

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

■ 32. 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).

■ 33. Add § 486.360 to subpart C to read as follows:

§ 486.360 Condition of participation: Emergency preparedness.

The Organ Procurement Organization (OPO) must comply with all applicable Federal and State 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 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 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 staff during and after an emergency.

(2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

(c) *Communication plan.* The OPO must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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 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) The OPO must ensure that staff can demonstrate 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.

(c) *Agreements with other OPOs and hospitals.* Each OPO must have an agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's Donation Service Area in the event that the OPO cannot provide such services due to an emergency. Each OPO must include within the hospital agreements required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

**PART 491—CERTIFICATION OF
CERTAIN HEALTH FACILITIES**

■ 34. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 491.6 [Amended]

■ 35. Amend § 491.6 by removing paragraph (c).

■ 36. Add § 491.12 to read as follows:

§ 491.12 Condition of participation: Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal and State emergency preparedness requirements. The RHC/FQHC 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 RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must:

(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, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(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 RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RHC/FQHC 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) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

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

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

(4) The use of volunteers in an emergency or 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.

(c) *Communication plan.* The RHC/FQHC must develop and maintain an emergency preparedness communication plan that complies with both Federal and State law 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 RHCs/FQHCs.

(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) RHC/FQHC's staff.

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

(4) 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).

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

(d) *Training and testing.* The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually.

(1) *Training program.* The RHC/FQHC 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) Ensure that staff can demonstrate knowledge of emergency procedures.

(2) *Testing.* The RHC/FQHC must conduct exercises to test the emergency plan. The RHC/FQHC must do 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 RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC 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 RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ ~~37. The authority citation for part 494 continues to read as follows:~~

~~Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).~~

§ 494.60 [Amended]

■ ~~38. Amend § 494.60 by—~~

■ ~~A. Removing paragraph (d).~~

■ ~~B. Redesignating paragraph (e) as paragraph (d).~~

■ ~~39. Add § 494.62 to subpart B to read as follows:~~

§ 494.62 Condition of participation: Emergency preparedness.

~~The dialysis facility must comply with all applicable Federal and State emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility 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 dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least annually. The plan must:~~

~~(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, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.~~

~~(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 dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency.~~

~~(b) *Policies and procedures.* The dialysis facility 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. These~~