



**American Hospital
Association**

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March 28, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re: CMS 3178-P, Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Proposed Rule, Dec. 27, 2013

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers.

Hospitals are dedicated to meeting the challenges posed by all types of disasters. The public recognizes that in times of crisis hospitals are places of safe refuge and comfort, and hospital leaders and caregivers know that their communities depend on them. Hospitals often serve larger community needs during emergencies, from providing places where individuals who depend on medical equipment requiring electricity can “plug in” to housing, feeding and protecting members of the community whose homes have lost power or otherwise been damaged. There is no excuse not to be prepared. However, as recent disasters such as the Moore, Okla., tornado and Superstorm Sandy have illustrated, no matter how much hospitals plan, unanticipated challenges can and do occur during emergencies. Thus, hospitals must plan for, and be ready to handle, the unexpected.

We support CMS's goal for Medicare providers and suppliers to have comprehensive emergency preparedness plans and generally think that CMS has chosen the correct framework for the proposed Conditions of Participation (CoPs) and Conditions for Coverage (CfCs). We encourage CMS to consider five principles, detailed below, and to examine more closely its estimates of both the associated burden and cost as it finalizes its recommendations.



Guiding Principles. The number one priority of hospitals during a disaster is to ensure that patients in the hospital's care are safe and can receive the services they need. This is why the majority of hospitals already meet existing emergency operations standards promulgated by The Joint Commission (TJC), National Fire Protection Association (NFPA) and/or the Hospital Preparedness Program (HPP), as well as state and local governments. Hospitals plan, and drill, for disasters regularly.

We urge CMS to ensure that its proposed requirements enhance readiness without adding confusion or creating additional administrative burden. We suggest that CMS consider five guiding principles:

- **Align policies with existing and current standards** – CMS standards should be aligned as much as possible with existing standards, laws and regulations to avoid conflict and confusion, and the standards should be evaluated and updated periodically to reflect new knowledge and advances in technology.
- **Define leadership roles for community planning** – CMS should recognize that local emergency management and public health authorities are the best-placed entities to coordinate their communities' disaster preparedness and response, collaborating with hospitals as instrumental partners in this effort.
- **Accept an integrated approach to emergency planning** – Integrated health systems should have the option to maintain one coordinated emergency plan in cases when a single plan improves preparedness.
- **Collaborate to develop interpretive guidance** – CMS should use a transparent process working with stakeholders to develop interpretive guidance.
- **Balance implementation and compliance with education** – State surveyors should assess compliance as appropriate and also realize that they can play an important educational role in helping providers meet and exceed the standards.

Need for Accurate Estimates. We strongly believe that CMS's projections of burden and cost for compliance with this proposed rule are greatly underestimated. Many of our members, especially smaller hospitals, have expressed concern about the financial implications for compliance with certain provisions. In addition, CMS severely underestimates the amount of time and work it will take many providers and suppliers to come into compliance with the proposed requirements. For example, tasks such as updating policies and procedures involve more than merely assembling key hospital staff to attend a limited number of meetings, draft revisions and obtain approval. Updating policies and procedures also involves researching alternatives, assessing any costs involved (such as technology that may be needed), reviewing potential changes with employees who may be affected, implementing the changes, training staff and testing outcomes.

While the appropriate timeframe for each provider or supplier to implement the proposed requirements will depend upon the final requirements, as well as the circumstances and resources of each individual facility, we believe the proposed one-year timeframe will likely be too short for many hospitals and other providers and suppliers. For TJC-accredited hospitals, we believe that two years should be sufficient. Some hospitals may need more time.

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In cases where hospitals must make significant structural changes, the affected hospitals should be able to articulate to CMS a reasonable period of time to comply. Other providers and suppliers, including critical access hospitals (CAHs), home health agencies and hospices, also may need additional time. We would be happy to work with CMS and experts in the field to ensure a more accurate estimation of the resources actually required to meet these requirements.

Thank you for the opportunity to comment on this proposed rule. Our detailed comments follow. If you have any questions about our comments, feel free to contact me or Nancy Foster, vice president of quality and patient safety policy, at (202) 626-2337 or nfoster@aha.org; Roslyne Schulman, director of policy, at (202) 626-2273 or rschulman@aha.org; or Evelyn Knolle, senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

GUIDING PRINCIPLES

Below we describe in more detail five guiding principles CMS should follow as the agency finalizes the proposed CoPs and CfCs and develops sub-regulatory guidance for new regulations. We provide specific recommendations about individual provisions in the proposed rule in another section.

PRINCIPLE 1: ALIGN POLICIES WITH EXISTING AND CURRENT STANDARDS

CMS should align its proposed requirements as much as possible with existing standards that are already widely followed. Failure to align with the patchwork of existing standards will add confusion and make compliance unnecessarily complicated. Multiple private and public organizations have developed disaster preparedness standards. For example, TJC imposes extensive emergency management standards for hospital and CAH accreditation. **We believe that if hospitals and CAHs already meet current TJC emergency management standards, CMS should consider them to be compliant with the finalized CoP standards.**

Many hospitals and CAHs have developed comprehensive emergency preparedness capabilities using funding from the HPP, which has its own requirements. Additionally, hospitals and CAHs must conform with certain NFPA 99 and 110 standards related to emergency power through the current CoP requirement to comply with the Life Safety Code (NFPA 101). Some hospitals voluntarily look to the comprehensive body of NFPA emergency preparedness standards in developing their plans, and we believe CMS can do more to align with this framework.

