March 10, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1526-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-3178-P—Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

Dear Ms. Tavenner:

On behalf of Trust for America's Health (TFAH), we are pleased to submit the following comments in response to the proposed rule on emergency preparedness requirements for Medicare and Medicaid participating providers. TFAH is a nonprofit, nonpartisan organization dedicated to improving the health and lives of all Americans through prevention. One of our priorities is America's ability to respond to health emergencies, ranging from bioterrorist threats to serious disease outbreaks to extreme weather events. We publish reports on public health preparedness called *Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism*, which examine these issues and identifies areas of vulnerability. Our work has emphasized the importance of ensuring that all health care providers – including hospitals, primary care providers and institutional care facilities – are well-equipped to address health emergencies when they arise.

We are very supportive of this proposed rule and the approach by the Centers for Medicare and Medicaid Services (CMS) to establish national emergency preparedness requirements for all Medicare- and Medicaid-participating providers. The rule, if finalized, will help improve the healthcare system's preparedness for emergencies, enhancing the country's readiness to respond to large-scale emergencies and natural disasters. We are especially supportive of CMS' efforts to ensure that non-hospital facilities are included in the rule, as we see this as a gap in the country's ability to respond to health emergencies. We urge you to finalize and implement the rule as soon as possible, with recommendations below.

In order to further strengthen the rule, we recommend that CMS:

1. Require facilities to address surge capacity in their emergency plans. In addition, we urge CMS to require facilities to develop and maintain an emergency plan that addresses the specific needs of highly vulnerable patients.

Major disasters can severely challenge the ability of healthcare systems to adequately care for large numbers of patients (surge capacity) or victims with highly-specialized medical needs (surge capability). We applaud the proposed rule for addressing both surge capacity and surge capability, but we recommend additional requirements to make the rule stronger on both fronts.

Surge Capacity. The proposed rule requires facilities to have some policies and procedures in place to address surge capacity, but does not require facilities to evaluate strategies for addressing surge capacity within the initial risk assessment and planning to develop their emergency preparedness plan. This is a gap; facilities should be required to carefully assess their ability to meet surge capacity. This assessment is needed to ensure that facilities adopt appropriate policies and procedures to provide adequate medical care during incidents that exceed the limits of the normal medical infrastructure. We urge CMS to require facilities to address surge capacity in their emergency plans.

Surge Capability. The proposed rule requires a facility to: (i) have policies and procedures in place that include a system to track the location of patients in the facility's care both during and after the emergency; and (ii) have in place a communications plan that includes a means of providing information about the general condition and location of patients under the facility's care. While these requirements will assist high-risk patients, we do not think these requirements go far enough to ensure that patients with highly-specialized medical needs are appropriately managed during emergencies. We believe that facilities need to develop specialized plans to address the needs of their patients with disabilities, patients who are medically dependent (e.g. patients requiring dialysis or medication), patients who are technoelectric dependent (e.g. patients requiring a ventilator or feeding pump for life support/maintenance), and other patients who are highly vulnerable during emergencies. Tracking the location of all patients is not the same as ensuring that high-risk patients are stabilized and secure throughout the duration of an emergency. Such planning will improve surge capacity by ensuring vulnerable patients do not become acute patients during an emergency, when health facilities may be overwhelmed with immediate victims from an event. We urge CMS to require facilities to develop and maintain an emergency plan that addresses the specific needs of highly vulnerable patients.

2. Require facilities to address recovery of operations planning in their emergency and communication plans.

The proposed rule contains a requirement that facilities develop arrangements with other facilities/providers to "receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients." We applaud the proposed rule for addressing continuity of services throughout the duration of a disaster. However, we encourage CMS to require facilities to plan for efficiently and effectively recovering operations post-event.

Facilities should have a plan in place to rapidly identify facility recovery needs and develop an efficient and organized recovery process that will support a return to normalcy of operations. By planning ahead, facilities will be better prepared to prioritize recovery of certain functionalities (e.g. focusing on reestablishment of certain essential services, or recovering operations that meet the needs of high-risk patients) and will be better equipped to communicate recovery needs to local and state agencies and other healthcare facilities who can assist. We urge CMS to require facilities to address recovery of operations planning in emergency and communication plans.

3. Bolster healthcare coalition participation by requiring facilities to collaborate with local or regional healthcare coalitions where they exist; where healthcare coalitions do not exist,

provide technical assistance to help eligible facilities leverage the expertise and experience of other facilities in their communities.

