Proposed Rule on Emergency Preparedness Conditions of Participation

At a Glance

The Issue:
The Centers for Medicare & Medicaid Services (CMS) published in the Dec. 27 Federal Register a proposed rule that would establish emergency preparedness conditions of participation (CoPs) and conditions for coverage (CfCs) that hospitals, critical access hospitals (CAHs) and 15 other provider and supplier types would have to meet in order to participate in the Medicare and Medicaid programs. CMS has identified four key areas that the agency believes are central to an effective emergency preparedness system. These are:

- Risk assessment and planning based on an “all hazards” approach;
- Policies and procedures based on risk assessment and planning;
- Communications plan; and
- Training and testing.

The proposed rule would require participating providers and suppliers to adopt standards in these areas, although the specific proposed requirements are adjusted to reflect the characteristics of each type of provider and supplier. In addition, inpatient providers, including hospitals, long-term care facilities and CAHs, would be required to comply with emergency and standby power systems requirements.

Our Take:
The AHA supports the need for hospitals and other providers and suppliers to plan appropriately for natural and man-made disasters and coordinate with federal, state and local emergency preparedness systems so that patients’ needs are met during disasters and emergency situations. We are carefully reviewing the agency’s comprehensive and broad-based proposed requirements and evaluating the effects that they will have on hospitals and health systems. We are concerned that CMS may have significantly underestimated the burden and cost associated with complying with this rule.

Upon initial review, it appears that these regulations would be similar, but not identical, to the emergency preparedness accreditation requirements of The Joint Commission. However, as this is the first time that such comprehensive emergency preparedness CoPs and CfCs have been proposed for the identified provider and supplier types, the AHA is actively seeking input from its members regarding these proposed requirements and their effects on hospitals and health systems.

What You Can Do:
- Share this advisory with your chief operating officer, chief medical officer, chief nursing officer, chief quality officer, risk manager, compliance officer, facilities manager, emergency manager, emergency department director, and other relevant staff. If you have an organ transplant program, hospice program, post-acute care unit, ambulatory surgical center, rural health clinic, dialysis program, inpatient psychiatric residential treatment facility, or comprehensive outpatient rehabilitation facility, you will want to share this advisory with the leaders of those functions, too.
- Submit your hospital’s comments to CMS on the proposed rule by Feb. 25. In addition to feedback on its specific proposals, CMS seeks comments on four key questions related to implementation (see page 21 of this advisory).
- Share your thoughts about this proposed rule and your comments to CMS with the AHA at: emergencyprep@aha.org

Further Questions:
Please contact the AHA’s Roslyne Schulman at rschulman@aha.org, or Evelyn Knolle at eknolle@aha.org for more information about the rule.
Proposed Rule on Emergency Preparedness
Conditions of Participation

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BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) published in the Dec. 27 Federal Register a proposed rule that would establish emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers. The proposed rule would revise the Medicare and Medicaid conditions of participation (CoP) and conditions for coverage (CfC) for hospitals, critical access hospitals and 15 other provider and supplier types. Comments are due to CMS on or before Feb. 25.

CHANGES TO THE MEDICARE AND MEDICAID COPs AND CfCs

Overview and Purpose

In preparing its proposed rule, CMS reviewed emergency preparedness guidance from federal agencies, such as the office of the Assistant Secretary for Preparedness and Response (ASPR), as well as state-level requirements for some states. CMS also reviewed industry best practices and standards from The Joint Commission and other accrediting bodies and the National Fire Protection Association (NFPA). Many of these resources are listed in the rule’s Appendix; the AHA also has posted the listing on our Emergency Readiness webpage. CMS encourages providers and suppliers to use these resources to develop and maintain their emergency preparedness plans.

The agency also examined existing Medicare and Medicaid emergency preparedness requirements for providers and suppliers and concluded that they are not comprehensive enough to address the complexities of actual emergencies. In particular, CMS states that the requirements do not address the need for communication to coordinate with other systems of care within cities or states, or contingency planning and training of personnel.

CMS concludes that the current set of federal, state and local laws and guidelines, combined with the various accrediting organizations’ emergency preparedness standards, fall short of what is needed to require that health care providers and suppliers be adequately prepared for a disaster.

Thus, CMS’s proposed emergency preparedness requirements are intended to 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.” The agency further observes that the proposed regulations would encourage providers and suppliers to coordinate their preparedness efforts within their own communities and states, as well as across state lines.

SUMMARY OF MAJOR PROVISIONS

CMS proposes four core elements that it defines as central to an effective and comprehensive framework of emergency preparedness requirements. These are:

- Risk assessment and planning: CMS proposes each facility would establish an emergency plan, which would be based upon a risk assessment performed using an “all-hazards” approach. An all-hazards approach is “an integrated approach to
emergency preparedness planning that focuses on the facility’s capacities and capabilities that are critical to preparedness for a range of emergencies or disasters. This approach is specific to the location of the provider and considers the particular types of hazards which may most likely occur in its area."

