

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:

(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.

(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.

(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.

(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).

(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) OPO's staff.

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

(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**.

(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.

(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.

(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.

(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.