Hospitals also must align their preparedness efforts to comply with state and local requirements for emergency planning. We are concerned that several of CMS's proposals may conflict or overlap with state and local laws and requirements. For example, we understand that CMS's proposed load testing requirements for generators may conflict with state environmental protection standards. **As a general rule, CMS should defer to state and local standards where the proposed CoPs and CfCs would overlap with, be less stringent than, or conflict with those standards.**

CMS will further reduce confusion if it adopts the terms already used by stakeholders. For example, both NFPA and TJC use the term "hazards vulnerability assessment" (HVA)¹, whereas

¹ According to TJC, a hazards vulnerability analysis (HVA) is a process for identifying potential emergencies and the direct and indirect effects these emergencies may have on the organization's operations and the demand for its services. TJC-accredited hospitals are expected to conduct a HVA to identify potential emergencies that could affect demand for the hospital's services or its ability to provide those services, the likelihood of those events occurring, and the consequences of those events. Under TJC standards, a hospital reaches out to community partners it selects to prioritize the potential emergencies identified in its hazard vulnerability analysis (HVA).

CMS uses “risk assessment.” If CMS can align with the language of current standards, it will simplify the task of building “crosswalks” across the requirements.

CMS should routinely update the requirements so that the CoPs and CfCs stay current with new knowledge and the standards of other oversight bodies. We appreciate that CMS has aligned many of its proposals with TJC standards, but we note that the proposed rule references standards from 2008, which have since been updated. The NFPA is a consensus-based organization that consistently reviews and updates its standards. Its process allows for detailed input and discussion from subject matter experts and interested stakeholders. Expectations within the NFPA framework can be scaled to individual capabilities of a facility.

PRINCIPLE 2: DEFINE LEADERSHIP ROLES FOR COMMUNITY PLANNING

CMS should recognize that local emergency management and public health authorities are the most appropriate organizations to take the lead in coordinating disaster preparedness and response across the community and should work in partnership with hospitals and other providers. CMS states in the preamble that “hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities.” We agree that hospitals are focal points for health care for their communities and are instrumental to community planning. However, we are concerned that CMS’s statements in the proposed rule may create an expectation that hospitals should be the designated entities for coordinating the community response.

In the final rule, CMS should clarify the roles of state and local governments in leading community-wide efforts to prepare for disasters. While these efforts can be challenging at times, CMS regional offices should use their relationships with state and local governments to encourage cooperation and collaboration from all partners, not just providers and suppliers.

PRINCIPLE 3: ACCEPT AN INTEGRATED APPROACH TO EMERGENCY PLANNING

Integrated health systems should have the option to maintain one coordinated emergency plan in cases where a single plan improves preparedness. Throughout the proposed rule, CMS encourages all providers and suppliers to plan together and with their communities to achieve coordinated responses to emergencies. At the same time, each provider and supplier type will have to comply with its own set of emergency preparedness regulations and each will be required to have its own emergency plan.

An integrated system, such as a health system comprised of two nearby hospitals, a nursing facility and a home health organization, should be allowed to develop a universal plan that encompasses one community-based risk assessment, separate facility-based risk assessments, integrated policies and procedures that meet the requirements for each facility, and coordinated communication plans, training and testing. Thus, a surveyor reviewing an emergency plan would find acceptable a plan that has been developed centrally with input and participation by each facility within the system.

PRINCIPLE 4: COLLABORATE TO DEVELOP INTERPRETIVE GUIDANCE

CMS should develop interpretive guidance that allows for differences in communities, risks and available resources. We urge CMS to consider using a more open and transparent process for developing the guidance and to pilot test this guidance before implementation.

We concur with CMS's emphasis on flexibility for providers in implementing the finalized requirements. A "one-size-fits-all" approach is impractical for regulating hospitals, especially when there are significant differences in the types of emergencies that are likely to affect hospitals and distinctly different community resources and needs.

We urge CMS to adopt an open process for developing the guidance. First, CMS should bring key stakeholders together, such as NFPA and accrediting organizations that already have emergency preparedness standards, to address consistency among standards. CMS also should seek broad input from the myriad organizations to which these regulations will apply. CMS should post the draft guidance electronically for a period of 30 to 60 days and provide an email address for stakeholders to offer comments. As a last step, guidance should be pilot-tested, and revised if necessary, prior to adoption.

PRINCIPLE 5: BALANCE IMPLEMENTATION AND COMPLIANCE WITH EDUCATION

State surveyors should assess compliance as appropriate. At the same time, they can play an important educational role in helping providers meet and exceed the standards. While the majority of hospitals have achieved a high level of emergency preparedness, some smaller hospitals, as well as other providers and suppliers, may need time and support to meet the expectations of the proposed CoPs and CfCs. CMS should recognize when substantive progress has been made and should direct surveyors to provide education and resources to a provider to help it comply within a reasonable time frame.

