



Southern California
Renal Disease Council
INCORPORATED

New Conditions for Coverage: Clinical Implications



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Part 494 – Conditions for Coverage for ESRD Facilities

- Subpart A: General Provisions
 - 494.1 Basic and Scope
 - 494.10 Definitions
 - 494.20 Condition: Compliance with Federal, State, and CMS- 3818-F569 local laws and regulations



Subpart B – Patient Safety Conditions:

- 494.30: Infection Control
- 494.40: Water and Dialysate quality
- 494.50: Reuse of hemodialyzers and blood lines
- 494.60: Physical Environment

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Subpart C – Patient Care Conditions

- 494.70: Patient rights
- 494.80: Patient assessment
- 494.90: Patient plan of care
- 494.100: Care at home
- 494.110 Condition: Quality Assessment and Performance Improvement (QAPI)
- 494.20: Special purpose renal dialysis facilities
- 494.30: Laboratory Services

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Subpart D – Administration Conditions

- 494.140: Personnel Qualifications
- 493.150: Responsibilities of Medical Director
- 494.170: Medical Records
- 494.180: Governance. CMS-3818-F 570

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Infection Control

- From one tag to a Whole Condition
- Adopts
 - CDC's 2001 *Recommendations for Prevention of Infections in Hemodialysis*
 - CDC's 2002 *Guidelines for the Prevention of Catheter-Related Infections*
- Hepatitis
 - All new facilities must have a separate room
- Must report issues to Medical Director & QAPI

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Water & Dialysate

- Adopts AAMI RD52:2004 as regulation
- Written for the user
- Specifics & required monitoring detailed for all water treatment components
- Separate requirements for water treatment for home hemo under Care at Home Condition

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Dialysate

- For the first time, specific regulations for dialysate
- AAMI RD52:2004 addresses acid & bicarbonate concentrate:
 - Labeling
 - Mixing
 - Distribution
 - Use

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Water & Dialysate

- From ~8 tags to about 175 tags!
- Very detailed & thorough
- Most questions will now have a regulatory answer
- Use RD52:2004 to update facility policy & practice for water treatment & dialysate preparation & distribution

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Reuse

- Adopts AAMI RD:47:2002/2003
- Requires reuse be suspended if a cluster of adverse patient reactions is associated with reuse

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Physical Environment

Life Safety Code (LSC) Requirements:

- Must meet provisions of NFPA 2000
- Grandfather clause for current facilities in non-sprinklered buildings if built prior to 1/1/2008
- State fire safety codes may be used in lieu of LSC
- Specific provisions of LSC may be waived in some cases

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Physical Environment

- Every facility must have an AED or a defibrillator (& ACLS qualified staff)
- All equipment maintained & operated according to manufacturer's directions
- Emergency preparedness for staff & patients, including disaster prep—get to know your local Emergency Ops Center (shelter, transportation)

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Patients' Rights

To be treated with respect & dignity and to:

- Receive information on all modalities, including those not provided at the current facility
- Receive alternative scheduling options [from other facilities] for working patients
- Receive necessary services listed in the Plan of Care
- Be informed of the right to have an advance directive
- Be informed about transfer & discharge policies

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Patient Assessment

- Comprehensive
- Interdisciplinary team (minimum – the patient or patient's designee (if patients chooses), RN, Nephrologist, Social Worker, and Dietitian)
- Initial completed within the latter of 30 days or 13 HD treatments

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Patient Assessment: Required Components

- Current Health Status
- Appropriateness of dialysis prescription
- Lab profile, immunization history, and medication history
- Anemia, adequacy, vascular access, bone disease, nutritional status, nutrition, psycho psychosocial status, home dialysis, transplant status, functional status, rehab

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Patient Assessment

- Comprehensive reassessment within 3 months of completion of the initial assessment for all patients
- Adequacy assessed
 - monthly for HD;
 - every 3 months for PD
- Stable patients require annual review

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Patient Assessment

Assessments and plan of care done monthly for “unstable patients,” examples include:

