

Survey Protocol for Long Term Care Facilities

The provision of home dialysis treatments in a Long Term Care (LTC) facility place an increased burden on the LTC facility staff and may place the resident population at increased risk for negative outcomes. To protect the residents and ensure adherence to and compliance with Federal regulatory requirements and current standards of quality, it is critical for survey teams to recognize situations where home dialysis is occurring in the LTC setting and to understand the roles and responsibilities of both the LTC and the End-Stage Renal Disease (ESRD) facilities.

This survey protocol includes references to potential regulatory citations for LTC Facilities by F-Tag numbers, though not all-inclusive, to assist the survey team in determining the facility's compliance or non-compliance with regulatory requirements. These references are provided after each highlighted protocol.

Survey Preparation and Procedures for Long Term Care Facilities (SNF/NF)

The provision of home dialysis in the LTC facility is the responsibility of the Medicare-approved ESRD facility. The LTC survey teams are to survey the LTC facility with the existing regulations for all residents who receive dialysis whether in an outpatient treatment setting or onsite in the LTC facility. For all residents who receive dialysis, the LTC facility is responsible for the delivery of care and services to residents before transferring the resident 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 facility team. When the ESRD facility is providing the home dialysis procedure on the premises of the LTC facility and the facility allows their staff to contract with the ESRD facility to provide aspects of the dialysis care, the LTC surveyors must be more astute to issues surrounding this hybrid model of care. To evaluate the LTC facility's compliance with current regulations and standards of quality, the LTC survey team uses current survey procedures. The survey team must use the skills of observation, record review, and interview to validate or invalidate the facility's compliance.

Entrance Conference:

During the entrance conference, interview staff to determine if:

- The Skilled Nursing Facility (SNF) or Nursing Facility (NF) is Medicare-approved as an ESRD provider, has a designated area in the facility that is Medicare-approved as an ESRD provider, and/or has home dialysis services onsite. If home dialysis occurs onsite in the facility, identify this as an area of concern for the survey.
- There are residents in the facility who are receiving home dialysis. If so, have the facility provide a list of the residents' names, room numbers, the name of the ESRD assigned caregiver/technician (and identify if this caregiver is provided by the ESRD facility, the DME supplier, or the LTC facility), and the days and times when each resident will receive his/her dialysis treatment.

- The care is coordinated for residents who receive dialysis. Ask the Administrator to explain how the coordination of care is developed, implemented, and monitored. Obtain a copy of the written contract, agreement, arrangement, policies/procedures and/or plan of care, specifying how care is coordinated, to assist with the evaluation of care. Review the documents as described in the LTC survey protocol (Appendix P, page P-54). Alert the State Survey Agency's (SA) ESRD survey team that dialysis is being provided within this LTC facility and to any concerns identified during the survey of the LTC facility.

Initial Tour:

During the tour and observation of the facility, observe and interview residents, staff, and/or family to determine if 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.

During the LTC survey, 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.**

NOTE: This protocol is to be used with existing survey procedures and guidance to surveyors found in the State Operations Manual, Appendix P and PP. The following investigative components are added to address the home dialysis component of the survey.

Resident Rights

Many residents in the LTC facility will not be able to independently participate in the dialysis process and will require the ESRD facility/DME supplier to assign a caregiver/technician. Determine through interview with residents, families/responsible party, LTC facility staff and medical record review if:

- 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.

483.10 Resident Rights (b) Notice of rights and services and (d) Free Choice

F154 (3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition; **(d) (2)** Be fully informed in advance about care and treatment and of any changes in that care for treatment that may affect the resident's well being.

F155 (4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section

F156 (5) The facility must—**(i)(b)** inform each resident of those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; **(6)** The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and or charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate. **(9)** The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

483.75 Administration

514 (I) Clinical Records (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are **(i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized.**

Coordination of Care

The LTC and ESRD facilities' 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 through observation, record review, and interview with residents, family/responsible party, and LTC facility staff if:

- 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 dietician, 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.
- The care plan was reviewed and revised based on the resident's response to home dialysis and outpatient dialysis in accordance with regulatory requirements.
- The LTC facility staff communicates identified concerns with the resident's nutritional status or psychosocial needs to the ESRD social worker and/or dietitian.

483.20 Resident Assessment

F272 (b) Comprehensive Assessments. (1) Resident Assessment Instrument (RAI). A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State.

F274 (ii) Within 14 days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition.

F279 (k) Comprehensive Care Plans. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following: (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well being as required under 483.25.

F280 (k)(2)(ii) A comprehensive care plan must be prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

F281 (k)(3) The services provided or arranged by the facility must (i) Meet professional standards of quality.

F282(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

483.75 Administration

514 (I) Clinical Records (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized.

Provision of Care

The ESRD/ DME assigned caregiver/technician and licensed health professional designated by the ESRD facility is responsible for the surveillance of the resident(s) during the dialysis treatment and documentation of the resident's response to dialysis. During the LTC survey process, determine if:

- The LTC facility ensures the availability of sufficient staffing for other residents in the facility when home dialysis is provided onsite.
- The LTC facility ensures physician supervision of the care for the resident who receives dialysis treatments, physician availability during emergencies and how this is accomplished.

