

## **PART 486--CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS**

33. The authority citation for part 486 continues to read as follows:

**Authority:** Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

34. Add § 486.360 to read as follows:

### **§ 486.360 Condition for Coverage: Emergency preparedness.**

**The Organ Procurement Organization (OPO)** must comply with all applicable Federal, State, and local emergency preparedness requirements. The OPO must establish and maintain an emergency preparedness program that meets the requirements of this section. 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 operations. Assume everyone who’s familiar with your OPO 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 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 OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least **annually**. The plan must do all of 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 the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity 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 OPO's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

***Tip #2 – We recommend ensuring the above elements are included in your existing Comprehensive Emergency Management Plan (CEMP), if you have one. There’s no need to create a completely new response plan to satisfy these CMS requirements. Florida-based hospitals are already required to develop a CEMP. If your OPO is affiliated with a hospital it may be possible to incorporate your processes into the larger disaster plan for the hospital. If your OPO is a stand-alone agency and do not already have a CEMP, you will need to develop one.***

***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 – Who’s in charge? If current OPO leadership isn’t available who’s in charge? Identify a listing of staff who are authorized to “step-up” should the need arise. Also, ensure these staff are aware of this assignment and are trained on those responsibilities.***

***Tip #5 – 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 #6 – 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 OPO 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) A system to track the location of on-duty staff during and after an emergency. If on-duty staff is relocated during the emergency, the OPO 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” 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. This process is necessary to ensure the safety and health of ALL staff. It also gives you quick access to this information in case of an unforeseen emergency.***

- (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.

***Tip #8 – 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 or donor charts?***

### **(c) Communication Plan**

The OPO 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) Volunteers.
  - (iv) Other OPOs.
  - (v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

***Tip #9 – 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, partner transplant organizations, maintenance and repair vendors, the vendor that picks up the trash, 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 #10 – See Tip# 9 above. Include contact details for emergency management and local health & medical lead agency (usually public health department) in each county where your OPO operates. This information must be updated ANNUALLY to ensure accuracy and CMS Emergency Management Rule compliance.***

- (3) Primary and alternate means for communicating with the following:
- (i) OPO's staff.
  - (ii) Federal, State, tribal, regional, and local emergency management agencies.

***Tip #11 – Telephones and cell phones are probably your primary and back-up communication methods. What if they're not functioning? We recommend a third level of emergent communication capability. If all other options fail, sending a runner is a viable option. Also see Tip #10 above.***

#### **(d) Training and Testing**

The OPO 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 #12 – 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 agency staff. This includes staff who work nights and weekends. Ensure your OPO maintains detailed records on ALL training and testing activities.***

***Tip #13 – Additionally, CMS is also expecting to see healthcare agency 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 #14 – Ensure all real-world emergencies and training drills are documented using the Homeland Security Exercise and Evaluation Program (HSEEP) standards and formats. If your OPO 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. The OPO 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 roles.
  - (ii) Provide emergency preparedness training at least **annually**.
  - (iii) Maintain documentation of the training.
  - (iv) Demonstrate staff knowledge of emergency procedures.

***Tip #15 – 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 normally requires holding multiple 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 (if your OPO has multiple shifts).***

- (2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:
  - (i) 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.
  - (ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

***Tip #16 – While the CMS Emergency Management rules above only require 1 table-top exercise per year, if you operate multiple work shifts you may need a more frequent exercise schedule to ensure all staff on all shifts are given an opportunity to demonstrate their emergency duty skills. Also see Tip #15 above.***

***Tip #17 – Actively seek opportunities to participate in community-wide exercises and drills. These events are typically designed and executed by others, thus saving your OPO significant time and money. Plus, they’ll involve a much wider range of community partners than a single healthcare agency can recruit. Then, ensure your organization participates in the After Action Report process and obtains a copy of that final report. This documentation will help during CMS, ACHA, or accrediting agency audits.***

**(e) Continuity of OPO operations** during an emergency. Each OPO must have a plan to continue operations during an emergency.

- (1) The OPO must develop and maintain in the protocols with transplant programs required under § 486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency.
- (2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have:
  - (i) An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency;
  - (ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or
  - (iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.

***Tip #18 – Ensuring Continuity of Operations should be addressed long before you actually need them. A detailed review and inventory of every item your OPO would need (down to specific forms and office supplies) should be developed. We recommend building the items needed into a “grab and go kit” that’s reserved for this purpose only. Consider the amount of space needed, number of telephone lines, type of computer equipment used, and even the number of desks and chairs needed to operate from a separate location. It’s also possible to consider letting staff work from home (if this approach fits into other OPO policies). Don’t forget to ensure staff would have access to patient and donor records from the remote location.***

## **(f) Integrated Healthcare Systems**

If an OPO 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 OPO may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

- (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.
- (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 all of 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 #19 – If a multi-facility / multi-agency 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, more frequently if possible***
- ***Ensure active attendance and participation from key staff at all participating healthcare facilities / agencies***
- ***Maintain detailed records of meeting agendas, meeting minutes, and formal presentations of each meeting***
- ***Ensure the specific needs or hazards at each location / agency are addressed by this corporate level committee***