



HOME DIALYSIS QUESTIONNAIRE (February 2004)

I. Introduction

Because your request to provide home dialysis is evaluated by this questionnaire and/or a survey, the Centers for Medicare & Medicaid Services/Chicago Regional Office (CMS/Chicago) requests detailed information about your program prior to determining whether approval should be granted. Please enclose explanatory documentation if needed to supplement your answers. If approved, home dialysis services will be monitored by State Agency surveys (facility inspections) of your end stage (ESRD) renal dialysis facility (RDF) or renal dialysis center (RDC).

These questions derive from the regulatory requirements found in Subpart U – Conditions for Coverage of End Stage Renal Disease (ESRD) Services (42 CFR 405.2100-405.2171) and 42 CFR 414.330 - Payment for Home Dialysis Equipment, Supplies, and Support services. Copies of these ESRD regulations are enclosed for your reference. We have also used questions from the State Operations Manual §2286 for section V. regarding continuous ambulatory peritoneal dialysis/continuous cycling peritoneal dialysis CAPD/CCPD services. Finally, we have included questions based upon survey and certification experience with home dialysis programs.

This questionnaire must be accompanied by an End Stage Renal Disease Application (HCFA-3427), a copy of which is enclosed. For initial ESRD applications your response is returned to the State agency with other application information. Similarly, Medicare certified RDCs or RDFs wishing approval to add home dialysis services should send their response to their State Agency. If you have any questions about the completion of this form, please call the CMS/Chicago Certification Specialist responsible for ESRD for your State:

IL/IN/WI Ted Feaster, 312/353-4711.
MI/MN/OH Bob Anderson, 312/886-0326.

II. Identifying Information (for the dialysis facility requesting approval to furnish home dialysis)

Medicare number (if certified): _____

Name of ESRD facility: _____

Address: _____

Phone number: _____

Fax number: _____

E-mail: _____

Name of Physician-Director (Medical Director): _____

Name, title, and phone number (if different) of person completing this questionnaire: _____

Home Dialysis Services Offered. *Check whichever applies:*

CAPD/CCPD for any patient (Complete sections III, IV, & V.)

Hemodialysis for patients residing at (Complete sections III & V.)

If both CAPD/CCPD and home hemodialysis are offered, complete a separate section IV for each.

Indicate the date on which the above services were first provided or will be offered. _____

Note: Although coverage guidelines exist for dialysis being provided to long-term care (nursing home) patients, CMS currently has no process for evaluating the safety of home hemodialysis provided to nursing home patients. Therefore, this questionnaire should only be used to describe home hemodialysis for patients residing in their own home with a trained caregiver.

III. General Home Dialysis Information (for all applicants) *(Provide your responses to this section on a separate sheet.)*

Please provide a narrative description of your home dialysis program, and send us copies of any policies, procedures, or training materials supporting the program. Reference any such materials in your response. Your response should include answers to all of the following:

Use of Outside Resources. Fully describe any home hemodialysis services that are not furnished directly by your ESRD facility. Indicate who or what entity provides them by name, address and phone number. How does your facility monitor these services? *Attach copies of any contracts (arrangements or agreements).*

Physician Medical Supervision and Emergency Coverage. How does the governing body ensure that every patient is under the continuing supervision of a physician and that a physician is available in emergencies? See 42 CFR 405.2136(g) for a description of physician responsibilities. Indicate the names and phone numbers of the physicians to be called in emergencies and how they can be reached. Do you place any limit on the distance between the physician and the patient's residence in the event the physician is needed to attend to the patient quickly?

Facility Emergency Procedures. Describe your emergency procedures in detail. Who does the patient call, if the patient lives in his own home? What if the patient cannot communicate? How is the caregiver involved? How is your ESRD facility involved in an emergency? Do you place any limit on the distance between the ESRD facility and the patient's residence in the event facility staff is needed to attend to the patient quickly? What is the role of the patient's local 911 or EMS?

Electronic Surveillance of Hemodialysis. Do you use electronic monitoring of the home hemodialysis equipment (via modem for instance)? If so, who does the remote site monitoring? How is this done? Explain the emergency procedures, if the remote site monitor detects a malfunction. How does ESRD facility ensure that the sensors are maintained in working condition?

Training Nurse. Identify and *attach the curriculum vitae* for the nurse in charge of the home dialysis training program. This nurse must meet the requirements at 42 CFR 405.2102(d). How many months and years experience in home dialysis and home dialysis equipment does this person have? Will this nurse be responsible for training at more than one renal dialysis facility? Will this nurse provide all training services directly or through others? If other persons are involved with home dialysis training, how will they be instructed and how will their performance be monitored?

