



*The Florida ESRD Network*

# Criteria & Standards for Quality of Care in Florida Hemodialysis Facilities

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Adopted by FMQAI: May 2004  
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## DOCUMENT CONTROL

### Document Information

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<i>1.4</i>	<i>12-5-2007</i>	<i>Document revision: Table of Contents, Disclaimer, Food and Drink in the Dialysis Unit</i>
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### Document Approvals

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Executive Director	Martha Hanthorn, MSW	<i>Martha Hanthorn, MSW</i>	11-14-11

## Preface

On May 11, 2004, FMQAI: The Florida ESRD Network's Medical Review Board adopted the Network 7 Criteria & Standards for use in Florida dialysis facilities. Following the release of the updated Conditions for Coverage, which were published to the Federal Register in October 2008, Network 7 has revised the Criteria & Standards. Please visit [www.cms.hhs.gov/center/esrd.asp](http://www.cms.hhs.gov/center/esrd.asp) to view the federal regulations.

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## History

*The Criteria & Standards were originally developed by the Standards Task Force of the Medical Review Board of the ESRD Network of Florida (previous Network 7 contractor) to assist ESRD health care givers in providing a high quality of treatment to patients in their units.*

### **1992 Standards Task Force**

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## RESOURCES:

Centers for Medicare & Medicaid Services (CMS)  
7500 Security Boulevard  
Baltimore, MD 21244  
(800) 633-4227  
[www.cms.hhs.gov](http://www.cms.hhs.gov)

Association for the Advancement of Medical Instrumentation (AAMI)  
1110 North Glebe Road, Suite 220  
Arlington, VA 22201-4795  
(703) 525-4980  
[www.aami.org](http://www.aami.org)

National Fire Protection Association  
1 Batterymarch Park  
Quincy, MA 02169-7471  
(617) 770-3000  
[www.nfpa.org](http://www.nfpa.org)

Occupational Safety & Health Administration (OSHA)  
200 Constitution Avenue  
Washington, DC 20210  
(800) 321-6742  
[www.osha.gov](http://www.osha.gov)

Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road  
Atlanta, GA 30333  
(800) 232-4636  
[www.cdc.gov](http://www.cdc.gov)

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**TOPIC: APPROPRIATENESS OF INITIATION OF ESRD CARE**

SAMPLE: All patients who are entering a maintenance dialysis program

**CRITERIA**

**STANDARD**

**100%**

The medical record shall indicate that the patient has been evaluated by a physician on staff of a Medicare approved dialysis facility. Such evaluation shall include, but is not limited to, documentation of:

1. Diagnosis (primary cause of renal failure using ICD code terminology; uremia, ESRD or CRF alone are not acceptable);
2. Permanence or irreversibility of renal failure - This is defined as, "that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life." The Network recognizes the rare occurrence of recovery of renal function in this situation, and considers that such patients fit the Medicare definition of ESRD;
3. Age, sex, weight and height;
4. In absence of laboratory values congruent with ESRD, the provider must maintain sufficient documentation within the medical record to justify the initiation of dialysis.

**Non-diabetic patients – one of following:**

- a. MDRD GFR (glomerular filtration rate) < 10 ml/min
- b. Estimated GFR: 24 hour urine for urea clearance + creatinine clearance/2 = <10 ml/min
- c. Cockcroft-Gault < 10 ml/min
- d. 24 hour urine creatinine clearance < 10 ml/min

**Diabetic patients – one of following:**

- a. MDRD GFR < 15 ml/min
- b. Estimated GFR: 24 hour urine for urea clearance + creatinine clearance/2 = < 15 ml/min
- c. Cockcroft-Gault < 15 ml/min
- d. 24 hour urine creatinine clearance < 15 ml/min

**Special Note: Regular assessment of the ongoing need for continued dialysis should be maintained throughout the course of the renal replacement treatment.**

**TOPIC: VACCINATION SCREENING FOR PATIENTS**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

Vaccinations should be offered to prevent the spread of diseases within the facility. The ESRD facility shall have a written policy under which all appropriate patients are informed of the advisability and local sources of the currently recommended protocols for the following vaccinations, including, but not limited to:

1. Hepatitis B
2. Pneumococcal Pneumonia Vaccine
3. Influenza
4. Pediatric vaccinations

The ESRD facility shall directly provide the following Vaccines to consenting, eligible patients:

1. Hepatitis B
2. Pneumococcal Pneumonia
3. Influenza

The ESRD facility shall document acceptance / refusal and administration of immunizations in the patient medical record.

