ACHC STANDARDS

Program

Renal Dialysis

Services

Home Dialysis Support

ACHC ACCREDITATION STANDARDS

RENAL DIALYSIS

FOR PROVIDERS. BY PROVIDERS.

The following packet contains the 2019 ACHC Accreditation Standards.

Release Date: February 1, 2019

Effective Date: June 1, 2019

ACHC is pleased to announce the release of a new program. ACHC has developed standards for Renal Dialysis; these facilities are entities that provide outpatient maintenance dialysis services, and/or home dialysis training and support services. Our standards were developed specifically for Medicare Certified Renal Dialysis Facilities. ACHC's Accreditation Standards help providers succeed in meeting the Medicare Conditions for Coverage (CfCs) and provide quality patient care.

In-Center Dialysis (ICD): In-Center Dialysis facilities are entities that provide outpatient maintenance dialysis service in an in-center/facility setting for patients with End-Stage Renal Disease (ESRD). ACHC's Accreditation Standards were developed specifically for Medicare Certified facilities performing in-center care. Our standards assist providers with the knowledge to succeed in meeting the Medicare Conditions for Coverage (CfCs) and equip your facility with the opportunity to better provide safe, compliant, and quality patient care.

Home Dialysis Support (HDS): Home Dialysis Support entities are those that provide home dialysis training and support services for patients being treated for End-Stage Renal Disease (ESRD), as well as training and support services to their care partner. ACHC's Accreditation Standards were developed specifically for Medicare Certified home dialysis training and support programs. Our standards assist providers with the knowledge to succeed in meeting the Medicare Conditions for Coverage (CfCs) and equip your home program with the opportunity to better provide safe, compliant, and quality patient care.

The attached Accreditation Packet contains:

- Preliminary Evidence Report (PER) Initial Checklist (if applying for ACHC Accreditation for the first time)
- ACHC Accreditation Standards for Renal Dialysis
- Items Needed for Survey
- Glossary of Terms for Renal Dialysis
- Glossary of Personnel Qualifications for Renal Dialysis

PRELIMINARY EVIDENCE REPORT CHECKLIST

FOR PROVIDERS. BY PROVIDERS.

RENAL DIALYSIS

This checklist constitutes the requirements of the Preliminary Evidence Report (PER), which is mandatory for organizations applying for initial Renal Dialysis accreditation.

Review and acknowledge that all of the following requirements have been met and submit this signed checklist with the required items listed below.

Verification of the following is required for organizations seeking an initial Medicare Provider Number:

- ☐ The organization has completed the CMS-855 application and received written confirmation the application has been *"processed"* and *"the application is being forwarded with a recommendation to the state and CMS Regional Office."*
  - **Submit a copy of the letter from CMS or the Medicare Administrative Contractor (MAC). This is applicable for organization seeking an initial Medicare Provider Number**
- ☐ A copy of CMS form 3427
  - **Submit a copy of the form**
- ☐ A signed agreement between the organization and applicable End-Stage Renal Disease (ESRD) network is required prior to the initial certification survey
  - **Submit a copy of the agreement**
- ☐ The organization can demonstrate they are able to provide all services needed by patients being served and is able to demonstrate operational capacity of all facets of the organization
- ☐ Life Safety Code (LSC) attestation or waiver, if applicable
  - **Submit a copy of the waiver**
- ☐ The organization must have one patient on the census for each modality offered
- ☐ The organization has a full and current license, NOT PROVISIONAL, in the state it is currently doing business, if applicable
  - **Please note: all states may not require a license therefore this only pertains to organizations that reside in states that require a license**

Confirmation of the following (initial in spaces provided):

_____ I attest that this organization possesses all policies and procedures as required by the ACHC Accreditation Standards

_____ **I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____date.**

Your organization will be placed into scheduling once this document, the Agreement for Accreditation Services and Business Associate Agreement are submitted to your Account Advisor and payments are up-to-date. ACHC will strive to conduct your survey as soon as possible.

****PLEASE NOTE: YOUR ORGANIZATION MUST ALWAYS BE IN COMPLIANCE WITH MEDICARE REGULATIONS, CONDITIONS FOR COVERAGE, AND APPROPRIATE STATE REGULATIONS.**

I, having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. If this organization fails to meet any of the aforementioned requirements when the ACHC Surveyor arrives for your survey, the survey performed by ACHC will not be accepted as a legitimate Initial Medicare Certification Survey by CMS. This will result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC it has met all of the above requirements.

_____ _____

(Name) (Title)

_____ _____

(Date) (Signature)

ACHC ACCREDITATION STANDARDS

Customized for Home Dialysis Support

Section 1: ORGANIZATION AND ADMINISTRATION

The standards in this section apply to the leadership and organizational structure of the company. All items referring to business licensure including federal, state, and local licenses that affect the day-to-day operations of the business should be addressed. This section includes the leadership structure including board of directors, advisory committees, management, and employees. Also included is information about leadership responsibilities, conflicts of interest, chain of command, program goals, and regulatory compliance.

Standard RD1-A: The facility must be in compliance with applicable federal, state and local laws and regulations. (494.20) V100

This standard requires compliance with all laws and regulations including but not limited to:

- Current local and state licensure
- Professional licensure/certification
- The Americans with Disabilities Act
- Equal Employment Opportunities Act
- Fair Labor Standards Act
- Title VI of the Civil Rights Act of 1964
- Section 1557 of the Patient Protection and Affordable Care Act
- Occupational Safety and Health Standards (OSHA) and training requirements
- Medicare and Medicaid regulations
- Public health regulations relating to infectious diseases (Centers for Disease Control)
- Health Insurance Portability and Accountability Act (HIPAA)
- U.S. Food and Drug Administration (FDA), If applicable
- Drug Enforcement Administration (DEA), if applicable
- Medical Device Reporting requirements
- The facility's policies and procedures
- ACHC Accreditation Process
- Laws and regulations as applicable to the care/service provided by the facility
- The facility complies with all accepted professional standards and practices

Copies of all required federal and state posters are placed in a prominent location for easy viewing by personnel.

Evidence: Reports of Federal, State, or Local Surveys or Inspections
Evidence: Observation

Services applicable: HDS, ICD

Standard RD1-B: The facility is licensed when required by the state or local law. (494.20) V101

The facility and its personnel must operate and furnish care/services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides for licensing, facility must be licensed.

The facility has current required licenses and/or permits and is posted in a prominent location accessible to public view in all locations and/or in accordance with appropriate regulations or laws.

Each separate physical location for dialysis services must be certified separately, and all approved services for a particular facility must be provided on the premises of that location. Hospital-based facilities may be located on the same campus of the hospital, with various services (e.g., home training vs. in-center dialysis) being provided in different rooms or areas, but sharing the same address on that campus.

All services provided by the facility must be under the direction of the same professional staff and governing body.

The entity, individual or facility has a copy of the appropriate documentation or authorizations to conduct business.

Evidence: Current State License and Required Permits

Services applicable: HDS, ICD

Standard RD1-D: The facility is under the control of an identifiable governing body, or designated person(s) functioning, with full legal authority and responsibility for the governance and operation of the facility. (494.180) V750-751, (494.180(b)(1-4))

V757-761, (494.180(c)(1-3)) V762-763, (494.180(d)) V764

There is a governing body that demonstrates responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program.
The governing body adopts and enforces rules and regulations relative to its own governance, to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

The governing body or designated person responsible must ensure that:

- An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients
- A registered nurse, social worker and dietitian are members of the interdisciplinary team and are available to meet patient clinical needs
- A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated
- All staff, including the Medical Director, have appropriate orientation to the facility and their work responsibilities
- All employees have an opportunity for continuing education and related development activities
- All medical staff appointments and credentialing is in accordance with state law, including Medical Director, attending physicians, physician assistants, nurse practitioners and clinical nurse specialists
- All medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specific to 42 CFR 494.110
- Expectations are communicated to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients
- The dialysis facility provides services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises
- Internal grievance or complaint process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services
    - The grievance or complaint process must include:
        - A clearly explained procedure for the submission of grievances
        - Timeframes for reviewing the grievance
        - A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance
- All staff follow the facility's patient discharge and transfer policies and procedures
- All ethical issues are reviewed by the governing body or appropriate platform for clinical ethics

Evidence: Governing Body Meetings Minutes
Evidence: Patient Interview

Services applicable: HDS, ICD

Standard RD1-E: Written policies and procedures are established and implemented by the facility in regard to the disclosure of ownership and management information as required by 42 CFR 420.000 through 42 CFR 420.206. (494.180(j)) V773

Written policies and procedures are established and implemented by the facility regarding the action required and time frames for a change in ownership, governing body, or management.

The facility must disclose the following information to the state survey agency at the time of the facility's initial request for certification, for each survey, and at the time of any change in ownership or management:

1. The name and address of all persons with an ownership or control interest in the facility as defined in 42CFR 420.201, 420.202 and 420.206
    - Disclosure of persons having controlling interest or ownership of greater than 5%
    - Disclosure of persons with controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs

2. The name and address of each person who is an officer, a director, an agent or a managing employee of the facility as defined in 42CFR 420.201, 420.202, and 420.206

3. The name and business address of the corporation, association, or other company that is responsible for the management of the facility, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the facility

A disclosing entity must furnish updated information to CMS, state agencies, and ACHC at intervals between recertification, re-enrollment, or contract renewals, within 30 days of a written request or change in authority, ownership, or management.

Evidence: Written Policies and Procedures

Evidence: Organizational Chart
Evidence: Response to Interviews

Evidence: Observation

Services applicable: HDS, ICD

Standard RD1-F: The governing body appoints a qualified Chief Executive Officer (CEO) or Administrator who is responsible for the management of the facility and the provision of all dialysis services. (494.180(a)(1-4)) V752-756

The CEO or Administrator is appointed by the governing body as the administrator responsible for the overall operation, management, enforcement of rules and regulations, and oversight of health care and safety of patients.

The Chief Executive Officer (CEO) or Administrator qualifications should be defined in the facility's job description and include sufficient educational and practical experience to fulfill the responsibilities of management of the facility and provision of all dialysis services.

The governing body delineates the responsibilities of the Chief Executive Officer/Administrator; and ensures that they are sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

When the CEO/Administrator is not available, a qualified, pre-designated person, who is authorized in writing by the CEO/Administrator and the governing body, assumes the same responsibilities and obligations as the Administrator. The responsibilities of the CEO include but are not limited to:

- Staff appointments
- Fiscal operations
- The relationship with the End Stage Renal Disease (ESRD) networks
- Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in 42 CFR 494.110

Evidence: Job Description
Evidence: Governing Body Meeting Minutes/By-Laws

Services applicable: HDS, ICD

Standard RD1-H: The governing body is responsible for ensuring that the facility provides patients and staff with written instructions for obtaining emergency medical care. (494.180(g)(1-3 i-ii)) V768-770

The facility provides information to all patients, including home patients, regarding who to call and how to obtain emergency medical care when away from the facility. The facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

The governing body is responsible for ensuring that the facility provides patients and staff with written instructions for obtaining emergency medical care.

If only one physician is on the staff, there needs to be a plan for coverage in case the physician is ill or otherwise unavailable.

The facility must have a written agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must ensure that hospital services are available promptly to the facility's patients when needed and include reasonable assurances that patients from the facility are accepted and treated in emergencies.

