

*The Florida ESRD Network (Network 7)*

# **Clinical Performance Guidelines and Standards of Care for Florida Dialysis Facilities**

**2018 | V. 6.0**

# TABLE OF REVISIONS

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The contents of this plan are subject to change without prior notice. Should revisions become necessary, written updates will be distributed to Network staff for inclusion in the plan. The Quality Improvement Director is responsible for updating the *Clinical Performance Guidelines and Standards of Care*; however, all staff are responsible for updating and knowing the actions/activities within their areas of responsibility, keeping them current, and being familiar with their content. The Network Executive Director shall ensure that all staff members are updated and current on the *Clinical Performance Guidelines and Standards of Care*.

When inserting revisions to this plan, the person revising the document shall complete the table below.

Revision #	Date	Section, Page(s)	Change	Revised By
1.0	January 1993	Initial Publication		The ESRD Network of Florida
2.0	May 2004	Updated document		FMQAI: The Florida ESRD Network
3.0	August 2011	Updated document		Network 7 staff, Medical Review Board (MRB)
4.0	February 2015	Revised Overall	Updated standards and clinical guidelines	Network 7 Quality Improvement (QI) Staff, MRB
5.0	May 2016	Standards	Updated to add Infection Control and Experience of Care.	Network 7 QI Staff, MRB
6.0	August 2018	Updated document	Updated standards and clinical guidelines	Network 7 QI staff, MRB

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# CLINICAL PERFORMANCE GUIDELINES

## OVERVIEW

A primary goal of Network 7 is to improve the quality of healthcare services provided to end stage renal disease (ESRD) patients. The Network's Medical Review Board (MRB) adopted the following revised Network Clinical Performance Guidelines in August 2018, to align with the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, ESRD Conditions for Coverage Measures Assessment Tool (MAT 2.5), and the ESRD Quality Incentive Program (QIP) measures.

The objective of these clinical guidelines is to provide guidance for dialysis providers to attain specific clinical outcomes for their adult ( $\geq 18$  years old) patient populations on chronic dialysis.

The Condition for Patient Plan of Care (V540) reviews individual patient outcome data and addresses the goals and plans set for individual patients. When a specific target is not met, the plan of care (POC), revised after each patient assessment, should either be adjusted to achieve the target or provide an explanation in areas where the targets are not able to be achieved.

## CLINICAL GUIDELINES

ESRD-specified clinical outcomes include:

- **Hemodialysis Adequacy**

Each provider should strive to attain and subsequently maintain a:

- Hemodialysis patient population achieving a spKt/V levels of  $\geq 1.2$ .

- **Peritoneal Dialysis Adequacy**

Each provider should strive to attain and subsequently maintain a:

- Peritoneal dialysis patient population achieving a weekly Kt/V urea of 1.7 (dialytic + residual) during a four-month period.

- **Anemia Management**

Each provider should strive to attain and subsequently maintain a:

- Dialysis patient population (on dialysis for  $\geq 90$  days), on erythropoiesis stimulating agent (ESA), achieving Hgb levels less than 12 gm/dl.
- Dialysis patient population achieving T-Sat levels of  $\geq 25$ .

- **Nutrition Management**

Each provider should strive to attain and subsequently maintain a:

- Hemodialysis patient population achieving serum albumin (ALB) level of  $\geq 3.5$  gm/dL (BCG) with the optimal goal of  $\geq 4.0$  gm/dL (BCG).

- **Mineral Metabolism**

Each provider should strive to attain and subsequently maintain a:

- Dialysis patient population achieving serum phosphorous levels between 3.5 and 5.5 mg/dl.
- Dialysis patient population achieving uncorrected calcium levels less than 10.2 mg/dl.

- **Vascular Access Management**

Each provider should strive to attain and subsequently maintain a:

- Facility long-term catheter ( $\geq 90$  days) rate of less than 10%.
- Facility arteriovenous fistula rate of  $\geq 68\%$ .

## STANDARDS OF CARE

### OVERVIEW

The Network 7 Standards of Care were revised to address appropriate delivery of care and facility requirements. These standards include quality statements that describe the care patients should be offered and define facility requirements to assist all Medicare-certified ESRD programs in providing a high quality of treatment to their patients.

The Network 7 MRB adopted the revised Standards of Care on August 3, 2018.

## STANDARDS

### 1. Appropriateness of Initiation of ESRD Care

For all patients entering a maintenance dialysis program, 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:

- Diagnosis
  - Primary cause of renal failure using Internal Classification of Diseases (ICD) code terminology such as uremia, ESRD, or chronic renal failure (CRF) alone are not acceptable
- 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.

