

Stage II – Critical Elements for a Resident Who Receives Dialysis Treatments

Facility Name: _____ Facility ID: _____ Date: _____
Surveyor Name: _____
Resident Name: _____ Resident ID: _____
Initial Admission Date: _____ Interviewable: Yes No Resident Room: _____
Care Area(s): _____

Use
Use this protocol for a sampled resident receiving end stage renal disease services such as hemodialysis, peritoneal dialysis or (home dialysis) either in the nursing facility, or offsite in a dialysis unit. NOTE: The Nutrition CE must also be completed. If concerns with Pain are identified, the Pain CE must also be completed.

NOTE: Part 42 CFR §405.2102 defines home dialysis as dialysis performed by an appropriately trained patient at home. CMS has considered LTC facilities as the patient's home for purposes of this benefit. This CE further defines self-dialysis and home dialysis training as programs that train ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis. In order for Medicare payment of home dialysis to be made, the patient must have actively elected to become a home dialysis patient and have completed a training program provided by an approved ESRD facility. Home dialysis is intended to be self-dialysis performed by the patient and/or with the assistance of other individuals, (i.e., a designated family member or caregiver). However, there is the recognition that some Medicare beneficiaries may have physical, developmental, or cognitive limitations that would preclude the patient from completing the required home dialysis training without significant involvement and assistance from other individuals. As a result, for purposes of payment CMS permits the patient to play a secondary or limited role in the dialysis training and service provision in instances where a designated family member or caregiver is present to actively participate.

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Procedure

- Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made.
- Corroborate observations by interview and record review.

NOTE: The LTC facility is responsible for the delivery of care and services to residents before transferring to the ESRD facility or onsite team, and after the resident has received dialysis and is assessed as stable for transfer back to the LTC or LTC facility team.

Observations

- Observe whether staff consistently implement the care plan over time and across various shifts. Staff are expected to assess and provide appropriate care from the day of admission. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes.
- Observe and interview residents, staff, and/or family to determine whether home dialysis is being provided in the facility, and document any facility practices that appear questionable. Observe locations for the storage of dialysis equipment (in resident's room or on the unit). For identified concerns, share information with team members and add selected residents to the sample.
 - If residents, family, or staff voice concerns about the provision of care to residents during the home dialysis procedure, or if you identify concerns through your investigations related to the care of the resident during dialysis, identify the involved resident(s), specific issues, and copy pertinent documents in the resident(s) record pertaining to the concerns.
 - Notify the SA and file a complaint against the ESRD facility for review by the ESRD survey team.
- For all residents receiving dialysis, observe whether staff consistently implement the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes, including but not limited to the following:

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Observations	
<ul style="list-style-type: none"> ▪ Exhibited signs or symptoms of pain. If yes, complete the Pain CE; ▪ Knowledge of proper infection control procedures; ▪ Care needed and provided for shunts/fistulas, dressings, nutritional/fluid needs and restrictions; ▪ Room accommodations including necessary equipment and access to call light; and ▪ Knowledge of emergency complications such as equipment failure, alarm systems (if any) and identifying complications such as bleeding/hemorrhage, infection, bacteremia, septic shock. 	
Resident/Representative Interview	
<p>Interview the resident, family or responsible party to the degree possible to identify:</p> <ul style="list-style-type: none"> <input type="checkbox"/> The resident's/representative's involvement in the development of the care plan, defining the approaches and goals, and if interventions reflect choices and preferences; <input type="checkbox"/> The resident's/representative's awareness of specific procedures and services provided and if according to the care plan; <input type="checkbox"/> Knowledge of restrictions, such as foods, fluids; <input type="checkbox"/> Knowledge of type of dialysis, care required such as dressings, monitoring of weights and vital signs; <input type="checkbox"/> Awareness of complications and signs and symptoms to bring to staff attention; and <input type="checkbox"/> If interventions are refused, whether counseling on alternatives, consequences, and/or other alternative approaches was offered. 	<p>Notes:</p>

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Staff Interviews	
<p>Interview staff on various shifts to determine:</p> <ul style="list-style-type: none"><input type="checkbox"/> Knowledge of treatment and procedures, including facility-specific guidelines/protocols and specific interventions for the resident;<input type="checkbox"/> Whether nursing assistants know what, when and to whom to report possible complications or changes in condition;<input type="checkbox"/> Whether the nurse monitors for the implementation of the care plan, effectiveness of the plan, and any changes in the resident's condition; and<input type="checkbox"/> What information is obtained from the dialysis center, how the information is communicated between the facility and the dialysis center, how often the communication takes place, and where communication is recorded (e.g., labs, vital signs).	<p>Notes:</p>

NOTE: Home dialysis services — many residents will not be able to independently participate in the dialysis process and will require the ESRD facility/DME supplier to assign a caregiver/technician.

