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RENAL DIALYSIS

ACHC Certified Consultant Training

Renal Dialysis Intensive

ACHCU

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- Any questions regarding this presentation and post test can be addressed to:
  - Lindsey Holder – lholder@achcu.com

Also Joining Our Training

- Greg Stowell - Associate Director, Education & Training
- Lindsey Holder – Senior Manager, Education & Training
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Items Needed for Virtual Training

- You should have received an email with a link to the following information:
  - ACHC Standards
  - ACHC Accreditation Process
  - The presentation for today
  - The *ACHC Accreditation Guide to Success* for Renal Dialysis
- If you have not received the email or are unable to download the information, contact customerservice@ACHCU.com for assistance

Objectives

- Review the Centers for Medicare & Medicaid Services (CMS) requirements for coverage in the Medicare program for End Stage Renal Disease providers.
- Review the expectations for compliance with the Medicare Conditions for Coverage (CfCs) and ACHC Standards in order to guide ACHC customers through the survey process.
- Review the *ACHC Accreditations guide to Success* workbook and how to use the tools to prepare customers through the survey process.

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RENAL DIALYSIS

CMS End Stage Renal Disease Requirements

Initial Medicare Certification & Recertification

Centers for Medicare & Medicaid

- ACHC earned deeming authority for renal dialysis in 2019.
- This allows ACHC to conduct an initial Medicare certification survey and re-certification survey in lieu of the state.
- This does not allow ACHC to conduct the initial licensure survey unless ACHC is approved by the state to conduct such surveys.

Renal Dialysis Services

- In-Center Dialysis organizations provide outpatient maintenance dialysis services. A Renal Dialysis organization may be an independent or hospital-based unit, as described in 42 CFR 413.174 (b) and (c).
- Home Dialysis Support organizations provide home dialysis training and support services.

Certificate of Need

- A Certificate of Need (CON) is an endorsement that numerous states require before approving the construction of a new healthcare facility.
- CON programs are aimed at restraining healthcare facility costs and facilitating coordinated planning of new services and facility construction in a specified area by restricting duplicative services and determining whether new capital expenditures meet a community's needs. Many "CON" laws initially were put into effect across the nation as part of the federal "Health Planning Resources Development Act" of 1974.
- Certificate of Need State Laws
  - www.ncsl.org

Licensure

- A licensure survey is conducted on organizations that are required to obtain a license before beginning to conduct business.
- The organization's license must be current; if license has been suspended or is probationary, the organization must notify the Account Advisor.
- ACHC is not currently authorized to provide renal dialysis licensure surveys, however ACHC has applied for state approval.
  - Without specific state approval to complete the licensure surveys, the renal dialysis organization has to obtain the license through the State agency.
- To determine if state licensure is required in the state that the customer wants to operate a renal dialysis facility, they must call or visit the state's Department of Health and Human Services website.

CMS Requirements

- Renal dialysis providers must complete the Medicare Enrollment Application, CMS 855A:
  - The applicant completes and submits a CMS 855A enrollment application and all supporting documentation to its fee-for-service contractor/Medicare Administrative Contractor (MAC).
  - The fee-for-service contractor/MAC reviews the application and makes a recommendation for approval or denial to the State survey agency, with a copy to the CMS Regional Office.
  - The State agency or approved accreditation organization conducts a survey. Based on the survey results, the State agency makes a recommendation for approval or denial (a certification of compliance or noncompliance) to the CMS Regional Office. Certain provider types may elect voluntary accreditation by a CMS-recognized accrediting organization in lieu of a State survey.

CMS Requirements

- A CMS contractor conducts a second contractor review, as needed, to verify that a provider continues to meet the enrollment requirements prior to granting Medicare billing privileges.
- The CMS Regional Office makes the final decision regarding program eligibility. The CMS Regional Office also works with the Office of Civil Rights to obtain necessary Civil Rights clearances. If approved, the provider must typically sign a provider agreement.

- www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf

Sample Of CMS-855A Notification

Wisconsin Physicians Service (WPS) has assessed your Initial Medicare Enrollment Application and has forwarded it to Michigan Dept of Licensing & Regulatory Affairs for review. A copy has also been sent to the Chicago Regional Office of the Centers for Medicare & Medicaid Services (CMS). The next step will be a survey or site visit conducted by a State Survey Agency or a CMS approved deemed accrediting organization to ensure compliance with required Conditions of Participation.

Application Type: Initial Enrollment
Provider Legal Name: [redacted]
Provider DBA Name: [redacted]
Contractor ID: [redacted]
Provider Transaction Access Number (PTAN): Pending
Facility Type: End-Stage Renal Disease Facility (ESRD)
National Provider Identifier (NPI): [redacted]
Primary Practice Location: [redacted]
Medicare Year End Cost Report: [redacted]
Projected Effective Date of Initial Enrollment: [redacted]
Date Application Received: [redacted]

This provider is requesting to be enrolled as a freestanding End-Stage Renal Disease Facility (ESRD)

ACHC Application Requirements

- Required documentation for a Renal Dialysis provider to be placed into scheduling:
  - Complete the online Accreditation Application.
  - Complete the statistical information for all physical locations.
  - Submit the non-refundable deposit.
  - Download, review, and sign the Accreditation Services/Business Associate Agreement within the required time frame.
  - Upload the required PER checklist.
  - Submit required documents.

