



**CALIFORNIA  
HOSPITAL  
ASSOCIATION**

*Providing Leadership in  
Health Policy and Advocacy*

March 31, 2014

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Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***SUBJECT: CMS–3178–P, Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, Proposed Rule (Vol. 78, No. 249), December 27, 2013***

Dear Ms. Tavenner:

On behalf of our nearly 400 member hospital and health systems, the California Hospital Association (CHA) is pleased to submit comments on the Centers for Medicare & Medicaid Services proposed rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers.

During the comment period, CHA has convened nearly 10 separate statewide member calls to review and solicit input on the proposals laid out by CMS on December 27. Numerous staff — inclusive of clinical staff, administration and those tasked with emergency preparedness from CHA member hospitals, critical access hospitals, inpatient psychiatric hospitals and units, inpatient rehabilitation facilities and units, hospital-based distinct-part skilled nursing facilities, rural health clinics, home health and hospice providers — actively participated in these calls. **CHA continues to receive and process feedback from the field on these critically important proposals that impact so many providers. We appreciate the agencies recognition of the broad scope and impact of the proposed regulations and affording providers and additional 30 days for comment.** It is our understanding that CMS has been considering these proposed regulations for quite some time, and we hope that CMS will engage with providers following the close of the comment period prior to issuing a final rule.

California's hospitals are leaders in the area of emergency preparedness and are essential partners working collaboratively with local, state and regional government agencies in responding to numerous events in California, including the 1989 Loma Prieta earthquake, the 1991 Oakland Hills firestorm and the 1994 Northridge earthquake. California has a long history of catastrophic earthquakes, which can occur at any time on any of the seismically active major faults, and hospitals must be ready. In addition to earthquakes, California is also home to many other natural disasters, including wildfires, floods and mudslides. Beyond natural disasters, California has also experienced major utility outages, such as the 2011 southwest blackout. The high number of critical infrastructure icons native to our state also puts us at high risk for terrorism, both foreign and domestic.

In every major disaster, injured victims require immediate life-saving medical care and treatment. California hospitals must be trained and prepared to respond to a surge of incoming patients 24/7. In the field of emergency management, California leads the nation. Our hospitals are examples for the nation when developing and implementing best practices in emergency management.

To address its multiple disaster threats, California established the Standardized Emergency Management System, known as SEMS. SEMS is the cornerstone of California's emergency response system and the fundamental building block and infrastructure for the response phase of emergency management. SEMS is required by the California Emergency Services Act (ESA) for managing multiagency and multijurisdictional responses to emergencies in California. The system unifies all elements of California's emergency management community into a single integrated system and standardizes key elements. SEMS incorporates the use of the Incident Command System (ICS), California Disaster and Civil Defense Master Mutual Aid Agreement (MMAA), the Operational Area (OA) concept, and multiagency or inter-agency coordination. State agencies are required to use SEMS, and local government entities must use SEMS in order to be eligible for any reimbursement of response-related costs under the state's disaster assistance programs. As you know, following the events of Hurricane Katrina, the federal government established the National Incident Management System (NIMS). NIMS was modeled after California's SEMS.

California hospitals are required by state licensing and accreditation to use an Incident Command System (ICS). A 2009 CHA survey shows 99 percent of California hospitals have adopted and utilize the Hospital Incident Command System (HICS), developed in California and in use for more than 20 years. HICS has also been widely adopted and used across the country, as well as internationally. With an ICS system, hospitals can integrate and coordinate response activity with government agencies and others. Day in and day out, hospitals are cornerstones of the emergency response system in California and hold themselves to the highest standards of continuing to provide high-quality care in the face of adversity.

Throughout the state of California, hospitals and other providers have demonstrated their commitment to emergency preparedness through the accreditation process and voluntary participation in the Hospital Preparedness Program (HPP). Over 80 percent, and more than 300 hospitals and many other providers, are Joint Commission accredited. The state of California has recognized the emergency management standards of the Joint Commission as best practices, and has incorporated many of the requirements into state law and regulation. In addition, California has extensive regulation in Title 22 that applies not only to hospitals but to other providers, including but not limited to long-term care facilities and home health agencies.

**California hospitals are committed to meeting the challenges that they will face in any disaster, and they work day in and day out with their community partners to be ready 24/7. We recognize that many of the proposed requirements establishing the emergency preparedness CoPs overlap with, but are not identical to, The Joint Commission (TJC) standards. However, some of the proposed requirements are not the sole responsibility of a hospital, and are dependent upon the active engagement and cooperation of our community partners. Further, there are areas of the proposed rule that would be duplicative of the role and responsibility of government organizations and inter-dependent on established government plans that may or may not exist.**

As previously mentioned, CHA commends CMS for its thoughtful consideration of many state regulatory and accrediting body standards that are discussed in the proposed rule. **However, we have identified a number of areas where the proposed regulations are insufficient and must be clarified to improve consistent application of the standard nationwide. In addition, we are disappointed with the lack of recognition of some of the significant environmental laws and building codes that will also impact a hospital's ability to comply with both the proposed federal standards and existing state law. Finally, there are a number of proposals that we believe may be well intentioned, but are inappropriate for hospitals to be held accountable for, with a number of reasons discussed in greater detail below.**

In discussions with member hospitals and other providers, **CHA has identified several recommendations that must be implemented to allow for an efficient transition toward implementation:**

- ***Give deference to state law and regulation:*** In a number of areas, the proposed rule fails to recognize that hospitals and other providers are bound by state, local and municipal laws, jurisdictions and codes. California is one of the most highly regulated states in the nation and, as such, we are very concerned about CMS creating unnecessary burdens by requiring duplicative and conflicting requirements. **Deference to state law and regulation is essential in evaluating an organization for compliance with the CoPs.** For example, CMS does not specify a length of time in which a provider should be able to provide sustenance for patients and staff. Some specific assumptions are discussed in the assumptions made around the cost of compliance in the regulatory impact analysis, but not in the discussion of the rule, making this very confusing. We understand CMS's intention not to be prescriptive in this instance, allowing for deference to state law and not further burdening providers in states like California that have extensive regulations with a much more granular level of specificity.
- ***Clearly define the role of the hospital for appropriate CMS accountability:*** In the proposed rule CMS states:  
*“While the HPP Program continues to encourage preparedness at the hospital level, evidence and real-world events have illustrated that hospitals cannot be successful in response without robust community health care coalition preparedness - engaging critical partners. Critical partners include emergency management, public health, mental/behavioral health providers as well as community and faith based partners.”*