- Age, sex, weight, and height

In absence of laboratory values congruent with ESRD, the provider must maintain sufficient documentation within the medical record to justify the initiation of dialysis, including for:

- **Non-diabetic patients**, *one* of following:
  - MDRD GFR (glomerular filtration rate) < 10 ml/min
  - Estimated GFR:
    - ✓ 24-hour urine for urea clearance + creatinine clearance/2  $\leq$  10 ml/min
    - ✓ 24-hour urine creatinine clearance < 10 ml/min.
    - ✓ Uremic Symptoms
- **Diabetic patients**, *one* of following:
  - MDRD GFR < 15 ml/min
  - Estimated GFR:
    - ✓ 24-hour urine for urea clearance + creatinine clearance/2  $\leq$  15 ml/min
    - ✓ 24-hour urine creatinine clearance < 15 ml/min
    - ✓ Uremic Symptoms

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

### 2. Infection Control

- Every facility should have policies and procedures related to the prevention and management of healthcare-associated infections (HAIs), to include:
  - The training of staff and education of patients regarding:
    - Prevention measures
    - Identification and treatment of infections at the facility.

- Use of the [Centers for Disease Control and Prevention \(CDC\) Core Interventions for Dialysis Bloodstream \(BSI\) Prevention](#) and CDC training resources and tools.
- Infection control and patient safety issues should be continuously reported and discussed in Quality Assessment Process Improvement (QAPI) meetings.
  - Actions taken to address these issues should be documented.
  - Records of infection tracking should be a part of the facility’s QAPI program.
- The Centers for Medicare & Medicaid Services (CMS) and the Network recommend all in-center dialysis facilities report dialysis events in the National Healthcare Safety Network (NHSN) per the Dialysis Event Protocol.
- All dialysis facilities, including home units, also need to follow the guidelines and procedures for reporting in the Vaccination Module of the Healthcare Personnel Safety Component.

### **3. Vaccination Screening for Patients**

Every ESRD facility must:

- Have a written policy under which the currently-recommended vaccines and local sources are presented to all eligible patients. The recommended vaccinations for people on dialysis include, but are not limited to:
  - Hepatitis B
  - Pneumococcal pneumonia
  - Influenza
  - Pediatric
- Document acceptance/refusal and administration of vaccinations in the patient medical record and CMS-designated data collection system known as CROWNWeb.
  - CROWNWeb stands for Consolidated Renal Operations in a Web-Enabled Network.
- Maintain a Hepatitis Surveillance Log for all patients.

### **4. Vocational Rehabilitation (VR)**

- All ESRD patients between 18 and 54 years of age, receiving a regular course of renal replacement therapy or receiving a transplant, shall be evaluated annually for VR referral, which shall be documented in the patient's medical record.
- Each provider shall identify and provide patients with the VR resources available in the geographic area, including work incentive programs.
- Facility staff will reinforce the long-term benefits of continued employment and/or going back to school.

## 5. Patient Grievances

In an effort to ensure that patients are aware of their right to file a grievance, facilities must have written policies and procedures regarding how:

- The facility will receive and address patient grievances:
- Patients can file grievances anonymously.

Each step of the grievance process should be documented. Facilities must:

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

## 6. Patient Experience of Care

Facilities should encourage patients to complete the In-Center Hemodialysis Consumer Assessment of Healthcare Providers Survey (ICH CAHPS).

- ICH CAHPS results shall be analyzed at the facility level.
  - Action plans will be developed and implemented with a focus on improving the patient experience of care. Providers are encouraged to:
    - Obtain patient feedback in the development of action plans.
    - Ensure ICH CAHPS results and action plans are shared with patients.
    - Ensure ICH CAHPS results and action plans are monitored through the facility QAPI process.

## 7. Safe and Effective Dialysis Treatment

### **Intradialytic Monitoring:**

- Whenever applicable, the unit shall conduct pre- and post-assessments of each patient, to include standing and sitting blood pressure, temperature, weight, and pulse.
- Assessment and monitoring of a patient's condition shall be performed and documented on the treatment record 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.
    - Arterial and venous pressures, and blood flow rate.
- Any results outside normal limits should be reported to the charge nurse immediately and patients should be directed, as indicated, to the appropriate level of care for evaluation.

### **Ultrafiltration Rate (UFR) Monitoring:**

The Network recommends facilities maintain an average Ultrafiltration Rate (UFR) of <13 ml/kg/hr for all patients. Any diversions from this recommendation should include an order from the nephrologist and documentation that the patient has been educated regarding the risks of large and rapid fluid removal during hemodialysis treatment.

## 8. Facility Staffing

Staffing levels should be commensurate with providing the care outlined in the Conditions for Coverage (CfCs). There shall be at least one nurse or clinical technician for each four adult patients undergoing treatment.