We draw a distinction between a surveyor's review of the emergency plan, which could occur during a routine compliance survey, and an assessment of the activation of that plan in a real life event. Throughout the proposed rule, CMS conveys an underlying viewpoint that simply having a comprehensive emergency plan will *ensure* that everything will progress smoothly during an emergency. We agree that should be the goal of planning. At the same time, CMS must recognize that, no matter how well prepared a hospital is in an emergency, it will likely confront unanticipated situations. In any situation in which CMS evaluates the activation of any part of an emergency plan, it must be able to examine the totality of the circumstances and employ high but reasonable standards in that assessment.

At the very least, state surveyors should receive comprehensive training on the finalized emergency preparedness regulations before conducting a compliance assessment. CMS must provide sufficient education to avoid situations in which individual surveyors conduct their own research to determine what is adequate to meet the CoP/CfC standards, which leads to inconsistency across regions and states.

SPECIFIC RECOMMENDATIONS FOR HOSPITALS AND CAHS

We comment below on specific provisions of the proposed rule as they would apply to hospitals and CAHs. We address provisions for transplant centers, long-term care facilities, hospices and home health organizations in a later section of this letter.

RISK ASSESSMENT

All-Hazards Approach. CMS discusses the need to take an “all hazards” approach to emergency planning throughout the proposed rule, and confusion exists about what this term means. CMS’s preamble language emphasizes that “all-hazards planning does not specifically address every possible threat” but instead “ensures that hospitals and all other providers will have the capacity to address a broad range of related emergencies.” Further, CMS explains that it would expect a hospital to identify “all risks or emergencies that the hospital *may reasonably expect to confront*.”² **We encourage CMS to clarify this concept in the final rule by adding proposed language at § 482.15(a)(1) to require that the emergency plan “[b]e based on and include a documented, facility-based and community-based risk assessment (or HVA), utilizing an all-hazards approach that identifies the emergencies that the hospital may reasonably expect to confront.”**

We agree with CMS that a hospital should evaluate both community-based and facility-based risks in emergency planning. However, CMS does not provide sufficient clarity about which entity is expected to conduct the community-based risk assessment. CMS explains in the preamble that it expects a community-based risk assessment to be conducted *outside* of the hospital. Yet it is unclear whether CMS would expect a hospital to conduct its own community assessment outside of the hospital or rely on an assessment developed by other entities, such as regional health care coalitions or local emergency management and public health agencies.

With regard to the community-based plan, we suggest that CMS allow hospitals to either: (1) use a comprehensive community-based risk assessment (or HVA) developed by a different organization(s), where available, if the hospital deems it to be adequate; or (2) conduct their own community-based assessments, with input from key organizations in the community, as is consistent with TJC and NFPA standards.

THE EMERGENCY PLAN

Organization of the Emergency Plan. While we generally agree with CMS’s proposed framework for emergency preparedness, the organization of the proposed rule and the accompanying preamble discussion indicate that CMS may view an emergency plan as separate from emergency preparedness policies and procedures. Hospitals typically have an emergency

² Similarly, according to TJC, an “all hazards” approach supports a general response capability that is sufficiently nimble to address a range of emergencies of different duration, scale and cause.

preparedness plan that consists of emergency policies and procedures in a single document that is updated periodically. **Hospitals should be able to have a single, integrated document that contains the plan, policies and procedures. Further, CMS should recognize that the plan itself may represent the policies and procedures.**

Clarifying the Role of the Hospital in Community Planning. In proposed § 482.15(a)(4), CMS would require the emergency plan to “[i]nclude a process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials’ efforts to *ensure* [emphasis added] 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.” As CMS acknowledges, providers cannot ensure that officials will work with all health care entities in disaster planning.

Therefore, we suggest this language be modified to state that the emergency plan must “[i]nclude a process for ensuring *the hospital’s/CAH’s* cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials’ efforts *with the goal of implementing* 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.”

In addition, we note that one of the entities with which a hospital would be asked to collaborate would likely be the agency that surveys that hospital for compliance with the emergency preparedness requirements. State agencies play multiple roles with respect to hospitals, such as licensing them, disbursing HPP funding and conducting CoP surveys. We ask CMS to address how it believes state agencies should respond when these multiple roles present a potential conflict of interest for the state agency.

Addressing Patient Population. CMS proposes, at § 482.15(a)(3), that a hospital’s emergency plan must “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.” CMS defines “at-risk” to include populations that may have additional needs in functional areas, such as maintaining independence, communication, transportation, supervision and medical care, as well as children, seniors, pregnant women, those who have disabilities, live in institutionalized settings, are from diverse cultures, have limited English proficiency, have chronic medical disorders or pharmacological dependency.

We agree that hospitals should, and already do, plan to care for patients who need additional response assistance during an emergency. At the same time, we acknowledge that the wording of this regulation may create the expectation that hospitals should care for all individuals in the community who have additional needs. For example, individuals who are dependent on medical equipment that requires electricity may come to the hospital’s emergency department to access power in an emergency. Ideally, community-wide planning will ensure that alternate locations are established for this purpose. In addition, some hospitals are able to provide this service for

their communities. For others, however, this expectation could cause overcrowding and may hinder a hospital's efforts to provide urgent medical treatment to patients who are acutely ill or injured.