Evidence: List of Physicians on Call for Emergencies
Evidence: Written Contract/Agreement
Evidence: Observation
Evidence: Patient Interview

Services applicable: HDS, ICD

Standard RD1-J.01: A facility that uses outside personnel/organizations to provide services on behalf of the facility has a written contract/agreement for the services provided which is kept on file within the facility.

Arranged services are supported by written agreements that require that all services are:

- Authorized by the facility
- Provided in a safe and effective manner by qualified personnel/organizations
- Delivered in accordance with the patient's treatment plan

Facilities that utilize personnel/organizations under hourly or per visit have a written contract/agreement that includes, but is not limited to:

- The care/services to be provided
- The necessity to conform to all applicable facility policies and procedures, including personnel qualifications, orientation, competencies and required background checks

The facility has an established process to review and renew contracts/agreements as required in the contract.

Evidence: Written Contracts/Agreements

Services applicable: HDS, ICD

Standard RD1-L.01: The facility informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from regulatory inspections and/or audits.

Negative outcomes affecting accreditation, facility licensure or Medicare certification are reported to ACHC within 30 days. The report includes all actions taken and Plans of Correction.

Outcomes that must be reported to ACHC include, but are not limited to:

- Facility license suspension(s)
- Facility license probation; conditions/restrictions to license(s)
- Non-compliance with Medicare regulations identified during survey by another regulatory body resulting in a Condition Level deficiency or Immediate Jeopardy
- Revocation of Medicare/Medicaid/third-party provider number
- Any open investigation by any regulatory or governmental authority

Evidence: Governing Body Meeting Minutes
Evidence: Prior Regulatory Inspection Reports

Evidence: Response to Interviews

Services applicable: HDS, ICD

Section 2: PROGRAM/SERVICE OPERATIONS

The standards in this section apply to the specific programs and services an organization is supplying. This section addresses rights and responsibilities, complaints, Protected Health Information (PHI), cultural diversity, and compliance with fraud-and-abuse- laws.

Standard RD2-C: The facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the facility patient. (494.130) V675-676

The facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the patient. Any laboratory services, including tissue pathology and histocompatibility, must be provided by or obtained from a facility that meets the requirement for laboratory services specified in 42 CFR 493.

Facilities providing their own laboratory services such as waived tests, (e.g., spun microhematocrits and fingerstick blood glucoses obtained by glucose monitoring devices cleared by FDA specifically for home use,) and are required to have a CLIA certificate of waiver.

If a facility has a contract(s) or agreement(s) with certified provider(s) to perform laboratory testing, the arrangements must be in writing and must specify the types of lab tests to be performed; collection and handling of specimens, how the results will be reported and the time frame of which they are reported. In addition, there must be an approved list of alerts/panic value results and a policy on how those will be reported.

All facilities performing laboratory tests must have the appropriate CLIA certificate for the level of testing conducted. HLA Laboratories performing Panel Reactive Antibody (PRA) testing for patients on the transplant waitlist must have a “regular” CLIA certificate or certificate of accreditation which allows the laboratory to perform high-complexity testing.

Laboratory reports include, but are not limited to:

- Name and address of the laboratory performing the test
- Name of the ordering physician
- Identifying patient information:
    - Name
    - Medical record number
    - Date of birth
- Date of the specimen collection
- Date and time of the results

There is documentation in the medical record that all laboratory tests prescribed were provided as ordered.

Tests for clotting time (ACT) must be performed by a facility with a CLIA certificate to conduct tests of moderate complexity.

Evidence: CLIA Certificate
Evidence: Medical Records
Evidence: Observation

Services applicable: HDS, ICD

Standard RD2-E: Written policies and procedures are established and implemented by the facility in regard to the creation and distribution of the Patient Rights and Responsibilities statement. (494.70) V450-V451, (494.70(a)(1-17)) V452-467, (494.70(b)(1-2)) V468-469

Written policies and procedures are established and implemented outlining patient rights and responsibilities. The policy requires that the facility provide the patient (or their representatives) with a written copy of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights. The policies and procedures state that if a patient cannot read the statement of rights and responsibilities, it is read to the patient and a copy is provided. For a minor or a patient needing assistance in understanding these rights and responsibilities, both the patient and the parent or other responsible person are fully informed of these rights and responsibilities.

The Patient Rights include, but are not limited to:

- Receive information about the scope of services that the facility will provide and specific limitations on those services
- Be fully informed in advance about healthcare services to be provided, including diagnosis, planned treatment, anticipated outcomes, risks, alternatives, and prognosis
- Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD
- Receive all information in a way that he or she can understand
- Be free from discrimination

- Privacy and confidentiality in all aspects of treatment
- Privacy and confidentiality in personal medical records
- Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, to refuse to participate in experimental research, and the consequences thereof
- Be informed about his or her right to execute advance directives, information regarding advance directives, and the facility's policy regarding advance directives
- Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis
- The right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients
- Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients
- Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers
- Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the medical record, unless the medical record contains a documented contraindication
- Be informed in advance of services available in the facility and charges for services not covered under Medicare; including payment expected from third parties and any charges for which the patient may be responsible
- Receive the necessary services outlined in the patient plan of care described in 42 CFR 494.90
- Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities
- Be informed of the facility's internal grievance process and follow up investigation process
- Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the state survey agency
- Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing
- Informed regarding their suitability for transplantation and home dialysis
- Be informed of the facility’s policies for transfer, routine or involuntary discharge, and discontinuation of services to patients
    - Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in 42 CFR 494.180(f)(4)
    - In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed
- Be informed of health care coverage option

The facility must prominently display a copy of the patient’s rights in the facility, including the current state agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

When additional state or federal regulations exist regarding Patient Rights, the facility’s Patient Rights and Responsibilities statement must include those components. The patient has the right to be informed and exercise their rights. If the patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed to act on the patient's behalf. If a state court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with state law may exercise the patient's rights to the extent allowed by state law.

Personnel are provided training during orientation and at least annually thereafter concerning policies and procedures on the Patient Rights and Responsibilities.

Evidence: Written Policies and Procedures
Evidence: Statement of Patient Rights and Responsibilities
Evidence: Response to Interviews
Evidence: Medical Records
Evidence: Observation
Evidence: Patient Interview

Services applicable: HDS, ICD

Standard RD2-H.01: Written policies and procedures are established and implemented by the facility in regards to reporting and investigating all alleged violations involving discrimination, mistreatment, neglect, or verbal, mental, sexual, and physical abuse.

The patient has the right to be free of discrimination, mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property.

Staff is trained in the identification and/or reporting of any indication of potential discrimination, mistreatment, neglect, or verbal, mental, sexual, and physical abuse.

The facility ensures this right and investigates all alleged violations involving discrimination, mistreatment, neglect, or verbal, mental, sexual, and physical abuse by anyone providing services on behalf of the facility; these are reported immediately to the leader/ Administrator.

The facility immediately investigates all alleged violations involving anyone providing services on behalf of the facility and immediately

takes action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations are conducted in accordance with established policies and procedures.

The facility takes appropriate corrective action in accordance with state law if the alleged violation is verified by the facility's administration or an outside body having jurisdiction, such as ACHC, the state survey agency, or local law enforcement agency.

The facility ensures that verified violations are reported to ACHC, state, and local bodies having jurisdiction within five working days of becoming aware of the verified violation unless state regulations are more stringent.

Evidence: Written Policies and Procedures
Evidence: Incident Reports/Investigation Results
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD2-I: Written policies and procedures are established and implemented by the facility requiring that the patient be informed when they begin their treatment how to report grievances, complaints or concerns and explain how they are investigated and resolved. (494.180(e)) V765

The patient has the right to voice grievances/complaints either orally or in writing regarding care/service that is (or fails to be) provided by anyone who is providing care/service on behalf of the facility and must not be subjected to discrimination or reprisal for doing so.

The facility ensures this right and investigates all grievances/complaints. Written policies and procedures include, but are not limited to:

- The appropriate person to be notified of the grievance/complaint
- Time frames for investigation activities, to include after hours
- Reporting of information
- Review and evaluation of the collected information
- Communication with the patient or representative of steps taken to resolve the grievance/complaint
- Documentation of all activities involved with the grievance/complaint, investigation, analysis and resolution

The facility investigates and attempts to resolve all patient grievances/complaints and documents the results within a described time frame as defined in policies and procedures.

The facility maintains records of grievances/complaints and their outcomes, submitting a summary report to the governing body.

Personnel are oriented and familiar with the patient grievance/complaint policies and procedures. Personnel assist in implementing the resolution process when needed.

Evidence: Written Policies and Procedures
Evidence: Grievances/Complaint log
Evidence: Governing Body Meeting Minutes
Evidence: Patient Interviews
Evidence: Observation

Services applicable: HDS, ICD

Standard RD2-J: The facility provides the patient with written information concerning how to contact the facility, appropriate state agencies, and ACHC concerning grievances/complaints. (494.70(d)) V470

The facility provides all patients with written information listing a telephone number, contact person, and the process for receiving, investigating and resolving grievances/complaints.

The facility advises the patients in writing of the mailing addresses and telephone numbers of the appropriate state regulatory bodies. This may be a separate information sheet given to the patient incorporated into the Patient Rights information. ACHC's telephone number must be provided (the ACHC phone number requirement is not applicable to facilities undergoing its first ACHC survey.)

The facility must prominently display a copy of the patient's rights in the facility, including the current state agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

Evidence: Medical Records
Evidence: Observation

Services applicable: HDS, ICD

Standard RD2-K.01: Written policies and procedures are established and implemented by the facility in regards to securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

The patient has the right to a confidential medical record. The facility ensures this right and follows all policies and procedures to secure patient information.

The facility has clearly established written policies and procedures that address patient right to confidentiality of information which are clearly communicated to staff.

Confidentiality policies and procedures include, but are not limited to:

- A definition of protected health and confidential information, the types of information that are covered by the policy, including electronic information, telephone and cell phone communications, and verbal and faxed information
- Persons/positions authorized to release PHI/EPHI and confidential information
- Conditions which warrant its release
- Persons to whom it may be released
- Consent and signature of the patient or someone legally authorized to act on the patient's behalf
- A description of what information the patient is authorizing the facility to disclose
- Securing medical records and identifying who has authority to review or access medical records
- When records may be released to legal authorities
- The storage and access of records to prevent loss, destruction or tampering of information
- The use of confidentiality/privacy statements and required signatures a confidentiality/privacy statement

There is a signed confidentiality statement for all personnel and the governing body.

Personnel and the governing body abide by the confidentiality statement and the facility's policies and procedures.

The facility designates an individual responsible for seeing that the confidentiality and privacy policies and procedures are adopted and followed.

The individual seeing the patient for the first time will provide written information and will discuss confidentiality/privacy of patient-specific information as included in the Patient Rights and Responsibilities statement.

Evidence: Written Policies and Procedures
Evidence: Medical Records
Evidence: Personnel Files
Evidence: Observation

Services applicable: HDS, ICD

Standard RD2-N: Written policies and procedures are established and implemented by the facility in regard to the provision of care to patients with communication, language barriers, and/or cultural background barriers. (494.70(a)(1) V452, (494.70(a)(2) V453

The patient has the right to respect, dignity and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with end stage renal disease. Personnel communicate with the patient in the appropriate language or form understandable to the patient.

Mechanisms are in place to assist with language and communication barriers. This may include the availability of bilingual personnel, interpreters, or assistive technologies. Personnel communicate with the patient by using special telephone devices for the deaf or other communication aids such as picture cards or written materials in the patient's language.

