ACHC STANDARDS

Program

Renal Dialysis

Services

In-Center Dialysis

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 In-Center Dialysis

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-D: A special purpose facility is approved to furnish dialysis on a short-term basis at special locations. (494.120) V660-661, (494.120(a)) V662, (494.120(b)) V663, (494.120(c)(1-2)) no V code, (494.120(d)) V666, (494.120(e)) V667

A special purpose facility provides dialysis services short-term and are divided into two categories: vacation camps (locations that serve end stage renal disease (ESRD) patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

The period of approval for a SPDF may not exceed 8 months in any 12-month period.

A special purpose facility are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

A special purpose facility established to provide care to patients with medical or psychosocial needs which cannot be met in a standard outpatient dialysis setting must define the population it intends to serve in its admission criteria and include in those criteria the lack of outpatient dialysis service for these patients within the geographic area.

A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose facility established as a vacation camp must comply with the following requirements:

- Infection Control - 42 CFR 494.30
- Water and dialysate quality – 42 CFR 494.40
- Reuse of hemodialyzers - 42 CFR 494.150
- Rights and Responsibilities - 42 CFR 494.70
- Medical Record - 42 CFR 494.170
- Medical Director - 42 CFR 494.150
- Laboratory Services -42 CFR 494.130
- Portable Home Water System - 42 CFR 494.40 & 42 CFR 494.100

A special purpose facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose facilities must comply with (c)(1) of this section and addition to complying with the following conditions:

- Section 42 CFR 494.20 (compliance with federal, state, and local laws and regulations)
- Section 42 CFR 494.60 (physical environment)
- Section 42 CFR 494.70(a) through section 494.70(c) (patient rights)
- Section 42 CFR 494.140 (personnel qualifications)
- Section 42 CFR 494.150 (Medical Director)
- Section 42 CFR 494.180 (governance)

The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose facility, to discuss the patient's current condition to assure care provided in the special purpose facility is consistent with the patient plan of care.

All patient care provided in the special purpose facility is documented and forwarded to the patient's usual facility, if possible, within 30 days of the last scheduled treatment in the special purpose facility .

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

Services applicable: 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

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-P: There is a qualified charge nurse responsible for each shift to oversee patient care. (494.140(b)(3)) V686, (494.140(b)(3)(iii) V687, (494.140(b)(4)) V688

The qualified charged nurse is a currently licensed health professional (a registered nurse, licensed practical nurse, or vocational) in the state he or she is practicing and is experienced in providing ESRD care. He or she must have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and if such nurse is a licensed practical nurse or licensed vocational nurse, works under the supervision of a registered nurse in accordance with state nursing practice act provisions.

Each nurse who provides care and treatments to patients must be either a registered nurse or a practical/vocational nurse who meets the practice requirements in the state in which he or she is employed.

State Boards of Nursing may prohibit the LPN/LVN from supervising a RN.

A Registered Nurse must be present during a patient's treatment in the facility.

If state law requires a registered nurse or physician to administer emergency intravenous medications, then such a person must be present during dialysis treatments.

Evidence: Personnel File
Evidence: Observation
Evidence: Response to Interviews
Evidence: Staff Schedules/Job Assignments

Services applicable: ICD

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-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-E: Written policies and procedures are established and implemented regarding the operation of the water treatment system. The facility must follow the water and dialysate quality standards and equipment requirements developed by the Association for the Advancement of Medical Instrumentation (AAMI). (494.40) V175, (494.40(a)) V176-V260, (494.40(b)(1-2)) no V tag, (494.40(b-e)) V270-278

The facility must be able to demonstrate the following: Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, “Dialysate for hemodialysis,” ANSI/AAMI RD52:2004.

Written policies and procedures are understandable, current, and accessible. Written policies and procedures for the operation of the water treatment system should address the safe and effective operation of the system and include, but are not limited to:

- Basic operation and use of the system
- Preventive maintenance procedures and schedules
- Cleaning and disinfection procedures
- Calibration of measurement and monitoring instrument
- Trouble shooting and repair
- Documentation of annual contact to local water municipalities informing them of the size of the facility and to make them aware of the water needs for the facility

The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause at the time of installation given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality.
Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this standard.

The facility Medical Director is knowledgeable and responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these and AAMI requirements for water quality at the time of installation and ongoing monitoring.

Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall not contain chemical contaminants at concentrations in excess of those listed in ANSI/AAMI RD62 (See Appendix Table 2.)

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.

Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/ml and an endotoxin concentration lower than 2 EU/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml, and the action level for the endotoxin concentration shall be 1 EU/ml. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.

Conventional dialysate should contain a total viable microbial count lower than 200 CFU/ml and an endotoxin concentration of lower than 2 EU/ml. The action level for the total viable microbial count in conventional dialysate should be 50 CFU/ml and the action level for the endotoxin concentration should be 1 EU/ml. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.

Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/ml and an endotoxin concentration lower than 0.03 EU/ml. If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. The user is responsible for establishing a regular monitoring routine.

A facility should develop contingency plans to cover the failure of its water purification and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility’s municipal water supply or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component of the water purification and distribution system.

Water purification systems consist of three basic sections: A pretreatment section that conditions the water supplied to the primary purification device, which may be followed by other devices that polish final water quality. The pre-treatment section commonly includes a

sediment filter, cartridge filters capable of retaining particles of various sizes, a softener, and carbon adsorption beds. The primary purification process most commonly used is reverse osmosis, which may be followed by deionization and ultrafiltration for polishing the product water from the reverse osmosis system. Whether a particular device is included in an individual water purification system will be dictated by local conditions.

The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

The layout of the water purification system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance.

Critical alarms, such as those associated with deionizer or low water levels in a storage tank, should be configured to sound in the patient treatment area, as well as the water treatment room.

Water systems should include schematic diagrams that provide a convenient means of identifying pipe content and flow identify components, valves, sample ports, and flow direction.