- **Policies and procedures:** CMS proposes that each facility would be required to develop and implement policies and procedures based on its emergency plan and risk assessment.

- **Communication plan:** CMS proposes that each facility would develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care would be required to be well coordinated within the facility, across health care providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.

- **Training and testing:** CMS proposes that each facility would develop and maintain an emergency preparedness training and testing program which would include initial training in emergency preparedness policies and procedures as well as annual training. Thereafter, facilities would be required to ensure that staff can demonstrate knowledge of emergency procedures. In addition, facilities would be required to conduct drills and exercises to test the emergency plan.

CMS proposes to implement these four basic elements of emergency preparedness by revising and adding to the requirements that each provider and supplier type must meet in order to be eligible for Medicare and Medicaid participation. These requirements – the CoPs for providers and the CfCs for suppliers – are intended to protect public health and safety and ensure that high-quality care is provided to everyone.

**Categories of Providers and Suppliers:** Besides hospitals (which would include entities that must comply with the hospital CoPs at 42 CFR 482.1 – 482.66, such as acute care hospitals, IRFs, LTCHs and psychiatric hospitals), the categories of providers and suppliers for which CMS is proposing emergency preparedness requirements include:

1. Critical Access Hospitals (CAHs)
2. Religious Nonmedical Health Care Institutions (RNHCIs)
3. Ambulatory Surgical Centers (ASCs)
4. Hospice
5. Inpatient Psychiatric Residential Treatment Facilities (PRTFs)
6. Programs of All-Inclusive Care for the Elderly (PACE)
7. Transplant Centers
8. Long-Term Care (LTC) Facilities (includes Skilled Nursing Facilities (SNFs))
9. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
10. Home Health Agencies (HHAs)
11. Comprehensive Outpatient Rehabilitation Facilities (CORFs)
12. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy (PT) and Speech-Language Pathology (SLP) Services
13. Community Mental Health Centers (CMHCs)
14. Organ Procurement Organizations (OPOs)
15. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
16. End-Stage Renal Disease (ESRD) Facilities

CMS seeks public comments on when these requirements should be implemented and whether certain requirements should be implemented on a staggered basis.

CMS believes that hospitals are the focal points for health care in their communities. In addition, because of Emergency Medical Treatment and Labor Act (EMTALA) and discharge planning requirements, CMS states that hospitals are in the best position to coordinate emergency preparedness planning with other community providers. CMS expects hospitals to be prepared to care for as many disaster victims as possible during an emergency, depending on capacity, and to meet minimal obligations for care to all who are in need.

**CMS’s proposed regulatory requirements for each of the provider and supplier types listed above are based on the comprehensive emergency preparedness requirements that CMS is proposing for hospitals.** CMS uses the proposed hospital requirements as a “template” for the proposed requirements for other providers and suppliers, but modifies specific requirements to tailor them to the unique needs of each provider and supplier.

In general, CMS notes that other inpatient facilities (including CAHs, SNFs, RNHCIs, PRTFs and ICFs/IIDs) would have standards similar to those for hospitals because they have greater responsibility than outpatient facilities during an emergency for ensuring the health and safety of patients, employees and volunteers. For instance, all inpatient facilities would be required to provide for the subsistence needs of their patients and staff – including food, water and medical supplies and alternate sources of energy to maintain temperatures, emergency lighting, fire and alarm systems and sewage and waste disposal.

By contrast, in the event of a disaster, providers of outpatient services (such as ASCs, PACE organizations, HHAs, CORFs, RHCs, FQHCs and ESRD facilities) may not open their facilities, or may close them, sending patients and staff home or to a place where they may shelter in place. Such facilities may find it necessary to shelter patients until they can be evacuated, or may be called on to provide some level of care for community residents in the event of an emergency. Finally, CMS notes that hospice facilities may provide both inpatient and outpatient services, and transplant centers and OPOs are unique as well, so the proposed rule is tailored to address their specific circumstances.

Additionally, CMS clarifies that it expects implementation of certain proposed requirements would be different based on the category of provider or supplier. For example, a CAH’s implementation of the requirement to have policies and procedures in place to provide subsistence needs of patients and staff during an emergency would be different than that of a large hospital, due to the expected role that each type of provider would have in disaster response.

For each major element of the proposed rule, the agency identifies multiple resources available to assist providers in understanding and complying with the proposed requirements. A [listing of resources](#) CMS notes in the proposed rule is available on AHA’s [Emergency Readiness](#) webpage. In addition, we have inserted hyperlinks to the
proposed regulatory language for each specific provider or supplier type as those providers and suppliers are discussed below.

**PROPOSED HOSPITAL EMERGENCY PREPAREDNESS REGULATIONS**

CMS proposes new hospital CoP requirements:

“The hospital must comply with all applicable Federal and State emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.”

