National Association of Nephrology Technicians/Technologists

March 25, 2014
Conditions of Coverage
End Stage Renal Disease

- Code of Federal Regulations
- §494.1 through §494.180
  - Over 300 regulations included

- Acute Care Dialysis
- Hospital Conditions of Participation
- CFR 482.1 through 482.57
## Dialysis Regulation Integration

<table>
<thead>
<tr>
<th>State Rules and Regulations</th>
<th>• Basic Foundation requirements to provide services</th>
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<tr>
<td>ESRD Conditions of Coverage or Conditions of Participation and Acute Care</td>
<td>• Payer Requirements for Reimbursement</td>
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<td>ESRD Agency Governance Policies and Procedures</td>
<td>• Governing Authority Scope of Services and Expectations</td>
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Health and Wellness for all Arizonans

azdhs.gov
State Rules and Regulations

- Work with your State Agency to ensure understanding of the requirements
- Compliance with State rules and regulations required to be CMS Certified

Health and Wellness for all Arizonans
Centers of Medicare and Medicaid

- ESRD Conditions of Coverage
  CFR §494.1 through §494.180
- Acute Care Conditions of Participation
Governance Directives

ESRD Agency

Governance Policies and Procedures

Best Practices
Responsible Team for Compliance

• Governing Body
• Medical Director
• Administrator/Clinical Manager
• Clinical Staff Members
  – Social Workers
  – Registered Nurses

– **Dialysis Technicians and Technologists**
  – Dieticians
  – Medical Staff
  – Registration/Medical Records Personnel

Health and Wellness for all Arizonans
Hemodialysis Technicians and Technologists

• At the core of the Hemodialysis team

• Performing life sustaining treatment
  – Accessing the bloodstream
  – Maintaining extracorporeal volume
  – Monitoring patients changes to dialysis
  – First responder to situations
  – Testing and monitoring water for patient dialysis
  – Ensuring the safe reuse of dialyzers
  – Maintaining strict IC practices.
Achieving Success with Compliance

• Team Work
• Grassroots through Top Leadership
  • Knowledge and Understanding
  • State Laws, Rules, and Regulations
  • Conditions of Participation
• Function within your scope of practice
• Accept Accountability Personally at all Levels of the Care Delivery
• Hold each other Accountable
Survey Frequency

• CMS Survey Based on Tier Levels
  – Driven by Mission and Priority
    • Tier 2 --- Targeted Centers
      – Based on Outcomes
    • Tier 3 --- 3.5 year intervals

• Complaint Investigations
  – Based on Scope and Severity

Years fly by like the days and the months
Why a CMS Conditions of Coverage Survey????

- Reimbursement is determined by the compliance with the requirements.
- CMS is charged with establishing regulations and a survey process that focuses on improving patient outcomes through individualizing each survey based on the clinical areas where performance improvement is indicated.
Survey Process

• Facility-Based Survey
  – Data review prior to the survey based on facility specific reports
    • Dialysis Facility Reports (DFR)
    • Network contacted
      – Quality Concerns
      – Involuntary discharges
  • Complaint History
    – Trends
Survey Process

- Entrance Conference
  - Describes purpose of survey
  - Anticipated Timeline
  - Resources that might be needed
  - Document/Data requests from the provider
    - Survey will be focused on the clinical areas where improvement is currently needed
Survey Process

• Active Survey
  – Survey team will focus on the CMS Conditions
    • Observation/Tour
      – Infection Control Practices
      – Medication Administration
      – Patient monitoring activity
      – Dialysis preparation techniques
      – Discontinuance of Dialysis process and techniques
    • Interviews – Facility Based personnel
      – All levels of Personnel
      – Patients
      – Families
    • Documentation Review
      – Patient Records
      – Documents
      – Credential and Personnel Files
      – Culture Reports
Outcome of Survey

• Based on
  – Dialysis Facility Reports
  – Management Assessment Tool
  – Patient Care Records
  – Facility Records
  – Interviews
  – Observations
Survey Process

• Exit Conference
  – Findings
  – Findings with deficiencies
    • Requires a Plan of Correction
    • With condition level deficiencies required a second onsite survey
Provider Responsibility

- Always be prepared
- Interact with the surveyor(s)
- Be descriptive with your processes
- Know the regulations
- Know how you are in compliance with these regulations
- Know how you monitor compliance
- Know your performance measures and process improvement activities
# ESRD Survey Focus