If water system manufacturers have not done so, the facility should label major water system components in a manner that not only identifies a device, its function, how performance is verified, and what action to take in the event performance is not within an acceptable range.

Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae. Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.

Sediment filters should be monitored on a periodic basis for a pressure drop (ΔP) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations. Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.

The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams. When the maximum [pressure drop] ΔP recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer's instructions.

Cartridge filters should be monitored on a periodic basis for a [pressure drop] ΔP across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. Replace cartridge filters per the manufacturer's recommendations and/or an increase in ΔP to some specified value. A log sheet is to be developed to record the pressure drop measurements.

Prior to exhaustion, softeners are to be restored; new exchangeable sodium ions are placed on the resin by a process known as "regeneration". Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

The face of the timers used to control the regeneration cycle should be visible to the user. Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated. The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.

Users must ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reverse osmosis machine manufacturer. Total hardness of the water exiting the water softener is to be measured at the end of each treatment day. Water hardness test results are recorded in a water softener log.

Carbon adsorption systems shall be adapted specifically to the maximum anticipated water flow rate of the system. Two carbon adsorption beds shall be installed in a series configuration. Two carbon beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed.

Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of five minutes at the maximum flow rate through the bed. When series connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure that an equal volume of water flows through all beds.

Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring. When granular activated carbon is used as the media, it shall have a minimum iodine number of 900. Other forms of carbon should not be used unless there is performance data to demonstrate that each adsorption bed has the capacity to reduce the

chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines. Regenerated carbon shall not be used for hemodialysis applications. When granulated activated carbon is used as the adsorption medium each adsorption bed shall have an empty bed contact time (EBCT) of at least five minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes).

Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every four hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.

Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. If an on-line chlorine/choloramines monitor is in use which incorporates an automated alarm, particular testing times are not required. Facility policies and procedures must follow manufacturer's guidance regarding any required comparison testing and calibration of the monitor. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples are to be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced.

Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line. Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use. When acid is added to adjust pH, a mineral acid is to be used.

Systems for chemical injection should be monitored according to the manufacturer’s instructions. If a facility designs its own system, procedures should be developed to ensure proper preparation of the chemical, adequate mixing of the injected chemical with the water flowing through the pretreatment cascade, and reduction to a safe level of the concentration of any chemical residuals before the point of water use. The facility should also verify that the injected chemical does not degrade the performance of downstream devices, including the primary purification process. The adequacy of these procedures must be verified using an independent laboratory. Verification can be accomplished by testing samples from the chemical reservoir and the water line after the point of injection for at least three batches of chemical.

When the chemical to be injected is prepared at a facility from powder or by dilution of a liquid concentrate, the chemical injection reservoir must be labeled with the name of the chemical and its concentration, the date the solution was prepared, and the name of the person who mixed the solution.

Each batch of chemical should be tested for correct formulation before use. A batch of chemical must not be used or transferred to the injection system reservoir until all tests are completed. The test results—and verification that they meet all applicable criteria—should be recorded and signed by the individual performing the tests.

Protective clothing and an appropriate environment, including ventilation adequate to meet applicable OSHA environmental exposure limits, should be provided when chemicals for injection are prepared in a dialysis facility.

Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2. Users should carefully follow the manufacturer’s instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters. All results of measurements of RO performance are recorded daily in an operating log that permits trending and historical review.

Reverse osmosis devices shall be equipped with on-line monitors that allow determination of rejection rates and product water conductivity. The product water conductivity monitor should activate audible and visual alarms when the product water conductivity exceeds the preset alarm limit. The audible alarm must be audible in the patient care area when reverse osmosis is the last chemical purification process in the water treatment system. Monitors that measure resistivity or TDS may be used in place of conductivity monitors.

Reverse osmosis systems should be monitored daily using continuous-reading monitors that measure product water conductivity (or total dissolved solids (TDS.) When a reverse osmosis system is the last chemical purification process in the water treatment system, it is to include a means to prevent patient exposure to unsafe product water, such as diversion of the product water to drain, in the event of a product water conductivity or rejection alarm.

Chemical analysis for the contaminants listed in 4.1.1 (Table 2) should be done when the RO system is installed, when membranes are replaced, and at not less than annual intervals thereafter to ensure that the limits specified in 4.1.1 are met (see Table 2.) Chemical analyses should be done when seasonal variations in source water suggest worsening quality or when rejection rates fall below 90 %.

Deionization systems, when used to prepare water for hemodialysis applications, shall be monitored continuously to produce water of one megohm/cm or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25°C. Deionizers to be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Resistivity monitors shall have a minimum sensitivity of 1.0 megohm-cm. Patients shall not be dialyzed on deionized water with resistivity less than 1.0 megohm-cm measured at the output of the deionizer. Resistivity monitor readings should be recorded on a log sheet twice each treatment day.

For deionization, an audible and visual alarm is activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use, for example by being diverted to drain. The alarm must be audible in the patient care area. The resistivity monitor following the final deionizer bed shall be connected to an audible and visible alarm in the dialysis treatment area, and the DI system shall divert product water to drain or otherwise prevent product water from entering the distribution system should an alarm condition occur. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

Systems that include deionizers as a component shall also contain carbon adsorption upstream of the deionizer to avoid formation of carcinogenic nitrosamines. In all instances, deionizers shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device to remove microbiological contaminants that may originate in the deionizer resin bed.

The usual application for a deionizer is as a polisher following reverse osmosis or as a standby process if the reverse osmosis system fails. Use of deionization as the primary means of purification in an outpatient facility is not recommended because of the inability of deionization and ultrafiltration to remove certain low-molecular-weight toxic bacterial products, such as microcystins.

When deionization is employed as the primary method for removing inorganic contaminants (reverse osmosis is not employed), or when deionization is necessary to polish RO-treated water, chemical analyses to ensure that the requirements of AAMI 4.1.1 (Table 2) are met should be performed when the system is installed and at annual intervals thereafter.