We could not agree more with the sentiments expressed in this statement, and we view our role as one that is critical in these partnerships at the local level. **However, in many of the proposed requirements that follow, the regulations assume that the hospital take on and be held accountable to “ensure” many of the activities, that must be completed in concert with our partners, including state and local government. We disagree with the assumption that hospitals can “ensure” appropriate preparedness and response of others who share key roles and responsibilities for disaster response. CHA urges CMS to clearly delineate the role of the hospital from its coalition partners in assessing compliance with the CoPs. In addition, we urge CMS to use its influence with other federal agencies to support health care coalitions through funding and policies that support preparedness of all provider types. Many settings are currently not well resourced for training, supplies, equipment and joint-preparedness activities.** CHA is very concerned that, if these requirements go beyond what is appropriate, that hospitals may have no choice but to withdraw from other voluntary coalition efforts because they will need to divert scarce resources internally to comply.

- ***Use a multi-phased approach to implementation:*** **Critical to the success of implementation of these important CoPs is a phased approach.** CHA believes that acute care, PPS hospitals should proceed first, followed by critical access hospitals (CAH) and other types of inpatient facilities, including inpatient rehabilitation and long-term care facilities. Following hospital implementation, other providers and suppliers would proceed. As mentioned by CMS, CHA supports allowing evaluation and feedback from a phase-one rollout so that it can be shared with other providers and suppliers as appropriate. **With that said, CHA believes strongly in a period of non-enforcement at each phase while CMS takes the necessary actions to promote a seamless transition (see below).**

- ***Apply an integrated approach to emergency operations planning:*** California hospitals provide a diverse set of services that encompass many of the other provider settings outlined in the proposed rule. The current Joint Commission standards allow for an integrated survey approach to the assessment of their emergency management standards and, similarly, many hospitals have an integrated and comprehensive approach to their emergency operations plan. We believe that this approach to planning, while still meeting the requirements of each specific provider setting, will maximize collaboration and efficiency in operations.
- ***Ensure transparency in development of interpretive guidance:*** CHA has provided very specific recommendations to the proposed regulation and applicable requirements in the discussion that follows. However, the final rule is only the first of many critical components required to promote clear and concise interpretation and application of the CoPs nationwide. The interpretive guidance that subsequently will be developed is critical to the appropriate evaluation of hospitals and other providers. **CHA urges CMS to engage both state survey agencies and the provider community in soliciting input through a sub-regulatory process prior to finalization.** The proposed rule raises a number of unanswered questions, and such a process would help to facilitate shared understanding of expectations going forward.
- ***Allow a period of non-enforcement and adopt surveyor training and pilot tools:*** Noticeably absent in the proposed rule is an assessment of the state survey agencies' readiness to take on these additional compliance requirements in the short term. CHA is very concerned that states agencies, contracted by CMS (including the California Department of Public Health) do not have the staff or financial resources that would be needed to ensure that the more than 600 surveyors in the state are provided the resources and tools that they need to be successful in meeting the demands of this new workload. **Therefore, CHA urges CMS to delay enforcement of the final rule until such time as the following can occur:**
  - **Interpretive guidance has been finalized by CMS, inclusive of a period of engagement with hospitals and other providers;**
  - **Surveyor tools and pilot programs are developed and tested, similar to the successful approach undertaken for QAPI, discharge planning, and infection control; and**
  - **A readiness review of state survey agencies is complete and made publicly available.** We ask that CMS consider allocating additional resources as appropriate.
- ***Revisit cost and burden estimates:*** In 2009, CHA conducted a comprehensive hospital emergency preparedness survey. The survey revealed that almost every hospital has an assigned emergency preparedness coordinator. For over 60 percent of hospitals, this is a full-time employee (1 FTE). However, this individual has multiple responsibilities, one of which is emergency preparedness. In contrast, only about 12 percent of hospitals have a full-time position devoted exclusively to emergency preparedness. In approximately 8 percent of hospitals, the emergency preparedness coordinator position is a .25 FTE with a variety of responsibilities. These individuals are already tasked with meeting existing state regulatory, accreditation and HPP grant requirements. **CHA believes that without the significant changes discussed below, the cost and burden will far exceed what even the most adept and financially sound hospitals can accommodate. We are particularly concerned about the ability of our smaller and rural facilities to meet many of these requirements if not allowed time to scale up.**
- ***Words matter — clear regulatory text is essential:*** Insufficiently defined and vague requirements may cause misinterpretation by those trying to implement the standards as well as the surveyors who must evaluate providers against the standards. **CHA urges CMS to adopt many of the specific recommendations and wording changes discussed below. Further, it was very concerning to see**

**the word “ensure” used over 300 times in the proposed rule. The word “ensure” means “to make certain.” No entity - hospital or other private sector organization or government agency can guarantee anything when planning for or responding to a disaster.** A disaster situation creates a “not-business-as-usual environment” and the process of planning is more important than the actual plan itself. We ask that CMS remove the word “ensure” from the regulatory text and to use the words “make reasonable efforts”.

As you know, disasters do not occur according to a plan, and all plans require flexibility, adaptability and scalability. A regulatory framework that is also flexible, adaptable and scalable is also necessary. All disasters start “local” and, when the local community is overwhelmed, support and resources are brought in to assist or moved out if necessary. As previously mentioned, hospitals are vital assets to their communities and their states because of their mission and the critical life-saving services they provide. However, they are dependent upon the government-structured system (ESF 8) for support when responding to large-scale, catastrophic events. In times of disaster, it is the planning that is essential. Requirements must be clear, realistic and achievable and should take into account existing requirements under state law, regulation, accreditation and the federal HPP grant.