The ESRD facility shall maintain a Hepatitis Surveillance Log for all patients.

**TOPIC: VOCATIONAL REHABILITATION (VR)**

**SAMPLE:** All Medicare Certified Dialysis Providers

**SUBSAMPLE:** All ESRD patients initiating a regular course of therapy (hemodialysis, peritoneal; in-center, home) or receiving a transplant (deceased or living donor)

**CRITERIA**

**STANDARD**

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**100%**

Each patient between 18 and 54 years of age shall be evaluated annually for VR referral, which shall be documented in the patient's medical record.

Each provider shall identify and make available to patients the vocational rehabilitation resources obtainable in the area, including work incentive programs and long-term benefits of continued employment / going back to school.

**TOPIC: PATIENT GRIEVANCES**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

In an effort to ensure that patients are aware of their right to file a grievance, the provider shall:

1. Document that patients have been informed of their rights and responsibilities, including the right to file a grievance (internally, or externally to Network 7) and,
2. Post a copy of Network 7's contact information in a prominent location in the unit.

**TOPIC: SAFE AND EFFECTIVE DIALYSIS TREATMENT**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

Intradialytic Monitoring:

1. The unit shall conduct pre-assessment measurements of each patient, to include blood pressure, temperature, weight and pulse.
2. Where possible, temperature and standing and sitting blood pressure readings, following dialysis treatment, shall be taken for each patient.
3. Assessment and monitoring shall be performed and documented on the treatment record of a patient's condition at least every 30 minutes. The following minimum criteria should be included:
  - Patient's blood pressure and pulse,
  - Inspection of the vascular access to note blood loss or leakage, and
  - Negative pressure, blood flow rate and venous resistance.

## TOPIC: FACILITY STAFFING

SAMPLE: All Medicare Certified ESRD Providers

### CRITERIA

### STANDARD

**100%**

Staffing levels should be commensurate with providing the care outlined in the Conditions for Coverage.

There shall be at least one nurse or clinical technician for each four adult patients undergoing treatment (exclusive of self care units).

In an ongoing effort to provide quality care and ensure patient safety, please consider the following when developing staffing guidance for nurses, social workers and dietitians:

- Experience level of staff
- Size of the facility
- Type of patients: geriatric, pediatric, home, self-care
- Co-morbidities
- Location of facility (rural vs. urban)
- Admission rate of new patients

Pediatric units will need to observe the following:

1. For a patient weighing less than 10kg/22 lb.: 1 to 1 nursing care and size-appropriate equipment for dialysis (dialyzer and blood-lines), as well as the equipment needed for continuous monitoring of weight and vital signs, including, but not limited to, cardiac monitor, automatic doppler blood pressure equipment, continuous readout scales and/or automatic ultra-filtration control.
2. A patient weighing between 10 and 20 kg/22 and 44 lb.: 1 to 2 nursing care and size-appropriate equipment for dialysis (dialyzer and bloodlines), as well as the equipment needed for continuous monitoring of vital signs in (a) above and continuous readout scales or automatic ultra-filtration control.

**TOPIC: AVAILABILITY OF NUTRITIONAL SERVICES IN ESRD**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

The renal dietitian will be qualified to provide the level of expertise required to deal with the nutritional complications of renal disease in the outpatient dialysis setting:

The renal dietitian has at least one year's renal experience or has trained for at least 120 hours with supervision by an experienced renal dietitian who has worked in renal dietetics for at least 1 year. This shall be achieved within six months of employment.

**TOPIC: AVAILABILITY OF SOCIAL WORK SERVICES IN ESRD**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

The ESRD patient will have assistance to develop coping skills necessary to adjust to his / her chronic illness:

1. Social Services will be available to all patients on a weekly basis.
2. The social worker will serve as a patient advocate and will facilitate communications between patients and facility administration / staff.