All personnel are knowledgeable regarding the written policies and procedures for the provision of care to patients with communication barriers.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD2-P.01: Written policies and procedures are established and implemented by the facility in regards to a Compliance Program to prevent violations of fraud and abuse laws.

The facility has an established Compliance Program that provides guidance to the various internal anti-fraud and abuse controls. The Compliance Program identifies numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program details actions the facility takes to prevent violations of the fraud and abuse laws.

The guidelines include, but are not limited to:

- Implementation of written policies and procedures, standards of conduct, billing practices, marketing, conflict of interests, disciplinary, and corrective actions
- Designation of a Compliance Officer/Compliance Committee
- Risk assessment to be conducted
- Conducting effective training and education programs for staff
- Development of open lines of communication between the Compliance Officer/Compliance Committee and personnel for receiving complaints and protecting callers from retaliation
- Quality improvement techniques utilized for problem identification, investigation of problems, monitoring, and auditing
- Establishing and publicizing disciplinary guidelines for failing to comply with policies and procedures, applicable statutes, and regulations
- Prompt response to detected offenses through corrective action

The facility has written standards of conduct posted in staffing area which includes a non-retaliation statement.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD2-Q.01: Written policies and procedures are established and implemented by the facility for dialysis services to residents located in a nursing home.

The facility's policies and procedures for services to residents located in a nursing home must include protocols for the delivery of dialysis services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a facility. The protocols are developed in collaboration with the nursing home and must include procedures for:

- Infection control 494.30
- Patient assessment 494.80
- Patient plans of care 494.90
- Care of the dialysis patient at home 494.100

Policies and procedures must be reviewed and updated as necessary to be consistent with the most current standards of practice. Timeframes for re-evaluation of policies and procedures should be determined by each facility.

The facility is ultimately responsible for the safe delivery of dialysis to the nursing home resident which would include review of the qualifications, training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home and who provide on-site supervision of dialysis treatments. Documentation of training and competency verifications for nursing home staff will be maintained by both the facility and nursing home. The facility is responsible for the on-going monitoring of the competency of the personal caregiver.

The facility providing services to a resident in a nursing home must ensure:

- On-site supervision of dialysis by a trained registered nurse (RN) who has completed a training course approved by the facility whenever a resident is receiving hemodialysis (HD) in the nursing home, and by a trained RN or licensed practical/vocational nurse (LPN/LVN) who has completed a training course approved by the facility when a resident is receiving peritoneal dialysis (PD) treatment in the nursing home.
- Qualified/trained dialysis administering personnel are present in the room and maintain direct visual contact with the resident receiving HD throughout the entire duration of the treatment; and
- If a situation occurs where the nursing home is unable to provide dialysis treatments due to reasons such as insufficient trained staff and/or supervision, the facility is notified and provides the dialysis treatments to avoid a delay or cancellation of treatment.

The training must be:

- Equivalent to the facility training and competency verification for home dialysis patients at 494.100 (a)(3)(i-viii) and 494.100(b)(1).
- Approved by the facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at 494.100(b)(2); and
- Specific to the dialysis modality. The training program for HD and PD must include at least the subject matter listed at 494.100(a)(3)(i-viii).

To assure resident safety, the facility and the nursing home must ensure that qualified dialysis administering personnel remain in the room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment, in accordance with 494.60(c)(4).

The facility must have a written agreement with any individual nursing home for which they will provide dialysis services. The agreement delineates the responsibilities of the facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments. The written agreement must be signed by authorized representatives of the facility and the nursing home prior to the provision of dialysis care at the nursing home and must:

- Delineate the lines of authority of each party;

- Delineate the responsibilities of each party;
- Describe how coordination between the parties will occur;
- Describes the accountability for the dialysis services provided;
- Be consistent with the written policies and procedures of the facility and the nursing home;
- Specify the method by which the parties will ensure adherence to the terms of the agreement, communicate as issues arise, and take remedial action when appropriate;
- Describe emergency plans including:
    - Emergency staffing- The nursing home is responsible for notifying the facility If any delays or interruptions in the provision of the prescribed dialysis treatment. The facility is responsible for ensuring that a backup plan is in place to ensure the resident receives the treatment;
    - Emergency care- Nursing home residents receiving dialysis may have complications which require treatment with emergency medications or equipment. The physician treatment orders for the dialysis resident will include what emergency medications are to be kept on hand;
    - Equipment failure- The facility must provide nursing home staff with:
        - Adequate and appropriate education for possible equipment failures and risk(s) associated with equipment failures;
        - Troubleshooting techniques, and
        - Contact information for assistance in resolving issues with equipment failure
    - Emergency supplies- Nursing homes will maintain all necessary medication and supply inventories to prevent any delays or interruptions to a resident's prescribed dialysis treatment. The facility and the nursing home will ensure a reserve of supplies to be available in emergency circumstances. The emergency supply reserve is in excess of the routine supply inventory and generally includes at least five (5) days of emergency supplies for each resident. To assist with the inventory, the facility will provide nursing homes with medications, equipment, and dialysis related supplies through routine deliveries. Plans must be in place for the safe delivery of additional supplies in the event of an emergency.
- Be reviewed at least annually, and updated as needed.

The facility must provide to the nursing home an on-call schedule with the names and contact information of physicians and/or facility's RN's to be called for emergencies.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews
Evidence: Written Contracts/Agreements

Services applicable: HDS

Section 3: FISCAL MANAGEMENT

The standards in this section apply to the financial operations of the company. These standards will address the annual budgeting process, business practices, accounting procedures, and the company's financial processes.

Standard RD3-D.01: The facility provides guidance to patients and/or caregivers in regard to what type of financial assistance is available to them.

Each facility provides their patient's access to personnel who have the knowledge to aid them with access to financial assistance. These personnel will have extensive knowledge in regard to Medicare, Medicaid, Third party payors, Medicare Advantage plans and/or the Veteran's Administration.

Evidence: Observation
Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: HDS, ICD

Section 4: HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Personnel may include, but are not limited to, support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory employees, contract personnel, independent contractors, volunteers, and students completing clinical internships. This section includes requirements for personnel records including skill assessments and competencies.

Standard RD4-A.01: Written policies and procedures are established and implemented that describe the procedures to be used in the management of personnel files, their confidentiality and required documentation completed prior to hire.

The written policies and procedures include, but are not limited to:

- Positions having access to the personnel file
- Proper storage
- The required contents
- Procedures to follow for employees who wish to review personnel files
- Time frames for retention of personnel files

Prior to, or at the time of hire, all personnel complete the appropriate documentation which includes, but is not limited to:

- Application, curriculum vitae, or resume with references
- Dated and signed withholding statements
- Verification of citizenship status or legal authorization to work in the United States
- Contractual agreement
- There is documentation of receipt of the job description at time of orientation and whenever the job description changes (e.g., signed job description, orientation checklist, electronic verification)

Personnel files are maintained with required information for employment and related to their job responsibilities.

The facility has complete personnel records available for inspection by federal, state regulatory agencies and accreditation agencies.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Personnel Files

Services applicable: HDS, ICD

Standard RD4-C.01: All personnel files at a minimum contain or verify the following items. (Informational Standard Only) - .

Please refer to the standard listed for a detailed description of these requirements

Description:	Standard:
Orientation /Competency Assessment/Training	RD2-E, RD4-I, RD4-S, RD7-C
Annual performance evaluations	RD4-G.01
Verification of qualifications, license, registration and/or certification	RD4-D
OIG exclusion list verification	RD4-F.01
Background checks	RD4-F.01
National Sex Offender, if applicable	RD4-F.01
Hepatitis B Vaccine Record or Declination	RD7-B
Tuberculosis, (TB) testing, baseline TB test, risk assessment and symptom evaluation	RD7-A
BLS is required for all licensed and certified patient care personnel	RD4-D
Confidentiality agreement with signature	RD2-N

- Personnel include, but are not limited to: support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory personnel, contract personnel, and volunteers.
- For contract staff the facility must have access to all of the above items, except position application, withholding statement, I-9, and personnel handbook. The remainder of items must be available for review during survey but do not need to be kept on site.
- Direct patient care - care of a patient provided personally by a staff member or contracted individual/organization in a patient's

residence or healthcare facility. Direct patient care may involve any aspects of the health care of a patient, including treatments, counseling, self-care, patient education, and administration of medication

Evidence: Informational Standard Only

Services applicable: HDS, ICD

Standard RD4-D: Personnel are qualified for the positions they hold by meeting the education, training, and experience requirements defined in writing by the facility. Personnel credentialing activities are conducted through primary source validation of current license at the time of hire and upon renewal. (494.140) V680

Personnel hired for specific positions within the facility meet the minimum qualifications for those positions in accordance with applicable laws or regulations and the facility's policies and procedures, and job descriptions. Education, training, and experience are verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, certificates, and workshop attendance records.

All professionals who provide care/services directly, under an individual contract, or under arrangements with the facility, must be legally authorized (licensed, certified, or registered) in accordance with applicable federal, state, and local laws, and must act only within the scope of his or her state license, state certification, or registration. All personnel qualifications must be kept current at all times.

Current license, certification, and registration are verified through the primary source with the state appropriate upon hire and at expiration/renewal.

Evidence: Personnel Files

Services applicable: HDS, ICD

Standard RD4-F.01: Written policies and procedures are established and implemented in regard to background checks being completed on personnel that have direct patient care and/or access to medical records. Background checks include: Office of Inspector General Exclusion List (OIG), and criminal background record.

The facility obtains a criminal background check and OIG exclusion list check on all employees who have direct patient care and have access to medical records. The facility contracts require that all contracted entities and contracted personnel obtain a criminal background check, and OIG Exclusion List check, on contracted employees who have direct patient care.

Criminal background checks are obtained in accordance with state requirements. In the absence of state requirements, criminal background checks are obtained within three months of the date of employment for all states where the individual has lived or worked in the past three years.

It is preferred that the facilities recheck the criminal background history on all personnel that provide direct patient care at least every three years.

In the circumstance that an employee will go into a patient home that employee will have a National Sex Offender registry check.

The facility has policies and procedures regarding special circumstances, if any, for hiring a person convicted of a crime. The policies and procedures include, but are not limited to:

- Documentation of special considerations
- Restrictions
- Additional supervision

Evidence: Written Policies and Procedures
Evidence: Personnel Files

Services applicable: HDS, ICD

Standard RD4-G.01: Written personnel policies and procedures and/or an Employee Handbook are established and implemented describing the activities related to personnel management.

Personnel policies and procedures and/or Employee Handbook include, but are not limited to:

- Wages
- Benefits
- Grievances and Complaints
- Recruitment, hiring and retention of personnel
- Disciplinary action/termination of employment
- Conflict of interest

- Performance expectations and evaluations

Personnel policies and procedures and/or Employee Handbook are reviewed at least annually, updated as needed, and are in accordance with applicable law and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

Written documentation is kept verifying that the employee has reviewed and has access to personnel policies and procedures.

Wages
Information is available on, overtime, on-call, holiday pay, and exempt versus non-exempt status.

Benefits
An explanation of benefits is shared with all benefit eligible personnel. If a facility does not provide no benefits or if benefits are unavailable to certain personnel, communicate this fact in writing. For example, the contract/agreement with personnel who are utilized on an “as needed” basis should address that benefits are not available to persons employed in that classification.

Grievances and Complaints
Written grievance/complaint information addresses options available to personnel who have work-related complaints, including steps involved in the grievance process.

Recruitment, Hiring and Retention of Personnel
The facility has written policies and procedures on its recruitment, hiring, and retention of personnel which demonstrate nondiscriminatory practices.