CHA’s detailed comments and recommendations for the hospital requirements follow.

#### **A. Emergency Preparedness Regulations for Hospitals (§482.15)**

CMS proposes in a new §482.15 that a hospital must comply with all applicable federal and state requirements. Its emergency preparedness program must include the following elements.

##### **a. Emergency Plan (§482.15(a))**

CMS proposes at §482.15(a) that a hospital must develop and maintain an emergency preparedness plan that must be reviewed and updated annually. The plan must:

*(1) Be based on a facility-based and community-based risk assessment, using an all-hazards approach.*

CHA urges CMS to make a number of changes to provide clarity in this section of the CoPs.

**First, CHA urges CMS to change the language of the CoPs and adopt terminology consistent with existing health care emergency management standards that many hospitals, including those in California, already adhere to.** As CMS is aware, the term “risk assessment” (and business impact analysis) is often used within the business continuity discipline. Business continuity and emergency management are two separate disciplines with their own terms and definitions. Where appropriate, we ask CMS to utilize language from the emergency management discipline to limit confusion and build upon existing terminology.

For example, “emergency operations plan” is more often used than “emergency plan” or “emergency preparedness plan.” In addition, the hazard vulnerability analysis (HVA) as defined by The Joint Commission is a definition consistent with what CMS describes as the risk assessment, but more easily understood and commonly utilized by hospitals. **We urge CMS to use the term “hazard vulnerability analysis” and its Joint Commission definition.**

Second, CMS clearly states and CHA supports that, *“The hospital must develop and maintain a comprehensive emergency preparedness program (Emergency Operations Plan) that meets the*

*requirement of this section, utilizing an all-hazards approach.*” CMS describes an all-hazards approach as an integrated approach to emergency preparedness planning. *“Rather than managing planning initiatives for a multitude of threat scenarios, all-hazards planning focus on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters.”*

Building capacities and capabilities through an all-hazard approach is one that must be carefully considered, is detailed in TJC standards, and is within the definition of the HVA, which we support. The process of undertaking this work requires an organization to identify specific threats considering their location and environment and then rank them accordingly. **In reading the proposed rule, several of our member hospitals expressed concern that this requirement will lead to variability in the assessment by surveyors regarding the extent to which any number of threats must be documented and planned for. We ask CMS to consider some additional discussion in the final rule and subsequent interpretive guidance on specifically what the surveyors should be looking for in assessing compliance. For example, will hospitals be required to plan for their top three identified hazards, or will there be no benchmark?**

**Third, hospitals can conduct and document a facility-based risk assessment (or HVA) and do so on a regular basis. However, hospitals may or may not have access to the community-based risk assessment, and we agree that if it is made available, hospitals should be held accountable for its consideration. If not, hospitals should not be held accountable for its consideration.**

In the proposed rule, CMS assumes that hospitals have access to a community-based risk assessment and, unfortunately, that may not always be the case. Initially, there were many communities/counties where the local OES was resistant to sharing and engaging with hospitals in this type of collaborative planning. While we have made significant strides through the HPP program, we do not believe all hospitals will have access to these assessments, especially if the community crosses state lines. We do not agree that it would be appropriate for CMS to hold hospitals accountable for consideration of something that they do not have access to.

Fourth, §482.15(a)(1) also requires hospitals to identify essential business functions that should be continued in an emergency. California state licensing regulation (Title 22) dictates what services must be provided in an emergency and, therefore, there is some limitation on what a provider can do in addition to those services. Therefore, we ask CMS again to defer to state law and regulation when assessing compliance.

Finally, CMS discusses an emergency preparedness program and an emergency preparedness plan as the following;

*“We are proposing a new requirement under 42 CFR 482.15 that would require that hospitals have both an emergency preparedness program and an emergency preparedness plan. Conceptually, an emergency preparedness program encompasses an approach to emergency preparedness that allows for continuous building of a comprehensive system of health care response to a natural or man-made emergency.”*

CMS provides a definition for one term but not necessarily the other. In the proposed rule, the terms “program” and “plan” are used interchangeably throughout. We ask that CMS clearly define the two terms definitively and go beyond a conceptual framework. CHA recommends that CMS draw upon existing definitions that will promote clarity in understanding of the proposed rule.

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

CMS provides examples and notes that it expects strategies to include consideration of collaboration with hospitals and suppliers across state lines, if applicable. The requirement for strategies that address the risk assessment (HVA) and their application across state lines is largely dependent upon government support and coordination and may be duplicative of their efforts, wasting precious resources.

Hospitals acknowledge that collaboration is essential and is necessary under a number of circumstances, but we do not believe that requirement is something that should be completed in isolation. The government often plays a significant role in making resources available across a region and, as such, the burden for doing so is shared.

In the “just-in-time” inventory and supply delivery that exists today, hospitals and other health care providers and suppliers are dependent upon government coordinating centers to provide organizational direction, lend their expertise and secure clearance for crossing state/jurisdictional boundaries. This responsibility is one that should not fall solely on the backs of hospitals. Finally, most hospitals and health systems are dependent upon the same, primary suppliers and need appropriate government coordination assistance and oversight to promote this type of collaboration. This is an area where resource requesting and/or mutual aid may come in to play, and that requires support and coordination, with government agencies responsible. An example of the interdependencies was the shortage of N95 masks across the nation during the H1N1 flu outbreak.

**CHA urges CMS to allow hospital flexibility in establishing protocols consistent with the National Incident Management System and Emergency Support Function (ESF) #8 – especially in catastrophic events – to demonstrate compliance with this requirement. These protocols are proven best practices for hospitals.**

*(3) Address the patient population, including 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 notes that, in addition to individuals specifically identified as at risk in statute (children, senior citizens and pregnant women), it 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 goes on to note the definition includes the elderly, persons in hospitals or nursing homes, people with physical and mental disabilities, infants and children.