Initial Certification Requirements

- Approved 855A letter
- Form CMS-3427 – Part I to be completed by the provider
- A signed agreement with each applicable End-Stage Renal Disease (ESRD) Network (V755)
- Must be able to demonstrate operational capability of all facets of its operation
  - Medications, supplies,
  - Machines, emergency equipment
  - Water Treatment (meets all testing requirements per the CMS CfCs)
- LSC attestation waiver (otherwise a LSC survey will be conducted)

Initial Certification Requirements

- Established policies and procedures
- Required number of patients
  - Must have at least one active patient receiving treatment for each modality offered
- Required core personnel – must meet the qualifications per CfCs
  - Medical Director (a waiver is not applicable for initial certification)
  - Nurse Manager – must be a full-time employee
  - Registered Dietitian
  - Social Work (MSW)

  - With the exception of the Nurse Manager/Administrator, a facility may use contracted staff, if necessary, to supplement employees in order to meet the needs of the patients

Completing the Form CMS-3427

- Part I – Application – is to be completed by the facility during initial and re-certification surveys.
- Incorrect or incomplete CMS paperwork can delay the new provider's acceptance into the Medicare program and impact billing.

Establishing Policies & Procedures

- Policies need to be in compliance with the:
  - Medicare Conditions for Coverage (CfC)
  - State regulations
  - Medicare billing requirements
  - ACHC requirements
  - Best practice/facility expectations

Establishing Policies & Procedures

- Purchased policies and procedures:
  - Pre-approved policies and procedures.
  - Purchase an Extended Policy Review.
  - Conduct a review of policies identified on Appendix B of the ACHC Standards for the Renal Dialysis program.
- Readiness/Compliance date established on the Primary Evidence Report (PER) Initial Checklist.
- Confirmation of the following:
  - 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 XX date.

Questions?

Break time

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ACHC Accreditation Guide to Success

Utilizing the Workbook for a Successful Survey Outcome

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RENAL DIALYSIS

Achieving A Successful Survey Outcome

ACHC Renal Dialysis Standards

Review The Standards

- Identifier
  - RD – Renal Dialysis
- Standard
  - Provides a broad statement of the expectation in order to be in compliance with ACHC standards
  - Gives you more detailed information and specific direction on how to meet ACHC standards
- Evidence
  - Items that will be reviewed to determine if the standard is met
- Services applicable
  - ICD – In-Center Dialysis
  - HDS – Home Dialysis Services

Standard - Example

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.

Evidence: Governing Body Meeting Minutes/Bylaws, Job Description for appointed responsible manager (CEO or Administrator).

Standard - Example

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.

Reporting of negative outcomes within 30 days to ACHC

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

Evidence: Governing Body Meeting Minutes, prior Regulatory Inspection Reports, and response to Interviews.

Most Stringent Regulation

- Must be in compliance with the most stringent regulation in order to be determined compliant with ACHC Accreditation Standards
  - CfCs
  - State requirements
  - Facility policy
  - Scope of practice
  - ACHC Standards

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.

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

Standard RD1-B

The facility is licensed when required by the state or local law. (494.20) V101

If state or local law provides for licensing of a renal dialysis facility, the facility must be licensed.

The facility has current required license 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.

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.

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)(103) V762-763, (494.180(d))V764

Governing body requirements include the overall management of the facility

Responsible for:

- Operation of the facility
- Fiscal Management
- Staff training and coverage
- Medical staff appointments and coverage
- Quality Assessment/Performance Improvement
- Adopts and enforces rules and regulations

Standard RD1-D

The governing body or designated person responsible must ensure that:

- Adequate staffing of qualified personnel
- A registered nurse, social worker and dietitian are members of the IDT
- A registered nurse, responsible for nursing care provided is present at all times while patients are being treated
- All staff, including the Medical Director, have appropriate orientation, and opportunity for continuing education
- Staff appointment and credentialing is in accordance with state law
- All staff are informed of all facility policies & procedures
- Expectations are communicated to the medical staff regarding participation in improving the quality of care
- Internal grievance or complaint process is implemented so the patient may file an oral or written grievance without reprisal.
- Staff follow the facility's patient discharge/transfer policies & procedures
- All ethical issues are reviewed by the governing body

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

Disclosure of ownership and control information has been properly reported to CMS

- Review of organizational chart to ensure consistent with 855A
- Changes have been properly reported within 30 days
  - Name, address of person with ownership or controlling interest of greater than 5%
  - Those with controlling interest or are managing employees convicted of criminal offenses against Medicare, Medicaid, title V, or Social Services programs
- Any changes in management are properly reported as well.
- Information to CMS, state agencies and ACHC
  - Intervals between recertification, re-enrollment, or contract renewals, within 30 days of a written request or change in authority, ownership, or management.

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

CEO or Administrator Responsible for management of the facility

- Appointment by the governing body
- Resumé providing sufficient educational and practical experience
- Job description should define the qualifications and responsibilities
- Annual evaluation of the Administrator by governing body or designee
- Authorization in writing should provide who is pre-designated/authorized to assume the responsibilities and obligations if the CEO/Administrator is not available

Standard RD1-F

Responsibilities of CEO/Administrator include, but not limited to:

- Staff appointment
- Fiscal operations
- ESRD Network relationship
- Allocation of staff and resources for the QAPI program

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

Obtaining emergency medical care

- Written information for all patients (Home and In-Center)
  - Who to call and how to obtain emergency medical care when away from the facility.
- On-call schedule for physicians available for staff to call for emergencies (when they can be called and how they can be reached

Written agreement with hospital

- In-patient care
- Provide routine and emergency dialysis
- Other hospital services
- 24/7 emergency medical care
- Dialysis patients will be accepted and treated promptly in emergencies

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

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.

