

The following is a summary of the new Conditions for Coverage, published by the Department of Health and Human Services, Centers for Medicare & Medicaid Service on April 15, 2008. This information was obtained from a presentation by Glenda Payne and Judith Kari at the National Kidney Foundation Spring 2008 Clinical Meeting in Dallas.

Subpart A- - General Provisions

- ❖ Basis and scope / Definitions
- ❖ Condition: Compliance with Federal, State and CMS (local laws and regulations)

Subpart B - - Patient Safety

- ❖ Infection Control/Water and dialysate quality
- ❖ Reuse of hemodialyzers and bloodlines
- ❖ Physical Environment

Subpart C- - Patient Care

- ❖ Patient rights/Patient assessment
- ❖ Patient plan of care/Care at home
- ❖ Quality assessment and performance improvement
- ❖ Special purpose renal dialysis facilities
- ❖ Laboratory services

Subpart D- - Administration

- ❖ Personnel qualifications/Responsibilities of Medical Director
- ❖ Medical Records/Governance

Some of the Major Changes:

Infection Control:

- Adopts CDC's "2001 Recommendations for Prevention of Infections in Hemodialysis"/ Adopts CDC's "2002 Guidelines for the Prevention of Catheter-Related Infections
- Hepatitis: "Existing" facilities must have a separate room or area for HbsAg+ patients. All new facilities must have a separate room

Water & Dialysate:

- Adopts AAMI RD52:2004 as regulation
 - ❖ Specific & required monitoring detailed for all water treatment components
 - ❖ Separate requirements for water treatment for home hemodialysis under Care at Home Condition
 - ❖ Addresses acid & bicarbonate concentrate: labeling, mixing, distribution and use

Physical Environment:

- Life Safety Code (LSC) Requirements
- Every Facility must have an AED or a defibrillator
- Emergency preparedness for staff & patients including disaster preparation

Patients' Rights:

- Receive information on all modalities, transfer & discharge policies
- Be informed of the right to have an advance directive

Patient Assessment: Comprehensive and multidisciplinary

- Initial completed within the latter of 30 days or 13 HD treatments

- Components required include anemia, adequacy, access, bone disease, nutrition, home dialysis, transplant status and rehabilitation
- Comprehensive reassessment within 3 months of completion of the initial assessment for all patients
- Adequacy assessed monthly for HD and every 3 months for PD
- Stable patients require annual review
- Assessments and plan of care monthly for “unstable patients”
 - ❖ Examples of unstable 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

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 reassessment

Long Term Plan (LTP)

- No expectation for a long term program or “signature” of transplant surgeon
 - ❖ Use transplant written selection criteria to assess patients for transplant
- 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

Quality Assessment Performance Improvement (QAPI):

- Condition level, Process continuous & on-going
- Data driven process to assess and improve care
- Interdisciplinary team/Medical Director responsible
- Specific areas must be addressed-outcomes focused
- Includes medical errors, medical injuries and patient satisfaction
- Continuous monitoring expected using root cause analysis to identify problems
- Plan/Do/Check/Act: Close the Loop!

Personnel:

- Defines individual qualifications
- Patient care technicians:
 - ❖ 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: 18 months after 10/14/08

Medical Director:

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

Governance:

- 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
- Patient Involuntary Discharge / Specific requirements
 - ❖ Reassess the patient/Involve the Medical Director
 - ❖ Contact another facility and attempt to place
 - ❖ 30 days notice unless threat to safety/Notify Network and State Agency
- Electronic Data Submission
 - ❖ A facility must electronically submit data on all patients, including data on clinical performance measures to CMS
 - ❖ CROWNWeb (Consolidated Renal Operations in a Web-enabled Network) – February 2009

Effective Dates:

New Conditions for Coverage	10/14/2008
CROWNWeb Implemented	2/1/09
Life Safety Code and Separate Room for HbsAg + Patients	2/9/09
Certification of technicians hired after 10/14/08	18 months from hire
Certification of existing technicians	18 months after 10/14/08