<table>
<thead>
<tr>
<th>Themes</th>
<th>Threads</th>
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<tr>
<td>– Data Use</td>
<td>• Culture of Safety without Fear</td>
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<td>• Facility</td>
<td>– Open Communication</td>
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<tr>
<td>• Patient</td>
<td>• Consistent reporting</td>
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<tr>
<td>– Infection Prevention and Control</td>
<td>– Errors</td>
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<td>• 2nd leading cause of deaths in Dialysis</td>
<td>– Near Misses</td>
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<tr>
<td>patients</td>
<td>– Opportunities to Improve</td>
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<tr>
<td>– QAPI</td>
<td>– Clear expectations of Practice</td>
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<tr>
<td>• Protection of Patients and Assurance</td>
<td>• Safety of Dialysis Delivery</td>
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<tr>
<td>of Quality</td>
<td>– Follow precise procedures</td>
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<tr>
<td></td>
<td>• Maintenance</td>
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<td></td>
<td>• Monitoring</td>
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<td></td>
<td>• Patient Voice</td>
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<td></td>
<td>– Listening</td>
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<tr>
<td></td>
<td>– Seeking patient(s) input</td>
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Soooooo

How do surveyors evaluate the Facilities Compliance ????

Health and Wellness for all Arizonans

azdhs.gov
How do you and your organization measure up to compliance?
Surveyor Process and Questions:
Do you understand how you can demonstrate compliance with regulations?
Survey Focus -- Individualized

- Health and Safety
  - Governing Body Responsibility
  - Quality Management Performance Improvement Processes
- Patient Assessment
- Personnel Qualifications/Staffing
- Infection Control
- Emergency Management
Condition 494.180 Governance

- Overall Management
- Governing Body Accountable for Operations
  - Fiscal
  - Staff Training and Coverage
  - QAPI Program
    - Internal Grievance Process
    - Involuntary Discharge Prevention
    - Emergency Coverage
    - Electronic Data Submissions
    - Relationship with ESRD Network
Condition QAPI 494.110

- Surveyors Evaluate
  - Treatment Prescription Errors
  - Intradialytic modalities
    - Adverse Symptoms during dialysis
      - Seizures
      - Chest Pain
      - Hypertension/Hypotension
      - Blood Loss > 100ml
      - Cardiac Arrest
    - Needle Sticks
You have knowledge of the Quality Assessment & Performance Improvement Plan and current process at your facility.

TRUE or FALSE?
Quality Assessment & Performance Improvement

- Surveyors review for compliance based on 3 General Segments
  - 1. Monitoring care and facility operations
  - 2. Quality Assessment and Performance Improvement based on critical priority areas
    - Mortality review
    - Infection prevention and control
    - Medical error/adverse occurrence/clinical variance tracking and investigation system
    - Data-driven focus and survey findings
  - 3. Culture of Safety Review
    - Risk identification and reporting
    - Staff engagement
    - Patient engagement
Environmental Tour

- In-Center Dialysis
  - Patient Treatment Area
  - Patient Access Visible at all times
  - RN Present
  - Patient Needs are being MET
  - HD Transducers absent of Blood
  - Space Adequate if Emergency Equipment is needed
  - Emergency Equipment Present and Maintained
  - Machines in good condition
  - Freedom of Odors (Dialysis Reuse)
  - Confidentiality afforded Patients
  - Patient Privacy
Environmental Tour

- Water Treatment/Dialysate Preparation Area
  - Carbon System
  - RO - Alarm - Functioning Water Quality Monitor
  - Water Distribution Equipment in Good Repair
    - No contaminate
    - No Presence of Algae or Discoloration of water
    - Acid or Bicab dialysate Concentrate mixing distribution equipment in good repair
Do you have documentation of your microbiological monitoring?

Surveyors will expect an organized system for monitoring the machines and all microbiological monitoring.

Total chlorine testing
RO monitoring
DI if present
Product water chemical analysis
Microbiological monitoring of water, including in the reuse room, and dialysate
Environmental Tour

• Reuse Room
  - Reprocessed Dialysate aesthetically stored
  - Stored Dialysate Protected from Unauthorized access
  - Room and Equipment in good Repair
  - Dialysate refrigerator Temperature monitored

• Home Dialysis Training Area
  - Sufficient Space to Prevent Cross-Contamination between Patients
  - Patient Privacy
  - Method to summon Immediate Assistance
  - Blood and PD effluent Spills Cleaned Immediately
  - Equipment and Surfaces Clean and free of Contaminate
Your Facility will pass this Environmental Tour???

TRUE or FALSE?
Observations of Patient Care Practices and Infection Control

• Hemodialysis Patient Care and Equipment
  - Pre-Dialysis vascular access care and initiation
  - Discontinuation of dialysis
  - Cleaning & Disinfection the Dialysis station between Patients
  - Preparation of the machine and extracorporeal circuit
• Supply Management
  • Availability
  • Contamination Prevention
Are the following actions required at the Patient Station?

