



The New ESRD Conditions for Coverage: A Review of Changes

This resource will provide the renal community with information and resources related to the new conditions for coverage. It is not an all-inclusive document and should not be substituted for information contained in the official CMS Conditions for Coverage document(s). All dialysis facilities are expected to become familiar with the Conditions for Coverage.

Topic	Changes	Help for Facilities
Subpart B: Patient Safety; Infection Control	Procedure in clued CDC's Recommended Infection Control Practices for Hemodialysis Units At a Glance	Resources can be found at found at - http://www.cdc.gov/ncidod/diseases/hepatitis/spotlights/dialysis_recs.pdf
Subpart B: Patient Safety; Water Quality	<p>Incorporates the ANS/AAMI 2001 guidelines for water purity not 2004 AAMI Dialysate Practice Guideline (RD52) which includes water and dialysis ate guidance for end user</p> <p>Comments supported RD52</p> <p>What's new</p> <ul style="list-style-type: none"> • Monitoring for bacteria and endotoxin levels • Water analysis when rejection rate < 90% • 2 carbon tanks • Testing for chlorine/chloramine every patient shift • A corrective action plan if levels outside limits • Use of mixed bicarb by manufacturer's time limit 	<p>Resources can be found at found at –</p> <p>http://aami.org/publications/index.html</p> <p>http://www.heartlandkidney.org/quality/downloads/watermanual.pdf</p> <p>http://www.heartlandkidney.org/quality/downloads/waterposter.pdf</p>
Subpart B: Patient Safety; Condition: Physical Environment	<ul style="list-style-type: none"> • Fire safety requirements • Applicable provisions of 2000 edition of the Life Safety Code, but not Chapter 5) • Requires defibrillators but not AEDs specifically (comments favored AEDs) • Clinic temperature – must be comfortable for the majority of patients. Must make “reasonable accommodations” for patients who are not comfortable at that temperature. 	<p>Resources can be found at found at –</p> <p>http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=101&cookie%5Ftest=1</p>
Subpart C: Patient Care; Condition: Patient Rights	<p>What's new</p> <ul style="list-style-type: none"> • Advance directives • Complaint system (internal/external) 	<p>Resources can be found at found at –</p> <p>http://heartlandkidney.org/community/download/Advance%20Directives.pdf</p>

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<ul style="list-style-type: none"> • Discharge & transfer policies* (30 days written notice; sooner for immediate threat) • Must post rights including Network & state agency complaint numbers <p>*Decreasing Dialysis Patient-Provider Conflict (DPC) program was published after this rule or recommendations may have been included</p>	<p>http://heartlandkidney.org/community/pat_newsletters/discussing_death_and_dying_IA.pdf</p> <p>http://heartlandkidney.org/community/pat_newsletters/discussing_death_and_dying_KS.pdf</p> <p>http://heartlandkidney.org/community/pat_newsletters/discussing_death_and_dying_MO.pdf</p> <p>http://heartlandkidney.org/community/pat_newsletters/discussing_death_and_dying_NE.pdf</p> <p>http://heartlandkidney.org/community/download/NW12DPC%20Book.pdf</p> <p>http://www.esrdnetworks.org/dpcDPCProviderManual.pdf</p> <p>http://www.esrdnetworks.org/dpc.htm</p> <p>http://heartlandkidney.org/community/download/Grievance%20Procedure%20Book.pdf</p>
<p>Subpart C: Patient Care; Condition: Patient Assessment</p>	<p>What's new</p> <p>Comprehensive assessment developed by patient (if wishes) or designee, RN, nephrologist, MSW, RD used to develop treatment plan & expectations for care:</p> <ul style="list-style-type: none"> • Health status, medical condition, do-morbidities • Appropriateness of dialysis prescription, BP & fluid management needs • Lab profile & medication history • Anemia • Renal bone disease 	

