



STATE OF NEW YORK  
DEPARTMENT OF HEALTH

433 River Street, Suite 303 Troy, New York 12180-2299

Richard F. Daines, M.D.  
*Commissioner*

James W. Clyne, Jr.  
*Executive Deputy Commissioner*

October 15, 2009  
DCS 09-10

Dear Chief Executive Officer:

On October 14, 2008, the final rule for the federal Conditions for Coverage for End-Stage Renal Disease (ESRD) Facilities became effective. There are a number of important components to this ruling including provisions related to staffing, orientation and continuing competence of staff in outpatient ESRD Facilities. The full text of these provisions can be found at:  
<http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>

In summary, the following general requirements apply:

- Code of Federal Regulations (CFR) 494.150 (b) requires that the medical director of a dialysis facility is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities.
- CFR 494.180 (b) (1) requires that the governing body of an outpatient end-stage dialysis facility ensure there is an adequate number of qualified and trained staff on duty while patients are on dialysis in the center to meet the individualized needs of the patients. In addition, the rule adopts by reference ANSI/AAMI RD47:2002/A1:2003 5.2.2, which includes medical director certification of each person performing procedures for multiple use of dialyzers.
- CFR 494.180 (b) (2) requires that a registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated.
- CFR 494.180 (b) (3) requires that the governing body of an outpatient end-stage dialysis facility ensure all staff has appropriate orientation to the facility and their work responsibilities.
- CFR 494.180 (b) (4) requires that all employees have an opportunity for continuing education and related development activities. It is expected that continuing education programs be offered to all staff to help them maintain and improve their knowledge and skills.
- CFR 494.140(e) (1-4) specifies that Patient Care Technicians (PCTs), defined as unlicensed assistive personnel who have responsibility for direct patient care in an outpatient hemodialysis facility, must have a high school diploma or equivalency and must complete a training program approved by the medical director and the governing body, carried out under the direction of a registered nurse and that includes prescribed topics. In addition, PCTs must be certified under a State certification program or a national commercially available program.
- CFR 494.140 (f) requires that technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

It should be noted that the CMS rule further specifies that by April 15, 2010, PCTs employed as of October 14, 2008, must be certified by a state or national certification program. In addition, PCTs hired after October 14, 2008, must be certified within 18 months of their hire date. Since New York State does not have a state sponsored certification program for PCTs, the required certification must be obtained from a national certification program. Attached to this letter is a chart identifying the national certification programs recognized by CMS as of September 2009.

Because these national certification programs may include training in patient care responsibilities that unlicensed personnel are not authorized to perform in New York State, the Department is working to clarify the appropriate role of PCT's in the direct patient care of chronic hemodialysis patients. Both the Department of Health and the State Education Department are working cooperatively with ESRD clinicians and professional organizations to outline specific tasks that PCT's and other staff working in facilities may carry out under the direct supervision/direction of a Registered Nurse (see attached End-Stage Renal Dialysis Center Staffing Task Comparison for Outpatient Chronic Hemodialysis). It can be expected that facility compliance with these requirements will be monitored through routine New York State Department of Health surveillance activities.

If you have any questions, please contact Ms. Rosemarie Miller at (518) 402-1003 or at rxm04@health.state.

Sincerely,

A handwritten signature in cursive script that reads "Mary Ellen Hennessy".