A. Supplies taken to the station are dedicated to the patient
B. Disinfect the station between patients
C. Alarms are tested
D. Dialysate PH/Conductivity Tested
E. Perform reprocessed Dialyzer germicide tests

TRUE  FALSE
Medication Preparation and Administration

• Medications are prepared in a clean area away from the Dialysis Station(s)
• Single dose Medication vials are punctured once and used for single patient
• Multidose medication vials are punctured with new syringe and new needle each time.
• Aseptic technique is always used
• Medications are taken only to a station to be administered to the patient at the station
• Medications are prepared and administered by qualified personnel
Are you assigned to care for both HBV+ Patients and HBV susceptible patients at the same time?

**No - You should not be assigned to care for these two types of patients at the same time.**

- **HBV+ Patients are to be isolated**
- **Separate Staff are assigned to HBV+ patients and not to care for susceptible patients at the same time**
- **Isolated Equipment is Dedicated to the Patient**
How has your facility leadership defined your role in patient safety?

One aspect would be the responsibility for the measures of water and dialysate quality and safety.

Condition QAPI 494.110

Standard: The Program Scope achieves, measurable improvement in health outcomes & reduction of medical errors by using indicators or performance measures associated with improved health outcome & with identification and reduction of medical errors.
What do you do to prevent or reduce treatment errors or near misses at your facility?

A. Keep information related to errors to yourself
   Document in the medical record what was suppose to occur and not what occurred with the treatment

B. Report complaints and participate in the analysis, action plan for improvement of patient and staff injuries, and treatment or medication errors

D.

E.
Keeping Kidney Patients Safe
Renal Physicians Association 2008

1. Hand Hygiene
   - Use of alcohol-based hand rubs or soap and water before and after patient contact
   - Proper use of Gloves

2. Patient Falls
   - Prevention
     - Post Dialysis Blood Pressure evaluation
     - Assistance as patient initially stands up
     - Keep Obstacles out of the way

3. Incorrect dialyzer or dialyzing solution
   - Procedural Safeguards
     - Technician checklists
     - Rules for set up procedures
     - Patient involvement
Keeping Kidney Patients Safe
Renal Physicians Association 2008

4. Medication Omissions and/or Medication Errors
   - Administration
     • Wrong Med
     • Wrong Time
     • Wrong Dose
   - Omissions
     • Education
       - Staff
       - Patient

- System Safeguards
  - Medication Routines
  - Procedures

- What are you doing to ensure the RNs are receiving the information necessary to administer medications.?????
5. Non-Adherence to Procedures
   Pre and Post Dialysis Tasks
     Weight
     Blood Pressure
   Patients skipping treatments
   Patients requesting shorten dialysis
   Personnel determine to shorten dialysis
     Patient arrived late
   Volume of patients

Procedures Established
Guidance
Training
Enforcement
You are required to monitor in-center patients before, during and after dialysis every hour.

**TRUE or FALSE?**
494.80 Patient Assessment - Condition

- Overall Accountability Review
  - Evaluate Patient on an ongoing basis
- Interdisciplinary Comprehensive Assessment (IDT)
  - Current Medical Condition(s)
  - Co-Morbid Conditions
    » Medical History
    » Physical Examination
    » Nursing History
Hemodialysis Prescription

- Surveyors are going to review the Prescription
  - Number of Treatments per week
  - Length of Treatment Time
  - Dialyzer
  - Specific Parameters
    - Electrolyte composition of Dialysate
    - Blood Flow Rate
    - Dialysate Flow Rate
    - Anticoagulation
    - Target Weight
Blood Pressure and Fluid Management

- Lability of Blood Pressure
- Lability of Fluid Management
- Require Adjustment

- Required Evaluations
  - Pre/Intra/Post
    - Blood Pressures
    - Weight Gain
    - Target Weight
    - Hypertension
    - Hypotension
    - Muscular Cramping

Plan of Care

Report to RN
- Analysis
- Root Cause
- Physician
- Notification
Do you know how often you monitor in-center patients before, during and after dialysis?

CMS does not designate the specific interval
- Must meet the patient’s needs
- Arizona rules required every 30 minutes.
Surveyors will not review Personnel Qualifications.

