

CMS RELEASES REGULATION MODERNIZING DIALYSIS CENTERS

“The Centers for Medicare & Medicaid Services (CMS) released a final rule that will modernize the Medicare conditions for coverage for the nation’s dialysis centers and promote higher quality of care for patients receiving dialysis.

The final regulation will enhance the quality of care available to more than 336,000 Medicare beneficiaries with End-Stage Renal Disease (ESRD) who receive dialysis treatment from more than 4,700 Medicare-approved renal dialysis facilities across the U.S. The final rule went on display today at the Office of the *Federal Register* and was published April 4, 2008.

These regulations will serve as minimum standards that dialysis facilities must meet in order to meet to be certified under the Medicare program. These conditions for coverage are part of the Medicare survey and certification process. The rule focuses on the importance of patient rights, **patient safety** and the patient’s participation in the development of his or her own plan of care

Beneficiaries will benefit by the following updates in the rule:

- Incorporates sections of the **2000 Life Safety Code**, which upgrades fire safety standards.”

The final rule is displayed at: www.cms.hhs.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413, 414, 488, and 494

[CMS–3818–F]

RIN 0938–AG82

Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

DATES: The provisions of this final rule are effective October 14, 2008. Compliance with § 494.30(a)(1)(i) and § 494.60(e)(1) is not required until **February 9, 2009**.

To determine if a facility meets ESRD conditions for coverage, the State survey agency performs an on-site survey of the facility. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, we then certify the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions.

Dialysis Facility Compare (DFC) is an online tool at <http://www.medicare.gov> available for dialysis patients and their caregivers, which serves to enhance public accountability in healthcare by increasing transparency regarding the quality of dialysis facility care.

§ 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 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. **The dialysis facility 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. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits.

(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.