Reporting of negative outcomes within 30 days to ACHC

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

The report includes all actions taken and plans of correction.

Tips for Compliance

- Ensure license is current and posted
- Change in ownership/management properly reported
- Governing body meeting minutes
- Conflict of Disclosure statement
- Administrator/CEO, Medical Director
- Written Policies and Procedures
- Job Descriptions for CEO/Administrator

Tips for Compliance

- Any negative outcomes have been properly reported
- Review contracts – hospital and contracted care
- List of physicians on call
- Proof of professional liability insurance
- Evidence of physician licensure verification
- QAPI activities to ensure monitoring of care
  - Evidence of how contracted care is monitored
- Any prior regulatory inspection reports

Workbook Tools

- Compliance Checklist
- Governing Body Meeting Agenda Template
- Hourly Contract Staff Audit Tool
- Organizational Chart
- Conflict of Interest Disclosure Statement
- Self-Audit
- Sample Policies and Procedures

Questions?

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, incidents, 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

Laboratory Services

- Availability of laboratory services must be provided
- Facility providing their own laboratory services
  - Waived testing (e.g., spun microhematocrits, FSBG obtained by glucose monitoring devices)
  - Required to maintain a current CLIA certificate of waiver
- Contracted laboratory services with certified providers
  - Arrangement must be in writing
  - Specify parameters such as, types of test, collection/handling of specimens, how results will be reported and time frame of reporting
- Specific required content on laboratory report

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

Special Purpose Renal Dialysis Facility (SPDF)

- Requires specific approval /permission
- Patient's physician must be contacted for ensuring continuity of care
- Care provided by the SPDF is forwarded to the patient's usual facility within 30 days of last scheduled treatment at the SPDF
- Intended for short term periods of use (may not exceed 8 months in any 12-month period)
    - Vacation Camps
    - Emergency Circumstances
    - Required to operate under the direction of a certified renal dialysis facility
    - Must comply with specific requirements

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

Creation and Distribution of the Patient Rights and Responsibilities

- Written copy is provided to patient/patient representative upon beginning of treatment
- Must be read to the patient if the patient cannot read
- For a minor patient, the parent or other responsible person must be fully informed of the rights
- Copy of the rights is prominently displayed in the facility
- State agency and ESRD network address and contact number for complaints must be displayed in a prominent area in view for patients to see and read
- If additional state or federal regulations exist for Patient rights, these must be included in the facility's rights and responsibilities

Personnel are provided training at least during orientation and annually thereafter concerning Patient Rights and Responsibilities

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.

Reporting and investigating alleged violations

- Staff are trained to identify and/or report any indication of potential violations
  - Discrimination
  - Mistreatment
  - Neglect
  - Verbal, mental, sexual and physical abuse
- Facility investigates all alleged violations and reports immediately to the Administrator
  - Immediate action to prevent further potential violations during investigation
  - Appropriate corrective action is taken if violation is confirmed
  - Confirmed violations are reported to ACHC, state and local bodies with jurisdiction

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

Grievances and complaints or concerns reporting and investigation

- Patient is informed upon admission to facility of rights to voice grievances/complaints
  - Process on steps for reporting to designated person, investigation, and resolution
- Facility investigates, attempts resolution and documents results within a described time frame
- Records are maintained of grievance/complaints
  - Grievance tracking
  - Outcomes
  - Summary report to governing body
- Personnel receive education with grievance/complaint policies and procedures
- Personnel are involved in assistance with implementing the resolution when needed

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

Contact information for reporting grievances/complaints

- Written information provided to patient with phone number, and contact person for reporting grievances/complaints
- Patient is advised , in writing of the mailing addresses and phone numbers to the appropriate state regulatory bodies
- ACHC's phone number is also provided to the patient
- Prominent display of patient rights to include the current state agency and ESRD network mailing address and phone number for complaints are easily visible to all patients

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).

Protected Health Information (PHI) and Electronic Protected Health Information (EPHI)

- Patient has the right to a confidential medical record
- Confidentiality policies and procedures regarding communication, content and release of PHI/EPHI which are clearly communicated to all personnel
- Signed confidentiality statements for all personnel and governing body members
- Personnel abide by the confidentiality statement and facility policies
- Designation of individual responsible for ensuring privacy policies are followed
- Written information and discussion of confidentiality/privacy of information is covered with the patient upon the first encounter at the facility

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

Communication and Language Barriers

- Mechanisms are in place to assist with communication and language barriers
- All personnel are knowledgeable of policies and procedures for the provision of care to patients with communication barriers

Various cultural backgrounds, and religious beliefs

- Personnel are able to identify their own beliefs and the patient's beliefs and still support the patient
- All personnel are provided with at least annual education and resources to increase cultural awareness of the patient population they serve

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.

Compliance Program and prevention of fraud and abuse

- There is an established Compliance Program
- Compliance risk are identified, and guidance provided to internal anti-fraud and abuse controls
- Detailed actions are taken to prevent violations of the fraud and abuse laws
- Guidelines are specific for the requirements of the Compliance Program
- Designation of a Compliance Officer/Compliance Committee
- Written standards and conduct expectations are posted in staff areas to include a non-retaliation statement

Standard RD2-Q.01

Written policies and procedures are established and implemented by the facility for dialysis services to residents located in a nursing home.

