

Wake Forest Baptist Health
Comments on Healthcare Planning and Certificate of Need Section’s Proposed Readoption
of Certificate of Need Regulations : 10A N.C.A.C. 14C
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1. **NAME, ADDRESS, EMAIL ADDRESS, AND PHONE NUMBER OF COMMENTER**

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2. **COMMENTS ON PROPOSED REGULATIONS (10A N.C.A.C. 14C .2203)**

After careful analysis of the Healthcare Planning and Certificate of Need Section’s (the “Agency”) proposed Readoption of Certificate of Need Regulations—in particular the proposed language of 10A N.C.A.C. 14C .2203—Wake Forest Baptist Health (“WFBH”) offers the follow comments for review and consideration.

10A NCAC 14C .2203 Performance Standard

While rightly attempting to codify a performance standard for the provision of home hemodialysis, the proposed language of 10A N.C.A.C. 14C .2203 fails to fully and adequately define the provision of “Home Hemodialysis” with precision. Thus, a slight revision is needed to more succinctly reflect the realities of home hemodialysis training and, thereby, avoid confusion. The revisions suggested by WFBH are *de minimus* and fundamentally amount to a mere clarification and are not substantive in nature.

As promulgated, the language of 10A N.C.A.C. 14C .2203(c) reads as follows:

(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis services shall document the need for the total number of home hemodialysis stations in the facility based on six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.

WFBH contends that the language should be revised as follows (revisions underlined and in **bold**):

*(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis services shall document the need for the total number of home hemodialysis stations in the facility based on **the training of** six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.*

In addition to this, WFBH contends that the language of 10A N.C.A.C. 14C .2203(d) should be revised to read as follows:

*(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis services shall document the need for the total number of home hemodialysis stations in the facility based on **the training of** six home hemodialysis **patients** per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.*

The reason for these proposed changes owes to the fact that it is the number of **training sessions** for home hemodialysis patients which drives the provision of home hemodialysis services—not the number of home hemodialysis patients that a facility serves.

A given patient is trained through a course of educational instruction regarding the modality only one time (over a series of visits). This is the crux of what home hemodialysis services entail. This is made apparent by reference to Chapter 11 of the Medicare Benefit Policy Manual, § 30.2 which states:

The average training time for hemodialysis patients is based upon 5-hour sessions given 3 times per week. In some dialysis programs, the dialysis partner is trained to perform the dialysis treatment in its entirety. The patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.

A copy of the relevant portion of the Medicare Benefit Policy Manual is attached hereto as EXHIBIT A.

Nonetheless, after having received their training, that same individual remains a patient of the training facility for the purposes of monitoring, dietetic guidance, and as a backup dialysis patient.

Thus, it is far more accurate and sensible for the language of the proposed regulation to make it clear that the performance standard is speaking in terms of the number of training sessions for patients as opposed simply the number of patients. Clarifying this language will remove ambiguity in the language of the performance standard and ensure that the regulation meets the health planning goal for which it is intended.

3. CONCLUSION

WFBH is hopeful that the Agency will consider this proposed clarification and include it in the final version of 10A N.C.A.C. 14C .2203

Medicare Benefit Policy Manual

Chapter 11 - End Stage Renal Disease (ESRD)

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NOTE: For additional information on renal dialysis services furnished on or after January 1, 2011, and paid under the ESRD PPS, refer to §20 of this chapter.

B. In-facility Dialysis Sessions Furnished to Home Patients Who Are Traveling

Patients who are normally home dialysis patients may be dialyzed by a Medicare certified ESRD facility on an in-facility basis when traveling away from home. Patients who normally dialyze in an ESRD facility may wish to dialyze temporarily in another facility or as home dialysis patients while they travel or vacation. See Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §100, for billing services when traveling.

C. Staff Assisted Home Dialysis

Effective January 1, 2011, renal dialysis services for patients receiving home dialysis may only be billed under Method I. Staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service.

If an entity wishes to bill Medicare for a non-covered renal dialysis service they provide to Medicare beneficiaries, they must first enroll with the appropriate Medicare contractor (assuming that Medicare recognizes such type of provider/supplier for billing purposes). Providers/suppliers must enroll in the jurisdiction(s) where they intend to provide services and follow the jurisdiction rules specified in Pub. 100-04, chapter 1, §10.

Once the ESRD facility is enrolled with the appropriate Medicare contractor(s), they should work with the contractor(s) to determine the appropriate code to bill for the service, if any. Finally, entities enrolled in Medicare as Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers may not bill the DME MACs for professional or quasi-professional services, including but not limited to nurse caregiver staff-assistance services. Instead, if a DMEPOS supplier is permitted under State law to furnish such services under its licensure and wishes to bill Medicare for such services, it must enroll with the appropriate Medicare contractor under such professional or quasi-professional service category as Medicare may recognize for Medicare billing purposes, if any.

For additional information, contact your appropriate Medicare contractor.

30.2 - Home Dialysis Training

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

Self-dialysis and home dialysis training are programs provided by Medicare certified ESRD facilities that educate ESRD patients and their caregivers to perform self-dialysis in the ESRD facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. Self-dialysis training can occur in the patient’s home or the in-facility when it is provided by the qualified staff of the ESRD facility. CMS expects that the patients who elect for home dialysis are good candidates for home dialysis training, and therefore, will successfully complete their method of training before reaching the maximum number of sessions allotted. Dialysis training services are reimbursed in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

Home dialysis training services and supplies may include but are not limited to personnel services; dialysis supplies, parenteral items used in dialysis, written training manuals and materials, and renal dialysis laboratory tests. For more information on the requirements for ESRD facilities, see 42 CFR Part 494.