**Hospitals treat and provide acute medical treatment to at-risk individuals every day. In the event of a disaster, hospital services must be at the ready to provide treatment to a vulnerable population that will require acute medical care or services, in accordance with the mission and purpose of an acute care hospital. Hospitals are not and should not be considered a replacement for general population care and, therefore, be held responsible for the provision of less emergent services where state or local government agencies play a critical role and bear primary responsibility.** Social services and disaster response organizations like the Red Cross and faith-based organizations also play an essential role. Hospitals can and must prioritize the provision of medical care and treatment for the acutely ill or injured, and those resources should not be diverted to the provision of services that are the responsibility of other agencies.

**CHA urges CMS to clearly define the expectations for an acute care hospital in the provision of providing acute medical treatment. Hospitals should not be held accountable for the role of**

**government and other organizations when planning for and meeting the needs of a more broadly defined “at-risk” population.**

This issue was identified during the San Diego blackout in 2011. Individuals that were dependent upon medical equipment requiring power arrived at area hospitals seeking assistance. They required a power source, not medical treatment. Unfortunately, at the time, there was no local government plan to provide for the needs of these individuals, so hospitals assisted them as best they could, but this diverted scarce resources from their primary mission. Following the incident and upon debrief, it was agreed that local government needed a plan to support this population and lessen the burden on hospitals, preserving their ability to respond to the acutely ill or injured. Hospitals are an important partner in this planning, but there is agreement regarding the necessity of a shared responsibility.

**Therefore, CHA recommends revising §482.15(a)(3) to:**

*A hospital’s (including critical access hospitals) emergency operations plan should address the patient population, including patients in need of acute medical care or treatment in an emergency or following a disaster; the type of services the hospital (and CAH) have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession.”*

*(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.*

CHA agrees and 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, CMS notes that 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. **CHA appreciates this discussion in the preamble of the proposed rule and suggests the regulatory text be changed to account for this discussion to limit varied interpretation.**

**More specifically, as previously noted, CHA urges CMS to change the word “ensure” in the proposed regulatory text to *include a process for making reasonable efforts toward cooperation and collaboration*.** Hospitals can and do make many efforts to collaborate. However, they cannot *ensure* collaboration with other stakeholders as proposed in the regulatory text of the proposed rule. The NIMS provides a process and mechanism to foster collaboration in planning and response, but it is largely dependent upon how well the system is established and followed by government agencies and whether or not those agencies choose to engage hospitals and other health care providers.

While hospitals have their own organizational plans, in a disaster they are dependent upon local public health and government for coordination and collaboration. As previously mentioned, voluntary participation in the federal HPP grant program has been essential to fostering cooperation and collaboration. Hospitals are considered first receivers, and their mission is to provide medical care to injured or acutely ill victims in a disaster, in addition to providing continuing care and treatment to existing inpatients. In large scale events impacting their community, the health care delivery system is dependent upon written and tested community plans that include key partners such as fire, law enforcement, public health/EMS and emergency management, in addition to hospitals and health care providers.

CHA appreciates CMS's discussion in the proposed rule of the critical role of ASPR's Hospital Preparedness Program (HPP) and community health care coalitions (HCCs), as well as the continued recognition and support of these invaluable programs. Participation in these efforts by California's hospitals demonstrates their commitment to making efforts toward collaboration and coordination with our community partners.

**b. Policies and Procedures (§482.15(b))**

CMS proposes that the hospital develop and implement policies and procedures, based on the emergency plan and risk assessment and the communications plan under (c) (below), that are reviewed and updated at least annually.

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

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

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

CMS proposes that the policies and procedures address subsistence needs for staff and patients, whether evacuated or sheltered in place, including food, water and medical supplies. 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 seeks public comment on this proposed requirement.

The hospital emergency operations plan consists of policies and procedures based upon identified threats and hazards. Hospitals currently review and update their plans annually. Current California regulations require hospitals to provide food and subsistence needs for staff and patients in a disaster (Title 22 §70277).

Hospitals can plan to provide for basic needs (but may be rationed) should sheltering in place be necessary, but only for a limited time. **CHA does not support further expansion of this requirement as considered in the proposed rule, and noted above, that would require hospitals to provide for the basic needs of individuals from the community (general population). We believe these individuals could be better cared for by other entities coordinated through local emergency management, focusing the hospital on providing essential medical treatment that the community will also need.**

The decision to evacuate a hospital is a decision of last resort and often must be done very quickly in an effort to save lives and prevent injuries. Under these circumstances, it may not be realistic to expect a hospital to be able to provide food, water, medication, etc. to every patient and staff member, as this may be dependent on a number of factors — such as where the patient is evacuated to. In every event, the circumstances are different, thereby requiring significant flexibility. We do not believe it is feasible for hospitals to provide subsistence for patients or staff who have evacuated and are no longer in the care of the hospital.

**Once evacuated patients have been transferred or moved to another facility, the receiving facility or entity is then responsible for the patients' needs, including food, hydration, medication etc. CHA urges CMS to recognize this necessary and appropriate hand off and to modify the regulations as needed.**

**Hospitals have expressed concern regarding the lack of definition for the timeframe for which these services would need to be provided and have raised concerns regarding potential conflicts with state law. California hospitals have licensing requirements specific to emergency food planning, and we urge CMS to allow the COPs to again defer to state law and regulation when applicable, avoiding duplicating existing requirements that require scarce resources.**

*(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.*

**This section of the proposed rule gives us great pause.** Again, with this requirement, CMS notes that hospitals should provide for alternative sources of energy for the duration of the emergency. As you can imagine, it is impossible to plan and be held accountable for such an unknown. The “duration of an emergency” could be assessed at 72 hours in one state regulation, or at 96 hours in another accrediting standard or from one surveyor to another. Hospitals need flexibility to address the unknown and must do so in cooperation with their local partners. We urge CMS to respond to concerns raised by the field regarding some of the potential variation in evaluation of compliance.

**CHA wishes to express deep concern regarding the sewage and waste disposal requirements specifically.** CMS proposes to define the term “waste” as all wastes, including solid waste, recyclables, chemical, biomedical waste and wastewater, including sewage, and would require the facility to address the disposal of all such waste. For example, to properly dispose of solid waste a hospital would be required to incinerate the waste – a violation of California state law.