Disciplinary Action and Termination of Employment
Disciplinary action and termination of employment policies and procedures define time frames for probationary actions, conditions warranting termination, steps in the termination process, and appeal process.

Conflict of Interest
The facility has written policies and procedures that define the process for handling conflicts of interest.

Performance Expectations and Evaluations
The facility's policies and procedures outline general performance expectations of all personnel (e.g., dress code, professional conduct, etc.), along with conducting performance evaluations annually.

Job Descriptions
The facility has job descriptions for each position. The job description includes: job duties, reporting responsibilities, minimum job qualifications, requirements for job and physical and environmental requirements

Evidence: Written Policies and Procedures and/or Employee Handbook
Evidence: Observation

Services applicable: HDS, ICD

Standard RD4-I: Written policies and procedures are established and implemented requiring the facility to design a competency assessment program on the care/service provided for all direct care personnel. (494.140) V681

The facility designs and implements a competency assessment program based on the care/service provided for all direct care personnel. Validation of skills is specific to the employee's role and job responsibilities.

Competency assessment is an ongoing process and focuses on the care/services being provided. Competency assessments are conducted initially during orientation and prior to providing a new task..

Qualified personnel observe and evaluate each direct care personnel performing their job duties at frequencies required by state and/or federal regulations. If not specified in law and regulation, the evaluation is performed at least once annually to assess that quality care being provided. This activity is documented in the personnel file.

Policies and procedures for determining that direct care personnel are competent to provide quality care/service are in place and may be accomplished through observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment.

All competency assessments and training are documented. A self-assessment tool alone is not acceptable. All direct care personnel must be observed providing patient care within their scope of practice by a qualified clinician prior to providing care independently. Peer review of clinical personnel competency by like disciplines is acceptable if defined by the facility. Specific competencies that are expected to be demonstrated by staff assigned to these tasks include:

- Skills at testing for chlorine/chloramine levels
- Operating reuse equipment
- Following infection control practices designated for facilities by the CDC
- Identifying and treating intradialytic morbidities

- Monitoring patients and equipment alarms during treatment

There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

Evidence: Written Policies and Procedures
Evidence: Competency Assessment
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD4-L.01: Written policies and procedures are established and implemented that identifies which waived tests can be conducted and ensures appropriate training for individuals conducting tests.

The facility identifies through policies and procedures or through a listing of waived tests and which tests can be performed at the facility.

The person from the facility, whose name is on the CLIA certificate, identifies which personnel may perform waived tests, establishes and implements policies and procedures, and conducts and documents appropriate training for these individuals. Quality controls are completed according to manufacturer's guidelines for these trained individuals upon hire, ongoing as needed, and annually.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD4-M: The facility must have a qualified Medical Director who will be responsible for the delivery of patient care and outcomes in the facility. The Medical Director is accountable to the governing body for the quality of medical care provided to patients. (494.140(a)(1)) V682, (494.140(a)(2)) V683, (494.150) V710-V711, (494.150(a)) V712, (494.150(b)) V713, (494.150(c)(1)) V714, (494.150(c)(2)(i)) V715, (494.150(c)(2)(ii)) V716, (494.180(f)(1-3)) V766, (494.180(f)(4-5)) V767

Treatment is under the general supervision of a qualified Medical Director who is a physician appointed by and accountable to the governing body for the quality of patient care and outcomes. The physician-director of the facility is responsible for the execution of patient care policies.

The Medical Director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis. If a qualified physician is not available another physician may direct the facility, subject to the approval of the Secretary. A waiver of these requirements may be requested from the State Authority if a qualified Medical Director is not available to serve at a RDF. The RDF cannot apply for a waiver during their initial certification process and survey.

Each facility may only have a single Medical Director. The position of Medical Director may not be shared by several physicians.

Medical Director's responsibilities include, but are not limited to:

- Quality assessment and performance improvement program
- Overseeing/approving staff education, training, and performance
- Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility
- Ensure all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers
- The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in 42 CFR 494.180(f)
- The Medical Director ensures that no patient is discharged or transferred from the facility unless:
    - The patient or payor no longer reimburses the facility for the ordered services
    - The facility ceases to operate
    - The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs
    - The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the Medical Director ensures that the patient's interdisciplinary team:
        - Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record
        - Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge
        - Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility
        - Contacts another facility, attempts to place the patient there, and documents that effort
        - Notifies the state survey agency of the involuntary transfer or discharge
        - In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge process

Evidence: Personnel File

Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD4-N: The facility employs at least one full time qualified nurse manager responsible for nursing service. (494.140(b)(1)) V684

The facility must have a full-time nurse manager responsible for nursing service. The nurse manager is licensed as a registered nurse by the state in which he or she is practicing, and has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

The nurse manager is the only staff person who must be a direct employee of the facility rather than a contracted employee.

Full time means employed 40 hours/week by the facility or for the number of hours the facility is open, whichever is less. One nurse could be employed full time at two facilities if one was open Monday/Wednesday/Friday and the second was open Tuesday/Thursday/Saturday. A single RN could not be considered full time by three or more facilities.

Evidence: Personnel File
Evidence: Job Description
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD4-O: If the facility offers self-care dialysis training, a qualified nurse provides such training. (494.140(b)(2)) V685

The nurse responsible for self-care and/or home care training must be a Registered Nurse, licensed in the state he or she is practicing and have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

The registered nurse must be in charge of and provide self-care and home dialysis training for dialysis patients and/or their caregivers.

Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: HDS

Standard RD4-Q: The facility must have a qualified registered dietitian. (494.140(c)(1-2)) V689-V690

A qualified dietitian a registered dietitian with the Commission on Dietetic Registration and has a minimum of one year professional work experience in clinical nutrition as a registered dietitian.

The dietitian may be an employee of the facility or have a contractual relationship with the facility.

Evidence: Personnel Files
Evidence: Observation

Services applicable: HDS, ICD

Standard RD4-R: The facility must have a qualified social worker. (494.140(d)(1-2)) V691

A qualified social worker is a person who holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or has served at least two years as a social worker, one year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education.

The social worker may be an employee of the facility or have a contractual relationship with the facility.

Evidence: Personnel File(s)
Evidence: Observation

Services applicable: HDS, ICD

Standard RD4-S: The facility that employs and utilizes patient care dialysis technicians must meet specific qualifications and training. (494.140(e-f)) V692-696

Patient care dialysis technicians must meet all the applicable state requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the state in which he or she is employed as a dialysis technician; and have a high school diploma or equivalency.

The technician must be certified under a state certification program or a national commercially available certification program, as follows: For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or for patient care technicians employed on October 14, 2008, who are not yet certified under an approved program, must be certified before April 15, 2010.

The technician must have completed a training program that is approved by the Medical Director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients.

The training program must include the following topics:

- Principles of dialysis
- Care of patients with kidney failure, including interpersonal skills
- Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis
- Possible complications of dialysis
- Water treatment and dialysate preparation
- Infection control
- Safety
- Dialyzer reprocessing, if applicable

Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the Medical Director and the governing body.

Evidence: Personnel Files(s)
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Section 5: PROVISION OF CARE AND RECORD MANAGEMENT

The standards in this section apply to documentation and requirements for the service recipient/client/patient record. These standards also address the specifics surrounding the operational aspects of care/services provided.

Standard RD5-A: The facility must maintain complete, accurate, and accessible medical records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. (494.170) V725-V726, (494.170(b)(1)) V729, (494.170(b)(2)) V730, (494.170(b)(3)) V731

The facility must maintain a complete, accurate medical record that is readily retrieved for each facility patient. The facility must use the information contained in each medical record to ensure the delivery of appropriate care/service to each patient.

Completion of patient medical record and centralization of clinical information includes:

- Current medical records and those of discharged patients must be completed promptly
- All clinical information pertaining to a patient must be centralized in the patient's medical record, including whether the patient has executed an advance directive
    - These medical records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment
- The facility must complete, maintain, and monitor home care medical records, including the medical records of patients who receive supplies and equipment from a durable medical equipment supplier

Evidence: Medical Records
Evidence: Observation

Services applicable: HDS, ICD

Standard RD5-D: Written policies and procedures are established and implemented in regards to the facility maintaining the confidentiality of the medical record and providing safeguards against loss, destruction, or unauthorized use. (494.170 (a)(1-3)) V727-V728

The facility maintains the confidentiality of the medical record and provides safeguards against loss, destruction, or unauthorized use. The facility must have sufficient safeguards to ensure that access to all information regarding patients is limited to authorized individuals only.

Written policies and procedures are consistent with Health Insurance Portability and Accountability Act (HIPAA) standards, which include, but are not limited to:

- Who can have access to medical records
- Personnel authorized to enter information and review the medical records
- Any circumstances and the procedure to be followed to remove medical records from the premises or designated electronic storage areas
- A description of the protection and access of computerized medical records and information
- Back-up procedures, which include, but are not limited to:
    - Electronic transmission procedures
    - Storage of back-up disks and tapes
    - Methods to replace information if necessary
- Conditions for release of information

Paper and electronic medical records must be protected from loss or unintended destruction and must be protected from access by unauthorized individuals or unauthorized use by authorized individuals.

The facility must keep all information confidential contained in the medical record, except when release is authorized pursuant to one of the following:

- The transfer of the patient to another facility
- Certain exceptions provided for in the law
- Provisions allowed under third party payment contracts
- Approval by the patient
- Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program

Prior to releasing information from the patient’s medical record, the facility must obtain the written consent of the patient (or his/her representative), unless the release is required by law.

Medical records contain signed release of information statements/forms when the facility bills a third-party payor or shares information with others outside the facility as required by the Health Insurance Portability and Accountability Act (HIPAA) and other applicable laws

and regulations.

Staff receives training upon hire and annually on confidentiality of patient information.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Medical Records
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD5-E: Written policies and procedures are established and implemented in regards to the facility providing for the interchange of medical and other information necessary or useful in the care/service and treatment of patients transferred between treating facilities. (494.170)(d)) V733

The facility has established and implemented written policies and procedures for the prompt transfer of medical information between treatment facilities to facilitate continuity of care.

When a dialysis patient is transferred, the facility releasing the patient must send all requested medical record information to the receiving facility within one working day of the transfer.

The facility has a process in place that ensures patient medical records are complete when patients are referred or transferred. Information is shared as needed or requested with consent from the patient or family and in accordance with laws and regulations.

The facility establishes and implements policies and procedures for the prompt transfer of medical information between treatment facilities to facilitate continuity of care.

Evidence: Written Policies and Procedures
Evidence: Medical Records

Services applicable: HDS, ICD

Standard RD5-F: Written policies and procedures are established and implemented in regard to the retention and preservation of patient and equipment maintenance records. (494.170(c)) V732

In accordance with 42 CFR 164.530(j)(2), all patient records are retained for six years from the date of discharge, transfer, or death, unless state statute is more restrictive. Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks.

These retention requirements also apply to the records of machine maintenance, dialyzer reprocessing/reuse, water treatment, and dialysate preparation as each of these records is part of the medical record for the patients on service at the time those records were completed. Documentation of these processes is retained in logs rather than individual medical records. Since many patients are treated on the equipment each day, determination of the retention period may be difficult. Facility policies and procedures should address retention of these records.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: HDS, ICD

Standard RD5-G: Written policies and procedures are established and implemented that describe components and interdisciplinary approach required for a patient assessment. (494.80) V500-501, (494.80(a)(1-13)) V502-515, (494.80(b)(1-2)) V516-517, (494.80(c)(1-2)) V518, (494.80(d)(1-2)) V519-520

The facility has written policies and procedures that define the components of an assessment to be completed by the interdisciplinary team. The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.