Dialysis services to residents residing in a nursing home

- The delivery of dialysis services must be equivalent to the standards of care provided to patients receiving treatment in a dialysis facility
- Specific protocols are developed and collaboration with nursing home is occurring
- Policies and procedures are reviewed and updated to be current with required standards
- Written agreements with the SNF must delineate the responsibilities of each regarding the care before, during and after dialysis treatment
- On-call schedules for emergencies must be provided to the SNF of physicians and/or dialysis RNs
- The dialysis facility is responsible for the safe delivery of dialysis to the nursing home resident
  - Specific training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home is the responsibility of the dialysis facility
  - Qualified dialysis personnel must remain in the room with direct visual contact during treatments

Tips for Compliance

- Written Policies and Procedures
- CLIA Certificates
- Statement of Patient Right and Responsibilities
- Incident Reports/Investigation Results
- Grievance/Complaint log
- Governing body meeting minutes

Tips for Compliance

- Evidence staff know how to handle:
  - Complaints
  - Ethical issues
  - Communication barriers
  - Cultural diversity
- Compliance Plan
- Written contracts with SNF

Workbook Tools

- Compliance Checklist
- Patient Rights and Responsibilities Audit Tool
- Sample Patient Complaint/Concern Form
- Sample Ethical Issues/Concerns Reporting Form
- Self-Audit
- Sample Policies and Procedures

Questions?

Section 3

FISCAL MANAGEMENT

- The standards in this section apply to the financial operations of the organization. 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 assistance with

- Medicare, Medicaid
- Third party payors
- Medicare Advantage plans and/or the Veteran's Administration.

Tips for Compliance

- Evidence of staff availability to patients in need of resource information
- Ensure personnel files contain appropriate job description for financial counselor/SW

Workbook Tools

- Compliance Checklist
- Self-Audit

Questions?

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.

Personnel files and records requirement policies & procedures:

- 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

Standard RD4-A.01

- 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.

Standard RD4-C.01

All personnel files at a minimum contain or verify the following items. (Informational Standard Only)

- 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) 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

Standard RD4-C.01

Personnel includes, but is 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 statements, 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.

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

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.

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

All personnel qualifications must be kept current at all times.

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.

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.

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

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

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

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.

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.

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 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.

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

Qualified Medical Director:

- Only have a single Medical Director per facility
- Board –certified in internal medicine, completed a board-approved training program in nephrology and has at least 12 months of experience in care for patients receiving dialysis

Medical Director Responsibilities:

- 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

Standard RD4-M

Medical Director Responsibilities (cont.):

- 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

Standard RD4-M

Medical Director Responsibilities (cont.):

- 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

Standard RD4-M

A waiver of the requirements of the qualified Medical Director may be requested from the State Authority if a qualified Medical Director is not available to serve at the facility. The facility cannot apply for a waiver during their initial certification process.

Standard RD4-N

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

Nurse Manager Qualifications:

- Must be a full-time, direct employee of the facility
  - Full-time = employed 40 hours/week or for the number of hours the facility is open, whichever is less
- Licensed as a Registered Nurse by the state in which he/she is practicing
- Experience Requirements:
  - 12 months in clinical nursing
  - Additional 6 months in providing nursing care to patients on maintenance dialysis

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

Standard RD4-O

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

Qualified Nurse for Self-Care/Home Care training:

- Registered Nurse licensed in the state he/she is practicing
- Experience Requirements:
  - 12 months in providing nursing care
  - Additional 3 months of experience in the specific modality for which self-care training will be provided

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

Qualified Charge Nurse:

- Currently licensed as a Registered Nurse or licensed practical nurse, or vocational nurse in the state he/she is practicing
- If the nurse is a LPN or LVN, he/she must work under the supervision of a registered nurse in accordance with state nursing practice act
- Experienced in providing ESRD care:
  - 12 months in providing nursing care
  - Including 3 months of experience in providing nursing care to patients on maintenance dialysis
- RN must be present during a patient's treatment in the facility

Standard RD4-Q

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

Qualified Registered Dietitian:

- Registered with the commission on Dietetic Registration
- Minimum of one-year professional experience in clinical nutrition as a RD
- May be a contractual employee

Standard RD4-R

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

Qualified Social Worker:

- Holds a master's degree in social work with specialization in clinical practice OR
- Has at least two years of experience as a social worker
  - One year of which was in a dialysis unit or transplantation program prior to Sept. 1, 1976
  - Established a consultative relationship with a master's prepared social worker with a specialization in clinical practice (school accredited by the Council on SW Education)

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:

- Qualifications:
  - Must be certified by either a state certification program or a national commercially available certification program
  - Have a high school diploma or equivalency
- Newly employed PCTs :
  - Within 18 months of hire as a patient care technician
- Training:
  - Completed a training program approved by the Medical Director and governing body
  - Program is under the direction of a Registered Nurse

Standard RD4-S

Patient care dialysis technician training program focus and topics:

- Operation of kidney dialysis equipment and machines
- Providing direct patient care
- Communication and interpersonal skills
- Patient sensitivity training and care of difficult patients
- 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

RD4-T

Written policies and procedures are developed and implemented in regard to the requirement of all personnel to receive the COVID-19 vaccine. 494.30(b)(1-3) V-800

The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19.

