patient evacuations. These P&P must address when and how this information is

communicated to emergency officials and also include the clinical care needed for these patients. This should include, but is not limited to, the following:

- Whether or not the patient is mobile.
- Does the patient have special needs? (E.g., Communication challenges, language barriers, intellectual disabilities, special dietary needs, equipment, etc.)

P&P Including Evacuation §418.113(b)(6)(ii)

Facilities must have P&P which address the needs of evacuees and also staff members and families/patient representatives or other personnel seeking refuge. Additionally, the P&P must address staff responsibilities during evacuations.

Additionally, facilities should consider their triaging system when coordinating the tracking and potential evacuation of patients. Included within this system should be who (specifically) will be tasked with making triage decisions. Following the triaging system, staff should consider the communication of patient care requirements to the in-taking facility, such as attaching hard copy of abbreviated patient health condition/history, injuries, allergies, treatment rendered, and family member/representative contact information.

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

P&P for Sheltering §418.113(b)(6)(i)

Emergency plans must include a means for sheltering all patients, staff, and volunteers who remain in the facility in the event that an evacuation cannot be executed. Facilities are expected to include in their P&P the criteria for determining which patients and staff that would be sheltered in place. The plan should take into account the appropriate facilities in the community to which patients could be transferred in the event of an emergency.

P&P for Medical Docs §418.113(b)(3)

Policies and procedures must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.

Agreement with Other Facilities §418.113(b)(5)

Facilities are required to have P&P which include prearranged transfer agreements, which may include written agreements or contracted arrangements with other facilities and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients. Additionally, the P&P and facility agreements should include pre-arranged agreements for transportation between the facilities. The arrangements should be in writing, such as Memorandums of Understanding (MOUs) and Transfer Agreements, in order to demonstrate compliance.

Roles under a Waiver Declared by Secretary §418.113(b)(6)(C)(iv)

Hospices must develop and implement P&P that describe its role in providing care at alternate care sites during emergencies. State or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites.

P&P must specifically address the facility's role in emergencies where the President declares a major disaster or emergency under the Stafford Act or an emergency under the National Emergencies Act, and the HHS Secretary declares a public health emergency. Examples of 1135 waivers include some of the existing CoPs; Licensure for Physicians or others to provide services in the affected State; EMTALA; Medicare Advantage out of network providers and HIPAA.

P&P should address what coordination efforts are required during a declared emergency in which a waiver of federal requirements under section 1135 of the Act has been granted by the Secretary. For example, if due to a mass casualty incident in a geographic location, an 1135 waiver may be granted to waive licensure for physicians in order for these individuals to assist at a specific facility where they do not normally practice, then the facility should have P&P which outline the responsibilities during the duration of this waiver period. For instance, the policies may establish a lead person in charge for accountability and oversight of assisting physicians not usually under contract with the facility.

Additionally, facilities should also have in place P&P which address emergency situations in which a declaration was not made and where an 1135 waiver may not be applicable, such as during a disaster affecting the single facility. In this case, P&P should address potential transfers of patients; timelines of patients at alternate facilities, etc.

Development of Communication Plan §418.113(c)

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. Optional communication methods facilities may consider include satellite phones, radios and short wave radios.

Names and Contact Information §418.113(c)(1)

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,

The communication plan must include names and contact information for the following:

- Hospice employees
- Entities providing services under arrangement
- Patients' physicians
- Other hospices

While not required, facilities should also have contact information for other facilities not of the same type. For instance a hospital may have the contact information of LTC facilities within a reasonable geographic area, which could assist in facilitating patient transfers.

Emergency Officials Contact Information §418.113(c)(2)

The communication plan must include contact information for the following:

- Federal, State, tribal, regional, and local emergency preparedness staff
- Other sources of assistance

Primary/Alternate Means for Communication §418.113(c)(3)

The communication plan must include primary and alternate means for communicating with staff and Federal, State, tribal, regional, and local emergency management agencies.

it is expected that hospices 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.

Methods for Sharing Information §418.113(c)(4)-(6)

The communication plan must include a method for sharing information about the general condition and location of patients, and medical documentation as necessary with other health providers to maintain the continuity of care as permitted under 45 CFR 164.510(b)(1)(ii) and(4).

Sharing Information on Occupancy/Needs §418.113(c)(7)

The communication plan must include a means of providing information about the facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

Emergency Prep Training and Testing

§418.113(d)

An emergency preparedness training and testing program must be documented and reviewed and updated on at least an annual basis, must reflect the risks identified in the risk assessment, and be included in their emergency plan. For example, a facility that identifies flooding as a risk should also include policies and procedures in their emergency plan for closing or evacuating their facility and include these in their training and testing program. This would include, but is not limited to, training and testing on how the facility will communicate the facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities. Additionally, for facilities with multiple locations, such as multi-campus or multi-location hospitals, the facility's training and testing program must reflect the facility's risk assessment for each specific location.

Emergency Prep Training Program

§418.113(d)(1)

The hospice must do all of the following:

- Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.
- Demonstrate staff knowledge of emergency procedures.
- Provide emergency preparedness training at least annually.
- Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

Emergency Prep Testing Requirements

§418.113(d)(2)

At least annually, the facility must conduct exercises to test the emergency plan and do all of the following:

- 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 [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [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.
 - 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.
- Conduct an additional exercise that may include, but is not limited to the following:
 - A second full-scale exercise that is community-based or individual, facility-based.

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

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

Facilities that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment. For example, an inpatient facility might test their policies and procedures for a flood that may require the evacuation of patients to an external site or to an internal safe “shelter-in-place” location (e.g. foyer, cafeteria, etc.) and include requirements for patients with access and functional needs and potential dependencies on life-saving electricity-dependent medical equipment. An outpatient facility, such as a home health provider, might test its policies and procedures for a flood that may require it to rapidly locate its on-duty staff, assess the acuity of its patients to determine those that may be able to shelter-in-place or require hospital admission, communicate potential evacuation needs to local agencies, and provide medical information to support the patient’s continuity of care.

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

Integrated Health Systems §418.113€

If a hospice 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 hospice may choose to participate in the healthcare system's coordinated emergency preparedness program.

If elected, the unified and integrated emergency preparedness program must:

- Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
- Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
- 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].