



Center for Medicaid, CHIP and Survey & Certification/Survey and Certification Group

Ref: S&C-10-17-ESRD

DATE: April 23, 2010

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: End Stage Renal Disease (ESRD) Program Survey Guidance on Patient Care
Dialysis Technicians (PCTs) Certification

Memorandum Summary

- **PCT Certification Deadline: April 15, 2010:** Centers for Medicare & Medicaid Services (CMS) regulations require certification of PCTs by April 15, 2010, who have been employed in dialysis facilities since October 14, 2008.
- **Ongoing Certification Dates:** PCTs hired after October 14, 2008, must be certified within 18 months of their date of hire.
- **Surveys conducted after April 15, 2010:** Surveyors are expected to assess the certification status of the PCTs employed at ESRD facilities for determination of compliance with this requirement.
- **Condition level non-compliance:** Facilities should be cited at the Condition level if most of their PCTs are not certified as required. Standard or Condition level deficiencies may be cited under the Condition for Quality Assessment and Performance Improvement depending on the extent of the deficient practice. CMS will use administrative sources to verify that a plan of correction will be implemented.
- **Attachments to Memo:** Two appendices are attached to this memorandum. **Appendix A** is a compilation of the Frequently Asked Questions (FAQs) about PCT certification which have been received at the ESRDSurvey@cms.hhs.gov mailbox since the publication of the new ESRD Conditions for Coverage. These FAQs provide additional guidance which should be used in making survey decisions. **Appendix B** is an optional Surveyor Worksheet which may be used by surveyors to collect the information about the certification status of the PCTs.

Background:

The new ESRD Conditions for Coverage, published on April 15, 2008, require that PCTs who have been employed since October 14, 2008, must be certified by either a CMS-approved State or National dialysis technician certification program by April 15, 2010. PCTs hired after

October 14, 2008, must be certified within 18 months of their date of hire. Any surveys of ESRD facilities conducted after April 15, 2010, must include review of the certification of PCTs.

Refer to S&C-09-01, dated October 3, 2008, for the text and Interpretive Guidance to the ESRD Conditions for Coverage. Refer to S&C-10-03-ESRD, dated October 30, 2009, for detailed information regarding the definition of a PCT, additional requirements in the ESRD Conditions for Coverage for PCT qualifications, and State and National PCT certification programs which are currently approved by CMS.

After April 15, 2010, uncertified technicians who have been employed for more than 18 months may not provide direct patient care and may not be counted as direct care staff. The attached FAQs describe limitations on the role of uncertified patient care technicians after April 15, 2010.

Survey Procedures:

Determination of compliance with the PCT certification requirement should be reviewed routinely during Medicare ESRD certification, recertification and complaint surveys. Deficient practices will be cited when identified using the following Tasks from the Basic ESRD Survey Process:

- **Task 4-Entrance Conference:** Surveyors should ask the facility administrative staff for a current staff work schedule and a listing of all PCTs employed at the facility, along with their hire dates, and dates of their certification from a CMS-approved National or State certification program. The optional survey Worksheet for Verification of Dialysis Patient Care Technician Certification which is attached to this memorandum can be given to the facility to complete.
- **Task 3-Tour and Observation of Care; Task 10-Patient Interviews; Task 11-Medical Record Review; and/or Task 12-Personnel Interviews:** During the performance of any or all of these Tasks make note of any potential PCT-related issues, including name(s) of the individual PCT involved. PCT related issues occurring after April 15, 2010, should be used in identifying the sample for Personnel File Review (Task 14).
- **Task 14-Personnel File Review:** Select a sample of PCT files to review. This sample should include PCTs identified during the Tasks above and PCTs that represent discrepancies between the current staff work schedule and the information provided by the facility (e.g., Worksheet for Verification of Dialysis Patient Care Technician Certification). The sample size should represent 50% of the PCTs employed or at least 5 for facilities with fewer than 10 PCTs. The sample should include PCTs hired prior to as well as after 10/14/2008. Compare the facility-provided information (e.g., Worksheet) to personnel files for the sample selected to verify the accuracy of the information and identify deficient practice. You may need to look at assignment records and time records to see if uncertified PCTs are providing direct patient care. Recognize that the requirements for completion of an approved training program (V693) and demonstration of competency (V681) continue in addition to the requirements for certification. The PCT sample size may be expanded if concerns are identified, to determine the extent of non-compliance.