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<ul style="list-style-type: none"> • Nutritional status • Psychosocial needs • Dialysis access type & maintenance • Patients' interests, preferences, goals for participation in care, including home dialysis • Suitability for transplant referral (prospective transplant center's/surgeons criteria and basis for non-candidacy documented in chart) • Family & other support systems • Patient's current physical activity level • Vocational & physical rehab status & potential <p>Frequency</p> <ul style="list-style-type: none"> • New patient – 20 calendar days after 1st dialysis treatment to develop care plan* • Follow-up assessment within 3 months after 1st assessment to adjust care plan* <p>Assessment of treatment prescription:</p> <ul style="list-style-type: none"> • HD monthly (delivered Kt/V or equivalent) • PD every 4 months (delivered weekly Kt/V or equivalent) <p>*Commenter's opposed timeline, recommended more treatment days.</p> <p>Patient comprehensive reassessment</p> <ul style="list-style-type: none"> • Annually for stable patients • At least monthly for unstable patients, e.g. <ul style="list-style-type: none"> • Extended or frequent hospitalizations • Marked deterioration in health status • Significant change in psychosocial needs • Poor nutritional status, with unmanaged anemia & inadequate dialysis 	
<p>Subpart C: Patient Care; Condition: Patient Plan of Care</p>	<p>Plan developed by the interdisciplinary team & individualized to patient</p>	<p>http://www.vocrehab.state.ne.us/VR/offices.htm http://www.srskansas.org/rehab/text/VR.htm http://www.srskansas.org/rehab/text/VR.htm</p>

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<p>What's new</p> <ul style="list-style-type: none">• Specifies services necessary to address needs identified in assessment & changes in condition• States measurable & expected outcomes• States estimated timelines to achieve outcomes• Outcomes must allow patient to achieve current evidence-based community-accepted standards <p>Interdisciplinary team must provide necessary care & services to achieve & sustain:</p> <ul style="list-style-type: none">• Prescribed dose of dialysis• Nutritional status- measure albumin at least monthly• Anemia – monitor H/H monthly; if Hb <11 (Hct <33)<ul style="list-style-type: none">• Determine if patient is EPO candidate• Determine if home patients can safely store & self-administer• Monitor EPO response, BP & iron stores regularly• Appropriateness of vascular access type & monitoring to prevent failure, including stenosis of fistula or graft• Transplant referral candidate's status must be documented in interdisciplinary plan of care:<ul style="list-style-type: none">• Patient's referral & wait list status• Team must communicate with transplant center at least quarterly• Note: new transplant rule requires transplant facility to communicate routinely with dialysis clinic & provide written criteria to help dialysis staff assess candidacy• Rehabilitation status includes plan to provide necessary care & services to help the patient*	<p>http://heartlandkidney.org/community/voc_rehab/rehab_mo.pdf</p> <p>http://heartlandkidney.org/community/pat_newsletters/evaluating_alternatives.pdf</p>
--	---	---

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<ul style="list-style-type: none"> • Achieve & sustain his/her goals for productive activity, including vocational, as desired by patient • Meet educational needs for those under age 18 • Education & training for patient & family <ul style="list-style-type: none"> • Dialysis experience • Dialysis management • Quality of life • Rehabilitation • Transplantation <p>*Some commenter's assumed clinic must provide vs. refer</p> <p>Implementation of patient plan of care</p> <ul style="list-style-type: none"> • Completed by interdisciplinary team & signed by patient or designee • Implemented within 10 days post assessment* • Adjusted if expected outcomes are not achieved <p>Facility must ensure that physician providing ESRD care</p> <ul style="list-style-type: none"> • Sees all patients monthly (documented in monthly progress note) • Sees in-center patients while on dialysis periodically <p>*Comments opposed timeline, requested more treatment days</p>	
<p>Subpart C: Patient Care; Condition: Care at Home</p>	<p>What's new</p> <p>Home services must be at least equivalent to those provided to in-center patients</p> <p>Home training</p> <ul style="list-style-type: none"> • Facility must be approved for home dialysis • Provided by a qualified RN • Conducted to address list of specific needs in rule <p>Home dialysis monitoring</p> <ul style="list-style-type: none"> • Evidence the patient &/or caregiver received & 	