- Review policies and procedures:
  - A process for ensuring all personnel are fully vaccinated
  - A process for ensuring additional precautions are implemented for all personnel who are not fully vaccinated
  - A process for tracking and securely documenting vaccination status
  - A process for tracking vaccination status of personnel who have obtained any booster doses
  - A process for personnel who may request an exemption based on applicable federal law
  - A process for tracking and documenting personnel who have been granted an exemption

RD4-T

- Review policies and procedures continued:
  - A process for ensuring all documentation, which confirms clinical contraindication to COVID-19 vaccines, has been signed and dated by a licensed practitioner, and in accordance with all applicable state and local laws
  - A process for ensuring the tracking and secure documentation of the vaccination status of personnel for who the vaccination must be temporarily delayed
  - Contingency plans for personnel who are not fully vaccinated for COVID-19
- Review personnel files
- Review tracking method

Tips for Compliance

- Utilize the Personnel File tools to audit:
  - Personnel files
  - Contracted individual files
- Evidence of orientation to all personnel
- Evidence of a designated Medical Director
- Written Policies and Procedures
- Quality Control Logs
- Job Descriptions
- Orientation Checklist/Competencies

Workbook Tools

- Compliance Checklist
- Orientation Requirements Checklist
- Employee Educational Record
- Personnel File Audit
- Hints for Developing an Education Plan
- Self-Audit
- Sample Policies and Procedures

Questions?

Break time

Teaching Tool: Kahoot!

- Cellphone or laptop
- Go to Kahoot.it
- Enter Game PIN
- Enter your nickname
  See “You’re in”
- You’re ready!

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

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

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

Confidentiality maintained and safeguards against loss, destruction or unauthorized use

- Policies and procedures are consistent with Health Insurance Portability Accountability Act (HIPPA) 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
  - Backup procedures, which include, but are not limited to:
    - Electronic transmission procedures
    - Storage of backup disks and tapes
    - Methods to replace information if necessary
  - Conditions for release of information

Standard RD5-D

Confidentiality and safeguards against loss, destruction or unauthorized use (cont.):

- Written consent from the patient/patient representative for release of information (unless release is required by law)
- Required for third-party payor billing
- Staff receives training upon hire and annually on confidentiality of of the policy and procedure is required

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

Interchange of medical information between other treating facilities

- Transferred — facility releasing the patient is required to send the pertinent information to the receiving facility (within one working day of the transfer)
- Processes in place to ensure complete records are shared promptly for continuity

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

Retention and preservation of equipment maintenance records

- Records are retained for six years from date of discharge, transfer or death (state may be more restrictive)
- Retained in the original form or legally reproduced form in hard copy, microfilm or memory banks
- Applies to records for machine maintenance, dialyzer reprocessing, water treatment and dialysate preparation as part of the medical record (may be in logs)

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

IDT approach for the comprehensive patient assessment

- Conducted on all newly admitted dialysis patients
- Within the latter of 30 calendar days or 13 hemodialysis sessions
  - 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

Standard RD5-G

IDT approach for the comprehensive patient assessment (cont.):

- 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)

Standard RD5-G

IDT approach for the comprehensive patient assessment (cont.):

- 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

Standard RD5-G

- Follow-up comprehensive reassessment must occur within three months after completion of the initial assessment
- Adequacy of the dialysis prescription must be assessed on an ongoing basis
  - 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
- Comprehensive reassessment and revision of the plan of care should occur at least
  - Annually for stable patients
  - Monthly reassessments for unstable patients
    - Extended or frequent hospitalizations (longer than 15 days or greater than three per month)
    - Marked deterioration in health status
    - Significant change in psychosocial needs
    - Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis

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

IDT development and implementation of the Plan of Care:

- Patient/caregiver should be encouraged to participate
- RN on the IDT must have knowledge of the patient's treatments (if home patient, should work in the home program)

POC is inclusive of:

- 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

Standard RD5-J

POC inclusive of (cont.):

- 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

Standard RD5-J

POC (cont.):

- Every dialysis patient must be seen, at least on a monthly basis by a physician, nurse practitioner, clinical nurse specialist, or PA providing ESRD care
- Evidence of a progress note is in the medical record.

The POC addresses:

- 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

Standard RD5-J

The POC addresses (cont.):

- 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

Standard RD5-J

The POC addresses (cont.):

- 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

Standard RD5-J

The POC addresses (cont.):

- 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

Standard RD5-J

The POC addresses (cont.):

- 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)

Standard RD5-J

The POC regarding 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

Education for patients and family members/caregivers should be part of the plan of care

- Aspects of the dialysis experience and dialysis management
- Infection prevention and personal care
- Home dialysis and self-care
- Quality of life and rehabilitation
- Transplantation, and the benefits and risks of
- Monitoring for infection of various vascular access types

Standard RD5-K

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

IDT requirements for home dialysis patients

- Home hemodialysis and peritoneal dialysis
- Oversees the training before initiation of home occurs
- Training is must be inclusive of:
  - Be provided by a facility that is approved to provide home dialysis services
  - Be conducted by a registered nurse who meets the requirements of 42 CFR 494.140(b)(2)
  - Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:
    - The nature and management of End Stage Renal Disease (ESRD)

Standard RD5-K

IDT requirements for home dialysis patients (cont.):

