

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) is 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

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. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of staff and patients in the dialysis facility's care both during and after the emergency.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

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

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

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

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility 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.

(8) A process to ensure that emergency medical system assistance can be obtained when needed.

(9) A process ensuring that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) *Communication plan.* The dialysis facility 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 dialysis facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Dialysis facility's staff.

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

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

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

(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).

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

(d) *Training, testing, and orientation.* The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that must be evaluated and updated at least annually.

(1) *Training program.* The dialysis facility 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. Staff training must:

(A) Ensure that staff can demonstrate knowledge of emergency procedures, including informing patients of—

(1) What to do;

(2) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(3) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(4) How to disconnect themselves from the dialysis machine if an emergency occurs.

(B) Ensure that, at a minimum, patient care staff maintain current CPR certification; and

(C) Ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(D) Maintain documentation of the training.

(2) *Testing.* The dialysis facility must conduct drills and exercises to test the emergency plan. The dialysis facility must:

(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 dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the dialysis facility 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 dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

(3) *Patient orientation.* Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 28, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: December 12, 2013.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

**Editorial Note:** This document was received in the Office of the Federal Register on December 19, 2013.

**Note:** The following appendix will not appear in the Code of Federal Regulations