In an ongoing effort to provide quality care and ensure patient safety, facilities should 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 special requirements for staffing/equipment:

- For a patient weighing less than 10kg/22 lb.:
  - One-to-one nursing care.
  - Size-appropriate equipment for dialysis.
    - Dialyzer and blood-lines.
  - 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.
- For a patient weighing between 10 and 20 kg/22 and 44 lb.:
  - One-to-two nursing care.
  - Size-appropriate equipment for dialysis, including:
    - Dialyzer and bloodlines.
    - Equipment needed for continuous monitoring of vital signs.
    - Continuous readout scales or automatic ultra-filtration control.

## 9. Provision of Nutritional Services in ESRD

The evaluation of each patient's nutritional status must be conducted by a qualified renal dietitian. 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.
- Have at least one year's renal experience or have trained for at least 120 hours with supervision by an experienced renal dietitian who has worked in renal dietetics for at least one year.
  - This shall be achieved within six months of employment.

## 10. Provision of Social Work Services in ESRD

- All ESRD patients will have assistance offered to develop the coping and disease management skills necessary to adjust to his or her chronic illness.
- Social services will be available to all patients on a weekly basis.
- 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 a Licensed Clinical Social Worker (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.

## 11. Physical Environment

The facility shall meet the federal, state, local, and Network conditions and standards set forth for physical environment, including, at a minimum, the conditions for the physical structure of the individual patient care area. The patient area shall be defined as the space containing the dialysis machine and the patient chair, which shall have:

- A seven-foot 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.
    - This will provide privacy and access for emergency care and treatment.
    - Sufficient space should exist between patient stations to allow for patient access and thorough cleaning of the dialysis machines.

**Important Note:** Per CDC recommendations, and to prevent cross contamination, the facility should ensure the dialysis station has been fully vacated by the current patient prior to cleaning and disinfecting the station for the next patient.

## 12. Open Staffing Privileges

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

## 13. Access to Treatment

All Medicare-certified ESRD providers shall provide access to treatment for patients regardless of their race, color, religion, national origin, age, sex, familial status, sexual orientation, gender identity, disability, or veteran status per Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Dialysis facilities must:

- Work to maintain patients in a chronic outpatient dialysis setting, regardless of treatment or other related compliance issues, in an attempt to avoid patients having to use a hospital emergency room for chronic dialysis.
- Work with patients, nephrologists, and the facility Medical Director to avoid involuntary discharges from the facility when a nephrologist discharges a patient from their physician practice.
  - All attempts to address issues related to the physician discharge with the patient must be documented in the patient's medical record.
- Establish policies and procedures for admitting patients to the facility.
  - Any patient that meets the requirements of the facility admission policy should be considered, even if a patient has documented compliance issues.
    - A process should be in place to work with non-compliant patients to improve compliance rather than blacklisting non-compliant patients altogether.
      - ✓ e.g., Facilities should conduct root-cause-analysis (RCA), provide educational resources, involve the Social Worker, involve the Insurance Specialists, etc.

## 14. Food and Drink in the Dialysis Unit

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.

## 15. Data Submission Compliance

All Medicare-certified ESRD providers shall strive to attain and maintain 100% compliance for the following data reporting:

- CROWNWeb
  - All required data should be entered per the [CROWNWeb Data Management Guidelines](#).

- The Network recommends facilities always have at least one administrative and one clinical staff CROWNWeb user to ensure data accuracy and completeness.
- NHSN
  - Facilities can enroll in NHSN [here](#).
- Other CMS-designated data collection systems.

**Important Note:** All facilities identified for inclusion in a Network Quality Improvement Activity (QIA) are required to submit monthly self-reported data per QIA timelines.

## 16. Emergency Preparedness

All Medicare-certified ESRD providers shall have written policies and procedures that specifically define the handling of emergencies which may threaten the health and safety of patients. Such emergencies would exist during natural disaster (e.g., fire or hurricane) or during functional failures in equipment or utilities. Specific emergency preparedness procedures exist for different kinds of emergencies. At a minimum, the provider shall:

- Review and test the emergency preparedness plan, at least annually, and revise as necessary.
- Ensure all personnel are knowledgeable and trained in their respective roles in emergency situations.
- Ensure the availability of emergency medications, medical supplies, and equipment.
- Ensure that staff are familiar with the use of all dialysis equipment and procedures to handle medical emergencies.
- Ensure that patients are trained to handle medical and non-medical emergencies.
  - Patients must be fully informed regarding what to do, where to go, and who to contact if a medical or non-medical emergency occurs.
  - Additional resources related to emergency management for ESRD patients are located on the Kidney Community Emergency Preparedness (KCER) [website](#).
- Complete additional training and testing requirements contained in the CMS [Emergency Preparedness Rule](#).
- Notify the Network as soon as possible, but no later than 24 hours after, any facility status change that may cause the disruption of treatment schedules or any event that requires immediate/emergency actions by the facility, such as rescheduling or placement of patients at a backup provider.
- Provide the facility's open or closed status and patient location updates, at least daily, to the Network during identified emergencies or disasters.
  - This includes before and after a potential tropical storm or hurricane.