CMS notes that an emergency preparedness program should allow for continuous building of a comprehensive system of health care response to a natural or man-made emergency. An all-hazards approach is described as “an integrated approach to emergency preparedness planning.” Rather than managing separate planning initiatives for a multitude of threat scenarios, all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. CMS further states that it is imperative that each provider think in broader terms than its own facility and plan for how it would serve similar and other health care facilities as well as the whole community during an emergency event.

CMS proposes that the emergency preparedness program must include, but not be limited to, the following elements:

**EMERGENCY PLAN**

The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

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

CMS would require each hospital, and all other providers and suppliers included in this proposed rule, to perform a risk assessment based on an all-hazards approach prior to establishing an emergency preparedness plan. A facility-based risk assessment examines only the risks to the facility and its patients and describes what the facility and its staff should do to prepare for and manage during an emergency. A community-based risk assessment is carried out outside the organization, within the defined community. An analysis of the facility-based and community-based risk assessments would drive revision to the emergency preparedness program and the plan for response. CMS reviews a number of resources and guides available to assist a hospital in conducting its risk assessment and in developing an emergency plan.

In order to meet this requirement, CMS expects hospitals at least to consider:

- identification of essential business functions that should be continued in an emergency;

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1 Blue italic text in this document signifies CMS’s actual proposed regulatory language.
identification of all risks or emergencies that the hospital may reasonably expect to confront;
identification of all contingencies for which the hospital should plan;
consideration of the hospital’s location, including patient services and business operations;
assessment of the extent to which emergencies may cause the hospital to cease or limit operations; and
determination of whether arrangements with other hospitals or entities might be needed to ensure the provision of essential services

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

CMS provides examples of such strategies and notes that it expects strategies to include consideration of collaboration with hospitals and suppliers across state lines, if applicable.

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

In addition to individuals specifically identified as at risk in statute (children, senior citizens and pregnant women), CMS proposes to define “at risk populations” as individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. CMS notes the definition also includes the elderly, persons in hospitals or nursing homes, people with physical and mental disabilities, infants and children.

CMS states that in making the determination of the types of services the hospital can provide in an emergency, the hospital should consider factors such as the number of staffed beds, whether the hospital has an emergency department or trauma center, availability of staffing and medical supplies, the hospital’s location, and its ability to collaborate with other community resources during an emergency.

In terms of a hospital’s continuity of operations, CMS proposes that emergency plans should include delegations of authority and succession planning in order to ensure that the lines of authority during an emergency are clear and that the plan is implemented promptly and appropriately.

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

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CMS notes that planning with officials in advance of an emergency will foster a smoother, more effective and more efficient response during a disaster. While responsibility for ensuring a coordinated response lies with state and local authorities, the hospital would need to document its efforts to contact these officials. CMS recognizes that officials may opt not to collaborate with some providers or suppliers due to their limited size and role, and such providers need only document their efforts.

CMS also references the role of ASPR’s Hospital Preparedness Program (HPP), noting that while the HPP continues to encourage preparedness at the hospital level, hospitals cannot be successful in response without robust community health care coalition (HCC) preparedness; i.e. engaging critical partners such as emergency management, public health, mental/behavioral health providers, as well as community and faith-based partners. A key goal of HPP moving forward is to strengthen the capabilities of the HCC, not just the individual hospital. While CMS would not require providers to participate in HCCs, the agency encourages all providers to engage in such collaborations, where possible, to ensure better coordination surrounding an emergency event.

**POLICIES AND PROCURES**

*The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually."

CMS requests comment on the timing of the updates.

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

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

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

CMS provides examples of how a hospital might meet this requirement. For instance, a hospital could arrange for storage of supplies outside the facility, have contracts with suppliers for the acquisition of supplies during an emergency, or address subsistence needs of evacuees in an agreement with a facility that would be willing to accept the hospital’s patients during an emergency. Although CMS proposes that each hospital only address subsistence needs of its staff and patients, it notes that volunteers, visitors and individuals from the community may arrive at the hospital to offer assistance or seek shelter and that the hospital should consider whether it needs to maintain extra provisions. CMS is soliciting public comment on this proposed requirement.

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

(A) Temperatures to protect patient 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.”

CMS proposes to define the term “waste” as all wastes, including solid waste, recyclables, chemical, biomedical waste and wastewater, including sewage.

“(2) A system to track the location of staff and patients in the hospital’s care both during and after the emergency.”

CMS does not propose a requirement for a specific type of tracking system; however, the agency notes that the information must be readily available, accurate and shareable among officials within and across the emergency response system as needed. CMS proposes this requirement for providers and suppliers who provide ongoing care for inpatients or outpatients, including RNHCIs, hospices, PRTFs, PACE organizations, LTC facilities, ICFs/IID, HHAs, CAHs and ESRD facilities. ASCs would be required to maintain responsibility for staff and patients if patients were in the facility. Other outpatient providers, such as CORFs, RHCs, FQHCs and clinics that are providers of PT and SLP services have the flexibility to cancel appointments during an emergency, and CMS notes that they do not need to assume responsibility for patients. This requirement is not being proposed for transplant centers or OPOs, whose potential donors would be in hospitals. CMS solicits comments on the feasibility of this requirement for any outpatient facilities.