In California, hospitals are not allowed to have incinerators due to state environmental standards (22 CCR 66264.34 and 22 CCR 66264.342). An earthquake is the highest risk disaster threat in California. The majority of California’s sewer systems are not built to withstand an earthquake. Therefore, California hospitals have plans for waste storage on site while operating after a disaster. This is an acceptable strategy that addresses our environment and has been recognized by the state’s hospitals licensing program. **CHA recommends that the proposed COP standards for sewage and water disposal allow for plans to maintain sewage and waste water on site until it can be disposed of properly. Failure to allow such flexibility for hospitals would jeopardize California’s hospitals to comply with these regulations as proposed and put our fragile sewer and water systems at risk.**

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

CMS proposes that the policies and procedures address the need to track the location of staff and patients during and after an emergency, including evacuees. While CMS does not propose a specific system, the agency notes that the information must be readily available, accurate and shareable across the emergency response system as needed.

Hospitals currently have in place policies and procedures to track patients who are being cared for and on their property. We would not characterize those policies and procedures as a system as discussed in the proposed rule. Tracking injured victims and patients in a disaster is a highly complex issue and must be done in collaboration with other stakeholders. **Any “system,” as noted in the proposed rule, must be developed in collaboration with state and local government so that everyone’s needs are considered**

**and prioritized – and not be the sole responsibility of the hospital. Setting up such system requirements should be a consensus-based approach.** Requiring that the hospital have a “system” in isolation rather than in partnership may have unintended consequences (i.e., a community provider or agency refuses to use it). Further, any system that is not widely adopted would just be an additional cost and burden on the hospital.

In addition, hospitals have policies and procedures to account for staff working at the time of a disaster or emergency. It is neither reasonable nor a good use of resources to expect hospitals to be able to track the location of *all* staff during and after an emergency. Again, this is a shared responsibility with our community partners and should be part of a broader set of system requirements that could be considered and prioritized for implementation.

**CHA recommends revising 482.15(b)(2) to:**

*2) A means to track the location of staff and patients in the hospital’s care both during and after an emergency.*

This recommended change does not preclude the development of a system as described by CMS within a community, but it allows for hospitals to develop other processes that meet the needs of their community. Further, once a patient is transferred to another hospital or entity, the hospital should no longer be responsible for tracking that patient, rather documenting that transfer. The receiving entity would then assume responsibility for the tracking of that patient.

**Finally, we believe is unreasonable to expect outpatient providers to track patients in a disaster period.** A more reasonable approach would be for those providers to share a registration list for patients who signed-in or registered during the specified period of time. This information is readily available and can easily be shared.

*(3) Safe evacuation from the hospital.*

CMS proposes that the policies and procedures address a means to ensure safe evacuation, including consideration of care and treatment needs, staff responsibilities, transportation, evacuation locations, and primary and alternative means of communication. **CHA supports this recommendation.**

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

CMS proposes that the policies and procedures address a means to shelter in place for patients, staff and volunteers, and CMS expects that would include criteria for selecting patients and staff who would shelter in place and the means to ensure their safety. **CHA supports this recommendation.**

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

The policy described above would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) requirements.

The proposed rule focuses on both a “system of medical documentation” and the electronic health record (EHR). The proposed rule assumes that the EHR is widely adopted and fully implemented. It also assumes a fully functional and operational health information exchange where data is stored and can be retrieved from anywhere. There are very few examples of such systems in California or across the

country. Regardless, in an earthquake, it is likely that a hospital's entire electronic medical record would be destroyed in the collapse of a building – despite all attempts to back-up information off site.

The COPs must acknowledge the current medical record system that is still, despite our best efforts, largely paper based. Further, even with EHRs, due to the potential for the complete destruction of an EHR as discussed above, the state of California has defined in regulation a “disaster medical record” and has released extensive guidance for hospitals in developing such a record to address the circumstances described.

**CHA urges CMS to consider significant modifications to this requirement. We must first walk before we can run, and to divert resources from the current implementation of EHRs to contemplate accessing EHRs in a disaster would only slow adoption. Therefore, CMS must allow for hospitals to have a process to utilize a paper-based medical record (including those disaster medical records as defined in state regulation (Title 22 §70741(b)(b)) for each patient and to provide a copy for evacuation, transfer or discharge.**

In addition, CHA again objects to the use of the word “ensures” in this provision. Instead, we recommend using the phrase “makes reasonable efforts to.” To the extent that records are on paper, hospitals cannot always “ensure” that a fire won't destroy records or that a hurricane won't damage them or scatter them. To the extent records are electronic and available, hospitals cannot “ensure” there will not be unrecoverable destruction to the system – even with HIPAA-required backup and redundancy.

*(6) Use of volunteers and other emergency staffing including the process and role for integration of State and federally designated health care professionals to address surge needs during an emergency.*

CMS proposes that the policies and procedures address the use of volunteers and other emergency staffing strategies, including integration of state or federally designated health care professionals to address surge needs. **The proposed rule discusses the essential role of health care volunteers and we believe the regulation text should reflect that discussion. There is no discussion of the role of a more general volunteer until later in the regulation. CHA urges CMS to revise the requirement to “Use of health care volunteers” as to not confuse this requirement from the requirements (i.e., training discussed below) for our “general” volunteers.**

*(7) Arrangements with other hospitals and providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients.*

CMS proposes that the policies and procedures address arrangements with other hospitals and providers to receive patients in the event of limitations or cessations of operations. **CHA supports this recommendation.**

*(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 proposes that the policies and procedures address the role of the hospital under a waiver declared by the Secretary under section 1135 of the Social Security Act (SSA) in the provision of care and treatment at an alternate care site (ACS) designated by emergency management officials.

While the language of the proposed rule does not explicitly require a hospital to be responsible for setting up and running an additional ACS, hospitals are concerned that the interpretive guidance and/or surveyors may expect something more than just a description of how the hospital would be supportive of an alternative care site that is described below.

Our experience tells us there are likely two scenarios for the use of alternate care sites. In the first scenario, the building of the hospital itself is impacted by a disaster, and the hospital transfers services or partial services to an alternate care site that it has already outlined in its emergency plan. So the hospital is functioning at a single, but different, location. This location could be in the parking lot of the hospital or somewhere further away.

