

Survey Protocol for Medicare-Approved ESRD Facilities

The Medicare-approved ESRD facility must monitor the dialysis care of Long-Term Care (LTC) facility residents for whom they are providing care, whether the care is provided in an ESRD facility or in a LTC facility. The survey process must include a review for compliance with ESRD requirements at both the residents' LTC facility and the Medicare-approved ESRD training and support facility.

This survey protocol includes references to potential regulatory citations for ESRD facilities by V-Tag numbers to assist the survey team in determining the facility's compliance or non-compliance with Conditions for Coverage. These references are provided after each highlighted protocol.

Pre-Survey Preparation or Entrance Conference Information

All home dialysis in a LTC facility requires that a Medicare-approved ESRD facility be responsible for all aspects of the dialysis care, whether the care is provided by Method I (i.e., supplies, equipment, training, and support care delivered by a Medicare-approved ESRD facility) or by Method II (i.e., supplies and equipment provided by a Durable Medical Equipment [DME] supplier with support care and training delivered by a Medicare-approved ESRD facility). Determine either prior to the survey or during the entrance conference the type and extent of ESRD services provided to LTC residents who participate in home dialysis. When the ESRD facility provides home dialysis services onsite in a LTC facility, the survey team must make a visit to the LTC facility to conduct additional investigations.

Interview staff and conduct record review to determine:

- The contractual arrangements related to both financial aspects and patient care responsibilities between the ESRD training and support facility, the LTC facility, and the DME supplier.
- The number of LTC facility residents who are dialyzing in the LTC facility. Are they dialyzing as a skilled nursing facility's (SNF) or nursing facility's (NF) residents? How long have they been residents of the LTC facility? Are they on hemodialysis or peritoneal dialysis? Identify the number of LTC facility patients on Method I or Method II. If on Method II, what DME supplier is used? Review of the ESRD beneficiary selection form, CMS 382, will indicate which patients selected each method. For patients on Method II, determine if there is a backup agreement between the ESRD facility and the DME supplier.
- Whether residents in the LTC facility are dialyzed in a common room or in their bedrooms. During which days/hours is dialysis performed? Ideally, the surveyor will visit during a dialysis treatment.

NOTE: This protocol is to be used with existing survey procedures and interpretive guidelines found in the State Operations Manual, Appendix H. The following investigative components are added to address the home dialysis component of the survey. The Medicare-approved ESRD facility must meet the Conditions for Coverage at 42 CFR §405.2130-405.2163.

Coordination Agreement and Governance

The ESRD facility shall have a written coordination agreement, signed by the ESRD facility and each LTC facility in which home dialysis patients reside. The agreement needs to ensure that there is adequate coordination of care to provide home dialysis training and services to residents of LTC facilities. The ESRD facility assumes responsibility for appropriately delivering ESRD care, even if the care is delivered outside of the venue of the ESRD facility, i.e. the LTC facility.

If the ESRD facility provides home dialysis on the premises of the LTC facility, conduct an onsite visit to determine if:

- There is a written coordination agreement, signed by the ESRD facility and the applicable LTC facilities, which delineates respective responsibilities and accountability for routine and emergency care, care planning, and communication. The coordination agreement must include information on financial aspects and patient care responsibilities among the ESRD training and support facility, the LTC facility, and the DME supplier (if applicable).
- The coordination agreement is reviewed at least annually.
- The written coordination agreement clearly delineates where patients will be sent in the event of an emergency situation.
- There are clear lines of responsibility and accountability between the ESRD facility and the LTC facility that safeguard the health and safety of LTC patients who receive dialysis treatments.
- The ESRD facility staff communicates patient care issues with LTC facility staff.

§405.2136 Governing Body and Management

V110 Condition: Governing Body and Management. The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility.

V121 Operational Objectives Established. The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements.

V122 Operational Objectives in Writing. Such rules and regulations are in writing and dated.

V123 Revised Operational Objectives. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary.

V135 CEO: Administrative Function and Accountability. Organizing and coordinating the administrative functions of the facility, re-delegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

V156 Use of Outside Resources. If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resources, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

V157 Patient Care Policies. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients.

V165 Patient Care Policies: Emergencies. Care of patients in medical and other emergencies.

V175 Medical Supervision and Emergency Coverage. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician.

V176 Medical Emergency Coverage. That a physician is available in emergency situations.

V177 Medical Supervision: Orders. The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medication, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge.

V179 Medical Supervision: Emergency Roster. The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

§405.2140 Physical Environment

V276 Emergency preparedness. Written policies and procedures specifically define the handling of emergencies that may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies.

§405.2160 Affiliation Agreement/Arrangement

V411 Affiliation Agreement: Pts Accepted in Emergencies. The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its file documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies.