Training Program. What does the training program consist of? Describe. Does it take place on the premises of the dialysis facility? How many sessions over how many weeks? How long are the sessions? How are candidates for home dialysis screened? Will a backup caregiver or assistant be trained in addition to the patient receiving home dialysis? If not, explain the procedures for when the patient becomes incapacitated during home dialysis treatment and no one else is there.

Self-Dialysis Support Services. 42 CFR 405.2163(e)&(g) require the RDF or RDC to provide certain self-dialysis support services. Explain how and how often these services are provided. Who is responsible? How often will a nurse visit the patient? How often will there be a consultation with a qualified dietician and social worker? How will medical records be maintained and by whom? How often will equipment be inspected? How often will water be tested? Who in the dialysis facility has the responsibility for the dialysis support services?

Patient Care Plan and Monitoring Home Adaptation. Note the 42 CFR 405.2138(b)(1)-(5) requirements for the care plan. Refer to 42 CFR 405.2138(b)(6)-(7) for monitoring the patient's home adaptation. Explain how and how often the required monitoring activities take place. Who is responsible? How often will visits be made to the patient's home?

Network Participation. ESRD suppliers are required by 42 CFR 405.2133 to furnish information to a renal dialysis network. Identify by name and address the network where you send your data.

Technicians. If technicians are used, how and by whom are the technicians trained? How is their performance monitored?

IV. For suppliers of CAPD/CCPD services only (*Provide responses on the questionnaire.*)

Note: CAPD = continuous ambulatory peritoneal dialysis, CCPD = continuous cycling peritoneal dialysis.

The renal disease facility/center must furnish CAPD/CCPD training directly; but the required support services may be furnished via an arrangement or agreement with another Medicare certified renal dialysis facility/center. Reference the meaning of arrangement and agreement at 42 CFR 405.2102 Definitions.

The following questions are based upon State Operations Manual section 2286.

1. Will the director of the ESRD unit (renal dialysis facility or center) furnish a certificate of completion, including any pertinent limitations, whenever a person has successfully completed a course of training?
Yes _____ No _____
2. Will the director of the ESRD unit assure that instructional materials are available for use of all trainees during training and at times other than during the dialysis procedure?
Yes _____ No _____
3. Does the director of the ESRD unit assure that personnel involved in training have adequate knowledge of the CAPD/CCPD process?
Yes _____ No _____
4. Does the nurse responsible for the CAPD/CCPD training meet the standards in 42 CFR 405.2102(d) and have documented experience in peritoneal dialysis and in the care and maintenance of peritoneal access devices? *Attach the curriculum vitae for the nurse.*
Yes _____ No _____
5. How many years _____ and months _____ experience in peritoneal dialysis and maintenance of peritoneal access devices does this nurse have?

6. Upon completion of the patient's CAPD/CCPD training, the ESRD unit must furnish the following support services either directly or under arrangement or agreement with another Medicare certified renal disease facility/center approved to furnish staff-assisted peritoneal dialysis or peritoneal self-dialysis training.

Check whichever applies. (If any services are provided under arrangement or agreement, please attach a copy of the contract.)

a. Surveillance of the CAPD/CCPD patient's home adaptation which includes provision for visits to the home or patient visits to the facility.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

b. Consultation for the CAPD/CCPD patient with a qualified social worker and a qualified dietician.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

c. A record keeping system which assures continuity of care for the CAPD/CCPD patient.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

d. CAPD/CCPD supplies ordered on a continuing basis.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

e. Periodic visits, at least once every 90 days, to monitor the CAPD/CCPD patient's medical condition, review his continuing ability to perform CAPD/CCPD, and record whether the patient has, or has had, peritonitis requiring physician or hospital care.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

f. Testing and the appropriate treatment of water.

Provided directly.

Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

g. Hemodialysis or intermittent peritoneal dialysis as required.

___ Provided directly.

___ Provided under arrangement or agreement with another approved ESRD facility. Indicate Medicare number, name, and address of facility.

V. Director's Attestation (*The director's attestation must be returned to CMS/Chicago at the end of all other responses to this questionnaire.*)

Note: See 42 CFR 405.2102(e) for definition of physician-director and 405.2161(b) for a definition of the director's responsibilities.

The director's signature attests to the accuracy of all responses and attached materials.

Name, City & State of ESRD facility/center: _____

Director's signature: _____

Director's name printed: _____

Date: _____

Thank you for taking the time to formulate a thorough response. Be reminded to send your response to the State agency.

Enclosures: HCFA-3427 and ESRD regulations

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