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<p>demonstrated comprehension of training</p> <ul style="list-style-type: none"> • Retrieve, review self-monitoring data every 2 months & retain in record <p>Support services – facility must furnish services directly or assure those supplied by DMEs meet requirements</p> <ul style="list-style-type: none"> • Periodic monitoring of the home adaptation • Coordination of care • Development & periodic review of patient's plan of care • Patient consultation with interdisciplinary team • Monitoring water quality used by home HD patients • Providing supplies & equipment • Arranging emergency back-up dialysis when needed • Records system ensures continuity of care & privacy <p>Provision of dialysis within a long-term care facility was discussed at length in the "care at Home" section of the Preamble, but not discussed in the proposed rule*</p> <p>*Commenter's opposed CMS implementing a rule about care in nursing homes before publishing a proposed rule to comment on</p>	
<p>Subpart C: Patient Care; Condition: Quality Assessment & Performance Improvement (QAPI)</p>	<p>What's new QAPI scope:</p> <ul style="list-style-type: none"> • Ongoing program • Achieves measurable improvement in health outcomes & reduction of medical errors by using indicators or performance measures associated with such improvement <p>Each dialysis facility must</p> <ul style="list-style-type: none"> • Continuously monitor its performance • Take actions that result in improvements • Track performance to ensure improvements achieved are sustained over time • Participate in ESRD Network activities & pursue 	<p>Resources can be found at found at: http://heartlandkidney.org/quality/continuous_quality_improvement.html http://heartlandkidney.org/quality/downloads/2007_hkn_cpm_goals.pdf</p>

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	Network goals	
Special Purpose Facility	<ul style="list-style-type: none"> • Vacation camps. Facilities serving special needs patients, or emergency/disaster situations • Approved for up to 8 months/year • When dialysis resources are limited due to emergency or patient needs are greater than area facilities can meet • Special purpose facility must comply with specified provisions of regulations 	<p>Contact the State Agency for additional information needed to set up a special purpose facility:</p> <p>Bureau of Hospital Licensing and Certification Missouri Department of Health 912 Wildwood P.O. Box 570 Jefferson City, Missouri 65102-0570 Phone 573-751-6303</p> <p>Health Facility Licensure and Inspection Nebraska Department of Health P.O. Box 95007 Lincoln, Nebraska 68509-5007 Phone 402-471-0555</p> <p>Iowa Department of Inspections and Appeals Health Facilities Division 3rd Floor, Lucas State Office Bldg. 321 East 12th Street Des Moines, Iowa 50319-0083 Phone 515-281-8632</p> <p>Bureau of Health Facilities Division of Health Kansas Department of Health and Environment 1000 SW Jackson, Suite 330 Curtis Office Bldg. Topeka, Kansas 66612-1365 Phone 888-842-0078</p>
Subpart D: Administration; Condition: Personnel Qualifications	<p>What's Changed Medical Director</p> <ul style="list-style-type: none"> • Completed a board approved training program in nephrology* • At least 12 months experience in dialysis <p>*Current rule requires board eligibility in internal medicine only</p>	<p>Resources can be found at found at:</p> <p>http://www.bonent.org/</p> <p>http://www.annanurse.org/cgi-bin/WebObjects/ANNANurse.woa/1/wa/viewSection?wosid=uYT_K2jVvKjQ721v7RUt4LQ1Hqlb&tName=certification&s_id=1073744</p>

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland.
Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



[056&ss_id=1](#)

- Nurse Manager
 - Full time employee of facility
 - RN meeting State practice requirements with 12 months in clinical nursing plus 6 months providing care to patients on dialysis
 - Self-care training nurse
 - RN meeting state practice requirements with 12 months as a nurse plus 3 months in training modality
 - Charge nurse
 - RN/LPN meeting State practice requirements with 12 months as a nurse including 3 months in dialysis
 - Staff nurse
 - RN/LPN meeting State practice requirements
 - Dietitian
 - Registered dietitian meeting the State requirements for practice & 1 year's professional work experience in clinical nutrition as an RD*
 - Social worker
 - Masters in Social Work meeting the State requirements for practice**
- *CMS previously counted RD internship as experience
 **Some commenter's recommended retention of non-MSW grandfather clause
- Patient care dialysis technicians*
 - Meet all State requirements
 - Have high school diploma or equivalency
 - Complete training program approved by medical director & governing body
 - Supervised by an RN after training focusing on dialysis equipment & machines, direct patient care, interpersonal skills & communication
 - Water treatment system technicians
 - Complete training program approved by medical