Infection Control

Because of the extracorporeal blood exchanges in dialysis treatments, there is a risk of transmission of blood-borne infections/diseases.

Determine through observations, interviews, and record reviews if:

- There is evidence of collaboration between the ESRD facility and the LTC facility to investigate, control and prevent infections. Infection control policies of the LTC facility and ESRD facility are to be reviewed by the Medical Director of the Medicare-approved ESRD facility.
- The staff providing dialysis follows appropriate hand washing and gloving procedures.
- Items used for dialysis are either dedicated to single use or appropriately cleaned and disinfected.
- The multiple-use of single-use vials of Epoetin Alfa (EPO) is performed according to the Centers for Disease Control and Prevention (CDC) guidance.
- Clean and contaminated areas for dialysis are clearly separated and used appropriately.
- External transducer protectors are changed between patients and not reused.
- Dialysis stations and machines are disinfected between uses.
- Waste is managed and disposed of appropriately.

§405.2140 Physical Environment

V265 Functional, Sanitary, & Comfortable. The facility is maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

V266 Infection Control. There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items that conform to requirements for reuse.

V274 Contamination Prevention: Policies/Functions. The written patient care policies specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention.

§405.2150 Reuse

V388 Transducer filters. To control the spread of hepatitis, transducer filters are cleaned after each dialysis treatment and are not reused.

Water Treatment

For health and safety reasons, it is critical that the water used to reprocess dialyzers and to mix with concentrates to make dialysate is appropriately treated and monitored.

Determine through observations, interview and record review if the ESRD facility assures the following standards are met:

- The LTC location has equipment that ensures water used in dialysis treatments will meet the AAMI minimum standards for chemical contaminants and bacteriology.
- The LTC location ensures on a daily basis the water in the facility used for dialysis meets the AAMI minimum standards for the following: total chlorine less than 0.5 ppm and chloramines less than 0.1 ppm. Does the long-term care location test chlorines/chloramines daily prior to patient treatments?
- The water is cultured at least monthly. Are the results either less than 200 cfu/ml by culture for bacteria or less than 5 eu/ml by LAL for endotoxins?
- The dialysate is cultured monthly. Are the results less than 2000 cfu/ml for bacteria?
- The chemical analysis of the water done at least annually. Do the results meet AAMI standards?
- The person responsible for water treatment has an appropriate understanding of the water treatment equipment, testing, and procedures.

§405.2140 Physical Environment

V261 Water Treatment. The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in “Hemodialysis Systems,” second edition, which is incorporated by reference. (ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2 Maximum Level of chemical contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

V262 AAMI: Water Bacteriology. Total viable microbial count should not exceed 200/ml. A method of cleaning the equipment so that the equipment is capable of meeting this requirement shall be recommended by the manufacturer or supplier.

V263 AAMI: Dialysate Bacteriology. Total viable microbial count for the dialysate should not exceed 2000/ml.

V264 AAMI: Maximum Chemical Contaminants. The water used to prepare dialysate shall not contain chemical contaminants at concentrations in excess of those in Table 2, AAMI.

§405.2161 Physician Director

V423 Responsibility for Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

Reuse

If a home dialysis program in a LTC facility reuses dialyzers, the reuse process must conform to Federal standards for reuse per **42 CFR §405.2150 (V300-V392).**

Equipment Installation and Maintenance

If a DME supplier provides equipment for home dialysis in a LTC facility under Method II, the Medicare-approved ESRD support facility remains responsible for overall management and oversight of equipment maintenance and installation.

Determine through observations, interview and record review if:

- There is an emergency tray, including emergency drugs, medical supplies, and emergency equipment available and accessible at all times at the ESRD facility's LTC location. Emergency equipment and supplies should be comparable to those located in an outpatient ESRD facility.
- Staff/caregivers are appropriately monitoring machine safety alarms as needed and continuously monitoring machine-derived blood pressure and fluid status.
- Equipment records show that preventive maintenance and repairs were done in a timely manner.
- A system is in place to monitor equipment function, identify equipment problems, and to ensure updates on preventive maintenance.

§405.2140 Physical Environment

V258 Equipment Preventive Maintenance. All electrical and other equipment used in the facility is maintained free of defects, which could be a potential hazard to patients and personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

V281 Emergencies: Drugs and Supplies. There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment.

V283 Emergencies: Staff Trained in Procedures. The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

§405.2150 Reuse

V305 Equipment Maintenance Record. A log must be maintained of the date of preventive maintenance procedures and the date of results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.

§405.2161 Physician Director

V423 Responsibilities: Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks.

§405.2162 Staff

V434 Staff Numbers Meet Patient Needs. An adequate number of personnel are readily available to meet medical needs.