Mary Ellen Hennessy  
Director  
Division of Certification & Surveillance

Attachments

**END-STAGE RENAL DIALYSIS CENTER STAFFING  
TASK COMPARISON FOR  
OUTPATIENT CHRONIC HEMODIALYSIS**

Task	Dialysis Patient Care Tech	LPN	RN
<b>PREPARATION FOR DIALYSIS</b>			
Turn on machines	X	X	X
Assign staff to patients to meet patient special needs			X
Check water system settings, timers and monitors each day and log	X	X	X
Prepare dialysate concentrate and test	X	X	X
Perform required periodic water sampling and testing	X	X	X
Do chlorine/chloramine test at start of day and before each patient shift	X	X	X
<b>PRE-DIALYSIS PROCEDURES</b>			
Review dialysis treatment orders and flowsheets for each patient	X	X	X
Review medication orders for each patient		X	X
Perform machine testing	X	X	X
Assemble extracorporeal circuit, bloodlines, transducer protectors, drip chambers, blood pump, heparin line or pump, clamps, etc.	X	X	X
Check priming solution for color, seal, expiration date and type.	X	X	X
Rinse and fill the extracorporeal circuit with saline	X	X	X
Add heparin (not administered to patient) to priming solution		X	X
Examine new dialyzer for correct model, type and size	X	X	X
Check and examine new/reprocessed dialyzer for correct patient	X	X	X
Check and examine reprocessed dialyzer	X	X	X
Test and/or verify reprocessed dialyzer for presence of germicide	X	X	X
Verify correct dialysate concentrate for patient	X	X	X
Verify correct mix of “spiked” dialysate concentrate		X	X
Connect concentrate container to machine	X	X	X
Check dialysate temperature, conductivity and the pH	X	X	X
Prime the dialyzer and extracorporeal circuit	X	X	X
Check and test alarms, extracorporeal and dialysate	X	X	X
Perform manual checks such as conductivity, pH	X	X	X
Calculate transmembrane pressure and ultrafiltration rate	X	X	X
Check machine for correct bath and dialyzer for patient	X	X	X
Set ultrafiltration rate and transmembrane pressure (most machines auto set TMP)	X	X	X

**END-STAGE RENAL DIALYSIS CENTER STAFFING  
TASK COMPARISON FOR  
OUTPATIENT CHRONIC HEMODIALYSIS**

Task	Dialysis Patient Care Tech	LPN	RN
<b>PRE-DIALYSIS PATIENT PROCEDURES</b>			
Weigh the patient and record	X	X	X
Calculate and record weight gain from last treatment	X	X	X
Validate goals for today's treatment for fluid removal in conference with RN	X	X	X
Program fluid removal goal to machine that was verified by RN	X	X	X
Check reprocessed dialyzer for presence of germicide	X	X	X
Check machine for correct settings, correct dialyzer and bath for patient, (pt must be in chair)		X	X
Check system for air and absence of residual germicide	X	X	X
Verify correct transmembrane pressure and ultrafiltration rate	X	X	X
Take patient's vital signs (blood pressure (arm/leg), temperature, pulse, respiration and record	X	X	X
Check patient for edema, LPN report abnormalities to RN		X	X
Assessment of abnormal findings			X
Check if vital signs were recorded and are normal for patient.			X
Assess patient heart and breath sounds as indicated or as ordered by Dr.			X
Assess all vital signs and observations, and machine settings to ensure goals for today's treatment are correct			X
Document and record any unusual findings before initiation of treatment, report to RN for assessment and documentation	X	X	X
Prepare for heparin load and hourly doses		X	X
Administer heparin and other medications as ordered		X	X
Enter correct treatment time for patient	X	X	X
<b>VENIPUNCTURE</b>			
Check vascular access for patency and direction of flow, bruit and thrill. RN to provide guidance and direction in response to unusual/abnormal findings.	X	X	X
Examine the fistula or graft access for signs and symptoms of infection (redness, swelling, tenderness, warmth), patency, etc. Report abnormal findings to RN for assessment/direction	X	X	X
Select needle sites and confirm with RN	X	X	X
Anesthetize access site if ordered/required (topical vs. injection)		X	X
Clean site and insert needle in fistula or graft	X	X	X
Dress the access and tape securely	X	X	X
Draw blood samples from patient's bloodlines, except central lines	X	X	X

**END-STAGE RENAL DIALYSIS CENTER STAFFING  
TASK COMPARISON FOR  
OUTPATIENT CHRONIC HEMODIALYSIS**

Task	Dialysis Patient Care Tech	LPN	RN
<b>CENTRAL LINE PREPARATION</b>			
Examine the central venous line, subclavian vein or jugular vein access or PICC line for drainage, redness, swelling, bleeding, etc. (LPN report observations to RN)		X	X
Verify findings of examination of the central line			X
Perform pre-dialysis catheter care (after catheter assessment by an RN)		X	X
Prepare syringes to remove heparin lock from catheter		X	X
Draw blood if ordered before giving heparin		X	X
Attach heparin load syringe. Draw back on syringes to check for good draw. If there is any resistance, summon an RN		X	X
Push heparin load into each port of catheter. If any resistance met, summon an RN.		X	X
Draw blood samples from central line ports		X	X
Connect ports to dialysis lines		X	X
<b>INITIATE DIALYSIS TREATMENT</b>			
Administer saline prime to patient, if ordered	X	X	X
Start blood flow	X	X	X
Check tubing connections	X	X	X
Check venous and arterial pressure alarms	X	X	X
Perform isolated ultrafiltration		X	X
Record observations about treatment	X	X	X
Complete flowsheet accurately	X	X	X
Give patient blanket, call bell and settle patient	X	X	X
Troubleshoot access and catheter issues			X
<b>MONITORING PATIENT DURING DIALYSIS</b>			
Round and assess each patient for problems, needs for the day and verify dialysis prescription is implemented as ordered			X
Maintain access visibility	X	X	X
Take vital signs	X	X	X
Document observations of patient status (alert, sleeping, resting)	X	X	X
Monitor the extracorporeal circuits for pressure, air, functioning heparin pump and document. Check transducer protectors	X	X	X
Respond to alarms appropriately	X	X	X
Administer routine dialysis medications such as ESA, iron, etc. per facility policy and physician orders, and document		X	X