- Training is must be inclusive of (cont.):
  - The full range of techniques associated with the treatment modality selected, including the effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care
  - How to detect, report, and manage potential dialysis complications, including water treatment problems
  - Availability of support resources and how to access and use resources
  - How to self-monitor health status and record and report health status information
  - How to handle medical and non-medical emergencies
  - Infection control precautions
  - Proper waste storage and disposal procedures

Standard RD5-K

IDT requirements for home dialysis patients (cont.):

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

Records of results of chemical and microbial testing of home hemodialysis water and dialysate is required to be maintained in the home setting and the facility

- Logs of these records may be in a separate record or the patient's medical record

Standard RD5-L

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

Home dialysis services are equivalent to in-center facility services:

- Home support services include:
  - Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care
  - Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team
  - Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in 42 CFR 494.90
  - Patient consultation with members of the interdisciplinary team, as needed

Standard RD5-L

Home support services include (cont.):

- Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an on-site evaluation and testing of the water and dialysate system in accordance with manufacturers' instructions and FDA- approved labeling for systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate
- The facility must meet testing and other requirements of ANSI/AAMI RD52:2004
  - In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits

Standard RD5-L

Home support services include (cont.):

- The facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if:
  - Analysis of the water and dialysate quality indicates contamination
  - The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination
- Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician
- Identifying a plan and arranging for emergency backup dialysis services when needed

The facility must maintain a recordkeeping system that ensures continuity of care and patient privacy.

- Including items and services provided by durable medical equipment (DME) suppliers.

Standard RD5-P.01

Written policies and procedures are established and implemented addressing the administration, dispensing, storage, handling, and labeling, of drugs and biologicals.

Medication administration, dispensing, handling and labeling of drugs and biologicals (cont.):

- 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

Standard RD5-P.01

Medication administration, dispensing, handling and labeling of drugs and biologicals (cont.):

- 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

Standard RD5-P.01

Medication administration, dispensing, handling and labeling of drugs and biologicals (cont.):

- 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

There is a process for recall of drugs and biologicals

Current drug references and antidote information is available on-site

Tips for Compliance

- Utilize audit tools to audit medical records
- Do your policies and procedures include all the requirements?
- Is the content of the Medical Record clearly defined and evident?
- Do you have all required informed consents signed and dated appropriately?
- Are your medical records HIPPA compliant?
  - Do policies define who has access
  - Do you have backup procedures in place for storage, replacement, etc.
  - What conditions permit release of information

Tips for Compliance

- Are records shared appropriately for a transfer of care?
- Are maintenance records available for review and retained for the required time frame?
- Is there evidence of IDT involvement in the CIPA and POC?
  - Are they assessments completed within the required time frame?
  - Has the POC been implemented timely?
  - Can you clearly identify the requirements of the comprehensive assessment ?
  - Do you see evidence that issues identified in the assessments that interventions and goals are developed for those issues?
  - Do you see evidence that newly identified problems have interventions and goals developed?
  - Do you see evidence of progress towards goals?
  - Are resolved problems closed?

Tips for Compliance

- Are the hgb/hct being measured appropriately (and treated)?
- For home patients, is there evidence they are evaluated to safely administer ESA's ?
- Do you see evidence of vascular access monitoring?
- Do you see documentation of transplant referral information, is the patient a candidate, if no, is this documented appropriately?

- Do the medical records contain accurate diagnosis and most current ICD codes?
- Do the home program training requirements meet the standards for care?
- Is there evidence the home program is evaluated to ensure supplies are provided appropriately?
- Are the required home support services being furnished and met per the policy requirements?
- Does the patient education contain the specified requirements and represent the patients understanding of the information in regard to goals and outcomes and what to do in the event these are not met?

Tips for Compliance

- Do the Social Work staff have access to community-based services or resources to share with patients?
  - Are the other staff aware of who to inquire with if asked about resources from patients?
  - Are the patients provided with any potential community-based assistance to encouraged the continuum of care
- Is there evidence in the medical record of communication between the facility and the nephrologist?
- Are the medication policies clearly defined to include:
  - The rights of medication administration
  - Complies with laws and regulations
  - Storage of medications are appropriate to manufacturer guidelines
  - Proper labeling
  - Temperature of storage areas and monitoring with documentation of temperature
  - Are meds disposed of properly in regard to expired, deteriorated, etc.?

Workbook Tools

- Compliance Checklist
- Patient Record Audit
- Sample Medication Profile
- Refrigerator Temperature Log
- Self-Audit
- Sample Policies and Procedures

Questions?

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

Facility-wide, data-driven quality assessment and performance improvement (QAPI) program

Participation of professional members of the IDT

- Reflects the complexity of the program (including care/services provided under arrangement)
  - High-risk, high-volume, problem-prone areas
- Involves all dialysis services
  - Care provided directly or under contract
- Focus on indicators related to improved health outcomes
  - Including reduction of medical errors
- Takes action to improve performance

Standard RD6-A

Evidence of the tracking of quality indicators

- Adverse events per agency policy; ACHC has additional requirements
- Data driven elements with two primary goals
  - Monitor the effectiveness and safety of services and quality of care
  - Identify opportunities for improvement

Methods used to review data:

- 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

Standard RD6-A

Tracking of quality indicators:

- The components must influence or relate to the desired outcomes or be outcomes themselves
- Facility self-assessment includes:
  - 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

Standard RD6-A

Tracking of quality indicators (cont.):

- 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

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.

