



The Florida ESRD Network

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

Established: January 1993

Adopted by FMQAI: May 2004

“Draft” Revision: February 2010

5201 West Kennedy Boulevard, Suite 900

Tampa, Florida 33609

(813) 383-1530 ♦ (813) 354-1514 FAX

Table of Contents

DOCUMENT CONTROL	2
DOCUMENT INFORMATION.....	2
DOCUMENT HISTORY.....	2
DOCUMENT APPROVALS.....	2
PREFACE	3
RESOURCES	4
APPROPRIATENESS OF INITIATION OF ESRD CARE	5
VACCINATION SCREENING FOR PATIENTS	6
VOCATIONAL REHABILITATION	7
PATIENT GRIEVANCES	8
SAFE AND EFFECTIVE DIALYSIS TREATMENT	9
FACILITY STAFFING	10
AVAILABILITY OF NUTRITIONAL SERVICES IN ESRD	11
AVAILABILITY OF SOCIAL WORK SERVICES IN ESRD	12
PHYSICAL ENVIRONMENT	13
OPEN STAFFING PRIVILEGES	14
ACCESS TO TREATMENT	15
FOOD AND DRINK IN THE DIALYSIS UNIT	16
NOCTURNAL DIALYSIS	17
NETWORK CLINICAL PERFORMANCE GOALS	18

DOCUMENT CONTROL


Document Information

	Information
Document Owner	<i>FMQAI: The Florida ESRD Network</i>
Document Type	Network 7 Criteria & Standards
Release Number	1.5
Release Date	2-1-2010

Document History

Version	Issue Date	Changes
<i>1.0</i>	<i>1992</i>	<i>Document creation</i>
<i>1.1</i>	<i>1998</i>	<i>Document revision</i>
<i>1.2</i>	<i>4-1999</i>	<i>Document revision: Appropriateness of ESRD Care, Vaccination Screening for Patients, Provider Continuous Quality Improvement, Safe and Effective Treatment, Availability of Nutritional Services in ESRD, Availability of Social Work Services in ESRD</i>
<i>1.3</i>	<i>2004</i>	<i>Document re-adoption</i>
<i>1.4</i>	<i>12-5-2007</i>	<i>Document revision: Table of Contents, Disclaimer, Food and Drink in the Dialysis Unit</i>
<i>1.5</i>	<i>2-1-2010</i>	<i>Draft document revision to coincide with release of updated Conditions for Coverage</i>

Document Approvals

Role	Name	Signature	Date
Project Director	Kelly M. Mayo, MS		2-1-2010

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.gov/center/esrd.asp to view the federal regulations.

2010 Criteria & Standards Committee

Jeffrey Sands MD, MMM, Chairperson	Elizabeth Howard RN, CNN
Arif Asif MD	Norma Gomez RN, BSN, MBA, CNN
Mark Russo MD, PhD	Pran Kar MD
Catherine Barnett LCSW	Deborah Kostner RN
Maryann Blanchard RN	Candace Magiera
Victor Bowers MD	Jesus Navarro MD
Linda Carroll RN	M. Ramachandran MD
Lisa Chambers RN	Lisa Goodwin LCSW
Constance Cieszynski MS, RD	Ignacio Sotolongo MD, Vice Chairperson
Debbie Gliddon MSN, ARNP	Nayana Yyas MD
Delia Jervier, Patient	

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

Pauline Chusid MD, Chairperson
Lawrence Dewberry MD
Sadalia Gross RN
Anne Hetrick RD
Lucy Huyke-Garner PhD, LCSW
Vicki Kimmitt, Consumer
Maureen Michael, RN
Elizabeth McKay RN
Charlie Rodriguez, Consumer
Mark Zawiski MBA
Alphonso Campos MD, Special Advisor

1998 Standards Task Force

M. Ramachandran MD, Chairperson
Cathy Barnett MSW, LCSW
David Bobish RN
Thomas Braxton MD
Connie Cieszynski MS, RD, CS, LD
Norma Gomez MBA, RN, CNN
Elizabeth Howard RN, CNN
Maureen Michael RN, MBA
Hank Michael
Charlie Rodriguez, Consumer
Stephen Wojcechowskyj, Jr., Consumer
Mark Zawiski MBA

Published by FMQAI: The Florida ESRD Network and sponsored by the Centers for Medicare and Medicaid Services under Contract # HHSM-500-2006-NW007C as a resource for the professional renal community in Florida.

RESOURCES:

Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244
(800) 633-4227
www.cms.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

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

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

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

FMQAI: The Florida ESRD Network
5201 West Kennedy Boulevard, Suite 900
Tampa, FL 33609
(813) 383-1530
www.fmqai.com/esrd.aspx

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

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%

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

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

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

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.)

TOPIC:CLINICAL PERFORMANCE GOALS FOR ADULT HEMODIALYSIS & PERITONEAL DIALYSIS PATIENTS*

SAMPLE: All Medicare Certified ESRD Providers

<u>Indicator</u>	<u>Goal</u>	<u>Notes</u>
<u>Adequacy</u>		
Kt/V \geq 1.2 - HD; $>$ 1.7 - PD	96.1% 94.0%	Percentage of patients having Kt/V \Rightarrow 1.2 Percentage of PD patients having Kt/V \Rightarrow 1.7
URR \geq 65%	95.5%	Percentage of patients having URR \Rightarrow 65%
<u>Anemia</u>		
Hgb $<$ 10g/dL	3.8%	Percentage of patients having Hgb less than 10
% Saturation \geq 20	84.9%	Percentage of patients having %TSAT equal or greater than 20
Ferritin \geq 100 & \leq 1000ng/ml	85.6%	Percentage of patients having Ferritin equal or greater than 100 & equal or less than 1000
<u>Nutrition & Bone Mineral Metabolism</u>		
Albumin (BCG/BCP) $>$ 4.0/3.7g/dL	39.1%	Percentage of patients having Albumin greater than 4.0 / 3.7
Albumin (BCG/BCP) $>$ 3.5/3.2g/dL	86.0%	Percentage of patients having Albumin greater than 3.5 / 3.2
Calcium \leq 10.2mg/dL	97.3%	Percentage of patients having Calcium equal or less than 10.2
Calcium \leq 9.5mg/dL	73.0%	Percentage of patients having Calcium equal or less than 9.5
Phosphorus \leq 5.5mg/dL	61.0%	Percentage of patients having PO4 equal or less than 5.5
<u>Vascular Access</u>		
AVF	66%	Percentage of patients having AVF in use
Catheter only $>$ 90 days	\leq 10%	Percentage of patients with CVC only equal or greater than 90days

*The Network goals will be updated annually, and will be based on the most current data available. Providers should consider goals reflected in the Measures Assessment Tool (MAT), as the minimum standard of care. If facility outcomes are below the Network goals, a quality improvement plan(s) should be in place to address deficiencies. *Per the Network / Provider Memorandum of Understanding: providers will "meet Network goals and participate in the activities of the Network, including data collection, quality improvement activities, and special studies."*