When ultrafilters are used in a water purification system for hemodialysis applications, an ultrafilter shall be shown to reduce the concentrations of bacteria and endotoxin in the feed water to the ultrafilter by factors at least as great as those specified in the manufacturer's labeling. Ultrafilters are to have an opaque housing or that other means be used to inhibit proliferation of algae. Ultrafilters are to be included in routine disinfection procedures to prevent uncontrolled proliferation of bacteria in the feed water compartment of the filter.

The pressure drop across the ultrafilter (ΔP) should be measured using simple inlet and outlet pressure gauges. Ultrafilters operated in the cross-flow mode should also be monitored in terms of the flow rate of water being directed to drain (concentrate). Results of pressure measurements and bacteria and endotoxin levels are recorded in a log.

A water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.

If a facility uses storage tanks, they are to have a conical or bowl-shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2 µm air filter. The filter should be changed on a regular schedule according to the manufacturer’s instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system. An ultrafilter, distal to the storage tank, or some other form of bacterial control device is recommended. Storage tanks are therefore not recommended for use in dialysis systems unless they are frequently drained and adequately disinfected.

Routine monitoring of water storage tanks for bacteria and endotoxin levels is generally accomplished indirectly by monitoring the water at the first outlet to the distribution loop (see 6.3.3.) If direct monitoring of a water storage tank is performed as part of a troubleshooting process, bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001. All bacteria and endotoxin results should be recorded on a log sheet.

Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection.

To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/sec in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand. Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.

Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water.
Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. (e.g., bacteria <200 CFU/ml and endotoxin <2 EU/ml.)

Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for one month to verify that bacteria or endotoxin levels are consistently within the allowed limits. Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be

undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001. All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.

When ultraviolet irradiators are used to control bacterial proliferation in water storage and distribution systems, UV irradiation devices shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2, (except in the case described below.) The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions.

If the irradiator includes a meter as described above, the minimum dose of radiant energy should be at least 16 milliwatt-sec/cm2. To prevent the use of sublethal doses of radiation that may lead to the development of resistant strains of bacteria, UV irradiators shall be equipped with a calibrated ultraviolet intensity meter or with an on-line monitor of radiant energy output that activates a visible alarm, which indicates that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer’s instructions to maintain the recommended radiant energy output.

Ultraviolet irradiators intended for use as a direct means of bacterial control shall be monitored for radiant energy output. UV irradiators should be monitored at the frequency recommended by the manufacturer. A log sheet is used to indicate that monitoring has been performed.

UV irradiators [shall] be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water distribution system or reverse osmosis in the pretreatment cascade.

Ozone can be used for bacterial control only in systems constructed from ozone-resistant materials (see AAMI 5.3.3.) Ozone generators (refer to RD62:2001, 4.3.15) Ozone disinfection systems: When used to control bacterial proliferation in water storage and distribution systems, an ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer. Ozone generators should be monitored for ozone output at a level specified by the manufacturer. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration each time disinfection is performed. An ozone-in-ambient-air test should be conducted on a periodic basis, as recommended by the manufacturer, to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. A log sheet is used to indicate that monitoring has been performed.

Hot water disinfection systems: When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of delivering hot water at the temperature and for the exposure time specified by the manufacturer. Hot water disinfection systems can be used only in systems constructed from heat-resistant materials, such as crosslinked polyethylene, polypropylene, and stainless steel (see [AAMI] 5.3.3.)

The manufacturer’s instructions for using hot water disinfection systems should be followed. If no manufacturer’s instructions are available, the effectiveness of the system can be demonstrated by verifying that the system maintains a specified temperature for a specified time and by performing ongoing surveillance with bacterial cultures and endotoxin testing.

Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Also, hot water disinfection should be performed at least as often as recommended by the manufacturer. The temperature of the water should be recorded at a point farthest from the water heater—that is, where the lowest water temperature is likely to occur and measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.

Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly. A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.

A procedure is established and implemented for regular disinfection of the line between the outlet from the water distribution system and the back of the dialysis machine.

Dialysate is customarily prepared from two concentrates: the bicarbonate concentrate, which contains sodium bicarbonate (and sometimes additional sodium chloride), and the acid concentrate, which contains all remaining ions, acetic acid, and sometimes glucose. Acid concentrate can be supplied by the manufacturer in bulk (usually 55- gallon containers) or in gallon containers. There are systems available that allow a user at a facility to prepare acid concentrate from packaged powder and purified water using a mixer. Acid concentrate prepared at the facility from powder and water is the responsibility of the user. Bicarbonate concentrate can be supplied by the manufacturer in one of three ways: (1) in gallon containers, (2) as packaged powder that is mixed with purified water at the dialysis facility, and (3) in powder cartridges that are used to prepare concentrate on-line at the time of dialysis.

Procedures are established and implemented to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.

All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides or germicidal procedure used to disinfect the equipment. The use of materials that are known

to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited. Concentrate mixing systems require a purified water source, a suitable drain, and a ground fault protected electrical outlet. Protective measures should be used to ensure a safe work environment. Operators should at all times use appropriate personal protective equipment, such as face shields, masks, gloves, gowns, and shoe protectors, as recommended by the manufacturer.

If a concentrate mixing system is used, the preparer should follow the manufacturer's instructions for mixing the powder with the correct amount of water. When concentrate mixing system is used, the number of bags or the weight of powder added should be determined and recorded. Manufacturer's recommendations should be followed regarding any preventive maintenance and sanitization procedures. Records are maintained indicating the date, time, person performing the procedure, and results (if applicable). Systems for preparing either bicarbonate or acid concentrate form powder should be monitored according to the manufacturer's instructions.

If a facility designs its own system, procedures should be developed and demonstrated to ensure proper mixing of the concentrate, including establishment of acceptable limits for tests of proper concentration. The adequacy of those procedures must be verified using an independent laboratory that is capable of meeting the requirements of ANSI/AAMI RD61:2000 (see 2.4.)Verification can be accomplished by testing a sample from each batch prepared over a 3-day period.

Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine:

- Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared:
    - This labeling should remain on the mixing tank until the tank has been emptied
- Bulk storage/dispensing tanks are to be permanently labeled to identify the chemical composition or formulation of their contents
- At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility
- In addition to container labeling, there are permanent records of batches produced:
    - These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date, if applicable.

Acid and bicarbonate concentrates may be tested by using conductivity or by sing a hydrometer. Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests.

When cleaning mixing systems, the concentrate mixing equipment should be either completely emptied, cleaned, and disinfected according to the manufacturer's instructions; or cleaned and disinfected using a procedure demonstrated by the facility to be effective in routinely producing concentrate meeting regulations related to allowable bacterial and endotoxin levels. This disinfection data should be recorded for each disinfection cycle using a dedicated log.

Acid concentrate mixing tanks should be designed to allow the inside of the tank to be completely emptied and rinsed according to the manufacturer's instructions when concentrate formulas are changed. Acid concentrate mixing tanks should be emptied completely before mixing another batch of concentrate. Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Bicarbonate concentrate mixing tanks are to be designed to drain completely. Mixing tanks should have a tight-fitting lid and should be designed to allow all internal surfaces to be disinfected and rinsed. Concentrate solutions are highly corrosive, thus mixing systems are to be designed and maintained to prevent corrosion.

Once mixed, bicarbonate concentrate should be used within the time specified by the manufacturer of the concentrate. Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch. The manufacturer's instructions are to be followed, if available. Over agitating or overmixing of bicarbonate concentrate should be avoided, as this can cause CO_2 loss and can increase pH.

Concentrate additives should be mixed with liquid acid concentrates according to the manufacturer's instructions, taking care to ensure that the additive is formulated for use in concentrates of the appropriate dilution ratio. When liquid additives are used, the volume contributed by the additive should be considered when calculating the effect of dilution on the concentration of the other components in the resulting concentrate. When powder additives are used, care should be taken to ensure that the additive is completely dissolved and mixed before the concentrate is used.

If a chemical spike is added to an individual container to increase the concentration of an electrolyte, the label should show the added electrolyte, the date and time added, and the name of the person making the addition. Containers are to be labeled to indicate the final concentration of the added electrolyte. This information is recorded in a permanent record. Labels should be affixed to the containers when the mixing process begins.

When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate should be labeled with the name of the patient, the final concentration of the added electrolyte, the date on which the prescribed concentrate was made, and the name of the person who mixed the additive.

All components used in concentrate distribution systems (including concentrate jugs, storage tanks, and piping) that contact the fluid shall be fabricated from nonreactive materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass,

galvanized material, and aluminum, are specifically prohibited.

Elevated tanks for bicarbonate concentrate distribution should be equipped with conical or bowl-shaped bottoms, tight-fitting lids, a spray mechanism, and high- and low-level alarms. Any air vents should have 0.2 µm hydrophobic vent filters.

Bicarbonate concentrate delivery systems should be disinfected on a regular basis (weekly/dwell times/concentrate) to ensure that the dialysate routinely achieves the level of bacteriological purity required by these regulations. For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a “dead leg” in the system. Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems. The interval between disinfection should not exceed one week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol.

UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2. The device should be sized for the maximum anticipated flow rate according to the manufacturer’s instructions and be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer’s instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely.

When used to disinfect the pipes of a bicarbonate concentrate delivery system, an ozone generator should be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer. When ozone disinfection systems are used, ambient air should be monitored for ozone as required by the U.S. Occupational Safety and Health Administration (OSHA.)

Once a bicarbonate distribution system has been activated, dialysate should be monitored weekly until sufficient data has been obtained to demonstrate consistent compliance with acceptable levels of contamination. The frequency of monitoring may then be reduced, but monitoring should be performed at least monthly. If elevated bacteria or endotoxin levels are found in the dialysate, all systems involved in dialysate preparation, including the bicarbonate concentrate distribution system should be evaluated and appropriate action, such as disinfection, should be taken. The frequency of monitoring should then be increased until it can be demonstrated that the problem has been resolved.

Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day. When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be rinsed free of residual concentrate before disinfection and disinfected at least weekly. Following disinfection, jugs should be drained, rinsed, and inverted to dry.

Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection). All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary.

More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains. Bicarbonate concentrate delivery piping should be color-coded blue at the point of use (at the jug filling station or dialysis machine connection). All joints should be sealed to prevent leakage of concentrate. To prevent mix-ups with delivery of two or more types of acid concentrate, each concentrate should have its own outlet. Concentrate outlets should be compatible with the dialysis machine and have a means of minimizing the risk that the wrong concentrate will be connected to an outlet. The dispensing outlets should be labeled with the appropriate symbol indicating the proportioning ratio for the dialysis machine and should be color-coded blue for bicarbonate, red for acid. (See AAMI Table 3 for guidance.) A daily check to ensure that the appropriate acid and bicarbonate concentrate is connected to the corresponding concentrate delivery line is recommended if the storage tank is not permanently connected to its distribution piping.

The acid and bicarbonate concentrates [must] be matched with respect to the proportioning ratio and with the model and setup configuration of the dialysis machine. Several types of three-stream concentrates are available; with different ratios of acid concentrate to bicarbonate concentrate to water (AAMI Table 3) the different proportioning types are not compatible with one another.

Changing from one proportioning ratio to another requires recalibration for some models of dialysis machines. For those machines, the type of concentrate should be labeled on the machine or clearly indicated by the machine display. It is strongly recommended that facilities configure every machine to use only one type of concentrate.

Dialysate proportioning should be monitored following the procedures specified by the equipment manufacturer. The user should maintain a record of critical parameters such as conductivity and approximate pH. When the user has specific requirements for monitoring dialysate proportioning, such as when dialysis machine settings are changed to allow the use of concentrates with a different proportioning ratio, the user should develop procedures for routine monitoring of dialysate electrolyte values. It is necessary for the operator to follow the manufacturer’s instructions regarding dialysate conductivity. The pH and conductivity must be measured with an independent meter prior to each patient treatment and at any time there is a change in the concentrate (dialysate).