Written policies and procedures include components of the assessment as appropriate to the patient age and medical condition which may impact their care/service needs, including chronic health condition(s), and current health and lifestyle risk factors such as smoking and alcohol use.

The patient's comprehensive assessment must include, but is not limited to:

- Patient information: Patient demographics
- Responsible party/emergency contact, language, presence of risk factors
- The physical health component: Assessment of body systems, vitals, height, weight, and pain
- Evaluation of current health status and medical condition, including co-morbid conditions
- The mental component: Orientation, neuro/behavioral status
- Blood pressure and fluid management needs
- Evaluation of the appropriateness of the dialysis prescription
- Laboratory profile
- Immunization history and medication history
- Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s)
- Evaluation of factors associated with renal bone disease
- Evaluation of nutritional status by a dietitian
- Evaluation of psychosocial needs by a social worker
- Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters)
- Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes
- Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s)
    - If the patient is not suitable for transplantation referral, the basis for non-referral must be documented in the medical record
- Evaluation of family and other support systems
- Evaluation of current patient physical activity level
- Evaluation for referral to vocational and physical rehabilitation services
- Any environmental factors: identification of safety and health hazards

A follow up comprehensive reassessment must occur within three months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in 494.90.

The adequacy of the patient's dialysis prescription, as described in 494.90(a)(1), must be assessed on an ongoing basis as follows:

- Hemodialysis patients: At least monthly by calculating delivered Kt/V or an equivalent measure
- Peritoneal dialysis patient: At least every four months by calculating delivered weekly Kt/V or an equivalent measure.

A comprehensive reassessment of each patient and a revision of the plan of care must be conducted:

- At least annually for stable patients
- At least monthly for unstable patients including, but not limited to, patients with the following:
    - Extended or frequent hospitalizations (longer than 15 days or greater than 3 per month)
    - Marked deterioration in health status
    - Significant change in psychosocial needs
    - Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis

Evidence: Written Policies and Procedures
Evidence: Medical Records
Evidence: Response to Interview Questions

Services applicable: HDS, ICD

Standard RD5-J: Written policies and procedures are established and implemented in regard to the interdisciplinary team developing and implementing a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment. (494.90) V540-541, (494.90(a)(1-8)) V542-555, (494.90(b)(1)) V556, (494.90(b)(2)) V557-558, (494.90(b)(3)) V559, (494.90(b)(4)) V560, (494.90(c)) V561, (494.90(d)) V562

The interdisciplinary team as defined at § 494.80 has written policies and procedures in regard to developing and implementing a written, individualized comprehensive plan of care for each patient that specifies the care/services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes with estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.

The patient or caregiver(s) are considered part of the interdisciplinary team and encouraged to participate in the development of the plan. The patient's needs, wishes, and goals are considered in making decisions about the plan of care.

A registered nurse with knowledge of the patient must serve as a member of the team. The registered nurse participating in the plan of care for home dialysis patients should work in the home dialysis program and have knowledge of the home dialysis patient.

The patient's plan of care includes, but is not limited to:

- Completion by the interdisciplinary team, including the patient if the patient desires
- Signatures by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided
- Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session
- Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in 494.80(d)
- If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals
    - When a patient is unable to achieve the desired outcomes, the team must:
        - Adjust the plan of care to reflect the patient's current condition
        - Document in the medical record the reasons why the patient was unable to achieve the goals
        - Implement plan of care changes to address the issues

The facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

The plan of care must at least address the following:

- Patients receive effective pain management and symptom control as needed for conditions treated
- The interdisciplinary team must provide the necessary care and services to manage the patient's volume status for specific dose of dialysis
- Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis
- The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status
    - A patient's albumin level and body weight must be measured at least monthly
    - Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate
- Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease
- The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.
    - The patient's hemoglobin/hematocrit must be measured at least monthly
    - The facility must conduct an evaluation of the patient's anemia management needs
- For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration, if necessary
- The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis
- The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access
    - The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement
- The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis
- The interdisciplinary team must provide the necessary monitoring and social work interventions
    - These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis
- The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis
- The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate
- When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation
    - The patient's plan of care must include documentation of the:
        - Plan for transplantation, if the patient accepts the transplantation referral;
        - Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral
        - Reason(s) for the patient's non-referral as a transplantation candidate as documented in accordance with 494.80(a)(10)

The interdisciplinary team responsibilities in regards to transplant referral include:

- Track the results of each kidney transplant center referral
- Monitor the status of any facility patients who are on the transplant wait list
- Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status

The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks as well as monitoring for infection of various vascular access types.

Evidence: Written Policies and Procedures
Evidence: Medical Records
Evidence: Patient Interviews
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD5-K: A facility that is certified to provide services to home patients must ensure through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients. (494.100) V580-581, (494.100(a)(1-2)) V583-V584, (494.100(a)(3)(i-viii)) V585, (494.100(b)(1-3)) V586-587

The facility must be certified to provide home dialysis services and the interdisciplinary team consists of members as required and provided to in-facility patients.

Home or self-dialysis support services cover both home hemodialysis and peritoneal dialysis, including continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD).

The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in 42 CFR 494.10) and when the home dialysis caregiver or home dialysis modality changes.

The training for the home dialysis must:

- Be provided by a facility that is approved to provide home dialysis services
- Be conducted by a registered nurse who meets the requirements of 42 CFR 494.140(b)(2)
- Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:
    - The nature and management of End Stage Renal Disease (ESRD)
    - The full range of techniques associated with the treatment modality selected, including the effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care
    - How to detect, report, and manage potential dialysis complications, including water treatment problems
    - Availability of support resources and how to access and use resources
    - How to self-monitor health status and record and report health status information
    - How to handle medical and non-medical emergencies
    - Infection control precautions
    - Proper waste storage and disposal procedures

Requirements for home dialysis monitoring:

- Documentation in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training
- Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every two months
- Maintain this information in the medical record

The facility must provide and maintain a recordkeeping system which ensures continuity of care and up to date documentation of services provided.

Records of results of chemical and microbial testing of home hemodialysis water and dialysate should be available in the home setting and at the facility providing support; the log of these results may be included in the patient's record or in a separate record.

Evidence: Medical Records
Evidence: Response to Interviews
Evidence: Observation

Services applicable: HDS

Standard RD5-L: A facility that is certified to provide support services to home patients must ensure that home dialysis services are at least equivalent to those provided to in-facility patients. (494.100(c)(1-2)) V588-V599

A home dialysis training facility must provide (directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the facility or a durable medical equipment company.

Home support services include, but are not limited to:

- Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care

- Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team
- Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in 42 CFR 494.90
- Patient consultation with members of the interdisciplinary team, as needed
- Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with manufacturers' instructions and FDA- approved labeling for systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate
- The facility must meet testing and other requirements of ANSI/AAMI RD52:2004
    - In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits
- The facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if:
    - Analysis of the water and dialysate quality indicates contamination
    - The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination
- Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician
- Identifying a plan and arranging for emergency back-up dialysis services when needed

The facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services provided by durable medical equipment (DME) suppliers.

Evidence: Medical Records
Evidence: Observation
Evidence: Contracts/Agreements
Evidence: Response To Interviews

Services applicable: HDS

Standard RD5-P.01: Written policies and procedures are established and implemented addressing the administration, dispensing, storage, handling, and labeling, of drugs and biologicals.

Written policies and procedures are established and implemented regarding appropriate administration, storage, handling, labeling, and dispensing of drugs and biologicals to ensure safe and effective medication management for patients. The facility is in compliance with all dispensing laws/regulations.

Written policies and procedures include, but are not limited to:

- Administration, and dispensing of drugs and biologicals in accordance with laws and regulations
- Verification of order with correct patient, medication, dose, route, frequency and duration when administering or dispensing the medication
- Drugs are stored in the original manufacturer's containers to maintain proper labeling
- Drugs and dispensed to patients have complete and legible labeling of containers or packaging
- Multiple dose vials and single dose vials are stored according to current CDC infection control guidelines. Once opened, vials are labeled with date, time, and initials of nurse opening along with the expiration date
- Appropriate disposal of medications, disposal of single-dose vials after opening, no reuse of supplies labeled as single use
- Drugs and biologicals must be stored and maintained in accordance with the manufacturer's instructions for temperature and other environmental conditions as well as expiration dates, beyond use dates, etc.
- Refrigerators/freezers are specifically dedicated and labeled as storage of medications and vaccines only
- Refrigerated or frozen medications or vaccines are monitored for storage temperature continuously or at least twice a day
    - No drugs are to be stored in the door of refrigerator or freezer
- Expired, deteriorated, or adulterated drugs, biologicals and supplies are disposed of appropriately

All controlled substances are handled in accordance with FDA requirements:

- Scheduled II drugs are stored in locked compartments and separate from other drugs
- Scheduled III, IV & V are stored in a secure cabinet
- The facility maintains a written record/log of controlled substances and reconcilable log of the distribution as part of their process to monitor for diversion and theft

The facility has a process for recall of drugs and biologicals.

The facility has current drug references and antidote information available onsite.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Controlled Substance Log

Evidence: Response to Interviews

Services applicable: HDS, ICD

Section 6: QUALITY OUTCOMES/PERFORMANCE IMPROVEMENT

The standards in this section apply to the organization's plan and implementation of a Performance Improvement (PI) Program. Items addressed in these standards include who is responsible for the program, activities being monitored, how data is compiled, and corrective measures being developed from the data and outcomes.

Standard RD6-A: The facility develops, implements, and maintains an effective, ongoing, facility-wide Quality Assessment and Performance Improvement (QAPI) program. The facility measures, analyzes, and tracks quality indicators that enable the facility to assess processes of care, services, and operations. Facility-wide performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated for effectiveness. (494.110) V625-V626, (494.110 (a)(1-2)) V627-V637, (494.110(b-c)) V638-V640

The facility must develop, implement, maintain, and evaluate an effective, data-driven, QAPI program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the facility's and care/services (including those care/services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The facility must maintain and demonstrate evidence of its quality improvement and QAPI program.

The facility develops and maintains and ongoing QAPI program that is specific to its needs. The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

The methods used by the facility for reviewing data include, but are not limited to:

- Current documentation (e.g., review of medical records, incident reports, complaints, patient satisfaction surveys, etc.)
- Patient care and services
- Direct observation in care setting
- Operating systems
- Interviews with patients and personnel

The facility must continuously monitor its performance; take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time

The facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The data collected by the facility for self-assessment includes, but is not limited to:

- At least one important aspect related to patient care provided to include:
  - An important aspect of care that reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of patients), high risk (causes a risk of serious consequences if the care is not provided correctly), or problem-prone (has tended to cause problems for personnel or patients in the past).
- Satisfaction surveys
- Medical records
- Patient grievances/complaints
- Adequacy of dialysis to patients
- Patient's nutritional status
- Patient's mineral metabolism and renal bone disease
- Patient anemia management
- Vascular access
- Hemodialyzer reuse program, if the facility reuses hemodialyzers
- Medical injuries and errors
- Adverse Events to patients or personnel
- Infection control
  - Analyze and document the incidence of infections to identify trends and establish baseline information on infection incidence
  - Develop recommendations and action plans to minimize infection transmission and promote immunization
  - Take actions to reduce future incidents

The facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

Evidence: Written Policies and Procedures/QAPI Plan
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD6-H.01: Quality Assessment and Performance Improvement (QAPI) activities include ongoing monitoring of at least one important administrative function of the facility.