Staffing, Staff Training and Patient Monitoring During Treatment

In reviewing staffing and staff training, the survey process needs to determine that either the LTC facility resident or the resident's assistant (i.e., "caregiver") has the required knowledge and skills to perform required dialysis tasks. The surveyors also must determine if the staff in the LTC facility is trained to handle medical emergencies while residents are dialyzing and whether ongoing care is appropriate for dialysis patients. The LTC facility resident needs to be observed during dialysis treatment to ensure that treatments are delivered appropriately.

Determine through observation, interview and record review if:

- A "qualified" nurse, who has at least 3 months of his/her ESRD experience in training patients in self-care, is in charge of all training for "home" dialysis in a LTC facility, including caregivers and LTC facility staff.
- The training curriculum is appropriate for the type of dialysis provided and covers medical emergencies. Medical emergencies can include the administration of CPR and intravenous medication, and the treatment of air emboli, blood loss, and severe hypotension.
- There is an appropriately trained caregiver providing adequate monitoring while patients are dialyzing in the ESRD facility's LTC locations.

- For purposes of home dialysis in a LTC facility, the ESRD facility must ensure either through direct employment or other contractual arrangement with the LTC facility that one or more currently licensed health professionals experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are undergoing dialysis. The licensed health professional must have practical experience in or be trained by the ESRD facility to perform assessments, observe the patients pre and post dialysis, respond to emergency situations relative to dialysis treatments, and administer any necessary intravenous, intradialytic and intramuscular medications in accordance with all Federal and State requirements.
- A “qualified” renal dietitian monitors the dialysis patient’s nutritional and dietary needs.
- A “qualified” renal social worker monitors the social service needs and services provided to the dialysis patient.
- The Physician Director of the ESRD facility assumes responsibility for ensuring adequate training of the staff and the availability of patient teaching materials.
- Trained personnel (staff/caregiver) are responsible for treatments.
- There are patient care policies, which are specific to care provided in the LTC setting, that cover the care of patients in medical and other emergencies.
- The treatment being received match the orders for treatment, and blood pressure and fluid status are continuously being monitored.
- Staff/caregiver is appropriately trained in preparing the dialysate bath, dialysis machine, dialyzer, and priming the machine with initial settings.
- Staff/caregiver is appropriately trained to handle equipment emergencies.

§405.2136 Governing Body

V144 Personnel Policies/Procedures: Staff Qualified. These policies and procedures ensure that: **(1)** All members of the facility’s staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

V170 Patient Care Policies: Consultants. Consultant qualifications, functions, and responsibilities.

§405.2140 Physical Environment

V282 Emergencies: Staff Trained in Equipment. There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

V283 Emergencies: Staff Trained in Procedures. The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

§405.2161 Physician Director

V421 Qualifications. The director of a dialysis facility is a qualified physician director.

V423 Responsibilities: Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks.

V426 Responsibilities: Self Care. When self-dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

§405.2162 Staff

V430 Condition: Staff of a Renal Dialysis Facility or Renal Dialysis Center. Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

V431 Registered Nurse. The dialysis facility employs at least one full time qualified nurse responsible for nursing service.

V432 On-duty personnel: Licensend Person. Whenever patients are undergoing dialysis: (1) one currently licensed health professional (e.g. physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care.

V433 Staff Ratios Meet Patient Needs. An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients.

V434 Staff Numbers Meet Patient Needs. An adequate number of personnel are readily available to meet medical needs.

V436 Self-care dialysis training personnel. If the facility offers self-care dialysis training, a qualified nurse is in charge of such training.

§405.2163 Minimal Service Requirements

V446 Social Worker Qualified. Social services are furnished by a qualified social worker who has an employment or contractual relationship with the facility.

V448 (d) Dietetian Qualified. Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician who has an employment or contractual relationship with the facility.

Patient Care Plans and Long-Term Program

Coordination of care and communication between the ESRD facility staff and the LTC facility staff should be clearly documented in the patients' medical records at the ESRD facility and at the LTC location.

Determine through observation, record review and interview if:

- There is a multidisciplinary, written, individualized patient care plan that is updated as required.
- The LTC staff and ESRD facility staff communicates and coordinates the development and implementation of the individualized patient care plan.
- There is a long-term program that is updated annually.
- The ESRD renal dietitian and social worker participate in long-term care plans and patient care planning, and communicate and coordinate with the long-term care facility staff to address individual patient needs.
- The Physician Director of the ESRD facility assumes responsibility for participating in the long-term program.
- The physician responsible for the patient's dialysis treatments work with a professional ESRD team to develop and review the individualized patient care plans.

§405.2136 Governing Body

V174 Patient Care Policies. The governing body adopts policies to ensure there is evaluation of the progress each patient is making towards the goals stated in the patient's long-term program and patient's care plan. Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

§405.2137 Long Term Program and Patient Care Plan

V187 Patient Long-Term Program: Written There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

V188 LTP: Team Members. The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

V189 LTP: Reviewed by Team. The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment.

