

## § 494.10

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(b) *Scope.* The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

### § 494.10 Definitions.

As used in this part—

*Dialysis facility* means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

*Discharge* means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

*Furnishes directly* means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

*Home dialysis* means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

*Self-dialysis* means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

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*Transfer* means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

### § 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

## Subpart B—Patient Safety

### § 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control.* The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,” developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html).

The recommendation found under section header “HBV-Infected Patients”, found on pages 27 and 28 of RR05 (“Recommendations for Preventing

Transmission of Infections Among Chronic Hemodialysis Patients’), concerning isolation rooms, must be complied with by February 9, 2009.

(ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

(2) The “Guidelines for the Prevention of Intravascular Catheter-Related Infections” entitled “Recommendations for Placement of Intravascular Catheters in Adults and Children” parts I–IV; and “Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients,” Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal-register/code\\_of\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code_of_regulations/ibr_locations.html).

(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight.* The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

(3) Require all clinical staff to report infection control issues to the dialysis facility’s medical director (see § 494.150 of this part) and the quality improvement committee.

(c) *Standard: Reporting.* The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

**§ 494.40 Condition: Water and dialysate quality.**

The facility must be able to demonstrate the following:

(a) *Standard: Water purity.* Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, “Dialysate for hemodialysis,” ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal-register/code\\_of\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code_of_regulations/ibr_locations.html). Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(b) *Standard: Chlorine/chloramines.* (1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal;

(2)(i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then