The facility conducts monitoring of at least one important administrative/operational function of the RDF.

Examples of QAPI activities include, but are not limited to:

- Monitoring compliance of conducting performance evaluations
- Number of in-service hours completed by personnel
- Other personnel file audits

Evidence: QAPI Activities/Studies

Services applicable: HDS, ICD

Standard RD6-I.01: The Quality Assessment and Performance Improvement (QAPI) program includes a review of the medical records.

The medical records review consists of the following:

- At least quarterly, patient chart audits are completed representing the scope of the program, reviewing a sample of both active and closed medical records to determine if regulatory requirements are met and patient outcomes are achieved

Evidence: QAPI Activities/Studies

Services applicable: HDS, ICD

Standard RD6-L: Written policies and procedures are established and implemented in regard to mandatory information and data reporting to the End Stage Renal Disease (ESRD) Network designated for the facility's geographic area. (494.180 (h)(1-3)) V771, (494.180(i)) V772

Written policies and procedures describe the facilities reporting requirements to the ESRD Network.

Effective February 1, 2009, the facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment.

The data and information must:

- Be submitted at the intervals specified by the Secretary
- Be submitted electronically in the format specified by the Secretary
- Include, but not be limited to:
    - Cost reports
    - ESRD administrative forms
    - Patient survival information
    - Existing ESRD clinical performance measures and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary

The governing body receives and acts upon recommendations from the ESRD Network. The facility must cooperate with the ESRD Network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and purse network goals.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Section 7: RISK MANAGEMENT: INFECTION AND SAFETY CONTROL

The standards in this section apply to the surveillance, identification, prevention, control, and investigation of infections and safety risks. The standards also address environmental issues such as fire safety, hazardous materials, and disaster and crisis preparation.

Standard RD7-A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control and investigation of infectious and communicable diseases and the compliance with regulatory standards. (494.30) V110-V111, (494.30(a)(1)(i)) V112-V120, (494.30(a)(3) no tag (494.30(a)(4)(i)) V121, (494.30(a)(4)(ii)) V122

The facility maintains and documents an effective infection control program that protects patients and personnel by preventing and controlling infections and communicable diseases.
The facility's infection control program must identify risks for the acquisition and transmission of infectious agents in service settings. The facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

There is a system to communicate with all personnel and patients about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures identify the personnel who have the responsibility for the implementation of the infection control activities and personnel education.

Written policies and procedures are established and implemented to include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions. The facility must demonstrate that it follows standard infection control precautions by implementing the recommendations (with the exception of screening for hepatitis C), found in "recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28.

Written policies and procedures are established and implemented that includes, but are not limited to:

- General infection control measures appropriate for service provided
- Hand Hygiene:
    - A sufficient number of sinks with warm water and soap should be available to facilitate hand washing
- Use of standard precautions and personal protective equipment
- Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station:
    - Staff must remove gloves and wash hands between each patient or station
- Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood)
- Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory
- Needle-stick prevention and sharps safety
- Appropriate safe use and disposal use of single-use supplies or devices, including point-of-care devices according to manufacturer's guidelines
- Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment:
    - Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled
    - Do not handle and store medications or clean supplies in the same or an adjacent area where used equipment or blood samples are handled
- Items taken into the dialysis station should be disposed of, or dedicated for use only a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient
    - Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient
    - Unused medications (including multiple does vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients
- When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient
    - Do not carry multiple dose medication vials from station to station
    - Do not use common medication carts to deliver medications to patients
- Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once
- If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood:
    - Such carts should not be moved between stations to distribute supplies
    - Do not carry medication vials, syringes, alcohol swabs or supplies in pockets
- Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors
- If the external transducer protector becomes wet, replace immediately and inspect the protector:
    - If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the

machine after the treatment is completed and check for contamination
        - This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port
        - If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse
    - Change filters/protectors between each patient treatment, and do not reuse them
    - Internal transducer filters do not need to be changed routinely between patients
- Facility maintains procedures, in accordance with applicable state and local laws and accepted public health procedures for the handling, storage, and disposal of potentially infectious waste; and cleaning and disinfection of contaminated surfaces, medical devices, and equipment
- Appropriate cleaning/disinfecting procedures:
    - Low- level disinfection, high-level disinfection and sterilization according to manufacturer's guidelines and nationally recognized accepted standards of practice such as the Association for Professionals in Infection Control and Epidemiology (APIC), American Association of Medical Instrumentation (AAMI), and Association of Operating Room Nurses (AORN):
        - Processes to avoid cross-contamination prior to, during and post procedures
        - Appropriate separate areas for dirty, cleaning, and disinfection of instruments/equipment
- Storage of reprocessed items
- Infection surveillance, monitoring and reporting of employees and patients
- Precautions to protect immune-compromised patients
- Patient isolation procedures to minimize the spread of infectious agents and communicable diseases
- Employee health conditions limiting their activities
- Assessment and utilization of data obtained about infections and the infection control program

The facility has written policies and procedures that detail OSHA Blood Borne Pathogen and TB Exposure Control Plan training for all direct care personnel. The exposure control plans are reviewed annually and updated to reflect significant modification in tasks or procedures that may result in occupational exposure. The Exposure Control Plan includes engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent (e.g., use of safer medical devices and needle-less systems.) Plans are available to the personnel at the workplace during the work shift.

The facility has written policies and procedures in regard to all direct care personnel having a baseline Tuberculosis (TB) test at any point in the past or in accordance with state requirements. Prior to patient contact, an individual TB risk assessment and a symptom evaluation are completed.

Prior to patient contact, direct care personnel provide or have:
- Upon hire personnel provide evidence of a baseline TB skin or blood test.
- Prior to patient contact, an individual TB risk assessment and symptom evaluation are completed to determine if high risk exposures have occurred since administration of the baseline TB test.
- If there is no evidence of a baseline TB skin or blood test, TB testing is conducted by the facility.

The facility conducts an annual TB risk assessment to determine the need, type, and frequency of testing/assessment for direct care personnel.

Annual TB testing of health care professionals is not recommended unless there is a known exposure or ongoing transmission.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Patient Interviews
Evidence: Personnel Files

Services applicable: HDS, ICD

Standard RD7-B: Written policies and procedures are established and implemented in regard to vaccination of staff and patients that are susceptible to hepatitis B. According to the CDC, hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients and staff members, whether or not the facility accepts HBV+ patients. (494.30(a)(1)(i)) V124-V128 V130-V131, (494.30)(a)(1)(ii) V129

The facility established and implemented policies and procedures that follow the CDC recommendation and OSHA mandates in regard to Hepatitis B vaccination for patients and staff.

These policies and procedures include, but are not limited to:

- The HBV serological status (i.e.HBsAG, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit.
- Routinely test all patients as required for the hepatitis B virus and promptly reviewing results and ensure that patients are managed appropriately based on their testing results.
- When a seroconversion occurs, review all patients' routine laboratory test results to identify additional cases:
    - Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit,

including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures
- Vaccinate and monitor all susceptible patients and staff members against hepatitis B, according to CDC recommendations:
    - Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose
    - If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs
    - If anti-HBs are ≥10 mIU/mL, consider immune, and retest patients annually
    - Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually
- Isolate HBsAg positive patients by designating a separate room for their treatment:
    - For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activityDedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients
    - Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another
    - When dialysis isolation rooms are available locally that sufficiently serve the needs of patients in the geographic area, a new facility may request a waiver of such requirement
    - Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD7-C: The facility provides infection control training and education to employees, contracted providers, patients and family members regarding basic and high-risk infection control procedures as appropriate to the services provided. (494.30(a)(1)(i))) V132, (494.30(b)(1-3)) V142-V145 (494.30(a)(2)) V146-148

The facility provides infection control training that includes, but is not limited to:

- Infection control practices for hemodialysis units: Intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices
- Monitor and implement biohazard and infection control policies and activities within the dialysis unit
- Ensure that clinical staff demonstrates compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules

All clinical staff reports infection control issues to the facility's Medical Director and the Quality Assessment and Performance Improvement committee. The facility reports incidences of communicable diseases as required by federal, state and local regulations.

All personnel demonstrate competence and compliance with infection control principles in the process of providing care/service to patients as described in OSHA and CDC standards and as adopted into the facility's policies and procedures.

The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement on Intravascular Catheters in Adults and Children" parts I-IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002.

Recommendations for Placement of Intravascular Catheters in Adults and Children include:
- Health care worker education and training:
    - Educate health-care workers regarding the appropriate infection control measures to prevent intravascular catheter-related infections
    - Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters
- Surveillance:
    - Monitor the catheter sites visually of individual patients
    - If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site
- Catheter and catheter-site care:
    - Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections)
    - Appropriateness of catheter dressings being used to promote infection free exit sites
    - Types of caps used to close the catheter between use
    - Education provided to patient/patient care giver of signs and symptoms to report to the HCW

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients:
- Surveillance:
    - Conduct surveillance to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection-control practices
- Investigate events leading to unexpected life-threatening or fatal outcomes:

- This includes any process variation for which a recurrence would likely present an adverse outcome

Evidence: Written Policies and Procedures
Evidence: Personnel Files
Evidence: Observation
Evidence: Response to Interviews
Evidence: Medical Records

Services applicable: HDS, ICD

Standard RD7-J: Written policies and procedures are established and implemented in regard to the design, construction, equipment, and maintenance of the facility to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. (494.60) V400-401, (494.60(a)) V402, 494.60(b)) V403, 494.60(c)(1-4) V404-407

The facility is designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

The building is which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public:

- The physical plant is well constructed and arranged as such that it does not present barriers to patient access or hazards to patient safety
- All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition, including ADA accessible ramps and parking lot and entrance free of hazards
- The facility's layout and fixtures must not present hazards that increase risk of patient injury, such as slippery floors or torn carpets that may present tripping or fall hazards, or ceilings panels that are in danger of falling, etc.
- The facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations
- All equipment needed for the comfort and safety of patients and staff (air conditioners, heat, ventilation, exhaust fans, smoke detectors, etc.) should be in good working order
- The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff
- Maintain a comfortable temperature within the facility
- Make reasonable accommodations for the patients who are not comfortable at this temperature
- The facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required
- Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement)

All areas of the facility must be clean. These areas include, but are not limited to, the waiting areas, exam rooms, and staff lunch room, rest room, and office space. The facility must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and clean environment.

Written policies and procedures are established and implemented for an orderly and clean environment to include, but limited to the following:

- Measures taken to maintain a clean and orderly environment during internal or external construction/renovation
- Routine cleaning of environmental surfaces, carpeting, and furniture
- Disposal of waste, including regulated waste
- Food sanitation, if employee food storage and eating areas are provided
- Pest control

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Reports prepared by State and local authorities
Evidence: Response to Interview Questions
Evidence: Patient Interviews

Services applicable: HDS, ICD

Standard RD7-K: The facility is in compliance with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements. (494.60(d)(1-4)) V417-V420.

Facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), II(200), or V(000), as defined in the 2012 edition of the Life Safety Code section 21.1.6.1 which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level, must comply

with provisions of the Life Safety Code (NFPA 101 and its tentative interim amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12.4) applicable to Ambulatory Health Care Occupancies regardless of the number of patients served.

The facility must submit an attestation form to claim an exemption to the NFPA Life Safety Code (LSC) requirements if they are not located adjacent to high hazard occupancies and they do not provide at least one exit at grade level from the patient treatment area.