**END-STAGE RENAL DIALYSIS CENTER STAFFING  
TASK COMPARISON FOR  
OUTPATIENT CHRONIC HEMODIALYSIS**

Task	Dialysis Patient Care Tech	LPN	RN
Respond to initial episode of patient hypotension with elevation of lower extremities, reduction of ultrafiltration rate and/or infusion of 200 cc of saline as directed by facility protocol. Alert RN for assessment and further direction immediately.	X	X	X
Respond to repeated episodes of hypotension in same treatment with additional saline infusion, and RN assessment for further intervention.		X	X
Document response to PRN medications given		X	X
Treat patients for dialysis related complications per physician order		X	X
Assure patient targets/goals for the treatment day are met, if not consult with RN		X	X
Assess each patient and treatment targets using community based standard measures			X
Communicate with patient, and other team members. If problems or concerns are identified, report to RN.	X	X	X
<b>DIALYSIS TERMINATION PROCEDURES</b>			
Prepare supplies needed to terminate dialysis	X	X	X
Reduce flow rate and negative pressure	X	X	X
Rinse patient's blood back from extracorporeal circuit if appropriate	X	X	X
Remove needles, stop bleeding and dress puncture sites	X	X	X
If patient / partner holds access site to stop bleeding, ensure patient / partner wears gloves, washes hands	X	X	X
Complete post catheter care (after assessment by an RN)		X	X
Document time it takes for bleeding from access site to stop	X	X	X
Document end time of treatment	X	X	X
<b>POST DIALYSIS PATIENT ASSESSMENT</b>			
Take patient's vital signs, blood pressure, temperature, weight and record	X	X	X
Check if vital signs are normal for patient			X
Discharge patients that have no abnormal post treatment findings.	X	X	X
If abnormal findings identified, determine patient's appropriateness for discharge and follow center policy/protocol and/or contact MD for further direction.			X
Document any treatment aspects not already documented	X	X	X
Strip machine, and clean and disinfect patient station	X	X	X
Clean and disinfect equipment	X	X	X
Handle reprocess dialyzer if it is to be reused	X	X	X

## PERSONNEL REQUIREMENTS

V Tag	Position	Minimum Education	Minimum Experience	Minimum Competence
V501	Interdisciplinary Team Member	RN; physician treating the patient for ESRD; MSW & RD as qualified below	Experience specified for that discipline	Competence specified for that discipline
V682 V683	Medical director	Medical degree; successful completion of board-approved training program in nephrology	12 months providing care to dialysis patients	Board certified internal medicine, nephrology, pediatrics, or pediatric nephrology
V684	Nurse manager (Full-time employee)	Nursing degree (RN)	12 months experience as an RN plus 6 additional mo in dialysis	Registration by State
V685	Self-care & home dialysis training nurse	Nursing degree (RN)	12 months as an RN plus 3 additional mo in each specific modality	Registration by State
V686 V687	Charge nurse	Nursing degree (RN, LPN/ LVN)	9 mo nursing experience plus 3 additional months in dialysis	Registration or licensure by State
V688	Staff nurse	Nursing degree (RN, LPN/ LVN)	Experience not specified	Registration or licensure by State
V689 V690	Dietitian	Baccalaureate degree	1 year clinical experience post-registration	Registration by Commission on Dietetic Registration
V691	Social worker	Masters degree in social work or Complies with "grandfather clause"	- Experience not specified if masters degree is in social work; - To comply with "grandfather clause" must have worked as a social worker since 9/1/75 and have ≥2 years of social work experience in dialysis or transplant facilities prior to 9/1/76.	- Licensure or certification by State if required by State. and - To comply with "grandfather clause," must have consultative relationship (written agreement of supervision) with masters prepared social worker
V692 V693 V694 V695	Patient care dialysis technician (PCT)	- High school diploma or equivalency - If a PCT employed on 10/14/08 lacks evidence of high school diploma or GED, >4 years of dialysis work experience can be used in lieu of high school diploma or GED	Experience not specified if PCT meets educational requirement	- Successful completion of RN-directed training program approved by medical director and governing body - Certified by CMS-approved State or national certifying program by the latter of 4/15/2010 or 18 months post hire - Continuing certification required
V696 V260	Water treatment technician	Complete training program approved by medical director and governing body	Experience not specified	- Successful completion of training - Monitoring by audits of compliance with procedures at least annually or more often if problems are identified; retraining if needed. -Ongoing training required
V307 V308 V309	Reprocessing technician	Complete training program with specified curriculum	Sufficient to ensure patient safety, and a safe and effective reprocessing/reuse program	- Successful completion of a training course certified by medical director or designee and demonstrated competence - Annual competence review - Retraining as needed
V752	CEO/administrator	Education not specified	Experience not specified	Facility defined with sufficient education and experience to fulfill responsibilities
V753	Staff appointments - physicians, non-physician practitioners	Education as appropriate for position	Experience not specified	Registration or licensure by state