Healthcare facilities will not achieve full preparedness if they develop and execute emergency plans in isolation from other healthcare facilities in their community. Capabilities such as surge planning and evacuation require communication and cooperation between healthcare facilities. Healthcare coalitions serve as a collaborative network of healthcare organizations and public and private sector partners that work together to foster system-wide emergency preparedness activities. Healthcare coalitions have existed in some regions for years and in others as a result of investment by the Hospital Preparedness Program (HPP), administered by HHS' Assistant Secretary for Preparedness and Response (ASPR). Where present, these coalitions strengthen the overall emergency preparedness system by leveraging the expertise of coalition members, facilitating the sharing of resources, and enabling coordination of communications, all of which increase community capacity to launch a coordinated response to health threats. When providers participate in coalitions, they are better prepared to conduct disaster planning, train health care personnel, exercise plans and address issues such as communications, information sharing and fatality management. The resources and guidance provided by coalitions may be especially valuable for healthcare facilities that are addressing preparedness for the first time as a result of this rule.

The preamble to the proposed rule highlights the importance of healthcare coalitions: "evidence and real-world events have illustrated that hospitals cannot be successful in response without robust community healthcare coalition preparedness." While the proposed rule encourages facilities to participate in healthcare coalitions, CMS states that it is not requiring participation. We applaud CMS for recognizing the importance of healthcare coalitions to emergency preparedness, but we urge CMS to bolster coalition participation by requiring facilities to collaborate with local or regional healthcare coalitions where they exist.

We are concerned that facilities that do not participate in the healthcare coalition(s) in their region will be inadequately prepared, even if such facilities meet the requirements of this proposed rule on paper. We understand that the proposed rule requires facilities to include in their emergency plans a process "for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials to ensure an integrated response during a disaster or emergency situation," but this is not the same as being a participant in local and regional healthcare coalitions. Facilities producing emergency preparedness plans in isolation and then following their respective communication protocols when threats arise does not yield robust and organized community-wide preparedness. We are especially concerned that where a facility has not sought out active coalition participation, that facility may not be on the radar screen of area coalitions; as a result, that facility and its patients could be inadvertently left out of coordinated community response efforts. For these reasons, we think it is essential that facilities participate in healthcare coalitions where possible.

However, formal healthcare coalitions have not been established in every region. Where healthcare coalitions do not exist, we urge CMS to provide technical assistance to help facilities leverage the expertise and experience of other facilities in their communities. Because of state requirements and/or Joint Commission preparedness standards, hospital systems and other

networks of providers may already have emergency preparedness exercises, training, collaborations, and plans in place for health emergencies. In other communities, this rule may spur or strengthen healthcare emergency preparedness planning and exercises. To ensure that Medicare- and Medicaid-eligible providers that are newly impacted by this rule are able to build upon existing networks and/or preparedness expertise in their communities, CMS could consider hosting regional meetings for facilities to share information and resources, or providing a clearinghouse of region-specific resources on their website.

4. Require facilities to submit emergency plans to state or local health departments.

In every community, it is important to support and sustain complementary preparedness capabilities between health departments and the health care system. With trained experts and systems in place to quickly act in the face of major emergencies, public health departments are uniquely positioned to help communities prepare for health emergencies of all kinds. When facilities work collaboratively with health departments in their region, they have greater tools at their disposal to efficiently and effectively respond to health threats.

We think the final rule should promote coordination and communication between public health departments and the health care system. At minimum, we think it is appropriate for facilities to share their emergency plans with state and local health departments. Armed with information about ongoing emergency preparedness efforts at local facilities, public health departments can refine the system-wide emergency response to increase efficiency, fill gaps and enhance communication channels. Health departments may also assist in building collaboration between impacted facilities and healthcare coalitions.

In addition, because many facilities will be addressing emergency preparedness for the first time as a result of this rule, these facilities may not have previously had reason to construct relationships with public health decision-makers. By asking facilities to submit their emergency plans to their health department, CMS will serve to foster important new relationships between health care facilities and public health departments.

We urge CMS to require facilities to submit emergency plans to state and local health departments.

5. Require that facilities reevaluate and update their emergency and communication plans within 180 days of a specific emergency event. We also urge CMS to require facilities to file an after event report with CMS that details lessons learned.

The proposed rule requires facilities to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. Under normal circumstances, an annual review of emergency preparedness plans seems reasonable. However, when emergency events happen, we believe it is important for facilities to pause to evaluate the effectiveness of their response: *How did emergency and communications plans, policies and procedures actually work in practice? What are lessons learned? How can facilities apply their experience to addressing future health threats?* We urge CMS to establish a requirement in the final rule that facilities

reevaluate and appropriately update their emergency and communication plans within 180 days of a specific emergency event.