- **Task 13-Quality Assessment and Performance Improvement (QAPI) Review:** If there are PCTs employed without the required certification, the surveyor should look for evidence in the QAPI materials that the facility has (1) addressed the regulation of obtaining required certification; (2) developed and implemented a plan for achieving timely and appropriate PCT certification; and (3) provided a mechanism to ensure that uncertified PCTs with greater than 18 months experience are not providing direct patient care. Failure to comply with these requirements is a deficient practice at the Standard level under V628 or at the Condition level under V625.
- **Task 15-Decision Making:** Discuss the findings with the survey team (if applicable) to determine what to cite and the level of citation, and if further interviews, reviews, or observations are indicated. The following general guidelines apply to deficiency determinations for uncertified PCTs:
 - **Standard level non-compliance** should be cited under Personnel Qualifications in the Conditions for Coverage at V695 if the investigation shows that any PCT providing direct patient care does not have the required certification in place. If the facility's QAPI program did not fully address one or more of the three areas listed above under Task 13, cite this at the Standard level at V628.
 - **Condition level non-compliance** should be cited under Personnel Qualifications in the Conditions for Coverage at V680 if the investigation shows that most of the applicable PCTs were not certified as required. If the facility's QAPI program did not fully address any of the three areas listed above under Task 13, cite this at the Condition level at V625. CMS will use administrative sources to verify that a plan of correction will be implemented.

Please address questions and comments about this memorandum to Judith Kari at judith.kari@cms.hhs.gov.

Effective Date: The information contained in this memorandum is current policy and is in effect for all ESRD facilities. The State Agency should disseminate this information within 30 days of the date of this memorandum.

/s/

Thomas E. Hamilton

Attachments: Frequently-Asked-Questions regarding PCT Certification
Worksheet for Verification of Dialysis Patient Care Technician Certification
(optional)

**ESRD Conditions for Coverage
Frequently Asked Questions (FAQs) About Patient Care Technicians
April 2010**

V Tag	Question	Answer
692 695	Patient-care dialysis technicians (PCTs): Under the ESRD Conditions for Coverage what constitutes a “patient care dialysis technician?”	A “patient care (dialysis) technician” (PCT) means any person who provides direct care to patients and who is not classified as another professional, e.g., nurse, dietitian, or social worker. A biomedical technician or dialysis assistant would be classified as a PCT if he/she has responsibility for direct patient care or to set up machines for patient use. A technician who maintains or “takes down” machines after use without direct patient contact is not considered a PCT under these regulations.
692 695	Patient care dialysis technicians (PCTs): Define “setting up the dialysis machine for patient use.”	“Setting up the dialysis machine for patient use” means preparing the machine for use to include spiking the normal saline, checking and connecting the dialyzer, and all subsequent steps.
692 695	Patient-care dialysis technician (PCT) certification: Must a dialysis assistant who sets up machines for dialysis be certified as a PCT?	The Conditions for Coverage regarding certification for PCTs relates to the specific work that the PCT does, not to the title. A “dialysis assistant” may or may not be a PCT, depending upon the job description. CMS requirements for the “patient care dialysis technician” apply to the technician who has any responsibility for direct patient care, including setting up the dialysis machine for patient use. A technician who maintains or “takes down” machines (removes used supplies from the machine) after use without direct patient contact is not considered a “patient care dialysis technician” and does not require PCT certification.
692 695	Patient-care dialysis technician (PCT) certification: What is meant by “provide direct patient care.”	“Direct patient care” is defined as any aspect of healthcare for a patient provided personally by a staff member, including but not limited to collecting data (e.g., vital signs, weights, symptoms since last treatment), setting up the dialysis machine, initiating/terminating treatment, care of the dialysis access, delivering any aspect of the hemodialysis or peritoneal dialysis process, responding to machine alarms, and administering medications as allowed.
692 695	LPN/LVN: If a facility requires LPNs to function as patient care technicians, do the LPNs need to be certified as patient care technicians?	No. The CMS requirement for PCT certification applies to unlicensed/unregistered/uncertified individuals providing direct patient care.
692	Patient-care dialysis technicians (PCTs): Some experienced patient care dialysis technicians (PCTs) do not have evidence of a high school diploma or GED. How will this be handled?	CMS recognizes that some experienced PCTs working in dialysis facilities as of the effective date of these rules may not have evidence of a high school diploma or GED. PCTs with more than four years of work experience as of 10/14/08 who are lacking evidence of a high school diploma may use that work experience as an “equivalency” to a high school diploma.
692	Patient-care dialysis technicians (PCTs): If a PCT does not have 4 years of experience in lieu of a high school diploma, what role can they have?	If a currently employed PCT does not have 4 years of PCT experience by October 14, 2008, he/she may perform other functions in the dialysis facility, but would not qualify to function as a PCT after that date.