In the second scenario, public officials who are organizing a community response to the emergency will set up an alternate care site to provide patient surge capacity. In the second scenario, both the hospital and the ACS are operational simultaneously.

**We do not agree that CMS should assume that the hospital would be able to set up and run a second location while it is operating its own ACS. While hospitals have and will continue to provide support when they have the resources, holding a hospital accountable for the operations of a second scenario as described above is beyond feasible when trying to provide the highest quality of care and patient safety.**

In addition, it is very difficult to outline how a hospital will set up an alternate care site in its emergency plan if the government authorized/established ACS plan does not exist. There are too many unknowns in this situation. Some hospitals are located in communities where no public health and medical community-wide plan has been developed by public health/EMS agencies.

This requirement, as outlined in the proposed rule, assumes that the community has an established ACS plan, and the unfortunate reality is that many do not. While we agree it is a critically important plan to have, it is unreasonable to hold a hospital accountable for developing policies and procedures for a plan that may not exist.

**Therefore, CHA urges CMS to require that hospitals have policies and procedures for alternate care sites when the hospital itself is impacted. Further, the policies and procedures should “*identify alternative sites for care, treatment and services that meet the needs of the hospital’s patients during emergencies.*” This language is consistent with current Joint Commission standards, and we believe is most appropriate.**

This change would not preclude a hospital from having policies and procedures for how it would support an alternate care site set up by officials in an emergency. However, hospitals cannot develop policies and procedures for a government plan that has not yet been developed by the responsible agency.

**c. Communications Plan §482.15(c)**

CMS proposes that hospitals be required to develop and maintain an emergency preparedness communication plan, and that it be reviewed and updated annually. In general, CHA supports many of the provisions as outlined and offers some additional recommendations. The plan would include:

*(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.*

(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.*

(5) *A means to release patient information in the event of an evacuation as permitted under 45 C.F.R. Section 164.510.*

CMS proposes that hospitals have a means to release patient information, as permitted under HIPAA, in the event of an evacuation. However, the preamble refers again to a "system" to release patient information. A system implies some sort of electronic platform that we do not believe is necessary. **We ask CMS to allow for all means by which information may be made available, including the exchange of paper.**

In addition, California has many patient privacy laws. In many instances they exceed the requirements for current HIPAA standards. **We ask CMS to consider the additional phrase "and in accordance with state law" to §482.15(c)(5), emphasizing the need to address both federal and state standards in each of these areas when developing policies and procedures.**

(6) *A means of providing information about the general condition and location of patients under the facility's care permitted under 164.510(b)(5).*

CMS proposes that hospitals have a means of providing information about the general condition and location of patients under the facility's care, as permitted under HIPAA. For the reasons stated above, **CHA asks that CMS to consider the additional phrase "and in accordance with state law" to §482.15(c)(6).**

(7) *A means of providing information about the hospital's occupancy needs and its ability to provide assistance.*

CMS proposes that a hospital have a means of providing information about its occupancy, needs and ability to provide assistance to the authority having jurisdiction or to the incident command center, and notes again that hospitals and other providers engaging in coalitions in their area can effectively meet this requirement. We have no further comments on this requirement.

**d. Training and Testing §482.15(d)**

CMS proposes that 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.*

In addition, the proposed rule would require hospitals and CAHs to provide “initial 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 roles.”

**Hospitals conduct training on a regular and ongoing basis but, many do not provide training to individuals providing services under arrangement or to volunteers.** Today, a number of hospitals outsource a variety of services, and some may require specific training. As currently proposed, the language regarding the training of individuals providing services under arrangement and volunteers is too broad.

**CHA urges CMS to allow hospitals the flexibility to identify within their plan what, if any, outsourced services are essential during a disaster, and if any of these contracted individuals should receive specific training.** It is not reasonable to expect hospitals to train volunteers in emergency preparedness policies and procedures. Volunteers are just that – volunteers. They are under no obligation to report for duty and, therefore, cannot be relied upon to perform specified responsibilities. We differentiate them from health care volunteers, as noted above. More importantly, the hospital should identify and clearly indicate who of their employees and contracted individuals should receive basic/overview training, and who are the likely individuals to fill ICS command positions for managing the event.

**CHA urges CMS to require hospitals to provide a documented training plan for specified individuals with key responsibilities. That training should be scalable and consistent with individual roles and responsibilities. Hospitals, however, should not be expected to train all hospital staff, contractors or volunteers. We believe that the costs associated with such training far exceed the benefit and would not be prudent in a time of very scarce resources.**

*(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.*

**Conducting and/or participating in exercises and drills are critical to emergency preparedness, and CHA supports this requirement. However, CMS should not mandate that hospitals conduct a table-top exercise. Rather, CMS should require hospitals to conduct or participate in a mock**

**disaster drill as stated in the proposed rule, and allow flexibility to determine what type and number of additional exercises/drills best meets their needs.**

Requiring hospitals to conduct a table-top exercise would add a third requirement to the two that are already required under TJC standards. We ask that CMS exercise parsimony and create alignment, not duplication with existing standards.

**In summary, CHA recommends that hospitals be required to conduct two drills annually. One may be a mock disaster drill (facility or communitywide), and the other should be determined by the hospital in accordance with its identified needs.** Finally, CHA supports the CMS proposal to exempt for one year any hospital that experiences an emergency and activates its emergency operations plan, from the requirement to conduct a community/facility drill.

***e. Emergency and Standby Power Systems §482.15(e)***

CMS proposes that hospitals must implement emergency and standby power systems based on the plan and policies and procedures set out.

*(1) Emergency generator location*

The emergency generator would have to be located as required by the 2000 edition of the Life Safety Code of the National Fire Protection Association (NFPA). CMS notes that it intends to require compliance with future updates that may be adopted by the agency.

*(2) Inspection and testing*

At least once every 12 months, hospitals would have to test each emergency generator for a minimum of four continuous hours at a test load that is 100 percent of the load anticipated during an emergency. Hospitals would have to maintain written records of generator inspections, testing, operations and repairs, which would be available upon request.