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

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

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

Data reporting to the ESRD Network

- Mandatory participation and reporting requirements; 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

Tips for Compliance

- Review of QAPI materials
  - Job description of QAPI Coordinator or designee
  - What is being monitored
  - What are established thresholds
  - Performance Improvement Projects
  - Evidence of governing body involvement and approval
  - Evidence of personnel involvement
  - Complaint /grievance logs
  - Incident logs
  - Satisfaction surveys
  - Evidence of chart audits
  - CMS Reporting

Workbook Tools

- Compliance Checklist
- Sample QAPI Activity/Audit Descriptions
- Sample QAPI Plan
- Self-Audit
- Sample Policies and Procedures

Questions?

Break time

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

Infection control program:

- Staff/facility follow accepted standards of practice to prevent transmission of infections developed by the CDC and Prevention, Morbidity and Mortality Weekly Report, volume 50
- Detailed OSHA BBP and TB Exposure Control Plan
  - Training for all direct care staff
  - Includes work practice controls to elimination or reduce exposure
  - TB Exposure Control Plan includes a current facility assessment (prevalence rate of TB)
- There are specific policies and procedures for staff and patients
  - General infection control measures appropriate for service provided

Standard RD7-A

Specific policies and procedures for staff and patients (cont.):

- Hand hygiene (a sufficient number of sinks with warm water & soap to facilitate hand washing)
- Standard precautions and personal protective equipment
- Glove usage
- Disposal of biohazard waste
- External transducers
- Appropriate cleaning and disinfect procedures
- Storage of reprocessed items
- Isolation procedures
- Precautions for immuno-compromised patients
- Needle-stick prevention and sharps safety
- Designation of clean vs dirty areas
- Medication preparation and administration
- 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

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

Vaccination of staff and patients for Hepatitis B

- Policy follows the CDC recommendation and OSHA mandates

Standard RD7-B

Vaccination of staff and patients for Hepatitis B (con't):

- Patients:
  - HBV Serological status must be known prior to admission to the hemodialysis unit
  - Initial series and additional series if anti-HBs are <10
  - Patients are routinely tested- give booster dose if anti-HBs declines <10
  - Investigation and further surveillance is done for any seroconversions
  - Check titer
  - Isolation procedures for those HBsAg positive
- Staff:
  - Offer vaccine within 10 days of employment
  - Check titer after 1-2 months after last primary vaccine dose

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

Infection Control training and education:

- Staff demonstrate competence and compliance
- Medical Director and QAPI monitor Infection Control Issues
- Training and education requirements
  - 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

Standard RD7-C

- Training and education requirements (cont.):
- Follows guidelines for the “Prevention of Intravascular Catheter-Related Infections”
  - Healthcare worker education and training
    - Preventing access related infections
  - Surveillance
    - Staff and patient surveillance for s/s of infection
  - Catheter and catheter-site care
    - CRBSI (catheter related blood stream infections)
    - Antibiotic lock solution use
    - Dressings and type of caps used
    - Scrub the Hub during cap change
    - Education provided to patient/patient care giver of signs and symptoms to report to the HCW

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

Operation of the Water Treatment System:

- Policies are accessible and understandable to personnel
- Follow requirements found in the ANSI/AAMI RD52:2004
- Address at a minimum the safe and effective operation of the system:
  - 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

Standard RD7-E

Operation of the Water Treatment System (cont.):

- Medical Director is knowledgeable and responsible for the water treatment program
- Contingency plan is in place to cover the failure of the water system
- There are audible alarms for the system in the patient treatment area, as well as the water treatment room
- Schematic diagrams are visible in the water treatment room
- Appropriate PPE should be worn during preparation, mixing and other times of potential exposure
- Chlorine/chloramine testing
  - 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 at least every four hours
  - Results must be recorded on a log sheet

Standard RD7-E

Operation of the Water Treatment System (cont.):

- 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)
- Adverse patient reactions are monitored and actions taken for corrective action
- The water testing results including, but not limited to:
  - Chemical, microbial, and endotoxin levels
  - Must meet AAMI action levels
  - If deviation occurs from action levels a timely remedial action must occur

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

Reuse of hemodialyzers, bloodlines and other dialysis supplies

- Facility follows law /regulation, AAMI, and manufacturer's recommendations
- A Reprocessing Manual is available and current to include all specifications, policies and procedures, and training materials.
- All patients must be fully informed regarding reuse of dialyzers, bloodlines and other dialysis supplies
- Records must be maintained for preventive maintenance procedures in addition to the reprocessing logs
- Safe storage and handling of chemicals is observed
- Personnel wear appropriate PPE
- Labeling of dialyzers is inclusive of all requirements
- Two persons check the dialyzer for appropriate identifying information prior to use

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

Patient care in regard to using reuse dialyzers

- Records are kept of all adverse reactions to any dialyzer
- Blood leaks should be recorded in a log and kept in the complaint investigation file
- Monitor relevant patient results regarding the dialysis prescription
  - URR or Kt/V
  - Deterioration of a patient's clinical condition

Standard RD7-G

- Patients are observed and monitored throughout the clinical course of treatment
  - 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

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 training and competency for reuse of dialyzers

- Medical Director shall establish/approve the training course
- Annual review of competency is required
- The curriculum should include:
  - 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

Standard RD7-H

The curriculum should include (cont.):

- 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.