“(3) Safe evacuation from the hospital, 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 patients, staff, and volunteers who remain in the facility.”

CMS notes that when developing policies and procedures for sheltering in place, hospitals should consider the ability of their building(s) to survive a disaster and what proactive steps they could take prior to an emergency to facilitate sheltering in place or transferring of patients to alternate settings if their facilities were affected by the emergency.

“(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and ensures records are secure and readily available.”

Medical documentation policies would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.

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

CMS describes existing volunteer programs that could be helpful in an emergency, including the Medical Reserve Corps (MRC), a national network of community-based
volunteer units and the federal Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), which could be used by hospitals to verify the credentials of volunteer health care workers.

“(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients.”

CMS would apply this proposed requirement only to providers and suppliers that provide continuous care and services for individual patients. Thus, CMS is not proposing this requirement for CORFs, clinics that provide outpatient PT and SLP services and RHCs/FQHCs.

“(8) The role of the hospital 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.”

CMS intends for this proposed requirement to encourage providers to collaborate with emergency officials in proactive planning in the event that services are severely disrupted. Section 1135 of the Social Security Act provides the Secretary with authority to temporarily waive or modify certain Medicare, Medicaid and Children’s Health Insurance Program requirements for providers in an emergency area. This can include waiver of CoPs and the EMTALA requirements.

**COMMUNICATION PLAN**

The hospital must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law and must be reviewed and updated at least annually. The communication plan must include all of the following:

1. Names and contact information for the following: (i) staff; (ii) entities providing services under arrangement; (iii) patients’ physicians; (iv) other hospitals; (v) volunteers.

2. Contact information for the following: (i) Federal, State, tribal, regional, and local emergency preparedness staff; (ii) other sources of assistance.

3. Primary and alternate means for communicating with the following: (i) hospital’s staff; (ii) Federal, State, tribal, regional, and local emergency management agencies.”

CMS does not propose specific types of alternate communication systems that hospitals must have, but it notes options such as pagers, cellular telephones, walkie-talkies, HAM radio and satellite telephone communication systems. CMS recognizes that some hospitals, especially in remote areas, have difficulty using some current communications systems, and expects such hospitals to address these challenges in their emergency communications system. CMS also reviews options and resources available to hospitals, such as the National Communication System.
“(4) A method for sharing information and medical documentation for patients under the hospital’s care, as necessary, with other health care providers to ensure continuity of care.”

CMS would expect hospitals to have a system of communication that could ensure that comprehensive patient care information could be disseminated across providers and suppliers in a timely manner. Such a system would ensure that information would be sent with an evacuated patient to the next care provider or supplier, information would be readily available for patients being sheltered in place, and electronic information would be backed up both within and outside the geographic area where the hospital was located.

“(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510.”

Hospitals would need to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted by the HIPAA privacy regulations, to family members and others. This proposed requirement would not apply to transplant centers, CORFs, OPOs, clinics that provide outpatient PT and SLP services, or to FQHCs/RHCs.

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

Section 164.510(b)(4) of the HIPAA privacy regulations, “Use and disclosures for disaster relief purposes,” establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient’s location or general condition.

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

CMS notes that hospitals and other providers engaging in HCCs in their area can effectively meet this requirement.

**TRAINING AND TESTING**

*The hospital must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.*

(1) **Training Program. The hospital must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.
(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Ensure that staff can demonstrate knowledge of emergency procedures.”

CMS notes that small and rural hospitals may find it helpful to use the resources of their state and local governments in meeting this requirement, and promotes the value of participation in HCCs in the area in planning and conducting exercises.

“(2) Testing. The hospital must conduct drills and exercises to test the emergency plan. The hospital must do all of the following:

(i) Participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, conduct an individual, facility-based mock disaster drill at least annually.

(ii) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event.

(iii) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iv) Analyze the hospital’s response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital’s emergency plan, as needed.”

CMS expects that hospitals would conduct mock disaster drills and tabletop exercises using various emergency scenarios, based on their risk analyses. The agency reviews approaches and links to an extensive set of resources available to assist hospitals in designing and carrying out these drills and exercises. A listing of these resources is available on AHA’s Emergency Readiness webpage.

EMERGENCY AND STANDBY POWER SYSTEMS

The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1)(i) and (ii) of this section.

(1) Emergency generator location. (i) The generator must be located in accordance with the location requirements found in NFPA 99, NFPA 101, and NFPA 110.
(2) Emergency generator inspection and testing. In addition to the emergency power system inspection and testing requirements found in NFPA 99—Health Care Facilities and NFPA 110—Standard for Emergency and Standby Power systems, as referenced by NFPA 101—Life Safety Code (as required by 42 CFR 482.41(b)), the hospital must:

   (i) At least once every 12 months, test each emergency generator for a minimum of 4 continuous hours. The emergency generator test load must be 100 percent of the load the hospital anticipates it will require during an emergency.