V192 Patient Care Plan: Written, Assessed. There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

V193 PCP: Individualized. The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short term goals.

V194 PCP: Team. The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

V195 PCP: Patient Involved. The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

V196 PCP: Frequency. The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients' ongoing needs.

V197 PCP: Copy with Transfer. If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

V198 PCP: Home Patients. For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate.

V199 PCP: EPO at Home. Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following: (i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

§405.2138 Patient Rights

V222 Participation in Planning. All patients treated in the facility are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research.

Patient Rights and Responsibilities

Determine through interview with patients and families if:

- The patient/family was fully informed of options, including options for different modalities and settings. Form CMS-382, ESRD Beneficiary Selection, may be reviewed to verify patient election of Method I or Method II.
- Patients' rights are being observed, including the rights to privacy and respect.

- The patient/family is fully informed of services available in the facility and of related charges for services not covered under Medicare.
- If the patient/family is aware that there are grievance/complaint procedures.

§405.2138 Patients Rights and Responsibilities

V215 Condition: Patients' Rights and Responsibilities. The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency (ies), representative payees, and to the public.

V217 Informed of Rights/Responsibilities. All Patients in the Facility: (1) Are fully informed of these rights and responsibilities, and of all the rules and regulations governing patient conduct and responsibilities.

V218 Informed of Services/Charges. Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

V219 Informed of Medical Condition. Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records).

V220 Informed of Reuse. Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

V221 Informed of Modalities. Are fully informed regarding their suitability for transplantation and home dialysis.

V224 Respect, Dignity, and Privacy. All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment.

V225 Translators. Provision is made for translators where a significant number of patients exhibit language barriers.

V226 Confidentiality. All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

Medical Records

Patient records (electronic or paper) must be accessible at both the ESRD facility and the ESRD facility's LTC location.

Determine if:

- The medical records are complete and maintained both at the LTC facility and at the Medicare-approved ESRD facility.
- The records document the operation, disinfection and preventive maintenance and repair of dialysis, water treatment, and reuse equipment.
- The results of testing and cultures are consistently documented and reviewed.
- Affiliation agreements are appropriate and complete.

§405.2139 Medical Records

V230 Condition: Medical Records. The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

V231 Medical Records: Identify, Justify, Document. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately.

V232 Patient Assessments. All medical records contain the following general categories of information. Documented evidence of assessment of the needs of the patient,

V233 Reuse Information. Whether the patient is treated with a reprocessed hemodialyzer,

V234 LTP and PCP. Establishment of an appropriate plan of treatment, and of the care and services provided.

V235 Patient Involvement in LTP/PCP. Evidence that the patient was informed of the results of the assessment.

V236 ID and Social Data. Identification and social data.

V237 Consents. Signed consent forms, referral information with authentication of diagnosis.

V238 Medical & Nursing History. Medical and nursing history of patient.

V239 Physician Exams. Report(s) of physician examination(s).

V240 Orders. Diagnostic and therapeutic orders.

V241 Progress Notes. Observations and progress notes.

V242 Treatments and Findings. Reports of treatments and clinical findings.

V243 Lab Reports. Reports of laboratory and other diagnostic tests and procedures.

V244 Discharge Summary. Discharge summary including final diagnosis and prognosis.

V245 Protection of Medical Record Information. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

V246 Medical Records Supervisor. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

V247 Completion of Medical Records and Centralization of Clinical Information. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record.

V248 Self Care/Home Patients. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

V249 Retention and Preservation of Records. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

V250 Location and Facilities. The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

V251 Transfer of Medical Information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

Quality Assurance/Quality Improvement

The Medicare-approved ESRD facility must monitor the care of LTC facility residents who are receiving dialysis treatments, whether in an ESRD facility or in a LTC facility.

Determine through record review and interview if:

- The dialysis care, including patient outcomes, is monitored, reviewed, and identified problems are corrected.
- The ESRD staff report and review incidents and accidents regarding dialysis care in LTC facilities to both the LTC facility and the ESRD support facility.

§405.2136 Governing Body

V112 Governing Body: Health and Safety. And to the health care and safety of patients,

V146 Incidents Reviewed. Reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards.

§405.2150 Reuse

V387 Surveillance of Patient Reactions. In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility- (i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

§405.2161 Physician Director

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

Laboratory Services

The laboratory services may either be performed by the ESRD facility that is Clinical Laboratory Improvement Amendments (CLIA) certified or by arrangements with a CLIA-certified laboratory. Determine through record review and interview if the facility has systems in place to ensure laboratory services are provided to the patients.

§405.2163 Minimal Service Requirements

V443 Laboratory Services: In-house. The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.

V444 Laboratory Services: Outside. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.