In addition, we think that the final rule should require facilities to file an after-event report with CMS that details lessons learned. When communities undergo bioterrorist threats, serious disease outbreaks or extreme weather events, facilities undergo a real life test of their emergency and communication plans and their ability to respond robustly. In evaluating their response, facilities may identity areas of strength and vulnerability that could serve as best practices or lessons learned for other facilities. CMS could consider making information from after-event reports available on their website for other facilities to use when updating their emergency and communication plans, policies and procedures. CMS could also encourage facilities to work with area healthcare coalitions to evaluate strengths and weaknesses in the community-wide response.

6. Formally leverage the expertise of ASPR to provide technical assistance to facilities covered by the rule.

We support the proposed rule's provision of many resources related to emergency preparedness, including helpful reports, toolkits, and samples from the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention, the Federal Emergency Management Agency, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Institute of Medicine. It is important that facilities, especially those that have not previously been subject to emergency preparedness requirements, have supplemental information to help them understand their responsibilities under the rule and to act accordingly.

We are concerned, however, that despite the sources referenced in the rule, busy and resource-constrained facilities will not have a simple, organized way to access technical assistance and other valuable information when attempting to act in accordance with the new requirements. We note the proposed rule acknowledges that it imposes additional burdens on hospitals and new burdens on non-hospital facilities. To help mitigate some of this burden and ensure that facilities can successfully implement their emergency preparedness requirements under the rule, we believe that facilities will need more formal assistance. ASPR should have a formal role as the designated provider of technical assistance to facilities covered by the rule, given its expertise in emergency preparedness planning and its statutory charge to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies For example, ASPR could provide a clearinghouse of resources and support facilities in finding the information most applicable to them. ASPR already serves a similar function with the Hospital Preparedness Program, providing technical assistance to state, local and territorial public health departments to prepare the healthcare systems for disasters and enhance community and hospital preparedness for public health emergencies.

7. Ensure there is adequate expertise to appropriately monitor and evaluate facilities' emergency preparedness under this rule.

We support the addition of emergency preparedness standards to CoPs, and it is important that facilities adequately meet the new criteria set by the proposed rule. We are concerned, however, that because emergency preparedness falls outside the traditional roles of CMS, there may be a current lack of expertise and "bandwidth" to carry out this role solely within the agency. We suggest that CMS consider partnering with ASPR to ensure adequate monitoring and evaluation of facilities' emergency preparedness activities under the rule. Again, ASPR's expertise in this area makes it particularly well suited to assist CMS as a technical advisor in evaluating facilities' plans and to help CMS build its own expertise in this area.

8. Clarify that the standards in this rule do not preempt state preparedness laws.

We support the proposed rule's goal of providing consistent and enforceable emergency preparedness standards for Medicare and Medicaid providers and suppliers. We agree that there is need for a more consistent regulatory approach that ensures facilities plan for, and are able to respond to, emergencies.

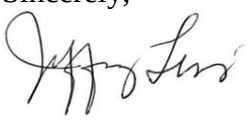
However, we are concerned that despite the assertion in the regulatory impact analysis that this rule will not preempt state law, it may in fact inadvertently impact state emergency preparedness laws and policies. States have primary legal jurisdiction and responsibility for the health of their citizens, and many states have emergency preparedness requirements comparable to those proposed in this rule. Yet, states differ in how they structure, deliver, and fund public health services, and different states have different strengths and vulnerabilities in capabilities. States with multiple, high-density urban areas may function very differently from those with fewer residents spread across smaller cities and towns. States in coastal areas may be concerned with different likely disaster scenarios than those in the middle of the country. These differences result in different policy needs, and lead to different regulatory choices. It is important that states are able to maintain their traditional role to regulate the health and safety of their citizens in emergencies, especially when their laws reflect individual needs of a state.

Therefore, we request that CMS clarify in the regulatory text that it does not preempt more comprehensive state preparedness laws.

Conclusion

The proposed rule, along with the recommendations we have made above, will greatly increase the healthcare system's ability to respond to disease outbreaks, natural disasters, and acts of bioterrorism. We appreciate your careful consideration of our comments and look forward to working with CMS to further strengthen emergency preparedness nationwide. If you have any questions, please contact Becky Salay, TFAH's Director of Government Relations, at bsalay@tfah.org or 202-223-9870 ext. 15.

Sincerely,



Jeffrey Levi, PhD