



Southern California
Renal Disease Council
INCORPORATED

New Conditions for Coverage: Are You Ready?



Vickie Peters, Executive Director
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Objectives

- Demonstrate understanding of the background & rationale for changes to the current ESRD regulations
- Describe the implementation challenges for facilities
- Discuss major changes from the current to the new regulations

ESRD Regulation Timeline

- 1976: First ESRD regulations published
- 1994: Community Forum Meeting to begin complete rewrite of ESRD regulations
- 2008: New ESRD regulations published

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1994 Suggested Changes

Change From:

- Paper reviews
- Policies, Procedures, Personnel Records

Change To:

- Safety Reviews (e.g. water, infection control, physical environment, reuse)
- Observation of care, patient & staff interviews

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Suggested Changes

- From: Structure to Outcomes
 - water treatment and dialysis adequacy, data reports (DFR), community/MRB standards

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Rationale for ESRD Changes

- Increasing realization of the need for regulatory support for an outcomes focus across provider types
 - Needed to drive improvements in care
 - Critical if CMS moves to value-based pricing (aka, Pay for Performance)
 - Necessary if CMS moves to bundled reimbursement for ESRD care

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Reasons for Change

- Changes in technology
 - Water treatment: more complex
 - Changes in dialysis equipment
- Differences in care delivery
 - 1970's: few technicians; regulations are silent or inconsistent between states
 - 2008: technicians provide most direct care; public is demanding regulation

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Reasons for Change, cont'd

- Evidence Based Practice: ESRD community coming to consensus on minimum standards of care
 - RPA's Adequacy of Dialysis Report
 - K/DOQI Guidelines
 - Fistula First Breakthrough Initiative
- QAPI: accepted process of self-assessment across provider types
- Electronic data submission required to keep pace with growing ESRD population & need for current

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Effective Dates for New Rules

- October 14, 2008
 - Majority of New Conditions in place
- February 2, 2009 – CROWN-Web live
- February 9, 2009
 - Separate HepB+ isolation room
 - Life Safety/Fire Code enforced
- April 14, 2010 – certification of existing technicians

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More Dates....

- For new technicians hired after 10/14/08: need official certification 18 months after their hire date.
- Interpretive Guidelines – publication date not announced yet; possibly August or September. SCRDC will post on website.

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Implementation for Facilities

1. Read the whole document (preamble & rule)
2. Review current practice (& policies) to be sure they meet rules
3. Identify staffing, practice, equipment, & training needs
4. Develop documentation tools to match the new rules (logs, audit tools, chart forms)

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What are the major changes?



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Primary Changes

- Many of the old CFR 405/subpart U standards are now conditions (e.g. infection control)
- Some specifics (e.g. Networks) remain in CFR 405

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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

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***494 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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***494 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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494 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
 - Includes electronic data submission

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More Notations Outside 494

- Prior to 494 is section 488
- 488.60 deals with approval for facilities
- 488 Subpart H deals with termination of Medicare coverage and alternative sanctions

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Part 488.60: Approval of ESRD Facilities

Approval or expansion of facility requires:

- Certification by State Agency
- Data from ESRD Network and recommendations on facility contributions
- Data on facility compliance with professional norms and standards
- Data pertaining to facility's qualifications

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Subpart H: Termination of Coverage

- Failure to meet one or more 494 conditions. CMS will reinstate if the reason for termination was removed and won't recur
- If termination based on failure to participate in Network activities/goals, CMS will reinstate if "reasonable efforts to meet condition" are made

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Subpart H: Alternative Sanctions

- Based on failure to participate in Network goals, and no other patient health or safety issues
- Can consist of any of the following:
 - Denial of payment after date of sanction
 - Reduction of payment by 20% for each 30 day period after sanction
 - Withholding of all payment without interest

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488, continued

- Notice of appeal rights for both termination of coverage and alternative sanctions

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Why This Matters

- With new C4C, CMS has laser focus on facility cooperation (494, governing body)
- Networks and state surveyors will be pressed to use sanction/alternative sanction process when necessary

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The Network is Here to Help!

- Find complete C4C on our website
- Look for WebEx training on CROWN-Web, QAPI, etc.
- If you have documents, examples that work for you and you'd like to share, contact us.

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