PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS & TRANSPLANT HOSPITALS

§ 482.15 Condition of participation: Emergency preparedness.

The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

> ***Tip #1 – When developing your emergency response plans, write them as if the target audience knows nothing about your organization, the larger community, or your specific facility. Assume everyone who's familiar with your operations are unavailable and the response actions are handled by others totally unaware of your circumstances.***
>
> - ***Include the name, address, and contact information for all key partners.***
> - ***Ensure your local emergency management agency name, address, phone numbers, email address, and GIS coordinates (if you can get them) are included.***
> - ***Include contact information and other details for your local health & medical lead agency (ESF8)***
> - ***Ensure these contact names, addresses and contact information is verified at least annually***
> - ***Be as specific as possible with every detail***
> - ***Due to the sensitivity of information contained in your disaster plans treating these documents as proprietary is acceptable***

(A) Emergency Plan

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

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

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

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

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

> ***Tip #2 – Florida-based hospitals are already required to develop a Comprehensive Emergency Management Plan (CEMP) and have that plan reviewed and approved by their local emergency management agency. We recommend ensuring the above elements are included in your existing CEMP. There's no need to create a completely new response plan to satisfy these CMS requirements.***

Tip#3 – The Tampa Bay Health & Medical Preparedness Coalition (TBHMPC) already performs a regional hazard vulnerability assessment every year. We recommend using our hazard assessment as a basis for your internal risk assessment. Remember to include specific threats or hazards that your facility or specific location pose to your operations.

Tip #4 – TBHMPC requires all "members in good standing" to sign a Memorandum of Agreement (MOA) committing the organization to helping / supporting / assisting other members during disasters. This MOA should be included as a strategy for addressing emergency events. It also means your organization should have a signed MOA on file with TBHMPC. If not, contact us to get that process started.

Tip #5 – Your organization's active participation in the TBHMPC should be mentioned to specifically explain paragraph (4) above. The TBHMPC is established specifically to focus on the areas and functions mentioned above.

(B) Policies and Procedures

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

Tip #6 – most Florida based hospitals already have a process in-place to ensure there's ample food and water available in your facility to support patients and staff during tropical weather threats or events. Ensure these specific details are included in your plan. Make sure the vendors you use and their full contact information is included in the plan.

(2) A system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the hospital must document the specific name and location of the receiving facility or other location.

Tip #7 – A "system to track the location of on-duty staff and sheltered patients" could be as simple as pen and paper, a hand-written form, or a laptop based spreadsheet. The important factor is that you have a reliable and robust process to track the location and assignments of on-duty staff and patients. This process is necessary to

ensure the safety and health of ALL patients and staff. It also gives you quick access to this information in case of an unforeseen emergency.

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

Tip #8 – If you had to evacuate your hospital, how would you ensure patients were sent to the appropriate level of care? Can some patients be transferred to a Skilled Nursing Facility? If so, which ones? Which patients could be moved using buses of some description and which patients need ambulance transport? How do you know which type of transportation is needed? Have you exercised this process with your ESF8 lead agency, emergency management, your local EMS agency, and local ambulance companies? Ensure ALL of these details are included in your CEMP and the full contact information for each outside partner is also included.

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

Tip #9 – Be specific about the locations within your facility where you would shelter-in-place. Don't assume the people reading your plan know where these sites or areas are. We recommend including a map of your building and / or campus showing specific shelter-in-place locations. Include this map in your CEMP.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

Tip #10 – Consider how your staff would access electronic medical records if you lost both primary and back-up electrical power (this advice comes from recent real-world experience). Do your staff know how to complete paper medical records? Are there emergent procedures in-place to perform manual or paper patient charts? How would you medically transfer patients to another facility if there were no medical records available to send with the patient?

Tip#11 – If you have patients with "Do Not Resuscitate" (DNR) orders, ensure the DNR order is correct / complete, is printed on yellow paper (an EMS requirement), and is with the patient.

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

Tip #12 – Do you have the means to provide emergency credentialing to licensed volunteers? Is there a system in-place to provide clinical oversight to these volunteers? How would you ensure during a disaster that someone who presents as an MD or RN actually holds that medical license? Would a Federal or State level disaster declaration change your volunteer credentialing? It's best to have these issues answered in advance, and have them detailed in your CEMP, so your staff isn't faced with addressing these challenges when the stakes are highest.

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

Tip #13 – As mentioned in Tip #4 above, the TBHMPC already requires "members in good standing" to sign an MOA committing to helping / assisting each other during emergencies. This MOA could be referenced as one element to address (7) above. Healthcare agencies within larger corporate structures can also cite internal policies and procedures that require them to assist and support each other as evidence toward this CMS rule requirement.

(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.

Tip #14 – The Florida Department of Health has developed an Alternate Treatment Site (ATS) plan that's designed to support any ATS operation at any location. One issue for hospitals to consider is the liability and volunteer credentialing (see Tip #12 above). These details together with recommended locations for an ATS should be addressed in detail in your CEMP.