   (ii) Maintain a written record, which is available upon request, of generator inspections, tests, exercising, operation and repairs.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply.”

CMS intends to require compliance with future updates of the Life Safety Code (LSC). The current LSC states that the hospital’s alternate source of power (for example, generator) and all connected distribution systems and ancillary equipment must be designed to ensure continuity of electrical power to designated areas and functions of a health care facility. Also, the LSC (NFPA 110) states that the rooms, shelters or separate buildings housing the emergency power supply shall be located to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures.

CMS has proposed the same emergency and standby power requirements for CAHs and LTC facilities. CMS requests information on this proposal and, in particular, on how it might better estimate costs in light of the existing LSC and other state and federal requirements.

The AHA is carefully reviewing CMS’s comprehensive and broad-based proposed requirements and evaluating the impact that they will have on hospitals and health systems. We are concerned that CMS may have significantly underestimated the burden and cost associated with complying with this rule (see CMS’s cost estimates on pages 19 and 20 of this advisory). We are seeking input from members regarding how closely these proposed rules align with their existing emergency preparedness plans and the time, assistance and cost that would be involved in complying. We also are seeking input from the American Society for Healthcare Engineering (ASHE), an AHA affiliate.

**PROPOSED REQUIREMENTS FOR OTHER PROVIDERS AND SUPPLIERS**

In the rule, CMS reviews the proposed requirements for the 16 other provider and supplier types by identifying how they differ from the hospital requirements. Table 1 in the proposed rule (located on pages 79102-79104) lists all the provider and supplier types and their proposed emergency preparedness requirements, noting both additional requirements and exemptions. For the purposes of this advisory, we do not summarize
the proposed requirements for the following five types of providers and suppliers due to their limited connection to hospitals: RNHCIs; ICFs/IIDs; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient PT and SLP Services; CMHCs and OPOs.

For the remaining 11 provider and supplier types, this section of the advisory follows CMS’s format of describing how proposed requirements differ from the proposed requirements for hospitals. As noted above, CMS uses the proposed hospital regulations as a “template” for the regulations that would apply to other providers and suppliers, but modifies specific requirements to tailor them to the unique needs of each provider and supplier. However, we note that the proposed requirements for “emergency and standby power systems” apply only to hospitals, LTC facilities and CAHs. We have inserted hyperlinks to the proposed regulatory language for each provider and supplier type as we discuss them below.

Proposed CAH Requirements. CMS states that existing CAH requirements provide only a limited framework for protecting the health and safety of CAH patients in the event of a major disaster. Since CAHs function as acute care providers in rural and remote communities, CMS believes that they should be prepared in the event of a disaster to provide critical care to individuals in their communities. Although CAHs are much smaller than most Medicare-and Medicaid-participating hospitals, CMS does not expect them to have difficulty meeting the same requirements as are proposed for hospitals. CMS notes that CAHs can draw upon a large number of resources at the federal, state and local level for assistance in meeting requirements.

Therefore, in order to ensure a well-coordinated emergency preparedness system of care, CMS proposes to replace the current emergency procedure CAH requirements with a new set of CAH emergency preparedness CoPs that would be the same as those proposed for hospitals, with one modification. In the training and testing section, CMS proposes to require specific training in extinguishing of fires; protection, and where necessary, evacuation of patients, personnel and guests; fire prevention; and cooperation with fire-fighting and disaster authorities.

The proposed hospital requirements for emergency and standby power systems would apply to CAHs.

Proposed ASC Requirements. ASCs are entities that provide surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an admission. The existing ASC CfCs do not contain requirements that address emergency situations. However, ASCs are currently required to have a disaster preparedness plan. CMS proposes to incorporate existing ASC preparedness regulations into new requirements.

The proposed regulation would require ASCs to meet most of the same proposed emergency preparedness requirements as hospitals, with two exceptions:

- **Policies and procedures**: CMS is not proposing that ASCs provide for subsistence needs of their patients and staff.
Communications plan: CMS is not proposing that ASCs communicate occupancy information, as that usually refers to bed occupancy.

CMS notes that small or rural ASCs may find it more challenging to meet the proposed requirements but believes the requirements are important and that ASCs would be able to develop the appropriate plan and meet the requirements with the assistance of resources in their state and local community guidance.

Proposed Hospice Requirements. Hospices provide palliative care, rather than traditional medical care and curative treatment, to terminally ill patients. CMS notes that hospices are unique providers in that they serve patients in a variety of settings, including patient residences or in inpatient facilities operated by the hospice. Therefore, the agency reorganizes the proposed requirements somewhat to accommodate that difference. CMS proposes to replace existing hospice emergency preparedness requirements with the proposed hospital requirements, with several exceptions, especially in the case of those without inpatient capacities.