Quality control and quality assurance procedures should be established to ensure ongoing conformance to policies and procedures regarding dialysate quality. This clause defines some of the monitoring activities to be conducted at the facility as part of the quality assurance process. The test methods described in [AAMI] 6.2 are intended to provide examples of acceptable methods. The frequency of monitoring is generally recommended by equipment manufacturer. See AAMI Table 4 which can be used in the absence of manufacturers.

For a new water system, the facility must perform cultures and LALs for four consecutive weeks and show results within acceptable ranges. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution. Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin. Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected. Sample taps should not be disinfected.

Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous three months to look for trends. The Medical Director also should be notified.

Dialysate samples should be collected from a dialysate port of the dialyzer [or] dialysate sampling ports that can be accessed using a syringe. At least 25 ml of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers. Culture dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution. Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines.

Cultures are repeated when bacterial counts exceed the allowable levels. If culture growth exceeds machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia and following a specific request by the clinician or the infection control practitioner.
If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer detected before collecting samples.

Dip samplers may be used for bacterial surveillance in conjunction with a quality assurance program designed to ensure their appropriate use. Elements of the quality assurance program should include staff training in areas such as the correct methods of inoculation, incubation, and interpretation, and verification involving duplicate samples sent to a certified laboratory on at least an annual basis. Plates shall be incubated at 35 °C for 48 hours. Colonies should be counted using a magnifying device. Samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours.
Use of a calibrated loop to apply the sample to the agar plate is not permitted.

For bacterial endotoxin testing, at a minimum, two tubes should be run each time the assay is performed. The first tube contains LAL reagent and the sample to be tested. The second tube contains LAL reagent, a known amount of endotoxin, and the sample to be tested. The second tube acts as a positive control to confirm the absence of any interference that might lead to a false negative result.

The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal.

Testing of free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed every four hours.

Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded on a log sheet. Individuals responsible for testing must have completed and successfully passed the training provided by the facility. In addition to the results being documented, the Charge Nurse (or designee) must also sign off on the checks being performed every four hours.

Samples for testing free chlorine, chloramine or total chlorine should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on site in a prompt manner since chlorine levels will decrease if the sample is not assayed promptly.

If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested; if the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in AAMI guidelines the facility must immediately take corrective action to bring chlorine or chloramine levels into compliance with and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine; only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with AAMI guidelines; immediately notify the Medical Director; and take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels according to AAMI guidelines.

When granulated activated carbon is used as the adsorption medium, each adsorption bed shall have an empty bed contact time (EBCT) of at least five minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes.)

The water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards, requires timely remedial action and must be addressed with a corrective action plan that ensures patient safety.

A facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must:

- Obtain blood and dialysate cultures and endotoxin levels
- Evaluate the water purification system
- Take corrective action through a written already established remediation plan

When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate; and must perform bacteriological and endotoxin testing on a quarterly or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

The facility provides personnel training that include quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues are mandatory. Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (e.g., mixing, disinfection, maintenance, and repairs.) Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

Evidence: Written Policies and Procedures
Evidence: Monitoring and Testing Records

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

Services applicable: ICD

Standard RD7-F: Written policies and procedures are established and implemented in regard to the facility that reuses hemodialyzers, bloodlines and other dialysis supplies. The facility follows laws, and regulations, and AAMI guidelines. (405.2150) (405.2150(a)(1)), (494.50) V300, (494.50(a)) V301, (494.50(a)(2)) no tag, (494.50(a)(3)) V303, (494.50(b)(1)) V304, V306, V311-V353

Written policies and procedures are established and implemented regarding the reuse of hemodialyzers and other supplies in accordance with law/regulation, AAMI, and manufacturer's recommendations; and include appropriate use of chemical germicide, surveillance for the possible patient reactions resulting from reuse, and proper handling of dialyzer end caps, transducer filters, and bloodlines

Certain hemodialyzers and bloodlines:
- May be reused for certain patients with the exception of hepatitis B positive patients.
- May be reused only for the same patient
- Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act

A facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:
- Meet the requirements of AAMI published in "Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003
- The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51

The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations.

Because the current human immunodeficiency virus (HIV), hepatitis B, or hepatitis C status of a patient cannot be known with certainty, all staff potentially exposed to the patient's blood shall observe Standard Precautions. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures should stipulate whether and how reprocessing will be done for patients who have shown sensitivity to materials used in the reprocessing of hemodialyzers.

All patients in a facility will be fully informed regarding reuse of dialyzers. Printed material such as brochures describing the facility's care/services should contain a statement about dialyzer reprocessing if reuse is performed.

In order to protect the health and safety of other patients, hepatitis B positive (HBV+) patients must be excluded from any reprocessing/reuse program. Facilities must provide single-use dialyzers and bloodlines for patients who are HBV+.

Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. Satisfactory operation of manual and automated systems shall be ensured by appropriate functional tests. Strict QC and QA shall be maintained for any type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operating procedures, potential system failures, and dialyzer-reuse criteria shall be included in the dialyzer reprocessing manual, known to the operator, and available for review.

The system providing water for reprocessing shall meet all of the requirements for pressure and flow rate for operating the reprocessing

equipment under minimal and peak load conditions. Product water used for rinsing, cleaning, filling, and diluting the germicide shall be shown to comply with the chemical and microbiological quality requirements [specified in these regulations]. Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.

The water used to rinse and clean dialyzers and dilute the germicide should be tested for bacterial contamination and pyrogens according to the requirements [of these regulations] before a reprocessing program are undertaken. Once dialysis with the reprocessed hemodialyzers has begun, testing for bacterial contamination should be frequent (e.g., weekly.) Less frequent testing, but not less than monthly, may be appropriate if there is a documented history of at least three months of results consistently below the required levels.

The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer or designer's recommendations for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.

Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, the recommendations of the vendor should be followed unless documented experience supports alternative approaches. If the manufacturer's recommendations are not available, reuse equipment, and safety equipment should be inspected on a semiannual basis.

Records shall be maintained of the dates of preventive maintenance procedures and the results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment. A place should be provided for the signature or other unique mark of identification of the person performing preventative maintenance procedures.

If the reprocessing system fails to function as expected, qualified personnel should investigate and repair the problem. The reprocessing system function testing should be repeated after repairs of automated equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.

The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (See Appendix Table 1 with OSHA limits and AAMI 8.5.)

The facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (See National Institute for Occupation Safety and Health (NIOSH/OSHA, 1980; Sax, 1979; material safety data sheets)

Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard precautions shall be observed. Personnel shall wear eye protection when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. When personnel are handling concentrated toxic substances, they shall wear gowns impervious to these substances.

Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. New, used, and reprocessed dialyzers should be segregated to make clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored, if the personnel determine those actions to be necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.

Each reprocessing material should meet a written specification. The fulfillment of that requirement may be determined by certification by the product's supplier that the product meets necessary specifications, labeling for its intended purpose, or by testing procedures by trained personnel, as appropriate. The requirement may also be complied with by purchasing a specific grade as specified by the process, such as USP citric acid. When the user performs testing, he or she should maintain a log of the date of test, the identifying number (lot number) of the batch, the person performing any testing, and the test results. When bleach is purchased from a commercial outlet, the labeled concentration should be between 5.25% and 6.15%, and the formula should not contain fragrances or scents.

As part of inventory control, the reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.

Process control testing and dialyzer test methods shall be established before clinical use of the reprocessed dialyzers in accordance with [AAMI] 11.3. Verification of tests should be repeated after each significant change in the reprocessing system. For automated systems, adherence to the manufacturer's instructions can verify the tests. For manual systems, confirmation of the accuracy of total cell volume (TCV) measurement and the membrane integrity test can verify the tests.

The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers ([AAMI] 11.4.1.6 and 12.3.2). For systems using heat disinfection, verifiable evidence shall be available before the next use that dialyzers have been exposed to the appropriate temperature for the time required. If chemicals are used to enhance heat disinfection, both a presence test and a verification of time and temperature shall be performed.

Records shall be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the procedure, his or her signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a

reprocessing log or the patient's chart, whichever is more convenient. Patients must be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers.

Each reprocessed hemodialyzer shall be used for only one patient. The labeling shall uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.

Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see AAMI 10.3.) Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood or dialysate flow or other pertinent information unless provision is made for recording this information on the label. The label on hemodialyzers with transparent casings should permit the blood path to be readily inspected.

The dialyzer shall be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with similar last names should have a warning to the user (such as a brightly colored name alert label) to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. If this information appears on the label, a permanent record should also be kept (see [AAMI] 4.2.) Electronic records are acceptable. If records are electronic, the test results should be available to the user. Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a facility for reprocessing.

Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within two hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.

When pre-cleaning is done, it is part of the reprocessing procedures. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for pre-cleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to. Pre-cleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the requirements AAMI guidelines related to allowable bacterial and endotoxin levels.

The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and o-rings shall be kept with their respective dialyzers. If the header cap is removed to clean the header space, cleaning shall be done with water meeting the requirements of these regulations related to allowable bacterial and endotoxin levels. Once the o-ring and the header cap are cleaned and before they are reassembled at the end of the dialyzer, they should be disinfected. The disinfectant shall not be rinsed and shall be allowed to remain on the dialyzer components as they are reassembled. If any cracking of the header occurs, the process should be evaluated. If the header space is cleaned with the header cap in place, it is necessary to ensure that the end of the fiber bundle is not damaged. If water is used, it shall meet the requirements of these regulations. If automated equipment is used, the manufacturer's instruction for use shall be followed.

Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, or other chemicals may be used as cleaning agents for the blood compartment, provided that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and has no significant adverse effects on the structural integrity and performance of the dialyzer. Each chemical shall be rinsed from the dialyzer before the next chemical is added, unless mixing is known to be safe and effective for reprocessing.

Total cell volume (TCV) measured after every use/original volume known. Total cell volume (TCV) may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80% of the original TCV. The dialyzer prescription should take into account the 10% loss in clearance (20% loss in TCV) that may occur with dialyzer reuse. A membrane integrity test such as an air pressure leak test shall be done between uses.

The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device. The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.

Chemical germicides or other procedures used for disinfecting of hemodialyzers shall have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms. If the germicide has an expiration date from the manufacturer, staff members should be sure that the chemical is not outdated.

Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If this is the case, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins.

The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see AAMI 12.4.) To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde.

If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration. The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer disinfectant that does not

adversely affect the materials of the dialyzer.

Reprocessing systems in which each batch of germicide is manually prepared, each batch of germicide shall be tested before use to verify the proper concentration of the germicide. This requirement does not apply in cases in which each dialyzer is tested for concentration before setup.

When the germicide is diluted on-line, its concentration in the hemodialyzer immediately after reprocessing should be checked at least monthly for each reprocessing system. When the germicide is partially or fully diluted by the user, the solution is thoroughly mixed.

The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material. For chemically disinfected dialyzers, a low-level germicide that is compatible with the dialyzer's materials of construction should be used for this purpose.

The hemodialyzer shall be examined after reprocessing to ensure that the external surface is clean, the dialyzer is not damaged, and the rinsing of blood has been satisfactorily completed. The dialyzer shoud also be aesthetically acceptable in the appearance to patients and staff with the following noted:

- The dialyzer should also be aesthetically acceptable in appearance to patients and staff
- The dialyzer jacket should be free of visible blood or other foreign material
- There shall be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports
- No more than a few dark, clotted fibers should be evident on inspection of the exterior of the hollow fibers
- The headers of hollow-fiber dialyzers should be free of all but small peripheral clots or other deposits
- Blood and dialysate ports shall be capped without evidence of leakage
- The label is properly filled out and legible

Reprocessed dialyzers that have been rejected for failure to meet performance, inspection, or other release criteria should either be immediately discarded or further reprocessed and subjected to the performance requirements of [AAMI] 11.3, 11.4, and 11.5. If the dialyzer is to be further reprocessed, rather than discarded, it shall be labeled as rejected and stored in a quarantine area to preclude use until requirements are met.

Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of [AAMI] 8.2. Prolonged storage (greater than one month) should be documented to be safe and effective. Dialyzers that have exceeded the facility's maximum storage time shall be reprocessed or discarded. The dialyzer and disinfectant labeling should be consulted regarding proper storage conditions.

A written procedure that has been shown to be effective shall be followed. There shall be a written procedure for all tests employed in preparing the dialyzer for use, including mention of each test's sensitivity. The germicide manufacturer's instructions for use should be consulted in determining the maximum residual level. The physician in charge of the reuse program shall approve any alterations in the procedures.

The dialyzer should be inspected before it is prepared for use. Completion of this inspection should be recorded in AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.5 Inspection the AAMI RDD Committee recognized that the patient should be included the reprocessing record (see [AAMI] 4.2,) along with the signature or other unique means of identifying the person completing the inspection. The inspection should include the following:

- The reprocessed dialyzer shall be legibly labeled with the information recommended in [AAMI] 10.3
- There should be no indication of structural damage or tampering with the dialyzer
- The ports of the dialyzer should be properly capped
- The presence of germicide in the dialysate and blood compartments, including headers, should be confirmed, and there should be no evidence of leakage from the ports or other portions of the dialyzer
- The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer
- The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient

Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be recorded, along with the signature or other unique means of identifying the person verifying patient identification.

The contact time of the germicide or disinfection procedure shall comply with the facility's protocol and the manufacturer's recommendations. The presence of chemical germicide in each hemodialyzer shall be ensured through either direct testing or an on-line process and procedural control. If other disinfection (e.g., heat) procedures are used, there shall be methods to ensure that each hemodialyzer has been properly subjected to the disinfection process. A record shall be kept indicating that the dialyzer has undergone the appropriate storage time, and the record shall be appropriately verified.

Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed. If a germicide manufacturer does not require testing each hemodialyzer for the presence of germicide], the presence of germicide may be ensured by either a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide.

Process control is to include use of hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process or use an indicator substance (e.g., FD&C Blue #1,) which has been added to the germicide, and that reliably indicates the presence of germicide. If blue dye is used, it should be added to the germicide concentrate before dilution, not to the fully diluted solution.

Sampling for process validation is to include:

- Sample at least one hemodialyzer per patient shift per reuse system with a direct presence test (do not use a Schiff test for formaldehyde for this purpose because it will detect the presence of inadequate concentrations of formaldehyde)
- Samples should be taken immediately after the dialyzers have been reprocessed
- For germicide prepared in batches, sample at least one hemodialyzer from each batch with a direct presence test
    - Samples should be taken immediately after the dialyzers have been reprocessed
- Sampling and testing are to be accomplished before patients use any hemodialyzers processed on this shift

If the manufacturer's instructions so require, a germicide presence test shall be performed before the germicide is rinsed from the dialyzer. The dialyzer shall be rinsed and primed according to a written procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and result in a physiological solution in the blood and dialysate compartments. The dialyzer manufacturer's instructions should be considered in developing these procedures.

- Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure to ensure that the germicide level is below the maximum recommended residual concentration:
    - Completion of this step shall be documented, along with the signature or other unique means of identifying the person performing the test
- A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis:
    - The priming, removal, and residual testing process should be reinstituted after a delay sufficient to bring concentrations of germicide above the recommended level (rebound)
    - Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis
- A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it
- If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline

Evidence: Written Policies and Procedures
Evidence: AAM/ANSI guidelines and Manufacturer's Recommendations
Evidence: Observation
Evidence: Response to Interviews
Evidence: Medical Records

Services applicable: ICD

Standard RD7-G: Written policies and procedures are established and implemented in regards to the patient care, monitoring, and documentation when being treated with reused hemodialyzers, bloodlines, and other dialysis supplies. The facility follows laws, regulations, and AAMI guidelines. (494.50(b)(1)) V305, V354-V359

An order to reprocess hemodialyzers shall be made by a physician knowledgeable about reprocessing and its medical and economic implications.

All records described in this recommended practice shall meet the requirements for medical records, including completeness, legibility, and security. A place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing procedure (e.g., the person performing preventive maintenance procedures, the person[s] investigating complaints, and the person[s] conducting quality assurance [QA] and quality control [QC] activities). Maintaining these records is the responsibility of the Medical Director.

The clinical course of the patient should be observed and recorded during each dialysis to identify possible complications caused by new or reprocessed dialyzers. Dialyzer failures should be recorded and systematically evaluated. Applicable home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.

- Patients' temperatures should be measured and recorded at least before and after dialysis with new and reprocessed dialyzers:
    - A temperature of over 37.8° C or 100° F, taken orally, or chills should be reported to the physician, [advanced practice registered nurse or physician assistant]
    - Any patient with an unexplained fever and/or chills should be evaluated for the possibility of a pre-existing infection (e.g., [at an] access site)
    - The dialysis procedure should also be evaluated to rule out the use of contaminated water, errors in treatment delivery, or incorrect dialyzer reprocessing
- Other unexplained symptoms such as pain in the blood-access arm at the onset of dialysis should be evaluated by the physician, [advanced practice registered nurse or physician assistant] and consideration given to the possibility that the symptom may be attributed to residual disinfectant in the new or reprocessed dialyzer or contamination of the water treatment equipment:
    - Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and a test for residual germicide (see [AAMI] 12.4.1)
- Any significant events such as the occurrence of symptoms listed in [AAMI] 13.2.1 and 13.2.2 should be recorded on an incident report form which would include the results of any evaluations conducted by the physician and others, and the event should be considered for reporting to the manufacturer(s) in accordance with the FDA's Medical Device User Reporting procedures:
    - The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated

        - This form should be kept in the complaint investigation record file (see [AAMI] 4.5)
    - Records shall be kept of all complaints by patients and staff members about failures of preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken:
        - The records shall be reviewed periodically for trends of adverse reactions
        - Compliance with the FDA's Medical Device User Reporting procedures shall be demonstrated
    - Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file (see [AAMI] 4.5):
        - If there is excessive deviation from the expected performance, testing should be repeated (see [AAMI] 11.3.1) and appropriate adjustments made in the reprocessing procedure
    - Monitoring of relevant patient results is recommended to ensure that all parameters relating to hemodialyzer clearance are being met:
        - Specifically, examination of urea reduction ratio (URR) or Kt/V over time is necessary. The failure of these results to meet the expectations of the dialysis prescription should be investigated
        - Deterioration of a patient's clinical condition or variability of routine dialysis procedures (heparinization, ultrafiltration, erythropoietin requirement) requires investigation of all practices, including reuse
        - Reports of investigations should be filed in the complaint log
    - If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated

Evidence: Written Policies and Procedures
Evidence: Medical Records

Evidence: Observation
Evidence: Response to Interviews

Services applicable: ICD

Standard RD7-H: Written policies and procedures are established and implemented in regard to the personnel training and competencies required when reused hemodialyzers, bloodlines and other dialysis supplies are used. The facility follows laws, regulations, and AAMI guidelines. (494.50(b)(1)) V307-V310

Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual facility relevant to the facility's multiple-use program. Education shall be geared to meet the needs of this wide range of personnel.

The facility's physician or director shall establish a training course for the persons performing hemodialyzer reprocessing. A written document should give details about the curriculum and, in particular, address the potential risks to patients and staff members of not following correct procedures.

The curriculum should include, but is not limited to:

- The facility's specific reprocessing procedure, including a rationale for each step
- Basic documentation requirements of the program
- The operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components
- Microbiology with respect to aseptic technique, the collection, and handling of samples, and personnel safety precautions for infectious hazards
- The risks and hazards of multiple use of hemodialyzers
- The consequences of not performing tasks properly
- The risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances
- The use and location of protective eyewear, respirators, masks, and special clothing
- Emergency procedures as required by the facility
- The principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.

Each person performing procedures for the multiple uses of dialyzers shall have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training shall be certified by the Medical Director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee having received the instruction. Retraining is necessary when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found.

A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies.

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

Services applicable: ICD

Standard RD7-I: Written policies and procedures are established and implemented in regard to the auditing requirements when reused hemodialyzers, bloodlines and other dialysis supplies are used. The facility follows laws, regulations, and AAMI guidelines. (494.50(b)(1)) V360-V368, (494.50(b)(2)) V378, (494.50(b)(3)) V379, (494.50(c)(1)) no tag, (494.50(c)(2)(i-iii)) V381-V383

The criteria chosen as the internal standards of a facility shall be documented in its policy and procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff members should affirm, modify, or repeat these observations to confirm or improve the process.

Clinical outcomes serve as the most important indicator of quality of all dialysis treatment practices Final oversight is the responsibility of the Medical Director. The facility is to follow the AAMI Quality Assurance Schedule. A record of review, comments, trend analysis, and conclusions arising from QA practices serve as a foundation for future review and as documentation to external evaluation.

Problems in a particular aspect of operations should be reviewed and tracked until a solution is in place and demonstrated to be effective. The Medical Director is responsible for scheduling review, endorsing findings, and, when appropriate, implementing changes.

Audits to be performed include:

- Personnel should audit at least annually compliance with the facility's policy and procedures to inform patients of the facility's reuse practices:
    - Designated staff members should audit written procedures and manuals for relevance at least annually and whenever adverse findings could be attributed to equipment failure. Designated staff should also audit maintenance and repair policies at least annually
    - Designated staff members should audit the provisions of [AAMI] 8.1, [Reprocessing area and ventilation], at least annually
    - The provisions of [AAMI] 8.2, [Storage area], and [AAMI] 8.4, [Personnel protection] should be audited quarterly
- Specifications and testing, and inventory control] at least semiannually
- Designated staff members should audit the provisions of [AAMI] section 10 - Hemodialyzer labeling, time of labeling, label composition, and information recorded quarterly
- Initially, designated staff members should audit the written procedures for the various steps in this process and verify implementation at least monthly
    - Subsequently, semiannual audits may be sufficient if there is a documented history of favorable results
    - Trend analysis should be performed
- At least quarterly, designated personnel should audit the written procedures and verify their implementation
- At least quarterly, designated staff members should verify the tests for the presence of germicide and the test for residual germicide by using positive and negative control solutions, on those products that are not specifically intended for use in dialyzer reuse germicide indicator tests and which have not been cleared by the FDA

Reprocess hemodialyzers and bloodlines–following directions for use (DFU) include:

- Following manufacturer's recommendations
    - Using an alternate method and maintaining documented evidence that the method is safe and effective
- Avoiding the exposer of hemodialyzers to more than one chemical germicide, other than bleach (used as cleaner in this application), during the life of the dialyzer:
    - All hemodialyzers must be discarded before a different chemical germicide is used in the facility

Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines include:

- Monitoring patient reactions during and following dialysis
- When clinically indicated (for example, after adverse patient reactions), the facility must:
    - Obtain blood and dialysate cultures and endotoxin levels
    - Undertake evaluation of its dialyzer reprocessing and water purification system
        - When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected
    - Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law

Evidence: Written Policies and Procedures
Evidence: Medical Records
Evidence: Quality Assessment and Performance Improvement reports
Evidence: Observation
Evidence: Response to Interviews

Services applicable: 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: ICD

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-E	Written Policies and Procedures	
RD7-F	Written Policies and Procedures	
RD7-G	Written Policies and Procedures	
RD7-H	Written Policies and Procedures	
RD7-I	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.