TRUE or FALSE?
494.140 Personnel Qualifications - Condition

- Surveyor Review
  - Personnel Files
  - Credential Files
  - Policies and Procedures
- Interview and Observe
  - Skills testing chlorine/chloramine levels
  - Operating reuse equipment
  - Infection Control Practices
  - Identification of and Treating Intradialytic modalities
  - Monitoring of Patients
  - Reactions to Alarms
  - Actions taken to address alarms or patient changes
Personnel Records

• Random sampling of all levels of personnel files and credential files
  - Health Records
  - Job Descriptions
  - Qualifications
  - Educations
  - Certifications/Licenses

• Outcome of review
  - Based upon
    • Facility Requirements
    • State Licensing/Certification Requirements
    • Performance Reviews
Personnel File must reveal at minimum: CPR; TB; Hepatitis Vaccine; Competencies; Em Training; Infection Control Training; and Water Dialysate Training.

**TRUE** or **FALSE**?
Are there sufficient qualified and trained staff in this facility to meet patients’ medical, nutritional, and psychosocial needs?

**TRUE** or **FALSE**?
Personnel

- Medical Director
- Nurse Manager
- Self-care and Home Dialysis trainer nurse
- Charge Nurse
- Staff Nurse
- Dietician
- Social worker
- Patient Care Dialysis Technician
- Water Treatment system Technician
- Re-use Technician
Staffing Considerations

- Adequate number of Qualified Trained Staff
  - Acuity of Patients
  - Staff Experience and Expertise
    - Adequately see ALL patient during dialysis
    - Patient Care needs are Met
      - Routine Care
      - Patient Assessments
      - Monitoring of the Treatment
      - Addressing Patient Needs
Chemical and Microbiological Monitoring

- Observation
- Interview
- Documentation Review
  - Logs
    - Chlorine Testing Logs
    - RO Function Monitoring
    - Product Water Chemical Analysis
    - Microbiological Testing of Water and Dialysate
    - DI Monitoring if DI Present
Machine/Equipment Maintenance

- Interview
- Documentation Review
  - PM Logs
  - Calibration Documents
I take time to educate and inform my patient of required services and plans for Dialysis

TRUE or FALSE?
Patient Interviews

- Surveyors will spend time with patients and seek out information related to patients being informed of:
  - Patient Rights and Responsibility
  - Education about Transplantation and Dialysis Options
  - Infection Prevention
  - Protection of Vascular Access
  - Disaster Preparedness
    - At Home
      - Evacuation plan from the facility in case of Emergency
  - Right to participate with IDT and Planning of Care
  - Culture of Safety
    - The right to express concerns related to care, staff, plan, etc.
Do you know your Disaster Plan for the Facility and the Patient? If so describe.

Our plan is integrated with the community, patients, families, other facilities and I know my responsibilities in the case of a disaster impacting the facility and/or individual patients residence.

THOUGHTS ON PLANS

• Plan is documented and individualized to the facility and the community.
• Disaster plan includes what to do when the facility and/or the patient is without electricity and/or water.
• Generator availability at the facility or an alternative location and if so how is fuel maintained.
• Tracking mechanisms in place to monitor patient location if evacuated from residence.
• All care providers are educated on the role and responsibilities during a emergency situation.
• Patients are educated on a personal plan to include: Diet; Where to go; What to do; Who to contact.
• Our facility has a backup facility in case the facility is unable to provide services during an emergency situation.
Patient Record Review

- **Selection**
  - Unstable Patients
  - New Admissions <90 Days
  - Involuntarily Discharged in the past 12 months
  - Long Term Care residents receiving home hemodialysis or peritoneal dialysis
  - Records that reflect the outcome goals that were demonstrating opportunities for improvement
  - Records that represent what was observed during the interviews and tours
Medical Record Review

- Dialysis Orders and Implementation of the Orders
- Dialysis Treatment
- Machine Safety
- Medication Administration according to Orders
- Assessment Documentation
  - Blood Pressure
  - Fluid Management
  - Labs
  - IDT documentation - Meaningful
- Anemia Management
- History and Physical document
- Progress Notes
Do you know the number of Patients you can impact related to Health and Safety?

**TRUE** or **FALSE**?
Dialysis Patients in the United States

- 430,000 Dialysis patients
- 185,000 Kidney Transplant Patients
- Greater than 6000 ESRD Facilities
- 270 Transplant Centers
- Averaging > 8% increase in Dialysis patients each year
- ** KCER Data from Dialysis Emergency Management Documentation
Summary

• How do you make a difference?
  - Know the Regulations
  - Understand the Regulations
  - Know the Policies and Procedures of your Organization
  - Accept accountability
  - Make Patient Care a priority
  - Connect with Key Resources
    • State Agency
    • Network 15
    • Professional Organization
    • NANT
Questions

Thoughts
For all that you do every day to provide Quality Patient Care