

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

FACILITIES (ESRDF) – DIALYSIS CENTERS

38. 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]

39. Amend § 494.60 by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

40. 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, State, and local 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 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 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 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 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 confirm 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 on-duty staff and sheltered patients in the dialysis facility's care during and after an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.
- (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 secures and maintains the availability of records.
- (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 maintain 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) How emergency medical system assistance can be obtained when needed.
- (9) A process by which the staff can confirm 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 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 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 maintain the continuity of care.

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

(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 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, testing, and patient orientation program must be evaluated and updated at least **annually**.

(1) Training program. The dialysis facility must do all of the following:

(i) Provide 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:

(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of--

(A) What to do;

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

(C) 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

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

(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and

(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.

(vi) Maintain documentation of the training.

(2) Testing. The dialysis facility must conduct exercises to test the emergency plan at least **annually**. The dialysis facility 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 dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD 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 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.

(e) Integrated healthcare systems

If a dialysis facility 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 dialysis facility 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 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 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.