Social workers practicing in a dialysis unit in the state of Florida must be licensed at the level of an LCSW. If a social worker is license eligible, they may still practice, but must be registered as an intern, and be under the clinical supervision of a qualified LCSW supervisor in a structured and consultative relationship. Supporting documentation regarding this supervision must be available for review.

**TOPIC: PHYSICAL ENVIRONMENT**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

The facility shall meet the Federal, state , local and Network conditions and standards set forth for physical environment, including at least those conditions for physical structure of the individual patient care area, defined as:

The space containing the dialysis machine and the patient chair, shall have a seven feet (7') linear separation between individual patient care areas, as measured from the center of the area occupied by the dialysis machine and chair to the center of the adjacent area containing a machine and chair to allow access for privacy, and emergency care and treatment. Sufficient space should exist between patient stations to allow for patient access and easy cleaning of the dialysis machines.

**TOPIC: OPEN STAFFING PRIVILEGES**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

The facility shall have a written policy which assures open staffing privileges to the area's qualified ESRD physicians.

**TOPIC: ACCESS TO TREATMENT**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

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**100%**

All Medicare certified ESRD providers shall provide access to treatment for all Medicare patients regardless of their race, color, creed, national origin, ethnicity or disability within the meaning of Section 504 of the Rehabilitation Act of 1973.

**TOPIC: FOOD AND DRINK IN THE DIALYSIS UNIT**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

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**100%**

Patients shall be allowed to have food and drink during dialysis unless it is medically contraindicated. Medical contraindication is determined by the treating nephrologist, medical director and/or governing body of the facility.

**TOPIC: NOCTURNAL DIALYSIS**

SAMPLE: All Medicare Certified ESRD Providers

**CRITERIA**

**STANDARD**

**100%**

At a minimum the provider must have policies and procedures that address the following:

1. Definition of nocturnal dialysis
2. Admission criteria
3. Role responsibilities and qualifications
4. Staff training
5. Infection control
6. Medical director oversight
7. Defined standards for:
  - a) Anemia
  - b) Adequacy
  - c) Hospitalizations/Missed Treatments
  - d) Mortality
  - e) Access
8. Back up and emergency plans
9. Machine monitoring
10. Water monitoring
11. Reuse procedures, if applicable

At a minimum, there shall be at least one licensed, registered nurse on duty and physically on the premises for each patient shift. There shall be at least one nurse or clinical technician for each four adult patients undergoing treatment.

To ensure patient safety, the facility should have a policy in place to address lighting in the facility. (Lighting shall be adequate so that patients undergoing treatment may be observed.)

# PERFORMANCE GUIDELINES FOR CLINICAL OUTCOMES

## Hemodialysis

**Purpose:** The purpose of the guidelines is to provide guidance in establishing suitable provider delivery of dialysis care to patients on chronic dialysis therapy.

**Applicability:** Dialysis providers serving adult ( $\geq 18$  years old) **hemodialysis** patients.

**Data source:** Lab Data Collection - 4<sup>th</sup> quarter 2010.

Clinical Indicator	Network 7 Goal	Notes
<i>Each provider should strive to attain and subsequently maintain...</i>		
<b>Adequacy</b>		
Kt/V $\geq 1.2$	96.0%	Percentage of patients having Kt/V $\Rightarrow 1.2$
<b>Anemia</b>		
HGB 10 – 12mg/dl	70%	Percentage of patients having Hgb between 10-12
HGB < 10mg/dl	8%	Percentage of patients having Hgb less than 10
% Saturation $\Rightarrow 20$	88%	Percentage of patients having %TSAT equal or greater than 20
<b>Nutrition &amp; Bone Mineral Metabolism</b>		
Albumin (BCG/BCP) >3.5/3.2g/dL	87%	Percentage of patients having Albumin greater than 3.5/3.2
Albumin (BCG/BCP) >4.0/3.7g/dL	43%	Percentage of patients having Albumin greater than 4.0/3.7
Phosphorus 3.5 – 5.5mg/dL	55%	Percentage of patients having PO4 between 3.5-5.5
Calcium 8.4 – 10.2mg/dL	85%	Percentage of patients having CA between 8.4-10.2
<b>Vascular Access</b>		
AVF	60%	Percentage of patients having AVF in use
Catheter only $\geq 90$ days	$\leq 10\%$	Percentage of patients with CVC only equal or greater than 90days