Emergency plan (for all hospices): In developing strategies for addressing events identified by the risk assessment, CMS proposes that all hospices specifically identify management of the consequences of power failures, natural disasters and other emergencies.

Policies and procedures: CMS proposes certain policies and procedures for all hospices as well as additional policies and procedures applicable to only those with inpatient facilities.

  o For all hospices:
    ▪ CMS proposes policies and procedures that are the same as several of the proposed hospital requirements including: a system to track the location of staff and patients; a system of medical documentation and the development of arrangements with other providers.
    ▪ Unlike the proposed hospital requirements, CMS also would require that all hospices have policies and procedures to inform state and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient’s medical and psychiatric condition and home environment.

  o For hospices with inpatient facilities:
    ▪ CMS proposes policies and procedures for the remaining items included in the hospital requirements: policies and procedures related to meeting subsistence needs, safe evacuation, a means to shelter in place, and the role of a hospice in the event of a section 1135 waiver.

Communications plan: CMS proposes that only hospices with inpatient facilities would be required to provide information about the hospice’s occupancy and needs and its ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee.
Proposed Inpatient PRTF Requirements. PRTFs are facilities that provide inpatient psychiatric services for patients under age 21. The current PRTF requirements do not include any requirements for emergency preparedness. CMS proposes that PRTFs meet the same requirements proposed for hospitals.

Proposed PACE Requirements. PACE is a unique model of managed care service delivery for the frail community-dwelling elderly. The PACE model of care includes the provision of adult day health care and interdisciplinary team care management as core services. Medical, therapeutic, ancillary and social support services are furnished in the patient’s residence or on-site at a PACE center. Hospital, nursing home, home health and other specialized services are generally furnished under contract.

The current CoPs for PACE organizations include some requirements for emergency preparedness. CMS proposes incorporating some of these existing requirements into the proposed new CoPs. The proposed CoPs would require that PACE organizations meet the same requirements proposed for hospitals, with several exceptions:

- Policies and procedures:
  - CMS does not propose that PACE organizations provide for subsistence needs of their patients and staff.
  - CMS proposes that PACE organizations must have policies and procedures to inform state and local officials about PACE patients in need of evacuation from their residences at any time due to an emergency situation based on the patient’s medical and psychiatric conditions and home environment. Such policies and procedures must be in accord with HIPAA. CMS notes that this requirement recognizes that many of the frail PACE patients may be unable to evacuate from their homes without assistance during an emergency.
  - CMS proposes that PACE organization policies and procedures address emergency equipment, including easily portable oxygen, airways, suction and emergency drugs; staff who know how to use the equipment must be on the premises at all times and be immediately available; and a documented plan to obtain emergency medical assistance from outside sources when needed.

- Communications: CMS does not propose that PACE organizations communicate occupancy information to the authority having jurisdiction or the Incident Command Center or designee.

Proposed Transplant Center Requirements. CMS notes that the proposed requirements for hospitals would apply to transplant centers since they are located within hospitals. CMS also proposes two additional emergency preparedness requirements for transplant centers:

- Transplant centers would be required to have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and other care for its patients during an emergency. CMS notes that, ideally, this would be a
center that performs the same type of organ transplant, but recognizes that this may not always be feasible. The agreement would be required to address the circumstances under which the agreement would be activated and the types of services that would be provided during an emergency.

- CMS proposes an additional requirement related to the existing required written agreement between the hospital in which the transplant center operates and the designated OPO. CMS proposes that transplant centers ensure that the written agreement also addresses the duties and responsibilities of the hospital and the OPO in an emergency.

**Proposed LTC Facilities (includes SNFs) Requirements.** The current emergency preparedness requirements for LTC facilities require written plans and procedures to meet all potential emergencies and disasters, requirements to train employees in emergency procedures and unannounced drills. CMS proposes to replace these existing requirements, which the agency describes as “not sufficient,” with proposed new CoPs requiring that LTC facilities meet the same requirements proposed for hospitals, with two exceptions:

- **Emergency plan:** CMS proposes that the all-hazards risk assessment include a directive to account for missing residents.

- **Communications plan:** Because many LTC facility residents have long-term or extended stays, CMS proposes that LTC facilities have a method, determined appropriate by the facility, for sharing information from the emergency plan with residents and their families or representatives.

CMS believes that the proposed requirement for a risk assessment, and the proposed requirement that the LTC facility address its patient population and continuity of operations, encompasses consideration of an individual resident’s power needs, such as for a motorized wheelchair or other supportive technology. However, CMS solicits comments on whether there should be a specific regulatory requirement for consideration of residents’ power needs.

The proposed hospital requirements for emergency and standby power systems would apply to LTC facilities.