If CMS finds that a fire and safety code imposed by the facility's state law adequately protects a facility's patients, CMS may allow the state survey agency to apply the state's fire and safety code instead of the Life Safety Code. In consideration of a recommendation by ACHC, or at the discretion of the secretary, the secretary may waive, for periods, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon the ESRD facility, but only if the will not adversely affect the health and safety of patients.

No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the Health Care Facilities Code (NFPA 99 and its Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6).

Building safety for dialysis facilities follow the following:

- Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the Health Care Facilities Code, regardless of the number of patients served.
- Chapters 7, 8, 12, and 13 of the Health Care Facilities Code do not apply to a dialysis facility.
- If application of the Health Care Facilities Code would result in unreasonable hardship for the dialysis facility, CMS may waive specific provisions of the Health Care Facilities Code for such facility, but only if the waiver does not adversely affect the health and safety of patients.
- *Incorporation by reference.* The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov*, or go to: *www.archives.gov/federal_register/cfr/ibr-locations.html*. If any changes in the editions of the Codes are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.
- National Fire Protection Association, 1 Battery march Park, Quincy, MA 02169, *www.nfpa.org*, 1-617-770-3000.
    - NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11 2011.
    - TIA 12-2 to NFPA 99, issued August 11, 2011.
    - TIA 12-3 to NFPA 99, issued August 9, 2012.
    - TIA 12-4 to NFPA 99, issued March 7, 2013.
    - TIA 12-5 to NFPA 99, issued August 1, 2013.
    - TIA 12-6 to NFPA 99, issued March 3, 2014.
    - NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.
    - TIA 12-1 to NFPA 101, issued August 11, 2011.
    - TIA 12-2 to NFPA 101, issued October 30, 2012.
    - TIA 12-3 to NFPA 101, issued October 22, 2013.
    - TIA 12-4 to NFPA 101, issued October 22, 2013.

Written policies and procedures address fire safety and management for all office and worksite environments in accordance with laws/ regulations including:

- The facility has mechanisms to provide and maintain emergency power to critical areas such as:
    - Alarm systems
    - Illumination of exit routes
    - Emergency communication systems
    - Testing of emergency power systems (at least annually)
- The facility has a no smoking policy which addresses how it will be communicated
- Maintenance and testing of smoke detectors, fire alarm system, and fire extinguishers
    - Fire and sanitation inspections are current as required by the state
    - Floor plans identifying the nearest emergency exit route are posted throughout the facility
    - The facility displays exit signs in appropriate locations and the facility takes other appropriate safety measures consistent with the particular conditions of the area in which the facility is located
    - Exit doors are clearly marked with illuminated signs
    - Exit doors must unlock from the inside
    - Exits from the building are unobstructed and accessible for occupants having limited mobility.
- Fire extinguishers are mounted and have been inspected annually by by a Licensed Fire Protection Professional
- In addition to the annual inspection, fire extinguishers should be inspected monthly for the following:
    - Confirm the extinguisher is visible, unobstructed, and in its designated location
    - Verify the locking pin is intact and the tamper seal is unbroken. Examine the extinguisher for obvious physical damage, corrosion, leakage, or clogged nozzle
    - Confirm the pressure gauge or indicator is in the operable range or position, and lift the extinguisher to ensure it is still full
    - Make sure the operating instructions on the nameplate are legible and facing outward
    - Check the last professional service date on the tag. (A licensed fire extinguisher maintenance contractor must have inspected the extinguisher within the past 12 months.)
    - Initial and date the back of the tag

- Floor plan identifies the location of the fire extinguishers
- Sufficient number of fire extinguishers for the size of and are conveniently located on each floor of the facility and in areas of special hazard
- Fire drills
    - Conduct at least annually
    - Fire drills are evaluated and results communicated to all personnel

Evidence: Written Policies and Procedures
Evidence: Written Floor Plan
Evidence: Fire Extinguisher Inspection and Maintenance
Evidence: Observation

Services applicable: HDS, ICD

Standard RD7-P.01: Written policies and procedures are established and implemented for identifying, monitoring, reporting, investigating, and documenting all, accidents, variances, or unusual occurrences involving personnel.

Written policies and procedures describe the process for reporting, monitoring, investigating and documenting a variance.

Policies and procedures include, but are not limited to:

- Action to notify the supervisor
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for medical care
- Follow-up reporting to the leader/administrator

Written policies and procedures address the compliance with OSHA guidelines regarding the recording of work-related injuries and illnesses that are diagnosed by a physician or licensed health care professional and any work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR 1904.8 through 1904.11.

Written policies and procedures identify the person responsible for collecting incident data and monitoring for patterns or trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

Incidents to be reported include, but are not limited to:

- Personnel injury or endangerment
- Environmental safety hazards
- Equipment safety hazards, malfunctions or failures
- Unusual occurrences

There is a standardized form developed by the facility and used to report incidents. The facility documents all incidents, accidents, variances, and unusual occurrences. The reports are distributed to management and are reported as required by applicable law and regulation. This data is included in the Performance Improvement program. The facility assesses and utilizes the data for reducing further safety risks.

A file must be kept of the results of medical examinations of personnel to monitor exposure to substances used dialysis and reprocessing that have known or suspected toxicity that may be required by OSHA or other regulatory agencies.

A file must be kept of all complaints by patients and staff about failures of reprocessed dialyzers or possible adverse reactions to reprocessed dialyzers; the results of a comprehensive investigation of these alleged problems; and if appropriate, the corrective actions taken. The file should be reviewed periodically for trends that may contribute to patient morbidity and mortality.

A record must be kept of the date and results of QA and QC evaluations and the person(s) conducting the evaluations and include direct observation of reprocessing by an objective individual, i.e., someone not directly involved in the process such as the director of nursing or administrator.

The facility educates all personnel on its policies and procedures for documenting and reporting incidents/variances.

Evidence: Written Policies and Procedures
Evidence: OSHA 300, 300A and 301 Forms, if applicable
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD7-Q: An Emergency Preparedness Plan outlines the process for meeting patient and personnel needs in a disaster or crisis situation. Part of this process includes conducting a community based risk assessment and the development of strategies and collaboration with other health organization in the same geographic area. (494.62) E-0003, (494.62(a)) E-0004,

(494.62(a)(1-2)) E-0006, (494.62(a)(3)) E-0007, (494.62(a)(4)) E-0009

The facility must comply with all applicable federal, state, and local emergency preparedness requirements. These emergencies include, but are not limited to:

- Fire
- Equipment or power failure
- Care related to emergencies
- Water supply interruption
- Natural disasters likely to occur in the facility's geographic area

The facility must establish and maintain an emergency preparedness program that meets the requirements of 42 CFR 494.62.

Emergency plan: The facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least every two years. The plan must do all of the following:

- Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
- Include strategies for addressing emergency events identified by the risk assessment
- Address patient population, including, but not limited to:
    - The type of services the facility has the ability to provide in an emergency
    - Continuity of operations, including delegations of authority and succession plans
- Include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation
- The facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the facility's needs in the event of an emergency

Evidence: Risk Assessment
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD7-R: Written policies and procedures and an Emergency Preparedness Plan outline the process for meeting patient and personnel needs in a disaster or crisis situation. Part of this process is the development of specific policies and procedures and the review of them every two years. (494.62(b)) E-0013, (494.62(b)(1)) E-0018, (494.62(b)(2)) E-0020, (494.62(b)(3)) E-0022, (494.62(b)(4)) E-0023, (494.62(b)(5)) E-0024, (494.62(b)(6)) E-0025, (494.62(b)(7)) E-0026, (494.62(b)(9) E-0028

The facility must develop and implement emergency preparedness policies and procedures that are reviewed and updated at least every two years. These policies and procedures are based on the risk assessment and communication plan developed by the facility. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. Based on the emergency plan, the policies and procedures include, but are not limited to:

- A system to track the location of on-duty staff and sheltered patients in the facility's care during an emergency:
    - If on-duty staff and sheltered patients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location
- Safe evacuation from the facility, which includes consideration of care and treatment needs of evacuees, staff responsibilities, transportation, identification of evacuation locations, and primary and alternate means of communication with external sources of assistance
- A means to shelter in place for patients, staff, and volunteers who remain in the facility
- A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records
- The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state and federally designated health care professional to address surge needs during an emergency
- The development of arrangements with other facilities or other providers to receive patient in the event of limitations or cessation of operations to maintain the continuity of service to facility patients
- The role of the facility under a waiver declared by the Secretary, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials
- How emergency medical system assistance can be obtained when needed
- A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Patient Interviews
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD7-S: An Emergency Preparedness Plan includes the development of a communication plan that includes personnel, patients and other emergency and health care organization in same geographic area. (494.62(c)) E-0029, (494.62(c)(1)) E-0030, (494.62(c)(2)) E-0031, (494.62(c)(3)) E-0032, (494.62(c)(4-6)) E-0033, (494.62(c)(7)) E-0034

The facility must develop and maintain an emergency preparedness communication plan that complies with federal, state, and local laws and must be reviewed and updated at least every two years. The communication plan must include all of the following:

- Names and contact information for the following:
    - Staff
    - Entities providing services under arrangement
    - Patients' physicians
    - Other facilities
    - Volunteers
- Contact information for the following:
    - Federal, state, tribal, regional, or local emergency preparedness staff
    - Other sources of assistance
- Primary and alternate means for communicating with the following:
    - Facility staff
    - Federal, state, tribal, regional, and local emergency management agencies
- A method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health care providers to maintain the continuity of care
- A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii)
- A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4):
    - (4) *Use and disclosures for disaster relief purposes:* A covered entity may use or disclose Protected Health Information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section
    - The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances
- A means of providing information about the facility's occupancy, needs and it ability to provide assistance, to the authority having jurisdiction, the incident command center, or designee

Evidence: Communication Plan
Evidence: Response to Interview

Services applicable: HDS, ICD

Standard RD7-T: An Emergency Preparedness Plan includes the process of training and testing the emergency preparedness plan. (494.62(d)) E-0036, (494.62(d)(1)) E-0038, (494.62(d)(2)) E-0039, (494.62(d)(3)) E-0040

Training and testing. The facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency preparedness plan, risk assessment and communication plan. The training, testing, and orientation program must be reviewed and updated at least every two years.