692	Patient-care dialysis technician (PCT) certification: If a technician has been certified by a CMS-approved national certification organization, i.e., BONENT, NNCO or NNCC, can the technician maintain recertification through a State program?	Yes. CMS will allow technicians who pass one of the 3 national certification exams to maintain ongoing certification through one of the CMS-approved State technician certification programs.
692	Patient-care dialysis technician (PCT): What can we do for staff members who have worked as patient care technicians for less than 4 years who were foreign educated, have a graduate degree certificate, but can't provide a copy of a high school diploma?	<p>If the technician has a graduate degree from a legitimate graduate program, his/her education would exceed the minimum requirement of a high school diploma or GED.</p> <p>Be sure that the diploma or GED certificate is legitimate. Information from the Federal Trade Commission about illegitimate "diploma mills" can be found at: www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt149.shtm</p> <p>The American Association of Collegiate Registrars and Admissions Officers website has a database called EDGE (Electronic Database for Global Education) that provides registered members information on education provided in 162 countries for an annual fee. http://aacraoedge.aacrao.org</p>
692	Patient-care dialysis technician (PCT): We have a technician who has worked in dialysis <4 years. He graduated from high school in another country but does not have proof of that diploma. He obtained a GED from a high school online, but NNCC is not accepting it. How can this situation be resolved?	<p>Although several online schools advertise GEDs, there are no legitimate online providers of the GED, which must be taken through on-site testing. The GED Testing Service Web site includes locations for on-site testing: www.acenet.edu/AM/Template.cfm?Section=GED_TS</p> <p>This PCT must either obtain proof of his/her official high school diploma from his/her high school in another country or the PCT must take the GED at a testing site in time to document that he meets Federal regulations.</p>
692	Patient-care dialysis technician (PCT): How can a dialysis clinic verify that a patient care technician's high school diploma is legitimate?	<p>As a first step, the Department of Education has a database that a facility can check if a high school exists: http://nces.ed.gov/globallocator/</p> <p>If the high school exists, it should be able to verify that the employee graduated.</p>
692	Patient-care dialysis technician (PCT): Will CMS accept the technician that has been grandfathered in? Example: In VA they put in a grandfather clause stating that techs who were working prior to April 2006 and have proof of training did not have to take a national exam. So will CMS accept them or must they now take the exam?	CMS will not grandfather any technicians. Thus, all patient care dialysis technicians will need to take one of the 3 national certifying exams or a state exam that complies with CMS' requirements. CMS will allow technicians who pass one of the 3 national certification exams to maintain ongoing certification through approved State programs.
693	Patient-care dialysis technicians (PCTs): With the new regulations, PCTs are expected to complete a training program focused on the operation of the kidney dialysis	For purposes of this rule, "experienced" PCTs "who have been employed as a PCT for more than two years as of the effective date of these regulations" and do not have documentation of a training program covering the listed content, may demonstrate competency by

	equipment and machines, providing direct patient care, and communication and interpersonal skills. What is expected of experienced technicians?	successful completion of a written exam over the required content and a skills checklist completed by observation of the PCT's skills by a registered nurse. These "experienced" PCTs would be expected to achieve certification within the specified time period.
693	Patient-care dialysis technician (PCT): Where is the written exam and skills checklist derived--from the individual hemodialysis outpatient centers/acute hemodialysis units? Does this need to be completed in order to place on the application to take the certification examination?	The "test" and "checklist" referred to in the Interpretive Guidance are the responsibility of the facility to develop or obtain from another source. These would serve to validate that training includes those areas required by the regulation and that the staff member was successful in completing the training as a PCT. These documents become a part of the individual's personnel file, and help meet the requirements for the ESRD Conditions for Coverage.
693	Patient care dialysis technician (PCT) training: According to CMS rules V-693 where an approved training program is administered under the direction of a registered nurse, what is the guideline for having the possibility of utilizing champion PCTs to assist in the training?	The regulation requires that the training program for patient care dialysis technicians be under the direction of a registered nurse. It does not prohibit others from participating in the training, including the physician, Advanced Practice Registered Nurse (APRN) or Physician Assistant (PA), dietitian, social worker, experienced patient care technicians, or other clinical staff. As examples, the Registered Dietitian(RN) could do the lessons on nutrition; the MSW could do the sessions on patient sensitivity; the biomed staff could do sessions on testing water for chlorine/chloramines; and experienced patient care technicians could do sessions on setting up and tearing down the dialysis machines pre and post treatment.
693 694	Patient-care dialysis technicians (PCTs): How is the content of PCT training verified when the personnel file only includes a certificate from the corporation and the training is done at a corporate off-site location?	Each facility must make available the content of the training program for the surveyor to validate that the program covers the specific topics required.
693 694	Patient-care dialysis technicians (PCTs): If a hemodialysis patient care technician took a training course prior to the CMS requirement for certification, will they meet the certification criteria?	If there is documentation that the course taken meets the curricula requirements, or if the PCT has been working for more than two years as a PCT and passes a test over the content of the curricula, the training course requirement would be met. Every PCT must successfully complete a certification exam from a qualified entity in order to meet the certification criteria.
695	Patient-care dialysis technicians (PCTs): Will CMS track technicians who do not have appropriate qualifications/certifications, who move from one facility to another?	CMS does not maintain a registry of technicians. However, CMS intends to "count" experience from one facility to another in determining the 18 months time limit for completing certification, unless the PCT has at least an 18 month break in employment as a PCT.
695	Proctored exam: What is a proctored exam? Who can proctor? Could the exam be offered at a dialysis provider corporate office?	A "proctored exam" means that an outside, independent person receives and protects the exam; provides oversight of the test administration (ensures candidates sit at a distance from one another, do not have potential to share answers, discuss the test, or take copies of the test away from the test site); and is responsible for returning the completed tests to the entity providing the exam. The tests are generally timed. The proctor must be independent of the dialysis facility. The exam can be offered at a dialysis facility or corporate office if the site