- Extended or frequent hospitalizations;
- Marked deterioration in health status;
- Significant change in psychosocial needs; or
- Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.
- FYI: ANNA/NKF have developed a tool

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494.90: Patient Plan of Care

- No “cookie-cutter” approach allowed
- Must address identified needs = individualized!
- Initial: within 30 days or 13 outpatient hemodialysis treatments of admission
- Update: within 15 days of each re-assessment

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Major Change: No LTP

- No expectation for a long term program or “signature” of transplant surgeon
- Requirements for patients to be informed of all modalities (transplant & therapies not offered at their current clinic) are addressed under:
 - Patients’ Rights
 - Patient Assessment
 - Plan of Care

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Care at Home

- Separate Condition for home therapies
- Care at home must be equal in quality to care provided in-center
- Training required for patient described in detail
- Water treatment / dialysate separately addressed, including newer technologies

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Home Dialysis in Residential Institutions

- Interim: home dialysis in residential institutions will be addressed in Survey & Certification Letter
- Long-Term: future rules will address this area

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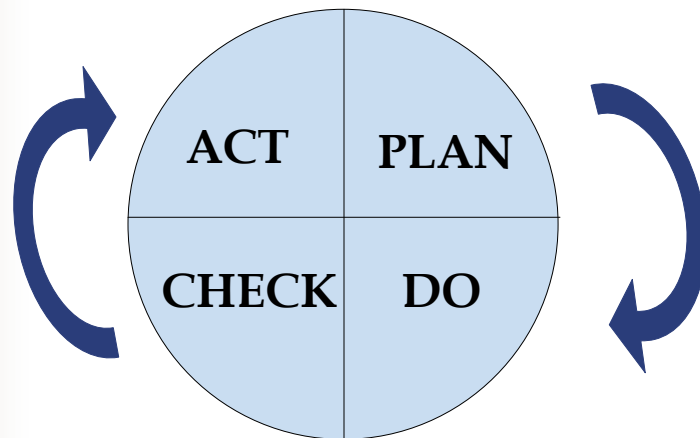
QAPI

(Quality Assessment and Performance Improvement)

- Condition level
- Interdisciplinary team
- Process continuous & on-going
- Outcome focused: use community accepted standards as targets
- Include patient satisfaction, infection control, medical injuries & medication errors
- Plan/Do/Check/Act: Close the loop!

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PDCA Style



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QAPI program requirements

- Action-oriented
- Data-driven
- Under the direction of Medical Director
- Requires RN and interdisciplinary team participation
- Quality Improvement Committee

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CMS-Approved QIPs

- Anemia Management
- Hepatitis B Vaccination
- AV Fistula Placement
- Hemodialysis Adequacy
- Stenosis Monitoring (100%)
- Fistula First

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Special Purpose Renal Dialysis Facilities

- For
 - Vacation camps
 - Facilities providing services in emergencies
- Approved for a maximum of 8 months

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Laboratory Services

- Dialysis facility must provide or make available appropriate lab services
- Lab services must meet CLIA regulations

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Personnel

- Defines individual qualifications:
 - Medical Director
 - Nurses: nurse manager, home training nurse, charge nurse, staff nurse
 - Dietitian
 - Social Worker
- Defines group qualifications:
 - Patient care technicians
 - Water treatment system technicians

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Personnel

- Patient Care Technician
- High school diploma or equivalency
- Complete a (defined) training course, approved by Medical Director & Governing Body; under direction of RN
- Be certified by a State or national program
 - New employees: within 18 months of hire date (starts after 10/14/08)
 - Current employees: within 24 months of 4/14/08

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Medical Director

- Accountable to the Governing Body
- Responsible for patient care and outcomes
- Responsible for effective QAPI and Infection Control programs
- Responsible to assure all staff, physicians & non-physician providers “adhere” to all policies
- Must be engaged in any involuntary patient transfer or discharge

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Medical Records

- Traditional rules on completeness & protection of medical records
- Transfer requested records to the receiving facility within one day

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Governance: RN Presence

“An RN, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated.”

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