We suggest that the regulatory language at § 482.15(a)(3) should emphasize the hospital's unique role of providing acute medical treatment and should require the plan to “*address patient population, including at-risk patients needing acute care services and/or treatment in an emergency; 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.*” This change would not prohibit hospitals from providing additional services but would help keep the focus on a hospital's unique responsibility during an emergency – a mission that other entities cannot fulfill for the community.

POLICIES AND PROCEDURES

We agree with CMS's proposal that a hospital's emergency plan should address how it will safely evacuate or shelter in place, what system it will use to preserve, protect and access medical records, whether and how it will use volunteers, and how it will develop arrangements with other facilities to receive patients. Below we outline recommendations and observations about three areas for policies and procedures that CMS outlines in its proposed rule.

Patient Tracking. CMS would require policies and procedures to address “[a] system to track the location of staff and patients in the hospital's care both during and after the emergency.” Although a hospital could use either a paper-based or electronic system, CMS states in the preamble that it would expect “the information [to] be readily available, accurate, and shareable among officials within and across the emergency response system as needed in the interest of the patient.”

Patient tracking in an emergency is a most difficult challenge. Patient tracking within the hospital should be distinguished from patient tracking outside of the hospital. We note that the proposed regulation focuses on tracking patients “in the hospital's care,” and that is appropriate. It is reasonable to expect that a hospital would track the location of the patients in its care during and after a disaster, whether they are located within the hospital or at an alternate care site operated by the hospital. In addition, if a hospital is managing the transfer or evacuation process for its own patients, it should know the next care setting to which its patients are sent.

However, moving and tracking patients may also be the responsibility of an entity other than the hospital. For example, one of our hospital members was designated as the special needs evacuation site before a recent hurricane. As part of the community response, the hospital was tasked with organizing these patients and ensuring that they were properly identified and “tagged.” However, state officials managed the placement and transportation for the patients. The hospital did not necessarily know the destination of each of those individuals; the state had that information.

CMS points out that a number of states already have tracking systems in place or under development, but we caution that these systems are in various stages of implementation and testing. In addition, the tracking system may not be compatible with a hospital's information technology system. Therefore, it will take the hospital longer to implement the state's process in an emergency. Further, if a system lacks interoperability, it becomes very difficult to share information among officials across the emergency management system. For these reasons, hospitals may need to rely on an alternate system, such as a paper-based system, which CMS implies it will accept.

With regard to "tracking the location of staff," hospitals have systems to locate personnel in an emergency. However, we believe this is different from "tracking" staff, which sounds more expansive than would be necessary in the event of most emergencies. **Thus, we recommend that CMS change the language of the proposed regulation so that a hospital would be required to have "[a] process to locate staff and track the location of patients in the hospital's/CAH's care both during and throughout the emergency."**

Subsistence Needs. CMS proposes that the hospital's policies and procedures address the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water and medical supplies. Hospitals generally have adequate plans for providing subsistence needs for staff and patients in the event that the facility shelters in place in an emergency. **However, we recommend that CMS delete the language requiring that the hospital provide for staff and patient subsistence needs in the event that the facility evacuates its population to another facility.** Instead, hospitals should address these subsistence needs as part of their plans under proposed § 482.15(b)(7), requiring the development of arrangements with other providers to receive patients in an evacuation.

CMS requests comment on whether hospitals should be required to maintain a store of extra provisions for volunteers, visitors and individuals from the community who may arrive at the hospital to offer assistance or seek shelter. We believe that provisions for volunteers would be addressed by the proposed requirement at § 482.15(b)(6), which would require hospitals to address the role and use of volunteers in an emergency. Further, as noted above, we think that identifying shelters for individuals from the community is best coordinated through community planning. Hospitals may, if they have the capacity and have considered factors that could affect patients and non-patients, serve as one location for this purpose. In the end, these decisions must be made on a case by case basis by individuals who are most knowledgeable about the resources of the hospital and the community. **Therefore, we do not recommend that CMS add such a requirement in the final rule.**

At § 482.15(b)(1)(ii), CMS proposes that hospitals have policies and procedures to address the provision of alternate sources of energy to maintain: (1) temperatures to protect patient 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. **We agree that these needs should be addressed by the emergency plan.**

In addition, these requirements should be interpreted in a way that aligns with current NFPA standards. Current CoPs require hospitals to follow NFPA 99 standards as referenced in chapters 18 and 19 of the 2000 version of the Life Safety Code. We expect federal regulations to be updated to reflect standards outlined in the 2012 version of the Life Safety Code in the near future. The NFPA standards detail the utilities a facility must plan to continue providing during an emergency, including the equipment that must be on the essential electrical system, consisting of the life safety, critical, and equipment branches. For example, current standards require the life safety branch to include power for illumination for means of egress, fire alarms, and communication systems and the critical branch to include power for, among other things, critical care and patient care areas.