Heartland Kidney Network QI

	<p>director & governing body</p> <p>*Commenter's overwhelmingly supported patient care tech certification</p>	
<p>Subpart D: Administration; Condition: Responsibilities of the Medical Director</p>	<p>What's new</p> <p>The Medical Director is responsible for:</p> <ul style="list-style-type: none"> • QAPI program • Staff education, training, & performance • Patient care policies & procedures <ul style="list-style-type: none"> • Their development, review, & approval • Ensuring policies & procedures for patient care & safety are followed by all staff & MDs • Ensuring interdisciplinary team adhered to discharge & transfer policies & procedures 	<p>Resources can be found at found at:</p>
<p>Subpart D: Administration; Condition: Relationship with the ESRD Network</p>	<p>What's new</p> <p>"The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work."</p>	<p>Resources can be found at found at:</p> <p>Heartland Kidney Network 7505 NW Tiffany Springs Parkway, Suite 230 Kansas City, Missouri 64153 Phone: 816-880-9990 Fax: 816-9-880-9088</p> <p>(Serving IA, MO, KS, and NE)</p>
<p>Subpart D: Administration; Condition: Medical Records</p>	<p>What's new</p> <ul style="list-style-type: none"> • Medical records supervisor not required • Transfer of patient record information to receiving facility <ul style="list-style-type: none"> • Includes patient's medical record & other information necessary for patient's care or treatment • Within 1 working day of transfer 	
<p>Subpart D: Administration; Condition: Governance</p>	<p>What's new</p> <p>Standard: Adequate number of qualified and trained staff</p> <ul style="list-style-type: none"> • Patient/staff ratio is appropriate to level of dialysis care given & meets patient needs • A registered nurse is present in the facility at all 	<p>Resources can be found at found at:</p> <p>http://www.cms.hhs.gov/esrdqualityimproveinit/06_data.asp?</p> <p>http://www.meiresearch.org/CoreCurriculum/index.php</p>

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<p>times that patients are being treated</p> <ul style="list-style-type: none"> • Approved written training program for techs, required curricula- Amgen's Core Curriculum plus facility specific policies & procedures <p>Governing body is responsible for medical staff appointments</p> <p>Furnishing services directly on premises, e.g. each facility must be certified so no uncertified satellites at nursing homes</p> <p>Internal grievance process must include</p> <ul style="list-style-type: none"> • Clearly explained procedure for submission • Timeframes for reviewing grievance • How patient/representative will be informed of steps taken to resolve grievance <p>Discharge & transfer policies & procedures set guidance for involuntary discharge must address:</p> <ul style="list-style-type: none"> • Reassessment of patient • Whether patient's behavior interferes with – <ul style="list-style-type: none"> • Delivery of care to patient, or • Ability of facility to operate effectively • Documented efforts to resolve problem <p>Discharge & transfer policies & procedures</p> <ul style="list-style-type: none"> • Written MD's order signed by medical director & patient's attending MD occurring with discharge or transfer • Attempt to place patient in another facility • Notification of State agency & Network of involuntary discharge or transfer <p>Emergency coverage (changes)</p> <ul style="list-style-type: none"> • Must have an agreement with a hospital that can provide ER & inpatient care 24/7 	
--	---	--

This resource was developed while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.



Heartland Kidney Network QI

	<ul style="list-style-type: none"> • No requirements for Affiliation Agreement with ESRD “center” <p>Furnishing data& information electronically for ESRD program administration & the national ESRD information system</p> <ul style="list-style-type: none"> • Cost reports • ESRD administrative forms • Patient survival information • Existing clinical performance measures & future clinical performance standards adopted by the Secretary <p>*for info about CROWN which is under development and will accept all this data, contact Network.</p>	
<p>What about Transplant Centers? Hospital Conditions of Participation: Requirements for Approval & Re-approval of Transplant Centers to Perform Organ Transplant. Notice of proposed rulemaking (NPRM) published 2/4/05. Final rule published in Federal Register 3/30/07</p> <p>Resources can be found at found at: www.cms.hhs.gov/CFCsAndCoPs/Downloads/trancenterreg2007.pdf Kidney transplant programs will be surveyed under Subpart U until 6/28/07.</p>		

Source: Lecture notes of Beth Witten, MSW, ACSW, LSCSW, including information from Glenda Payne and Teresa Casey both of CMS. National Kidney Foundation (NKF) meeting that was held in Kansas City, Missouri on May 15, 2007.

Resource suggestions: Heartland Kidney Network QI staff