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Interviews with Residents, Families/Responsible Parties, LTC Facility Staff, and Medical Record Review

Determine through interview with residents, families/responsible party, LTC facility staff and medical record review whether:

- The LTC and ESRD/DME provider coordinated the home dialysis care to ensure that the resident and/or family was informed of the resident's suitability for home dialysis and the role of the ESRD facility staff including the assigned caregiver/technician; and
- The ESRD facility staff documented that the resident or family/responsible party was given explanations of the benefits, reasonable risks of the home dialysis treatment, and any related charges for services not covered by Medicare.

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Assessment	
<p><input type="checkbox"/> Review the MDS, history and physical for medically defined conditions and prior medical history; physician orders; notes from dialysis service providers; whether off and/or onsite; social service notes; consults; treatment records; and any progress notes.</p> <p><input type="checkbox"/> Determine whether the assessment information accurately and comprehensively reflects the status of the resident for:</p> <ul style="list-style-type: none">▪ Medical status including vital signs (i.e., blood pressure) and if this information is communicated to the facility staff, if assessment is off site;▪ Psychosocial needs (e.g., spiritual needs, comfort needs, relationship issues and response to special equipment alarms, etc.); and▪ Risk factors and potential complications related to dialysis and end stage renal disease, such as potential for bleeding, alteration in fluid volume, potential for infection, alteration in nutrition, alteration in skin integrity and the effect of dialysis on medication therapy.	<p>Notes:</p>
<p>1. Did the facility assess to determine the care needed for the dialysis resident? <input type="checkbox"/> Yes <input type="checkbox"/> No F272</p>	
<p><i>The comprehensive assessment is not required to be completed until 14 days after admission. For newly admitted residents, before the 14-day assessment is complete, the lack of sufficient assessment and care planning to meet the resident's needs should be addressed under F281.</i></p> <p><i>NOTE: The facility may have completed a 5-day assessment for the Medicare beneficiary. Use the 5-day assessment as the comprehensive assessment only if it was completed with the RAPS.</i></p>	

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Care Planning

- Determine whether the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and current standards of practice, and included measurable objectives and timetables, with specific interventions related to dialysis services and end stage renal disease.
- If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol and should clarify any deviations from or revisions to the protocol for this resident. The treatment protocol must be available to the caregivers and staff should be familiar with the protocol requirements. If care plan interventions that address aspects of dialysis services and management of end stage renal disease are integrated within the overall care plan, the interventions do not need to be repeated.
- Review the care plan to determine whether the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine whether the plan:
 - Addresses risk factors, potential complications and/or specific dialysis related care needs identified during the assessment process including:
 - Special nutritional and fluid volume needs (See the Nutrition CE);
 - Risks for adverse medication effects;
 - Care of the access site;
 - Infection control measures;
 - Skin care measures;
 - Monitoring of vital signs, weights and other monitoring requirements, such as before and after dialysis treatments; and

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Care Planning

- Provides instructions for giving medications (to prevent dialysis treatments removing medication from the resident’s system).
 - Incorporates dialysis center protocols;
 - Is coordinated between the facility and an involved certified dialysis center;
 - Includes supportive and assistive devices/equipment needed to meet needs (such as special mattresses, peritoneal pumps and alarms, shunt catheters, etc.);
 - Addresses/reflects any “Do Not Resuscitate” orders and advance directives; and
 - If the resident refuses or resists dialysis interventions/services, determine whether the care plan reflects efforts to seek alternatives to address the needs identified in the assessment.
- For a resident who is receiving home dialysis, the LTC and ESRD staff are to coordinate the assessment and care planning to ensure that the ESRD and LTC interdisciplinary teams appropriately assessed the resident’s suitability for home dialysis and meet to develop and revise the plan of care, in accordance with the LTC facility regulatory requirements and the individual resident’s needs and preferences. Determine whether:
- The comprehensive care plan was developed by the interdisciplinary teams from both the ESRD and LTC facilities including the physicians, registered nurses, dietitians, social workers, ESRD social worker, ESRD dietitian, the resident, ESRD home dialysis assigned caregiver/technician (if applicable), and family member, or responsible party;
 - The care plan is implemented by qualified staff and the services implemented meet professional standards of quality;