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

Auditing requirements regarding reuse/reprocessing

- 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

Standard RD7-I

Auditing requirements regarding reuse/reprocessing (cont.):

- 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

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

Design/Construction of treatment environment:

- Equipment is maintained in safe operating condition
- Layout, fixtures, flooring do not present a hazard
- Parking lot, outside entrances are free from obstacles that impede safety
- Environmental temperature is kept at a comfortable level
- All areas of the facility are clean and functional
  - 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

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. (494.60(d)(5)), (494.60(e)(1-3)), 494.60(f)(1)(i-xi))

Health and Safety Requirements:

- Facility is in compliance with applicable laws and regulations
- Exemption to the NFPA Life Safety Code (LSC) requirements if they are not located adjacent to high hazard occupancies and they do provide exits at grade level from the patient treatment area.
- The facility has mechanisms to provide and maintain emergency power to critical areas
- 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 extinguishers are mounted and have been inspected annually (sufficient number)
- Floor plan identifies the location of the fire extinguishers
- Fire drills (at least annually — per state requirements)

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.

Accidents, variances or unusual occurrences involving personnel

- 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

Incidents to be reported

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

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

Emergency Preparedness Plan (EPP):

- Comply with all federal, state and local emergency preparedness requirements
- Plan is established and meets requirements of 42 CFR 494.62
- Plan is evaluated ad updated at least every two years
- Must include a facility-based and community-based risk assessment, utilizing an all-hazards approach
- Must address continuity of operations
- Cooperation and collaboration with local, tribal, regional, state, and federal EP officials
- Contact with local EP agency at least annually to confirm they are aware of the facility's needs

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

Emergency Preparedness Plan

- Based on the risk assessment and communication plan
- Tracking of staff
- Safe evacuation
- Care and treatment needs of evacuees
- Staff responsibilities
- Means of shelter in place if evacuation isn't possible
- Medical documentation which preserves patient information and protects confidentiality
- Use of volunteers
- Arrangement/contract with other facility
- Equipment /supplies immediately available

Standard RD7-R

Emergency Preparedness Plan (cont.):

- The role of the facility under a waiver, 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

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

Emergency Preparedness Communication Plan:

- This is in addition to your EPP
- Communication plan is reviewed at least every two years and must include 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

Standard RD7-S

Emergency Preparedness Communication Plan (cont.):

- 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 with other healthcare providers
- A means of releasing patient information if evacuation occurs
- Provide information about the general condition and location of patients
- Means of providing information regarding occupancy of facility, needs and the ability to provide assistance to the authority with jurisdiction, incident command center, or designee

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

Emergency Preparedness training and testing:

- Training, testing and patient orientation is based on the emergency preparedness plan, risk assessment and communication plan
- Training Program:
  - Provide initial training in emergency preparedness policies and procedures to all new and existing staff and emergency preparedness training at least every two years
  - Staff must demonstrate knowledge of emergency procedures and inform patients of:
    - What to do and where to go, including instructions for occasions when the facility must be evacuated
    - Whom to contact if an emergency occurs while the patient is not in the dialysis facility
      - An alternate emergency number to contact the facility
    - How to disconnect themselves from the dialysis machine if an emergency occurs

Standard RD7-T

Emergency Preparedness training and testing (cont.):

- 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

Testing is required at least annually by conducting exercises to test the plan. The facility must do the following:

- Participate in a full-scale exercise that is community-based every two years
- Conduct an additional exercise every two years, opposite the year the full-scale or functional exercise, 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 that 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

Standard RD7-T

Emergency Preparedness training and testing (cont.):

- 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

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
- How to disconnect themselves, if able, from the dialysis machine if an emergency occurs

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

Emergency Preparedness for those part of a healthcare system

- Multiple separately certified healthcare facilities
- Those electing to have a unified and integrated program
- Must demonstrate they actively participated in the development of the unified program
- Each separate facility is capable of actively using the unified and integrated plan
- Must be based on and include:
  - 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 for the communication plan, training and testing

Tips for Compliance

- Infection control plan
  - Staff in-service records
  - Patient education materials
  - Infection tracking log sample
  - Hepatitis B Declination
  - TB Risk Assessment Tool
  - Sample TB Declination
- Evidence of safety
  - Fire drill results
  - Testing of emergency power systems
  - Fire extinguisher checks
- Water Treatment
  - Monitoring and Testing Records
  - Staff training/education
  - Manufacturer guidelines/requirements

Tips for Compliance

- Reprocessing
  - Reuse manual
  - Staff training/competency records
  - Maintenance logs
  - Patient education materials
  - Patient observation records
  - Tracking of adverse events
  - Audit records
- Standardized form for reporting of employee incidents
- Safety and maintenance logs for equipment
- Check for expired supplies in warehouse/lab
- Stocked code cart (unexpired supplies)
- Emergency take out box (unexpired supplies)
- SDS availability

Tips for Compliance

- Emergency Preparedness Plan
  - Risk assessment
  - Communication plan
  - Communication with local emergency management
  - List of staff contact information
  - List of local, federal, state, regional, and tribal contact information
  - Emergency takeout box
  - Contract/agreement with facility to take patients
  - Documentation of two drills/exercises

Workbook Tools

- Compliance Checklist
- Emergency Drill Evaluation
- Hints for an Infection Control Plan
- Infection Control Tracking Form
- Safety Tracking Log
- Report of Employee Accident Investigation
- Quality Maintenance Log
- Self-Audit
- Sample Policies and Procedures

Questions?

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