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD. For information on how home dialysis training treatments are paid, see §60.C of this chapter.

NOTE: ESRD facilities that are certified for home dialysis training and support services are expected to provide training throughout the home dialysis experience. Information regarding home dialysis training certification may be found at the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

A. Hemodialysis Training

The average training time for hemodialysis patients is based upon 5-hour sessions given 3 times per week. In some dialysis programs, the dialysis partner is trained to perform the dialysis treatment in its entirety. The patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.

B. Intermittent Peritoneal Dialysis Training (IPD)

The IPD patients can be trained in approximately 4 weeks. IPD is usually accomplished in sessions of 10-12 hours. It is sometimes accomplished in fewer sessions of longer duration. In the IPD program, the patient's partner is usually trained to carry out the dialytic care. The patient plays a secondary or minimal role, as most are unable to perform self-care dialysis. IPD patients are usually unable to perform self-care dialysis because of other debilitating conditions.

C. Continuous Ambulatory Peritoneal Dialysis (CAPD) Training

The CAPD training is furnished in sessions that can last up to 8 hours (one session per day) 5 - 6 days per week. Typically, 6 - 8 CAPD exchanges can be performed per day for the purpose of teaching the patient the CAPD technique; however, no specific number of exchanges is required. Normally patients are trained within 2 weeks (5 - 6 training sessions per week); however, up to 15 sessions (i.e., 15 training days) may be covered routinely. Additional CAPD training sessions are covered only when documented for medical necessity. Extra training sessions raise questions about either the adequacy of CAPD for the patient or the patient's capacity to learn or perform the CAPD technique. The patient's physician should address these questions in the explanation of the need for extra training sessions. The A/B MAC (A) will make a determination whether or not to permit training sessions in excess of 15.

Once the patient is trained, CAPD is primarily a home service because the patient performs CAPD 24 hours a day. Therefore, renal dialysis services that are specifically CAPD services are training services and include associated services that are furnished in the ESRD facility during training. Persons who are primarily treated by CAPD may also require in-facility dialysis, either intermittent peritoneal or hemodialysis, occasionally.

Prior to the implementation of the ESRD PPS, there were specific frequency coverage requirements of the routine laboratory services furnished for CAPD. The CAPD laboratory tests that were included under the composite rate are those monthly tests listed in (§20.2.E.1.b of this chapter) and they are covered during training. The coverage frequency screens for these laboratory tests did not apply during training, as these tests were commonly given during each training session. All of these tests were included in the training screen, regardless of how frequently they were given, and may have been billed separately. Under the composite rate, separately billable laboratory tests must have been documented for medical necessity. However, under the ESRD PPS all renal dialysis laboratory services are included in the bundle regardless of the frequency they are furnished.

Supplemental Dialysis during CAPD Training

It may be necessary to supplement the patient's dialysis during CAPD training with intermittent peritoneal dialysis because the patient has not yet mastered the CAPD technique. Generally, no more than three supplemental intermittent peritoneal dialysis sessions are required during the course of CAPD training, and these may be covered routinely. If more than three sessions are billed during training, the claims must be

documented for medical necessity. Under certain circumstances, the form of supplemental dialysis may be hemodialysis.

D. Continuous Cycling Peritoneal Dialysis (CCPD) Training

Continuous cycling peritoneal dialysis training is furnished in sessions of 8 hours per day 5 days per week. Typically, five exchanges can be performed per day to teach the patient the technique; however, no specific number of exchanges is required. Most patients are trained within 2 weeks; however, up to 15 sessions may be covered routinely. The A/B MAC (A) will determine whether or not training sessions over 15 are medically necessary.

E. Retraining

Payment is made for retraining self-dialysis education after a patient or caregiver has completed the initial program if the patient continues to be an appropriate candidate for home dialysis. Most patients receive additional training on the use of new equipment, a change in their caregiver, or a change in modality. The ESRD facility may not bill for retraining services when they install home dialysis equipment or furnish monitoring services. For example, an ESRD facility nurse may not bill for retraining sessions to update treatment records, order new supplies, or add additional medicine for the treatment of infection.

NOTE: When retraining and educational services are furnished to a patient or caregiver already knowledgeable in some other form of self-dialysis or if training is being done for a change of equipment, fewer sessions are necessary because of the transferability of certain basic skills.

Criteria for retraining are explained in greater detail in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

40 - Other Services

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

ESRD beneficiaries may receive other services that may be related to their ESRD diagnosis but are excluded from the ESRD PPS payment.

A. Coverage under the Home Health Benefit for ESRD Patients

Services that are covered under the ESRD PPS are excluded from coverage under the Medicare home health benefit.

Services can be provided to dialysis patients under the home health benefit as long as the condition that necessitates home health care is not a renal dialysis service. A beneficiary, entitled to Medicare under the ESRD program, is eligible for home health benefits as is any other Medicare beneficiary if coverage conditions are met provided the patient's condition is not covered by the ESRD PPS. This is true even where the primary condition is related to kidney failure. For example, Medicare will pay for home health care, such as decubitus care or for severe hypotension that is not included in the ESRD PPS.

Medicare patients can receive care under both the ESRD benefit and the home health benefit. The key is whether or not the services are being furnished for the treatment of the patient's ESRD. Surgical dressing changes that are furnished for the treatment of ESRD are to be provided by the ESRD facility, but dressing changes furnished for reasons other than for the treatment of ESRD may be provided under the home health benefit provided all eligibility criteria have been met. See 42 CFR 409.49(e).

B. Coverage under the Hospice Benefit