§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) Standard: Building. The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer’s recommendations.

(c) Standard: Patient care environment.

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must:

   (i) Maintain a comfortable temperature within the facility; and

   (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

(d) Standard: Emergency preparedness. The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. 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.

1. Emergency preparedness of staff. The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

   (i) Ensuring that staff can demonstrate a 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.

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

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

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

3. Emergency equipment. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

4. Emergency plans. The facility must—

   (i) Have a plan to obtain emergency medical system assistance when needed;

   (ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and

   (iii) Contact its local disaster management agency at least annually to
Centers for Medicare & Medicaid Services, HHS § 494.70

Subpart C—Patient Care

§ 494.70 Condition: Patients’ rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) Standard: Patients’ rights. The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

(6) Be informed about his or her right to execute advance directives, and the facility’s policy regarding advance directives;

(7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician’s assistant treating the patient for ESRD of his or her own medical status as documented in the patient’s medical record, unless the

ensure that such agency is aware of dialysis facility needs in the event of an emergency.

(e) Standard: Fire safety. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009, dialysis facilities that are located adjacent to high hazardous occupancies or do not provide one or more exits to the outside at grade level from the patient treatment area level, must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter).

(2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter), section 21.1.6.3, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

(3) If CMS finds that a fire and safety code imposed by the facility’s State law adequately protects a dialysis facility’s patients, CMS may allow the State survey agency to apply the State’s fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility’s patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.