Experts at our affiliate, the American Society for Healthcare Engineering (ASHE), advise that facilities may not have the capability to provide total climate control and refrigerated storage of perishables with emergency power. During an emergency, hospital engineers will manage the needed utilities depending on the situation. For example, a hospital that does not need to be evacuated may limit the number of elevators in service in order to create electrical capacity for heating or cooling. If a hospital evacuates, it may prioritize elevators over other utilities, such as refrigeration.

Hospitals should be able to describe in their emergency plans how they will mitigate specific scenarios, such as if they are unable to maintain temperatures or refrigeration. At the same time, hospitals ought to review their current emergency power capacity and assess whether upgrades should be made using a capital expenditures planning approach. CMS's proposal could be interpreted to increase the requirements for what must be included on essential electrical systems and require existing facilities to upgrade their systems to meet the increased requirements. We do not believe that the proposed rule should be interpreted to require substantial retrofits of buildings, unless the hospital assesses that there is no other way to ensure patient safety in an emergency.

The expectations for sewage and waste disposal are also unclear. The language of the proposed regulatory text would require hospitals to address *alternate sources of energy* to maintain sewage and waste disposal. However, energy is not always required for these processes. Further, while some hospitals have incinerators or compactors for waste disposal, these items are not generally included on the essential electrical system. In addition, many hospitals have eliminated their incinerators in recent years due to changes in environmental and permitting requirements and currently have waste removed. **CMS should instead require hospitals to have back-up plans should their primary waste-handling operations become disabled or disrupted.** This could include storing waste in a secure area until removal can be arranged.

With regard to sewage disposal, ASHE observes that a hospital may experience sewage backup if the municipal plant is disabled by a disaster or if a discharge line is broken or clogged. We believe that **a hospital should identify and assess the risks related to its facility's wastewater system and describe in its emergency plan how it will address specific scenarios in which sewage could become a problem.** For example, the hospital may relocate patients off-site in

some cases or move them to other areas of the hospital that are unaffected by a disrupted discharge line.

Alternate Care Sites (ACSs). CMS would require a hospital's policies and procedures to address "[t]he 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." **We suggest that CMS instead use more general language similar to TJC requirements that the emergency plan identify "alternative sites for the care, treatment and services that meet the needs of the hospital's/CAH's patients during emergencies."**

We identified multiple scenarios for the use of ACSs in an emergency. For example, some disasters may impact the hospital building itself, such as a tornado. In this situation, the hospital may move its services to an ACS that it has already identified in its emergency plan or evacuate altogether. While it may be hard for the hospital to find a building whose owners will allow it to use their site during an emergency, overall we believe hospitals can and generally already do plan for this type of ACS.

In another scenario, the hospital facility is not damaged and is functioning, but public officials who are organizing a community response may set up an additional ACS to provide patient surge capacity. Ideally, hospitals and public officials work together prior to an event to identify ACSs and determine how they will be staffed and managed and what type of services they will offer. Because the hospital in this scenario would be functioning and full, local officials may need to staff the ACS with medical volunteers from outside the area. And while all communities should have a comprehensive community-based plan, if no ACS has been designated by officials before a disaster, then a hospital would be unable to define in its emergency plan a clear role for itself with regard to such an ACS.

COMMUNICATION PLAN

We agree with CMS's proposal for hospitals to develop and maintain communication plans that comply with federal and state law and to review these plans annually. We support the proposed framework for these plans and offer several recommendations to strengthen these provisions and bolster information infrastructure.

First, CMS would require providers to implement certain provisions of the proposed communications plan in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Hospitals should already have HIPAA compliance plans that, among other things, address emergency situations. We note that some states have stricter privacy laws than HIPAA and those state laws are not preempted by HIPAA. **Therefore, the regulatory language should make clear that the communication plan should comply with applicable state privacy laws in addition to HIPAA.**

Second, CMS proposes that the hospital's communication plan include "[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.” **We agree with CMS that this proposed requirement should remain flexible and should not require the use of any specific technology, as technologies often become obsolete.** In fact, compliance with this provision may not involve technology at all. In many instances, implementation of this aspect of the emergency plan likely would include sharing paper-based documentation that travels with a patient.

We share the vision of a health care system in which interoperable systems exchange secure information to support quality of care during emergencies and non-emergencies. Our members and partners enthusiastically support the promise of the Health Information Exchange (HIE) networks. The goal of these networks is to allow providers to share patient information among one another in a manner that is secure and can be backed up. Ideally, if a hospital along the coast evacuates before a hurricane, a facility further inland that receives those patients would be able to query the HIE to obtain patient information. However, HIEs are in varying stages of development throughout the country. In some areas, no HIE network is available. In other areas, multiple HIE efforts are underway, causing overlap and confusion.

We urge CMS and the Office of the National Coordinator (ONC) to support policies that accelerate the development of a robust infrastructure for health information exchange networks. We refer you to our [letter](#) dated April 19, 2013 responding to a request for information by CMS and ONC about advancing interoperability and HIE. In that letter, we provide examples of activities that federal agencies can and should undertake to support the infrastructure that providers need to share health information efficiently and effectively.

Finally, we are concerned about the discussion in the rule’s preamble that the hospital would share “comprehensive” information, because that term is not defined. In some places, the medical community and/or emergency planners have already determined what information is important to share during a disaster. We encourage CMS to focus on *relevant* information that enables a subsequent care provider to determine promptly what medical services and treatments are appropriate for each patient and to deliver that care safely.