(C) Communication Plan

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

(1) Names and contact information for the following:
- (i) Staff.
- (ii) Entities providing services under arrangement.
- (iii) Patients' physicians.
- (iv) Other hospitals and CAHs (***CAH = Critical Access Hospitals)***
- (v) Volunteers.

Tip #15 – Be specific and include these details in your CEMP. Ensure they are verified and updated at least annually. "Entities providing services" typically means any and all outside vendors that support your internal operations. This includes those providing direct patient care, maintenance and repair vendors, the vendor that picks up the trash, food vendors, and all others.

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

Tip #16 – See Tip 15 above.

(3) Primary and alternate means for communicating with the following:
- (i) Hospital's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

Tip #17 – Telephones and cell phones are probably your primary and back-up communication methods. What if they are not functioning? We recommend a third level of emergent communication capability. If all other options fail, sending a runner is a viable option.

(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to maintain the continuity of care.

Tip #18 – See Tip #10 above.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45CFR 164.510(b)(1)(ii).

Tip #19 – See Tip #10 above.

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

Tip #20 – See Tip #7 above.

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

Tip #21 – The Florida Department of Health maintains a healthcare facility tracking system for bed capacity and facility operational status. Your facility's regular updates in that system would address this requirement (daily updates preferred). All "authorities having jurisdiction" have access to this state-wide healthcare facility tracking system. The Agency for Healthcare Administration (AHCA) also mandates healthcare facility participation to ensure there's rapid information sharing during emergent events. If your facility isn't participating in this system, or if you're unsure, contact your local ESF8 lead agency for more information.

(D) Training and Testing

The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least ***annually***.

Tip #22 – In Florida we refer to "training and testing" as training and exercises or drills. CMS has clearly indicated they want to see robust training and disaster drills of ALL healthcare facility staff. This includes staff who work nights and weekends. Ensure your facility maintains detailed records on ALL training and testing activities.

Tip #23 – Additionally, CMS is also expecting to see healthcare executives (CEOs, COOs, CNOs, and other senior leadership) DIRECTLY involved in training and drills. Ensure After Action Reports from emergency drills include detailed specifics on any senior executive involvement in that drill.

Tip #24 – Ensure all real-world emergencies and training drills are documented using the Homeland Security Exercise and Evaluation Program (HSEEP) standards and formats. If your facility is unaware of the HSEEP process contact the TBHMPC for assistance and training on the process. Using the HSEEP processes will show great benefit when CMS, ACHA, or accrediting agencies review your records.

(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) Demonstrate staff knowledge of emergency procedures.

Tip #25 – We recommend incorporating the above training into your new-hire and annual training processes. Documentation should include details (by name) of who participated in the training and what they were trained on. The term "demonstrate staff knowledge of emergency procedures" can be accomplished by ensuring 100% of staff are directly involved in emergency drills. To accomplish a 100% participation in emergency drills will require having more than 2 drills per year and performing those drills at different times of the day (for all shifts) and on different days of the week to catch all work schedules.

(2) **Testing**. The hospital must conduct exercises to test the emergency plan at least ***annually***. The hospital must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community based exercise is not accessible, an individual, facility-based. If the 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-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) 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.

Tip #26 – While the CMS Emergency Management rules only require 2 exercises per year (1 full-scale and 1 table-top) you may find a need for a more frequent exercise schedule to ensure all staff on all shifts are given an opportunity to demonstrate their emergency duty skills (see Tip #24 above).

Tip #27 – Actively seek opportunities to participate in community-wide exercises and drills. These events are typically designed and executed by others. Plus, they'll involve a wider range of community partners than a single healthcare facility can recruit. Then, ensure your organization participates in the After Action Report process and

obtains a copy of that final report. This documentation will address the expectations spelled out in paragraph (iii) above.

(E) Emergency and Standby Power Systems

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

(1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) Emergency generator inspection and testing. The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) Emergency generator fuel. Hospitals that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

Tip #28 – Florida based healthcare facilities operating emergency generators are already required to comply with ACHA emergency generator testing and maintenance standards. The ACHA standards are more stringent that the CMS rules above. We recommend maintaining your current emergency generator testing and recordkeeping processes

(F) Integrated Healthcare Systems

If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Tip #29 – If a multi-facility healthcare organization elects use this provision we recommend the following:

- ***Establish a corporate level emergency preparedness committee chaired by someone from executive leadership and hold meetings at least quarterly***
- ***Ensure active attendance and participation from key staff at all participating healthcare facilities***
- ***Maintain detailed records of meeting agendas, meeting minutes, and formal presentations of each meeting***

(G) Transplant Hospitals

If a hospital has one or more transplant centers (as defined in § 482.70):

(1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program; and

(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant center, and the OPO ***(Organ Procurement Organization)*** for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*
If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

§ 482.68 Special Requirement for Transplant Centers

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation in §§ 482.1 through 482.57, except for §482.15.18. Add § 482.78 to read as follows:

§ 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(A) Standard: Policies and Procedures

A transplant center must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

Tip #30 – If your hospital operates a transplant center, we recommend including key transplant center staff in the Environment of Care committee and / or other groups involved in the emergency preparedness program.

(B) Standard: Protocols with Hospital and OPO

A transplant center must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.