**Proposed HHA Requirements.** There are no existing emergency preparedness requirements contained in the Medicare HHA regulations. CMS states that because there are so many patients depending on home health services nationwide, it is imperative that HHAs have processes in place to address the safety of patients and staff, and the continued provisions of services in the event of a disaster or emergency. Therefore, CMS proposes that HHAs meet the same requirements as hospitals would be required to meet with several exceptions, including additional requirements that would apply only to HHAs.
• **Policies and procedures:**
  
  o CMS proposes that HHAs include an individual emergency preparedness plan for each patient as part of the comprehensive patient assessment currently required in the existing regulations.

  o CMS proposes that HHAs have policies and procedures to inform state and local officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient’s medical and psychiatric conditions and home environment.

  o CMS does not propose that HHAs have provisions to meet the subsistence needs of patients and staff, safe evacuation plans, plans for sheltering patients or staff, or plans for an alternate care site in the case of a declared section 1135 emergency.

• **Communications plan:** CMS is not proposing that HHAs have a means to release patient information in the case of an evacuation, and would delete the reference to providing information about occupancy.

CMS notes that it expects an HHA to consider whether it would accept new referrals during an emergency, and would urge HHAs to include a method for providing information to all new patients and their families about the role the HHA would plan in an emergency.

**Proposed CORF Requirements.** A CORF is a nonresidential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic and restorative services to outpatients for the rehabilitation of injured, sick and persons with disabilities, at a single fixed location, by or under the supervision of a physician.

CORFs have existing emergency preparedness CoPs that CMS describes as important but insufficient to coordinate across emergency response systems necessary to ensure the health and safety of CORF patients during an emergency. Therefore, CMS proposes to replace existing CORF regulatory requirements with new CoPs that would require these facilities to meet the proposed hospital requirements with several exceptions and additions.

• **Emergency plan:** Consistent with current CORF requirements, CMS proposes that CORFs develop and maintain the emergency plan with assistance from fire, safety and other appropriate experts.

• **Policies and procedures:** CMS would not require CORF policies and procedures to address: basic subsistence needs of staff and patients; a system for tracking of staff and patients; arrangements with other providers; or plans for an alternate care site in the event of a section 1135 emergency. Furthermore, CMS proposes a more limited evacuation requirement than hospitals, requiring only that CORFs have policies and procedures for evacuation, including staff responsibilities and the needs of patients.
• **Communications plan:** CMS does not propose that CORFs have a means to release patient information in the event of an evacuation, or a means for sharing information about the general condition and location of patients under care, or information about occupancy.

• **Training and testing:** CMS proposes to relocate more stringent existing CORF emergency preparedness requirements into the proposed rule. These include requiring that all new personnel be oriented and assigned specific responsibilities regarding the CORF’s emergency plan within two weeks of their first work day, and that the training program includes instruction in the location and use of alarm systems and signals and fire-fighting equipment.

**Proposed RHC and FQHC Requirements.** RHCs and FQHCs currently do not have specific requirements for emergency preparedness; however, they do have emergency procedures requirements. CMS proposes to replace current requirements with CfCs requiring RHCs and FQHCS to meet the proposed hospital requirements with the following exceptions.

• **Policies and procedures:**
  o CMS does not propose to include requirements related to meeting subsistence needs of patients and staff, tracking the location of patients and staff, arrangements with other providers, or plans for an alternative site of care in the event of a section 1135 emergency.

  o In the proposal for a safe evacuation, CMS proposes to specify that the plans for evacuation include appropriate placement of exit signs, staff responsibilities and needs of patients.

• **Communications plan:** CMS does not propose to include requirements related to methods for sharing information with other health care providers, the release of patient information in the event of an evacuation, or the provision of information related to occupancy.

**Proposed ESRD Facilities Requirements.** CMS proposes to incorporate current ESRD emergency preparedness requirements into its proposed requirements and to adopt the proposed requirements for hospitals with the following exceptions.

• **Emergency plan:** CMS proposes, in addition to the hospital requirement for ensuring cooperation and collaboration with emergency preparedness officials, that the dialysis facility must contact the local emergency preparedness agency at least annually to ensure that the agency is aware of the dialysis facility’s needs in the event of an emergency.

• **Policies and procedures:**
  o CMS proposes to specify some types of emergencies that an ESRD facility must prepare for, including fire, equipment or power failures, care-related emergencies, water supply interruption and natural disasters likely to occur in the facility’s geographic area.

  o CMS does not propose that ESRD facilities provide basic subsistence needs.
CMS proposes a modified evacuation requirement, requiring that ESRD facilities provide for safe evacuation, which includes staff responsibilities and the needs of the patients.

CMS also notes and emphasizes, in commenting on the requirement for arrangements with other providers, the need for a robust system for back-up care at various dialysis centers.

CMS proposes two additional requirements: (1) that the policies and procedures address a process to ensure that emergency medical system assistance can be obtained when needed, and (2) that the policies and procedures address a process ensuring that emergency equipment, including but not limited to oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and are immediately available.

- **Communications plan:** CMS would not require that ESRD facilities provide information about occupancy.