Because the number one vulnerability to a prolonged disruption of hospital services in California is earthquakes, the state has enacted sweeping legislation to require all hospitals to at least be at a life safety level of structural integrity by 2020. Hospitals also are required to attain a structural and non-structural level of integrity, where the hospital will remain operational following major seismic activity, by 2030.

Hospitals with non-compliant buildings need to annually submit SB 499 reports to the Office of Statewide Health Planning and Development (OSHPD), the state hospital building official, detailing how non-compliant hospital buildings will become compliant. The RAND Corporation estimates the total cost of this unfunded seismic mandate is projected to be \$110 billion without financing costs.

The compliance requirements contain standards pertaining to water storage on site, as well as the placement of backup diesel generators and fuel above the flood plain. The hospital seismic mandate requirements for the location of diesel backup generators and fuel are based on NFPA 99 and NFPA 110 requirements, documents prepared through a consensus code development process and recognized by building code officials and TJC. **CHA urges CMS to align the COPs with NFPA 99 and NFPA 110 standards. While utilizing NFPA standards will be consistent with California state law and current TJC standards, CMS should defer to state law or regulation because applying the latest standards impacts building codes, environmental standards and other requirements that hospitals must also comply with.**

It is disappointing that CMS failed to recognize the vast array of other state laws that impact building codes, especially in the state of California. If CMS mandates that hospitals need to meet all the various requirements that affect mechanical, plumbing and structural systems prior to a hospital completing the seismic structural and non-structural requirements on the current timeline, it will add billions to the \$110 billion projected by 2030. **CHA urges CMS to allow hospitals to perform any work required to meet section §482.15(e) requirements in conjunction with future construction and renovation projects. Until such time, a hospital in California should be compliant with the state requirements of the California Department of Public Health and OSHPD.**

**Further, CHA has grave concerns regarding the unnecessary emergency generator testing** under Section 482.159(c)(2)(i), which requires that “Once every 12 months, the emergency generator(s) would be tested for 4 continuous hours at 100 percent of the load anticipated during an emergency.” As proposed, this would be required for hospitals, CAHs, and long-term care facilities. **This requirement is not necessary and would be detrimental to our environment.**

CHA concurs with the analysis of MGI Systems, a nationally recognized expert in hospital diesel backup generators, which concludes that the number one cause of emergency generator failure is the lack of proper maintenance and testing performed according to original equipment manufacturer (OEM) manuals and the minimum NFPA 110 requirements. **Neither the OEM nor the NFPA 110 recommends the four-hour test proposed by CMS.**

In addition, diesel particulate matter, which is released during testing of these generators, is one of the most dangerous known carcinogens. It is puzzling that CMS would promote the emission of more diesel particulate matter in areas around hospitals, especially when children and seniors are most vulnerable to diesel pollution.

**CHA recently conducted a survey of diesel backup generators at California hospitals. Knowing the brake horsepower (bhp) and the fact that the California Air Resources Board requires a maximum emission rate of 0.15 grams/bhp of particulate matter, we determined that in conducting the four-hour test, hospitals and CAHs would be adding more than 1,300 pounds of diesel particulate matter to the environment each year — solely from testing hospital generators. We are unable to fully calculate the particulate matter that would be generated from nursing home generator testing. Further, this would be in addition to what is released during the testing that is already required. Moving forward in implementing this proposal would create an irresponsible health risk. We believe the proposal is not well thought out and should be rescinded.**

**CHA recommends that diesel generator testing and inspection be conducted in accordance with state regulation and environmental laws if it is based on nationally recognized standards such as those of NFPA. California state law requires conformance with NFPA 99 and NFPA 110 standards, and aligning the COPs accordingly would be most appropriate. To review compliance with the state law, CMS may wish to review hospitals’ maintenance logs since timely maintenance is important to generators being operational when needed.**

## **B. Emergency Preparedness Regulations for Other Provider Types**

As you may know, the CHA membership is significant not only in numbers, but in the diversity of services provided by our hospitals and health systems throughout the state. CHA members include more than 300 acute PPS hospitals, 30 critical access hospitals, 16 long-term acute care hospitals (LTCHs), 75

inpatient rehabilitation facilities (free-standing and units), 127 inpatient psychiatric hospitals (freestanding and units), 100 distinct-part skilled-nursing facilities (DP/SNFs), and more than 125 home health and hospice agencies. In addition, we represent 124 hospital-based rural health clinics and more than 20 hospital-based ESRD facilities. As previously mentioned, CHA held extensive educational calls and solicited input regarding the breadth and depth of the proposals across settings.

**Upon further reflection, the hospital framework that CMS has proposed for the establishment of emergency preparedness CoPs, even with the CHA-suggested refinements, does not fully consider a number of setting-specific differences across inpatient providers.** While not an exhaustive list of the differences, the comments below represent a number of questions that have been raised regarding the application of these standards in other settings. We believe they warrant additional consideration and provider engagement. We ask that CMS consider the following in its response in the final rule.

*a. Additional Inpatient Setting Considerations*

In California, LTCHs, inpatient psychiatric hospitals and inpatient rehabilitation facilities (IRFs) are all licensed as hospital beds. Therefore, these organizations are subject to the same state and federal laws discussed above. Further, they are also subject to our seismic standards and other provisions in Title 22 that overlap with Joint Commission standards.

In reading the proposed rule, some of our post-acute care providers were concerned that in the event of an evacuation or the need to transfer patients, they would be required to transfer patients to similar facilities. For example, an IRF may be able to discharge and transfer patients home until such time as it would be appropriate for them to return for their intensive rehabilitation services, rather than transfer them to another IRF or perhaps a SNF. There is concern in the field that, as surveyors look at transfer and evacuation plans, these plans be allowed to consider multiple discharge destinations based on the acuity and needs of the patients. Therefore, we ask that CMS not limit the collaboration across settings solely to similar providers, but to emphasize other providers and other sites of care as appropriate.