TRAINING AND TESTING

Training Programs. The proposed rule would require a hospital to provide “[i]nitial 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.” The proposed rule would require a CAH to provide “[i]nitial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.” Hospitals and CAHs would need to provide and document training annually. In addition, hospitals and CAHs would be required to ensure that staff can demonstrate knowledge of emergency procedures.

We agree that training of staff and volunteers is a significant aspect of emergency planning. In a disaster, many members of the hospital staff will continue to perform the same job they do every day. Thus, we read the proposed rule to require the hospital to ensure employees are aware of its emergency plan, policies and procedures, and that each employee understands what he/she is required to do in an emergency. Most hospitals already provide basic awareness level training to staff as well as more comprehensive training for employees who are assigned a leadership or management role in the hospital's incident command system (e.g., the Hospital Incident Command System (HICS)) during an emergency, especially if the hospital has received HPP funding. In particular, the HPP requires hospitals that receive preparedness funding to implement the activities identified in Federal Emergency Management Agency's (FEMA's) National Incident Management System (NIMS)³, including the identified training and exercise requirements.

The proposed regulation imposes a duty to provide training about policies and procedures related to emergency preparedness for staff (new and existing), individuals providing services under arrangement, and volunteers in relationship to the duties they perform. We believe it would be helpful for CMS to provide detailed examples of what is meant by "individual providing services under arrangement" to eliminate any confusion about the use of the phrase. We assume that CMS is referring to groups of physicians, other clinicians, and others who provide services essential for adequate care of patients and maintenance of operation of the facilities, but whose relationship with the hospital is by contract rather than through employment or voluntary status. There may be others with whom a hospital would have an arrangement for the provision of services, but these may be services that would not be essential during the course of a disaster. For example, hospitals often have arrangements for servicing of office equipment, provision of staff training and education, grounds keeping, and so forth. We do not believe that CMS intended for all personnel covered by these arrangements to be trained for emergency preparedness, but would appreciate some clarification from the agency.

Another concern about this provision relates to the cost of training. Training is valuable and necessary, but it also can be expensive. This is especially true with some workforces within the hospital that experience high turnover. For this reason, we question CMS's cost and burden estimates related to developing a training program. CMS estimated that it would cost about \$2,000 for non-TJC accredited hospitals and \$834 for CAHs to develop a training program. These estimates appear to be low. In addition, the proposed rule does not take into account the cost of *implementing* the training program. We urge CMS to update its cost estimates in the final rule to recognize the significant investment that hospitals and other providers make in order to prepare for emergencies. CMS and its surveyors must understand the full context of what it is asking providers and suppliers to do so that the final expectations and timetables will be realistic.

Testing. The proposed rule would require a hospital to conduct drills and exercises to test the emergency plan. Each year, the hospital would be required to participate in at least one

³ NIMS provides a systematic, proactive approach guiding departments and agencies at all levels of government, the private sector, and nongovernmental organizations to work seamlessly to prepare for, prevent, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life, property, and harm to the environment.

community-based drill (or a facility-based drill if a community-based drill was not available) and conduct one paper-based tabletop exercise. However, if the hospital experienced an emergency and activated its emergency plan, the hospital would not need to participate in the community-based or facility-based drill. The hospital also would be required to analyze the results of the drills and exercises.

Testing the emergency plan is an extremely important aspect of disaster planning. Currently, TJC requires hospitals to conduct two drills per year instead of one, as CMS proposes. **We believe that hospitals and CAHs that conduct at least two drills annually (either community-based drills and/or facility-based drills) should be exempt from the table-top exercise.**

While we agree with the value of testing, CMS has greatly miscalculated the time and expense required to plan and carry out a community-based drill. CMS estimates that it will take non-TJC accredited hospitals 57 burden hours and cost \$3,883 to comply with the proposed drill and exercise requirements. For non-accredited CAHs, CMS estimates that it would take 28 hours and cost \$1,620. While most unaccredited hospitals probably would not be starting from scratch with regard to drills and exercises, CMS's description of the tasks and burdens associated with organizing a drill is completely insufficient. CMS outlines only a few steps of the emergency drill process, such as creating scenarios and methods of documentation and participating in the drills. Below we provide a more thorough picture of the steps hospitals might take to develop and/or participate in community-based emergency drills.

Some hospitals that choose to take a leadership role in planning will:

- contact other providers, suppliers and community emergency response agencies;
- bring these stakeholders together to determine what will happen during the drill;
- convene this group on a regular basis, such as once a month for an hour and a half or two hours to develop the scenario, and then meet weekly for longer periods of time as the date of the exercise gets closer; and
- write the hospital's part of the exercise and ensure that each provider or supplier writes its part of the exercise.

Hospitals that participate in community drills will:

- engage personnel in each participating hospital department, educating them and obtaining feedback;
- recruit observers and evaluators, which includes educating them about the drill and expectations;
- recruit volunteers to play the disaster victims/patients;
- prepare the volunteers, who are typically given scripts with symptoms and injuries;
- develop a way to inform actual patients about the drill;
- possibly obtain union approval for some participants, such as the local fire department;
- work through the hospital's financial approval process for conducting the drills;

- carry out the drills;
- gather feedback;
- analyze the results; and
- revise the hospital's emergency plan to reflect the lessons learned from the drill.