- **Training and testing:**
  - CMS proposes to incorporate additional specifications into the proposed training requirement that staff demonstrate knowledge of emergency procedures. That would include informing patients of:
    - what to do;
    - where to go, including instructions if the geographic area of the ESRD facility must be evacuated;
    - whom to contact if an emergency occurs, including an alternate emergency phone number for the facility when it is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working number in such conditions); and
    - how to disconnect themselves from a dialysis machine in the event of an emergency.

  - CMS also proposes that, at a minimum, patient care staff maintain current CPR certification and that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

  - CMS proposes to include a requirement for patient orientation, requiring appropriate emergency preparedness orientation and training for patients.

*Information Collection Requirements (ICR) and Regulatory Impact Analysis (RIA)*

Under the Paperwork Reduction Act of 1995, CMS is required to review the burden associated with information collection requirements (ICRs) in proposed rules and solicit public comment on: the need for the information collection; the accuracy of its estimate; the quality, utility and clarity of the information to be collected and recommendations to minimize the information collection burden on the affected public. Thus, for every covered provider and supplier category, CMS reviews each proposed provision that would require information collection and estimates the burden in terms of total hours and total dollars. The provisions of the regulation for which CMS estimates ICRs include: the risk assessment, the emergency preparedness plan, the emergency preparedness policies and procedures, the emergency preparedness communication plan and the
emergency preparedness training and testing program. The summary of the costs for each category is provided in column 3 of the summary table below.

In addition, CMS must prepare a regulatory impact analysis (RIA) for major rules with economically significant effects, defined as $100 million or more annually. **CMS estimates that the total cost of the proposed rule would be $225 million in the first year, and the subsequent projected annual cost would be approximately $41 million.** Therefore, CMS presents a RIA, which incorporates the ICRs and estimates costs for two other elements of the proposed rule: (1) the annual testing requirements for disaster drills and tabletop exercises and (2) the annual generator testing requirement for hospitals, LTC facilities and CAHs. CMS requests information on how it might better estimate the costs for this provision. The estimated RIA costs are presented in columns 4, 5 and 6 of the summary table below.

The agency considers including costs of the proposed rule provisions that would require all inpatient providers to meet the subsistence needs of staff and patients, whether they evacuate or shelter in place, including food, water and supplies as well as alternate sources of energy to maintain temperatures, emergency lighting, fire detection/alarm systems and sewage/waste disposal. However, CMS concludes that this requirement is a “usual and customary business practice” for inpatient providers and it does not assign any impact for this requirement.

<table>
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<tr>
<th>Number of providers</th>
<th>Information Collection Requirement (ICR)</th>
<th>Regulatory Impact Analysis (RIA)</th>
<th>Total (5)</th>
<th>Costs, Year 2 and thereafter (6)</th>
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<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
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<tr>
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<td><strong>$41,354,514</strong></td>
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1) For Hospitals, CAHs and Hospices, the figures in columns 3 and 4 do not add up to the totals in column 5. We believe that incorrect figures may have inadvertently been included in a table in the Federal Register.


**Source:** CMS estimated costs as included in the Dec. 27 Federal Register, pages 79117-79180.
REQUEST FOR COMMENTS ON ALTERNATIVE APPROACHES TO IMPLEMENTATION

CMS requests comments on the following issues.

- **Targeted approaches to emergency preparedness**: Should CMS cover one provider category or subset of provider categories at a time to learn from implementation prior to extending the rule to all groups?

- **A phase-in approach**: Should CMS implement the requirements over a longer time horizon, or differential time horizons for the respective provider categories? CMS proposes to implement all of the requirements 1 year after the final rule is published.

- **Variations of the primary requirements**: For example, CMS has proposed requiring two annual training exercises. CMS believes it would be instructive to receive public feedback on whether both should be required annually, semiannually, or if training should be an annual or semiannual requirement.

- **Integration with current requirements**: How can the proposed requirements be integrated with, or satisfied by, existing policies and procedures which regulated entities may have already adopted?

**NEXT STEPS**

Comments are due to CMS by Feb. 25. The AHA encourages members to submit comments to CMS describing how the proposed rule will impact their hospitals, other provider types and patients. **We also ask that you share your thoughts about this proposed rule and your comments to CMS with the AHA at emergencyprep@aha.org.**

Comments will be accepted electronically and by mail. In commenting, refer to file code CMS-3178-P. Please see the proposed rule for additional ways to comment, including by overnight mail and courier.

- **Electronically.** You may submit electronic comments on this regulation to [http://www.regulations.gov](http://www.regulations.gov). Follow the “Submit a Comment” instructions.

- **By regular mail.** You may mail written comments to the following address:
  
  Centers for Medicare & Medicaid Services  
  Department of Health and Human Services  
  Attention: CMS-3178-P  
  P.O. Box 8013  
  Baltimore, MD 21244-8013

  *Please allow sufficient time for mailed comments to be received before the close of the comment period.*