With that said, we are very concerned about the need for flexibility in addressing this requirement as we look at the current provision of services – in particular, mental health and substance abuse services in the state. The most pronounced challenge we anticipate is for our inpatient psychiatric hospitals, which would have to transfer or evacuate patients to other settings. In California, we face a significant shortage of beds and, due to increased prevalence of behavioral health and substance abuse illness as well as our crumbling state mental health infrastructure, our facilities cannot keep pace with current demand — let alone move patients from existing locations — without significant challenge. Additional resources and cooperation with state and federal agencies are greatly needed. In California, 26 out of 58 counties have zero inpatient psychiatric beds. These patients cannot easily be transferred or discharged; many pose a safety risk to themselves and others. **This a health policy issue that is substantially impacted by having to comply with the proposed CoPs. We ask CMS to consider these types of circumstances and to engage with providers directly about the flexibility that may be needed to comply under the proposed hospital framework.**

In addition, CHA is concerned and our members have expressed some doubt about the applicability of some of the hospital requirements to other settings. In some instances, we agree with the corresponding overlap, but in others we believe the framework is not well suited and is in need of refinement.

Due to the diversity of the services provided by hospitals and health systems in the state, we believe strongly that an integrated survey approach, when appropriate for the community served, is absolutely needed to improve efficiencies and promote collaboration across the settings. We provide our detailed comments and recommendations on a number of other setting-specific requirements below.

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

Many of California's building codes and environmental laws are also applicable to LTC facilities, including our DP/SNFs. Due to the threat of earthquakes, considerable attention has been given to these settings, and there is tremendous overlap with our hospital comments noted above. **Generally speaking, we believe that the framework for hospitals is applicable to this setting and, as such, we urge CMS to make the same changes noted above in regard to LTC facility regulations that are also applicable to our hospital-based DP/SNFs.**

In addition, in the proposed rule CMS asks for consideration of the following proposal:

*“In addition to the emergency preparedness requirements discussed earlier, we also believe that LTC facilities should consider their individual residents' power needs. For example, some residents could have motorized wheelchairs that they need for mobility or require a continuous positive airway pressure or CPAP machine due to sleep apnea... We believe that the currently proposed requirements encompass consideration of individual residents' power needs and should be included in LTC facilities' risk assessments and emergency plans. However, we are also soliciting comments on whether there should be a specific requirement for ‘residents' power needs’ in the LTC requirements.”*

**LTC facilities and DP/SNFs should only be required to address the power needs of residents when the power needs are essential to the life and safety of the patient. For example, we would not want power sources diverted from life-saving equipment to power wheelchairs when an appropriate alternative is available (standard issue wheelchair). As previously mentioned, during the blackouts in California, we had many patients flood our emergency rooms to address their power needs – these were neither urgent nor emergent patients requiring immediate medical attention. We are concerned that if this requirement is adopted and the LTC facility or DP/NF is unable to provide for the power needs of the residents (beyond what is required for life safety) in the event of such an emergency, this would result in an unnecessary evacuation of the facility and a burden on other care providers. We urge CMS not to adopt the policy as written but to consider significant modifications that address these concerns.**

***c. Emergency Preparedness Regulations for Hospices (§ 418.113) and Emergency Preparedness Regulations for Home Health Agencies (HHAs) (§ 484.22)***

CHA has a number of free standing and hospital-based home health agencies in its membership, as well as a number of hospice providers affiliated with our hospitals and health systems. In reviewing many of the regulations, we do see similar overlap with some of California Title 22 regulation that has been adopted for home health agencies. However, we find in this instance that the proposed hospital framework does not work well for these settings.

In California, HHA and hospice patients are not cared for in traditional institutional settings, but in their homes and within the community. We agree with the CMS proposals to ensure that both hospice and home health providers should make available information regarding the patients in their care, their location and their medical needs. Home health agencies are already required under Medicare regulation to have a plan of care for each patient. Educating patients and staff regarding what to expect and or consider in an emergency is an important component of planning. However, we believe additional dialogue is needed with these providers to better understand what CMS expects of them.

For example, CMS proposes, *“The development of arrangements with other HHAs or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services*

to HHA patients.” Most home health is provided in the home of the patient. In some instances care can be suspended for a period of time (i.e., physical or occupational therapy), and that flexibility should be accommodated in the regulation. Further, patients are not transferred to other HHAs. This type of hand-off does not occur and must be accounted for in the discussion.

CHA is concerned that if not given appropriate flexibility, HHAs may suggest that patients (regardless of their acuity level) be sent to the hospital during an emergency. As previously noted, we do not agree with this approach. Some (but not all) of these outpatient settings can suspend care during an emergency and further, patients can be treated in other care settings, including those set up through emergency management and other state and federal government agencies. This type of arrangement and discussion in the final rule would allow hospitals to preserve their ability to provide medical treatment for the most urgent and emergent patients.

***d. Emergency Preparedness Regulations for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§ 491.12)***

In general, we agree with the CMS comments regarding the ability of RHCs and FQHCs to comply and agree that additional time will be needed. With that said, the hospital-based RHCs in California are currently working with their hospitals on an integrated approach to emergency preparedness. Again, allowing for this type of overlap and survey approach would increase efficiencies and allow for more collaborative emergency planning.

In conclusion, we ask CMS to strongly consider proceeding with a phased approach to implementation, with PPS acute care hospitals proceeding first, followed by other inpatient settings (LTCHs, IRFs, LTCs), and then CAHs. We believe this phased approach is necessary given the level of questions raised during the comment period. As noted above, we believe that a period of non-enforcement is critical during this phase, as it would allow time for feedback and evaluation of the standards before they are applied to other settings.

CHA appreciates the opportunity to provide comments on the proposed rule and looks forward to working with CMS in developing interpretive guidance that is clear to both state survey agencies and providers. If you have any questions or wish to discuss further, please contact me at [akeefe@calhospital.org](mailto:akeefe@calhospital.org) or (202) 488-4688, or my colleague Cheri Hummel, vice president disaster preparedness and executive director of the California HPP program, at [chummel@calhospital.org](mailto:chummel@calhospital.org) or (916) 552-7681.

Sincerely,

/s/

Alyssa Keefe  
Vice President Federal Regulatory Affairs