		is proctored by an independent examiner.
695	Standardized test: What does CMS mean by a “standardized test?”	<p>For the purposes of these regulations, a “standardized” test must:</p> <ul style="list-style-type: none"> • Be developed by a group of experts representing more than one provider entity; • Be reviewed by a qualified entity (e.g., university, State licensing board, or test development company) for internal consistency and to ensure the test covers both common and critical tasks; • Test similar information under the same testing conditions. For example, all test takers (with the exception of those with certain disabilities) must be given the same amount of time to complete their exams and must have a quiet, controlled testing environment; • Measure a student’s performance against specific standards; in this case, against the required curricula items for a patient care technician and the knowledge and skills a PCT must demonstrate; • Produce consistent scores among different testing conditions or versions used; • Work the same way for all test takers. For example: the language and wording of test questions must be free of cultural, racial, ethnic, gender, and other forms of bias that may inappropriately affect students’ performance; • Be scored and have a set passing score; and • Be protected from casual distribution
695	Patient-care dialysis technician (PCT) certification: Is a technician who does not set up or monitor machines, but who functions as a nursing assistant for acute dialysis treatments provided to hospital inpatients required to be certified?	The PCT certification requirement applies to all ESRD facilities that provide chronic outpatient dialysis for ESRD patients. The certification requirement does not apply to hospitals that provide inpatient dialysis only.
695	Patient-care dialysis technician (PCT) certification: If a PCT worked in dialysis then left to work in a different field and later returned to work in dialysis, how long would he/she have to become certified?	<p>A PCT who has a gap in employment as a PCT for <18 months has a total of 18 months from his/her original hire date to obtain PCT certification. Changing jobs from one facility to another even across State lines does not restart the 18-month clock on obtaining PCT certification.</p> <p>However, if a PCT did not work as a PCT at any dialysis facility for >18 months, he/she would have 18 months from his/her rehire date to obtain certification.</p>
695	Patient care dialysis technician (PCT) certified: Does a reuse technician have to be certified?	The Federal regulations do not require reuse technicians to be certified as long as that reuse technician does not provide direct patient care.
695	Patient care dialysis technician (PCT) certified: Will reuse techs be able to set up machines without being certified?	No. Any unlicensed person responsible for setting up or operating machines or providing direct patient care must be certified as a PCT. Persons who tear down machines do not have to be certified, so a reuse tech could do that task.
695	Patient care dialysis technician (PCT) certified: What States have	Eleven State programs have been approved by CMS as of 4/16/2010. See S&C-ESRD-10-03 for more detail

	PCT certification exams that have been approved by CMS?	and the list of States.
695	Patient care dialysis technician (PCT) certified: If a PCT takes a leave of absence (medical/military/other) during the 18 month window for certification, is the leave counted in the timeline?	<p>The length of an approved leave of absence from work (medical/military/family medical leave act (FMLA), jury, other) is not counted in the 18-month timeline. The 18-month clock essentially stops on the last day the PCT works before the leave starts; the 18-month clock resumes when he/she returns to work.</p> <p>The PCT's personnel file should include a record of the start and end dates of the leave of absence. This can serve as documentation for an exception to the 18-month deadline.</p>

Worksheet for Verification of Dialysis Patient Care Technician Certification

Facility Name	CMS Certification #	Address		
Name of Person Completing Form			Date	

Ask a responsible staff member to complete the following information for each dialysis patient care technician (PCT) the facility employs (full or part time). For PCTs not certified, enter "none" in "Certified Date" column. The surveyor will verify information provided for the sample of the PCTs.

#	Name of PCT (Please type or print legibly)	Hire date DD/MM/YY	Certified Date DD/MM/YY	By Whom? NNCC, NNCO, BONENT, State	Certification Number	Completed Approved Training	Competency Documented	Comment
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

Please copy this form for listing additional PCTs.