- The Medical Director has reviewed the policies and procedures for care of the residents receiving dialysis.
- The resident is receiving EPO. Investigate to determine if:
 - a) the ESRD and LTC facility staff coordinated how hemoglobin and hematocrit lab values are ordered, monitored, and results reported to the physician;
 - b) the LTC facility pharmacist or consultant pharmacist reports irregularities of EPO administration and potential drug interaction concerns; and
 - c) the ESRD and LTC facility staff have established policies and procedures for the dispensing and storage of EPO.
- The LTC facility staff ensures that 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.
- Through observation and interview with LTC facility staff and review of training records if the LTC facility staff demonstrates competency in the:
 - a) Clinical monitoring and care of the resident's vascular access (fistula, graft or central venous catheter) and post dialysis complications;
 - b) Clinical monitoring for residents who receive EPO;
 - c) Clinical monitoring and reporting of medication side effects and adverse drug reactions; and
 - d) Identification, monitoring and reporting of nutritional and hydration complications.

483.10 Resident Rights

F157 (b) (11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications) (C) A need to alter treatments significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or (D) A decision to transfer or discharge the resident from the facility as specified in 483.12(a).

F164 (e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records. (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

483.15 Quality of Life

F241 (a) Dignity. The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

483.20 Resident Assessment

F282 (ii) Be provided by qualified persons in accordance with each resident's written plan of care.

483.25 Quality of Care

F309 Quality of Care. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well being, in accordance with the comprehensive assessment and plan of care.

F312 (3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

F316 (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

F326 The resident **(i) (2)** Receives a therapeutic diet when there is a nutritional problem.

F327 (j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

F329 (l) (1) Unnecessary drugs. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
(iii) without adequate monitoring; or
(v) in the presence of adverse consequences, which indicate, the dose should be reduced or discontinued.

483.30 Nursing Services

F353 The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

483.40 Physician Services

F385 (a) Physician supervision. The facility must ensure that (1) The medical care of each resident is supervised by a physician; and (2) Another physician supervises the medical care of residents when their attending physician is unavailable.

F389 (d) Availability of physicians for emergency care. The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

483.60 Pharmacy services.

F425 The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in section 483.75 (h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

F428 (c) Drug regimen review. (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

F429 (c) (2) The pharmacist must report any irregularities to the attending physician, and the director of nursing.

F432 (e) Storage of drugs and biologicals. (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

483.70 Physical Environment

F457 (i) Accommodate no more than four residents.

F463 (f) Resident call system. The nurse's station must be equipped to receive resident calls through a communication system from – (1) Resident rooms; and (2) Toilet and bathing facilities.

483.75 Administration

F501 (i) Medical Director. (2) The medical director is responsible for –
(i) implementation of resident care policies; and
(ii) the coordination of medical care in the facility.

F502 (3) Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

F505 (ii) Promptly notify the attending physician of the findings.

F507 (iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

F514 (I) Clinical Records. (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized.

Infection Control:

The LTC facility staff ensures that disposal of biohazardous waste is done in accordance with LTC facility infection control regulatory requirements and practices. Determine if:

- The LTC and ESRD facilities staff have coordinated policies related to infection control practices for the resident receiving home dialysis treatment.
- These policies and procedures have been reviewed and approved by the LTC Medical Director.
- The LTC facility staff ensures that the ESRD facility staff disposes of biohazardous waste in accordance with the LTC infection control practices and regulatory requirements.

483.65 Infection Control

F441 Infection control. The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) Infection control program. The facility must establish an infection control program under which it --

- (1)** Investigates, controls, and prevents infections in the facility;
- (3)** Maintains a record of incidents and corrective actions related to infections.

Equipment Maintenance

The ESRD facility is responsible for the maintenance of all dialysis equipment for the resident. Determine if the LTC facility ensures that there is an emergency electrical system available in the rooms used for dialysis; and that the plan for an emergency water supply addresses provision of additional water for dialysis treatments.

483.70 Physical Environment

F455 (b) Emergency Power. **(1)** An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted. **(2)** When life support systems are used, the facility must provide emergency electrical power with an emergency generator.

F466 (h)(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply.

Medical Records

Determine if the LTC facility ensures that the resident's medical record is complete, accurate, and reflects the resident's care during dialysis treatment as well as his/her response to the dialysis process. This includes documentation of complications and notifications to physicians, families/responsible party, and ESRD personnel.

483.75 Administration

F514 (1) Clinical Records. (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized. (5) The clinical record must contain— (i) Sufficient information to identify the resident; (ii) A record of the resident’s assessments; (iii) The plan of care and services provided; (iv) The results of any preadmission screening conducted by the State; and (v) Progress notes.

F515 (2) clinical records must be retained for – (i) The period of time required by State law; or (ii) Five years from the date of discharge when there is not a requirement in State law; or (iii) For a minor, three years after a resident reaches legal age under State law.

F516 (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use.

Quality Assurance

Determine if the LTC facility has identified problems with dialysis treatment and care through the Quality Assessment and Assurance Program. If so, interview LTC facility staff to determine if corrective actions have been implemented to ensure the quality and continuity of care, minimization of infections and injuries, and coordination of the plan of care.

483.75 Administration

(o) Quality assessment and assurance. F521 (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.