In fact, it could take six months to a year to plan and carry out a comprehensive emergency drill. CMS should revise its estimates to consider the complexity and coordination that community drills require and accordingly adjust the final rule provisions to reflect the time and resources involved.

EMERGENCY POWER REQUIREMENTS

Generator Location. The proposed rule would require a hospital's generator to be located in accordance with the requirements found in NFPA 99, NFPA 101 and NFPA 110. **We support this proposal and believe that hospitals already conform to these standards because the CoPs currently require compliance with the Life Safety Code (NFPA 101), which cross references NFPA 99 and NFPA 110. Further, we believe CMS should be aligned with NFPA in how it implements these standards.**

As we have learned from experience, the location of generators and associated equipment can be a crucial factor in ensuring that hospitals will be able to function and provide critical services to patients in a disaster. The optimal location for a hospital generator and its associated equipment depends upon the individual circumstances of each hospital. Ideally, the placement should be based upon the hospital's HVA, an assessment of the types of disasters that may impact the facility, as well as how the generator location could affect patient care due to noise and vibrations. Hospitals and local building officials will typically consider, for example, the NFPA standards in conjunction with reference documents such as flood maps, weather pattern charts, and zoning plans. Local building requirements may also impact the decision of where to place a generator and associated equipment, such as city codes that limit where fuel may be stored within the building.

We believe that hospitals should routinely review their emergency power supply systems to ensure that generators and associated equipment are located in the safest places possible. If, based upon its HVA, a hospital determines that the likelihood exists for a disaster to incapacitate its generators based upon their location (or the location of associated equipment), the hospital should develop strategies to move its generators or take mitigating actions that will address risks of harm to patients. The hospital should preserve, to the best of its ability, the capacity to care for those in need of medical attention during the disaster and its immediate aftermath.

We recognize that some of these projects will require major capital expenditures and that the lack of funding for these projects may be an impediment, especially for smaller hospitals and safety net hospitals. For example, ASHE estimates it can cost an average of \$1.5 million for a hospital to move two generators. Therefore, we urge CMS and the Office of the Assistant

Secretary for Preparedness and Response to create funding opportunities to expedite equipment location changes where they are needed.

Generator Testing. CMS proposes to require hospitals to test their generators annually for a minimum of four continuous hours at a test load of 100 percent. CMS does not offer a rationale for this level or frequency of testing, and the proposed 100 percent load requirement does not align with any existing NFPA requirement. The power needs for a facility can differ significantly depending on the time of year and time of day, and therefore a straightforward requirement to test at a 100 percent load does not consider the variation in power needs. **The AHA urges CMS to consult ASHE and NFPA about appropriate standards for generator testing.**

Hospitals currently employ multiple processes for testing generators. For example, hospitals typically perform weekly inspections as well as monthly generator tests for 30 minutes. In addition, TJC and NFPA standards require hospitals to test generators for a minimum of four hours every three years at a 30 percent load (for diesel powered generators).

Immediately after Hurricane Sandy, ASHE conducted a member survey that included hospitals in the areas affected by the storm. Of the respondents, 35 percent said they were without power from their electrical utilities provider for some period of time, including a few that lasted more than 150 hours. In the generator failures recorded, redundant systems (such as backup generators) and standard emergency procedures performed as planned and either restored or provided continued power to the facilities. This level of performance occurred even though the generators were tested for four hours every three years per NFPA standards, with a 30 percent load.

Emergency Generator Fuel. The proposed rule states, “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.” This language is incomplete, because it does not consider the situation in which a hospital would evacuate or close during a prolonged emergency. **We suggest changing it to: “*The hospital must have a plan for how it will keep emergency power systems functioning during the emergency, unless it evacuates.*”**

TRANSPLANT CENTERS

Under the proposed rule, CMS would require transplant centers to have agreements with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency. In addition, the transplant center must ensure that the written agreement required under § 482.100 addresses the duties and responsibilities of the hospital and the organ procurement organization (OPO) during an emergency.

We agree with CMS’s goal in proposing this requirement, which is to increase the likelihood that patients will receive transplants if organs become available during an emergency, and that the transplant center’s current patients will continue to receive vital post-transplant care. **As**

hospitals develop their emergency plans, they already evaluate their services and consider the needs of all of their patients, including transplant patients. Therefore, we do not think that a separate regulation is needed for transplant centers, especially as CMS proposes to require that hospitals consider “at-risk” individuals in the patient population in its emergency plan. If CMS does finalize its proposal, it should not duplicate or contradict the requirements of the United Network for Organ Sharing (UNOS).

REQUIREMENTS FOR OTHER PROVIDERS AND SUPPLIERS

In part because they are the focal points for emergency medical care in their communities, hospitals have received significant attention and resources over the past 13 years from federal and state governments, emergency management organizations and accrediting bodies to help them increase their preparedness for natural and man-made disasters. Generally speaking, hospitals and CAHs have made good progress toward establishing preparedness frameworks that are already, by and large, aligned with CMS’s proposed requirements. Skilled nursing facilities (SNFs), home health agencies and hospices have not been subject to such scrutiny with regard to emergency preparedness and may need more time to comply than hospitals.