Training program - The facility must do all of the following:

- Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles
- Provide emergency preparedness training at least every two years
- Staff training must:
- Demonstrate staff knowledge of emergency procedures, including informing patients of:
    - What to do
    - Where to go, including instructions for occasions when the geographic area of the facility must be evacuated
    - Whom to contact if an emergency occurs while the patient is not in the dialysis facility
    - This contact information must include an alternate emergency phone number for the facility for instances when the facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions)
    - How to disconnect themselves from the dialysis machine if an emergency occurs
- Demonstrate that, at a minimum, its patient care staff maintains current CPR certification
- Properly train its nursing staff in the use of emergency equipment and emergency drugs.
- Maintain documentation of the training
- If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures

Testing - The facility must conduct exercises to test the emergency plan at least annually. The facility must do the following:

- Participate in a full-scale exercise that is community-based every two years
    - When a community-based exercise is not accessible, an individual, facility-based functional exercise every two years; or
    - If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency

plan, the dialysis facility is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event
- Conduct an an additional exercise every two years, opposite the year the full-scale or functional exercise as referred to in 42 CFR 494.62(d)(2)(i) that may include, but is not limited to the following:
    - A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or
    - A mock disaster drill; or
    - A tabletop exercise or workshop is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan
- Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed

Patient orientation: Emergency preparedness patient training.
- The facility must provide appropriate orientation and training to patients
- Demonstrate staff knowledge of emergency procedures, including informing patients of:
    - What to do
    - Where to go, including instructions for occasions when the geographic area of the facility must be evacuated
    - Whom to contact if an emergency occurs while the patient is not in the facility
        - This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions)
    - How to disconnect themselves from the dialysis machine if an emergency occurs

Evidence: Training Log
Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Standard RD7-U: The Emergency Preparedness Plan identifies each separately certified facility and how each facility participated in the development of the unified and integrated program. (494.62(e)(1-5)) E-0042

If a facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

- Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program
- Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered
- Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program
- Include a unified and integrated emergency plan that meets the requirements of standard RD7-Q to RD7-T
- The unified and integrated emergency plan must also be based on and include the following:
    - A documented community-based risk assessment, utilizing an all-hazards approach
    - A documented individual facility based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach
- Include integrated policies and procedures that meet the requirements set forth in standard RD7-R, a coordinated communication plan and training and testing programs that meet the requirements of standards RD7-S and RD7-T, respectively

Evidence: Observation
Evidence: Response to Interviews

Services applicable: HDS, ICD

Appendix A: Reference Guide for Required Documents, Policies and Procedures
Customized for: HDS

Standard #	Documents, Policies and Procedures	Agency Notes
RD2-E	Written Policies and Procedures	
RD2-H.01	Written Policies and Procedures	
RD2-I	Written Policies and Procedures	
RD2-K.01	Written Policies and Procedures	
RD2-N	Written Policies and Procedures	
RD2-P.01	Written Policies and Procedures	
RD4-A.01	Written Policies and Procedures	
RD4-F.01	Written Policies and Procedures	
RD4-G.01	Written Policies and Procedures and/or Employee Handbook	
RD4-I	Written Policies and Procedures	
RD4-L.01	Written Policies and Procedures	
RD5-D	Written Policies and Procedures	
RD5-E	Written Policies and Procedures	
RD5-F	Written Policies and Procedures	
RD5-G	Written Policies and Procedures	
RD5-J	Written Policies and Procedures	
RD5-P.01	Written Policies and Procedures	
RD6-A	Written Policies and Procedures/QAPI Plan	
RD6-L	Written Policies and Procedures	
RD7-A	Written Policies and Procedures	
	Personnel Files	
RD7-B	Written Policies and Procedures	
RD7-C	Written Policies and Procedures	
RD7-J	Written Policies and Procedures	
RD7-K	Written Policies and Procedures	
RD7-P.01	Written Policies and Procedures	
RD7-R	Written Policies and Procedures	

ITEMS NEEDED FOR ON-SITE SURVEY

FOR PROVIDERS. BY PROVIDERS.

ACHC

RENAL DIALYSIS

Below are items that will need to be reviewed by the Surveyor during your on-site survey. If you have any questions, please contact your Account Advisor.

1. List of current patients by name, separated by modalities.
2. List of organization key personnel: medical director, administrator, nurse manager, social worker, dietician, chief technician, and home training nurse(s).
3. Current in-center hemodialysis patient schedule by days and shifts with any isolation patients identified (seating chart or assignment sheet).
4. List of patients admitted to this organization within the past 90 days who are currently on census (do not include visiting patients) separated by modality with date of admission.
5. List of patients who have been designated "unstable" for any month in the past three months, including reason for unstable and month.
6. List of all patients who were involuntarily discharged (not transferred to another outpatient dialysis organization) from this organization in the past 12 months.
7. List of all discharged patients categorized as "lost to follow up" (i.e., not transferred out or discontinued by dialysis) for the past 12 months.
8. List of home hemodialysis (HD) or peritoneal dialysis (PD) patients scheduled to be seen at the organization during the survey.
9. List of residents of long-term care facilities who receive their hemodialysis or peritoneal dialysis at the long-term care facility and the name of the long-term care facility where they are receiving dialysis.
10. Hospitalization logs with admitting diagnoses listed for six months.
11. List of current patients readmitted to the hospital within 30 days of discharge in the past 6 months, separated by modality.
12. Infection logs for the last 6 months.
13. List of in-center hemodialysis patients who are dialyzed with 0 K+ or 1.0 K+ dialysate.
14. All patients' individual laboratory results for hemoglobin, Kt/V, uncorrected calcium, phosphorus and albumin for the current three months; separated by modality.
15. Vaccination information:
    a. Number of patients who received a complete series of hepatitis B vaccine.
    b. Number of patients who received the influenza vaccine between August 1 and March 31.
    c. Number of patients who received the pneumococcal vaccine.

16. Staff schedule for the last two weeks by day.
17. Policy and procedure manuals for patient care, water treatment, dialysate preparation and delivery, and dialyzer reprocessing/reuse, if applicable.
18. Patient suggestion/complaint/grievance log for the past six months.
19. Adverse events (e.g., clinical variances, medical errors) documentation for the past six months.
20. QAPI team meeting minutes for the past 6 months and any supporting materials.
21. Copy of CMS-approved waivers for medical director and/or isolation room.
22. Organization's Life Safety Code attestation or waiver (required if the in-center dialysis or home dialysis support training treatment area does not provide exit at grade level or if the organization is adjacent to industrial high hazard occupancy).
23. Staff practice audits for infection prevention while performing direct patient care (12 months).
24. Water and Dialysate Review

    Logs for:

    a. Daily water system monitoring (two months).
    b. Total chlorine testing (two months).
    c. Bacterial cultures and endotoxin results – water and dialysate (six months).
    d. Chemical analysis of product water (12 months).
    e. Staff practice audits for water testing, dialysate mixing and testing, and microbiological sampling (12 months).
25. Equipment Maintenance Review:
    a. Documentation of preventative maintenance and repair of hemodialysis machines (12 months).
    b. Documentation of calibration of equipment used for machine maintenance (12 months).
    c. Documentation of calibration of equipment used to test dialysate pH/conductivity (12 months).
26. Dialyzer Reprocessing Review (if applicable)

    Logs for:

    a. Bacterial cultures and endotoxin results from reuse room sites (six months).
    b. Preventative maintenance and repair of reprocessing equipment (12 months.)
    c. Reuse QA audits (12 months).

GLOSSARY OF TERMS

RENAL DIALYSIS

FOR PROVIDERS. BY PROVIDERS.

Dialysis Facility: An entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge: The termination of patient care services by a dialysis facility or the patient voluntarily terminates dialysis when he or she no longer wants to be dialyzed by the facility.

Furnishes Directly: The Renal Dialysis facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home Dialysis: Dialysis performed at home by an End-Stage Renal Disease patient or caregiver who has completed an appropriate course of training.

Self-Dialysis: Dialysis performed with little or no professional assistance by an End-Stage Renal Disease patient or caregiver who has completed an appropriate course of training.

Medical Records: A systematic documentation of a single patient's medical history and care across time within one particular healthcare provider's jurisdiction. The medical record includes a variety of types of "notes" entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, X-rays, reports, etc. The maintenance of complete and accurate medical records is a requirement of health care providers and is generally enforced as a licensing or certification prerequisite.

Written Policies and Procedures: Written policies and procedures can be a variety of documents, such as Standard Operating procedures (SOP), written procedures, and/or written policies.

References to Life Safety Code requirements:

Defining "Exit to the Outside at Grade Level from the Patient Treatment Area Level":

The phrase "exit to the outside at grade level from the patient treatment area level" applies to ESRD facilities that are on the ground or grade level of a building where patients do not have to traverse up or down stairways within the building to evacuate to the outside. Accessibility ramps in the exit area that provide an ease of access between the patient treatment level and the outside ground level are not considered stairways.

An ESRD facility which provides one or more exits to the outside at grade level from the patient treatment level and which has a patient exit path (which may include an accessibility ramp that is compliant with the Americans with Disabilities Act) to the outside would be exempt from complying with the applicable provisions of the NFPA LSC 101 as long as the ESRD facility is not located adjacent to an "industrial high hazardous" occupancy.

Defining Adjacent to an "Industrial High Hazardous" Occupancy:

An "industrial high hazardous occupancy" is based upon the definition in the NFPA LSC 101, 2000 Edition at section A.3.2.134.8.2, Annex A: "occupancies where gasoline and other flammable liquids are handled, used, or stored under such conditions that involve possible release of flammable vapors; where grain dust, wood, or plastic dusts, aluminum or magnesium dust, or other explosive dusts are produced; where hazardous chemicals or explosives are manufactured, stored, or handled; where cotton or other combustible fibers are processed or handled under conditions that might produce flammable flyings; and where other situations of similar hazard exist."

Being "Adjacent" means an ESRD facility that shares a common wall, floor, or ceiling.

ESRD and LSC: Attestation for Exempt Facilities and LSC Survey for Non-Exempt Facilities:

The ESRD facility administrator may submit an attestation to the applicable State Survey Agency that the facility meets the requirements for an exemption to compliance with NFPA LSC 101. Those facilities that do not submit an attestation claiming exemption will be considered a non-exempt facility and will be surveyed for compliance with chapters 20 and 21 of the NFPA 101 LSC, 2000 Edition.

GLOSSARY OF PERSONNEL QUALIFICATIONS

RENAL DIALYSIS

FOR PROVIDERS. BY PROVIDERS.

Medical Director

The Medical Director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis. If a physician, as specified in the Medical Director description, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the secretary.

Nurse Manager

The nurse manager is responsible for the nursing services in the facility and must:

1. Be a full-time employee of the facility.
2. Be a registered nurse.
3. Have at least 12 months of experience in clinical nursing, and an additional six months of experience in providing nursing care to patients on maintenance dialysis.

Self-Care and Home Dialysis Training Nurse

The nurse responsible for self-care and/or home care training must:

1. Be a registered nurse.
2. Have at least 12 months experience in providing nursing care and an additional 3 months experience in specific modality for which the nurse will provide self-care training.

Charge Nurse

The charge nurse responsible for each shift must:

1. Be registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed.
2. Have at least 12 months experience in providing nursing care, including three months of experience in providing nursing care to patients on maintenance dialysis.
3. If the charge nurse is a licensed practical nurse or licensed vocational nurse, they must work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

Staff Nurse

A staff nurse is a nurse who provides care and treatment to patients and must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

Dietitian

The facility must have a dietitian who must:

1. Be a registered dietitian with the Commission on Dietetic Registration.
2. Have a minimum of one year professional work experience in clinical nutrition as a registered dietitian.

Social Worker

The facility must have a social worker who must:

1. Hold a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education.
2. Have served at least two years as a social worker, one year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and have established a consultative relationship with a social worker who qualifies under number one.

Patient Care Dialysis Technicians

Patient Care Dialysis Technicians must:

1. Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification and licensure in the state in which he or she is employed as a dialysis technician.
2. Have a high school diploma or equivalency.
3. Have completed a training program that is approved by the Medical Director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients.
    a. The training program must include:
        i. Principles of dialysis.
        ii. Care of patients with kidney failure, including interpersonal skills.
        iii. Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring and termination of dialysis.
        iv. Possible complications of dialysis.
        v. Water treatment and dialysate preparation.
        vi. Infection control.

vii. Safety.

viii. Dialyzer reprocessing, if applicable.

4. Be certified under a state certification program or a national commercially available certification program as follows:

a. For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician.

b. For patient care technicians employed on October 14th, 2008, within 18 months after such date.

Water Treatment System Technicians

Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the Medical Director and the governing body.