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Care Planning	
<ul style="list-style-type: none"> ▪ The care plan was reviewed and revised based on the resident’s response to home dialysis and outpatient dialysis in accordance with regulatory requirements; and ▪ The LTC facility staff communicate identified concerns with the resident’s nutritional status or psychosocial needs to the ESRD social worker and/or dietitian. <p><input type="checkbox"/> If care plan concerns are noted, interview staff responsible for care planning as to the rationale for the current plan of care.</p> <p>2. Did the facility develop a care plan to meet the needs of the dialysis resident? <input type="checkbox"/> Yes <input type="checkbox"/> No F279</p> <p><i>The comprehensive care plan does not need to be completed until 7 days after the comprehensive assessment (the assessment completed with the RAPS). Lack of sufficient care planning to meet the needs of a newly admitted resident should be addressed under F281.</i></p> <p><i>Additionally, lack of physician orders for immediate care (until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan) should be addressed under F271.</i></p>	

Care and Services Meet Professional Standards	
<p>Interviews with Health Care Practitioners and Professionals: If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident’s condition. If there is a medical question, contact the physician if he/she is the most appropriate person to interview. If the attending physician is unavailable, interview the medical director, as appropriate.</p>	<p>Notes:</p>

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Care and Services Meet Professional Standards

Depending on the issue, ask about:

- How it was determined that chosen interventions were appropriate;
- Risks identified for which there were no interventions;
- Changes in condition that may justify additional or different interventions;
- How staff validated the effectiveness of current interventions;
- Infection control precautions and treatments are monitored (i.e., shunt sites for hemodialysis and catheter sites for peritoneal dialysis);
- Fluid used for dialysis purposes meets quality standards for chemical and/or bacteriological contamination;
- Procedures are identified and implemented so that medications are given timely to prevent dialysis treatments removing medication from the resident's system;
- Staff are aware of potential medication adverse effects, special nutrition needs and environmental conditions needed to provide for the resident's comfort;
- Rates of fluid infusion are set appropriately for peritoneal dialysis;
- Weights and fluid consumption/elimination are monitored;
- Prescribed protocols are followed (such as additives to solution, amount to infuse, and lab values to collect); and
- (If dialysis is provided by an outside entity), care implementation is coordinated between the outside resource and the facility.

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Care and Services Meet Professional Standards	
<p><input type="checkbox"/> For home dialysis, if concerns regarding the provision of care are identified, determine which ESRD/ DME assigned caregiver/technician and licensed health professional has been designated by the ESRD facility to be responsible for the surveillance of the resident(s) during the dialysis treatment and documentation of the resident’s response to dialysis. Determine whether:</p> <ul style="list-style-type: none"> ▪ The facility ensures the availability of sufficient staffing for other residents when home dialysis is provided onsite; ▪ The facility ensures physician supervision of the care for the resident who receives dialysis treatments, physician availability during emergencies and how this is accomplished; and ▪ The facility medical director, along with management staff, has been involved in the development, review and provision of the policies and procedures for care of the residents receiving dialysis. 	
If the resident is receiving Epoetin Alfa (EPO):	
<p>Investigate to determine whether:</p> <p><input type="checkbox"/> The ESRD and LTC facility staff coordinated how hemoglobin and hematocrit lab values are ordered, monitored, and results reported to the physician;</p> <p><input type="checkbox"/> The LTC facility pharmacist or consultant pharmacist reports irregularities of EPO administration and potential drug interaction concerns; and</p> <p><input type="checkbox"/> The ESRD and LTC facility staff have established policies and procedures for the dispensing and storage of EPO.</p>	<p>Notes:</p>

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Care and Services Meet Professional Standards

Environmental issues with home dialysis:

- The resident's room or area used for dialysis has a functioning resident call system or other device to summon help in the event of an emergency.
- The resident's room or designated area in the LTC facility is set up and equipped to afford personal privacy and respect during the home dialysis treatment.

Notes:

Determine through observation and interview, (including, as necessary, a review of training records):

The provision of:

- Clinical monitoring and care of the resident's vascular access (fistula, graft or central venous catheter) and post dialysis complications;
- Clinical monitoring for residents who receive EPO;
- Clinical monitoring and reporting of medication side effects and adverse drug reactions; and
- Identification, monitoring and reporting of nutritional and hydration complications.

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Care and Services Meet Professional Standards	
Infection Control:	
<p>Determine whether disposal of biohazardous waste is provided in accordance with infection control requirements and that:</p> <ul style="list-style-type: none"><input type="checkbox"/> The LTC facility and ESRD staff coordinated the development of infection control practices for the resident receiving home dialysis treatment;<input type="checkbox"/> The policies and procedures were reviewed and approved in collaboration with the LTC management staff and medical director; and<input type="checkbox"/> The LTC facility staff ensure that the ESRD facility staff disposes of biohazardous waste in accordance with the LTC infection control practices and regulatory requirements.	Notes:
Equipment Maintenance:	
<p>Interview and observe to determine and assure that:</p> <ul style="list-style-type: none"><input type="checkbox"/> The ESRD facility is responsible for the maintenance of all dialysis equipment for the resident;<input type="checkbox"/> The LTC facility ensures that there is an emergency electrical system available in the rooms used for dialysis; and<input type="checkbox"/> The plan for an emergency water supply addresses provision of additional water for dialysis treatments.	Notes:

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Care and Services Meet Professional Standards	
<p>3. Did the facility implement practices that meet professional standards of quality? <input type="checkbox"/> Yes <input type="checkbox"/> No F281</p> <p><i>NOTE: If the care plan addressed the risks and identified needs of the resident, but the care plan was not implemented as written, consider F282 for failure to implement the care plan.</i></p>	<p>Notes:</p>
Care Plan Revision	
<p><input type="checkbox"/> Determine whether the staff have been monitoring the resident's response to interventions related to end stage renal disease and dialysis services and have evaluated and revised the care plan based on the resident's response, outcomes, and needs.</p> <p><input type="checkbox"/> Review the record and interview staff for information and/or evidence that:</p> <ul style="list-style-type: none">▪ Staff identify changes in the resident's condition that require revised goals and care approaches; and▪ Appropriate staff disciplines with an understanding of renal dialysis and end stage disease are involved in evaluating outcomes (appropriate staff may include one or more staff from the dialysis facility). <p>4. Did the facility revise the care plan as needed? <input type="checkbox"/> Yes <input type="checkbox"/> No F280</p>	<p>Notes:</p>

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Provision of Care and Services	
<p>Criteria for Compliance with F309, Quality of Care: When determining compliance with regulations that address dialysis needs, the facility is in compliance with these requirements, if staff have:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Recognized and assessed factors related to end stage renal disease and the need for dialysis services; <input type="checkbox"/> Defined and implemented pertinent interventions consistent with resident conditions, goals, and recognized standards of practice; <input type="checkbox"/> Monitored and evaluated the resident’s condition related to end stage renal disease and response to dialysis and related services; and <input type="checkbox"/> Revised the approaches as appropriate. <p>5. Based on observation, interviews, and record review did the facility provide care to meet the needs of the resident receiving dialysis services? <input type="checkbox"/> Yes <input type="checkbox"/> No F309</p>	<p>Notes:</p>

Concerns with Structure, Process, and/or Outcome Requirements Related to Process of Care	
<p>During the investigation of care to meet the needs of the resident receiving dialysis, the surveyor may have identified concerns with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of requirements that should be considered include the following (not all inclusive):</p> <ul style="list-style-type: none"> <input type="checkbox"/> F157, Notification of changes — Determine whether staff notified the physician and/or notified the resident’s representative (if known) of any significant changes in the resident’s condition or a need to alter treatment. <input type="checkbox"/> F164, Privacy — Determine whether staff provided privacy during the provision of dialysis treatments. 	<p>Notes:</p>

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Concerns with Structure, Process, and/or Outcome Requirements Related to Process of Care

- F282, Qualified Staff** — Determine whether in-house dialysis services were provided by qualified staff. If outside dialysis services are provided, determine whether facility staff have a general knowledge of the care and services being provided by the outside resource and an understanding of the expected outcomes of this care. If home dialysis was implemented, determine whether staff were trained in the provision of this service.
- F353, Sufficient Staff** — Determine whether the facility has qualified staff in sufficient numbers to provide necessary care and services, based upon the comprehensive assessment and care plan, to appropriately and adequately manage the end stage renal disease, including receipt of dialysis services according to plan.
- F385, Physician Supervision** — Determine whether the physician has evaluated and addressed, as indicated, medical issues related to the end stage renal disease.
- F425, Pharmacy Services** — Determine whether policies and procedures are established regarding accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals.
- F441 Infection Control** — Determine whether the facility has infection control procedures to address dialysis services and biohazardous wastes.
- F444, Infection Control: Hand Washing** — Determine whether staff wash their hands appropriately when providing in-house dialysis or care related to dialysis services such as care of the shunt site.
- F455, Emergency Power** — Determine whether there is emergency power available to provide life support in the event normal electrical supply is interrupted.

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Concerns with Structure, Process, and/or Outcome Requirements Related to Process of Care

- F463, Resident Call System** — Determine whether a call light is available and functioning.
- F466, Water Supply** — Determine whether the facility has procedures to ensure that a water supply is available for dialysis treatments in the event that the provision of water is lost.
- F501, Medical Director** — Determine whether the medical director, in collaboration with facility staff,
 - Provided for the development and use of policies and procedures to manage or treat end stage renal disease, based on current standards of practice; and
 - Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident.

If the surveyor determines that the facility is not in compliance with any of these related requirements, the appropriate F tag should be surveyor initiated.