LONG-TERM CARE (LTC) FACILITIES

LTC facilities are residential nursing homes that often also provide skilled nursing facility services. For the most part, we believe that our guiding principles and specific comments for CMS’s implementation of this rule should generally apply to LTC facilities. This includes comments related to risk assessment, the development of the emergency plan, patient tracking, subsistence needs, alternate care sites, sharing information, training and testing, and emergency power requirements.

CMS articulates two main differences between the proposed requirements for hospitals and those for LTC facilities. First, a LTC facility would be required to use an “all hazards” approach to risk assessment that would include a directive to account for missing residents. **We agree that LTC facilities should have plans in place to account for missing residents.** Current regulations require LTC facilities to develop detailed written plans and procedures to meet all potential emergencies, including missing residents. We believe that the wording of this proposed provision, however, is confusing. For example, the language could be read as directing a facility to consider the possibility of missing residents as one of many potential hazards included in the emergency plan. It also could be read as directing facilities to account for missing residents during disasters. CMS should clarify in the final rule that LTC facilities should have plans to account for missing residents in both emergency and non-emergency situations.

Second, under the proposed rule, a LTC facility would be required to share information with residents and their families or representatives, as appropriate. **We agree with this proposal.**

CMS asks for comment on whether it should include specific language in the regulation requiring LTC facilities to address the power needs of their individual residents. **We agree with**

CMS that the proposed regulations already encompass consideration of individual residents' power needs by virtue of the requirement that all providers and suppliers affected by the proposed rule address their patient populations in their emergency plans, including patients at risk. CMS has adopted a very broad definition of "persons at risk." According to the preamble, CMS would consider the following individuals to be "at-risk:"

- persons who may have additional needs in one or more of the following functional areas: maintaining independence, communication, transportation, supervision and medical care; and
- 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, the elderly, persons in hospitals and nursing homes, people with physical and mental disabilities, infants and children.

Thus, we believe this definition includes residents of LTC facilities, and the facility would be prompted to address all of their care needs, including power for medical devices, in its emergency plan. **However, we have no objection to CMS including such a provision.**

INPATIENT HOSPICE FACILITIES

For inpatient hospice facilities, our comments about the proposed rule echo our comments related to hospitals and CAHs, including our guiding principles, as well as concerns about the community-based risk assessment, "ensuring" collaboration with government officials, patient tracking and information sharing, subsistence needs and training.

HOME HEALTH AGENCIES (HHAs) AND HOSPICES PROVIDING SERVICES IN RESIDENTIAL SETTINGS

We agree that CMS should adopt regulations requiring HHAs and hospices providing services in residential settings to have emergency plans, which would at a minimum include conducting comprehensive risk assessments (or HVAs), developing strategies for addressing the events identified in the risk assessments, collaborating with government officials, addressing the types of services the organization can provide in an emergency, and defining continuity of operations and succession plans. **However, before finalizing more detailed requirements for policies and procedures, CMS should work with the stakeholder community to ensure the agency fully comprehends how these organizations function, the needs of their patients, the communities in which they deliver services and their resources.**

The proposed rule does not provide a complete description of CMS's vision for the role that these organizations would play during an emergency. To develop requirements for HHAs and hospices, CMS has tailored the proposed emergency preparedness framework for organizations providing inpatient care to try to fit organizations providing services in residential settings. However, we expect the roles of those providing home-based services will be different, and more

limited, than hospitals based on fundamental differences in how they provide care and how disasters will affect them. **Despite CMS's attempt to customize the regulatory provisions for these providers, some of the proposals need more clarification and/or modification.**

For example, it is not clear why a facility-based drill is necessary for organizations that may have small, central offices where no patients stay and where most staff do not work on a daily basis. Further, CMS would require these providers to have policies and procedures that address a system to track the location of patients in the organization's care both during and after the emergency. CMS does not define what it means for HHAs and home-based hospices to track patients, but we question how CMS envisions the HHA or home-based hospice would track patients from setting to setting during an emergency. In fact, some patients may leave the area with family and others may take part in an evacuation not organized by the HHA or hospice.

We are also curious about the requirement that the emergency readiness policies for these organizations must address arrangements with other HHAs/hospices and providers to "receive patients" in the event that the HHA or hospice providing residential services is unable to operate. It is unclear how a home-based patient is "received" by a similar entity. This language makes more sense for institutional settings that would be evacuating or transferring patients. If the HHA's patients are dispersed over a wide geographic area, does CMS envision that the HHA will have arrangements with other HHAs in every possible location in which a patient may be placed?

We believe that all HHAs and home-based hospices should be doing many of the things outlined in CMS's framework for hospitals. However, we simply do not have a clear picture for how CMS expects these organizations to provide care during disasters. **The proposed requirements for these providers need more clarity.** CMS should work with the stakeholder community to define the most appropriate standards for these providers and to ensure that the finalized requirements are not duplicative of state and local government efforts.