**NATIONAL COMMERCIAL DIALYSIS TECHNICIAN CERTIFICATION ORGANIZATIONS\* (AS OF SEPTEMBER 2009)**

<b>National Organization</b>	<b>Board of Nephrology Examiners Nursing and Technology (BONENT)</b>	<b>Nephrology Nursing Certifying Commission (NNCC)</b>	<b>National Nephrology Certification Organization (NNCO)</b>
<b>Certification provided</b>	Certified Hemodialysis Technologist/Technician (CHT)	Certified Clinical Hemodialysis Technician (CCHT)	Certified Clinical Nephrology Technology (CCNT)
<b>Certification period</b>	Every 4 years	Every 2 years prior to 11/1/2009; every 3 years effective 11/1/2009	Every 4 years
<b>Recertification offered</b>	Re-exam or 40 contact hours of in-person continuing education, of which 15 contact hours can be earned from other education specified on BONENT Web site	Re-exam or <b>prior to 11/1/09</b> , 20 contact hours of continuing education plus 2000 work hours every 2 years; <b>effective 11/1/2009</b> , 30 contact hours of continuing education plus 3,000 work hours every 3 years; <b>effective 11/1/2011</b> , 10 contact hours of continuing education plus 1,000 work hours/year with recertification every 3 years.	Re-exam or 30 contact hours of continuing education, of which 15 contact hours can be earned from work in nephrology (3.75 contact hours/year)
<b>Educational requirement(s) to apply for examination</b>	High school diploma or equivalency; if no evidence of high school diploma, > 4yrs of dialysis work experience can substitute	High school diploma or GED; if no evidence of either, dialysis work experience >4 years can substitute	High school diploma or equivalency OR four years of full time experience in the field of nephrology technology
<b>Training/experience requirement(s) to apply for examination</b>	12 months of experience in nephrology patient care and current active work in an ESRD facility or successful completion of an accredited dialysis course approved by the BONENT Board.	Successful completion of PCT training program (classroom & supervised experience); signed verification by preceptor of training and clinical experience; recommend $\geq$ 6 months (1000 hours) of clinical experience, including training, prior to exam	1 year training program in nephrology technology with clinical experience and/or training program and clinical experience equivalent to 1 year. OH requires 12 months specified dialysis care experience
<b>Testing sites</b>	Providers may be test sites for paper & pencil tests. Independent test sites are used for computer-based tests. BONENT accommodates people with ADA disabilities.	ANNA chapters & dialysis clinics may host paper & pencil tests at on or off-site locations. In 2010 NNCC will offer computer-based tests at CBT centers. NNCC accommodates disabilities & religious convictions against Saturday tests.	Computer-based tests are offered at hundreds of PSI/LaserGrade Computer Testing sites in the U.S. and Canada. NNCO accommodates ADA disabilities & religious convictions against Saturday tests.
<b>Proctored Test</b>	Yes	Yes	Yes
<b>Website</b>	<a href="http://www.bonent.org">http://www.bonent.org</a>	<a href="http://www.nncc-exam.org">http://www.nncc-exam.org</a>	<a href="http://nnco.nbccc.net">http://nnco.nbccc.net</a>